Mindful Self-Compassion for Co-occurring PTSD/SUD in Trauma-Exposed Women Experiencing Homelessness, Phase II

Study Protocol

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SECTION 1A. RESEARCH STUDY OVERVIEW

Subsection 1A.1 Overview & Introduction

This three-year study will be a mixed-method, open-label cluster randomized clinical trial to test the benefit of the adapted mindful self-compassion intervention (MSC) at improving primary (PTSD, substance use) and secondary outcomes (depression, anxiety, helplessness, loneliness) among a sample of women experiencing homelessness (WEH) with PTSD/SUD residing in a residential drug treatment site (RDTS). An exploratory aim will be to elucidate mechanisms of treatment-response and maintenance or remission of symptoms.

Phase 1 of this three-year study was completed in December 2023. In Phase 1, a Community Advisory Board (CAB) was created, with women from the RDTS as well as site staff (including clinicians and substance use counselors). The CAB and the UCLA research team jointly created a semi-structured interview guide that was used with four focus groups (total N=27) of trauma-exposed WEH living at the RDTS. The participants completed acceptability and feasibility questionnaires and provided feedback on program design and administration. These suggestions were brought to the CAB and together the study design was finalized accordingly.

Phase II of this study will begin in Winter/Spring 2024. This will be a clinical trial comparing the MSC intervention to treatment as usual (TAU).

Subsection 1A.2 Research Team and Responsibilities

Principal Investigator (PI): Dana Rose Garfin, PhD

Oversees scientific and administrative direction of the project. Makes executive decisions regarding the implementation of the study, data entry and data analysis approaches, and interpretation of study findings. She will train the research staff and assistants to perform content. Dr. Garfin will select all questionnaires and oversee the design, implementation, and evaluation of the MSC and treatment as usual (TAU) control. Dr. Garfin takes final responsibility for the integrity of the data and the accuracy of the data analysis. She will also be responsible for tracking and reporting any adverse events that occur.

Mindful Self Compassion Instructor: Amy Noelle, MPT

Amy Noelle, MPT will help lead the administration of the MSC course. Ms. Noelle has developed and taught mindfulness and SC courses for over 10 years. Ms. Noelle has previously taught MBSR to WEH with PTSD/SUD and has worked with our community partners at HealthRIGHT 360 since 2020. Ms. Noelle worked closely with Dr. Garfin and the CAB to develop and adapt the MSC intervention. Ms. Noelle will be responsible for training and supervising any additional MSC trainers on the project.

Graduate Student Researchers (GSRs):
First line contact for RAs, responsible for RA scheduling, delegates lab responsibilities to other RAs, oversees RAs on site at the RDTS, keeps track of supplies, reimbursements, and participant compensation, assists with research tasks including qualitative data group coding, setting up REDCap, and writing papers.

Undergraduate Research Assistants (RAs):
Assist with delegated lab tasks, including ordering supplies, screening and interviewing study participants at the RDTS, and inputting data into REDCap.

Subsection 1A.3 Research Study Contact List

Name	Role	Organization	Email
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Subsection 1A.4 Phase II Timeline

Table 3. Study Timeline											
Year 1											
Month 1	2	3	4	5	6	7	8	9	10	11	12
Study start up	Phase 1: CAB & FGS						Phase II: Cohort 1			Cohort 2	
Year 2											
Month 1	2	3	4	5	6	7	8	9	10	11	12
Cohort 3			Cohort 4				Cohort 5			Cohort 6	
Year 3											
Month 1	2	3	4	5	6	7	8	9	10	11	12
Cohort 7			Cohort 8				Analysis & Dissemination				
CAB=Community Advisory Board; FGS=Focus Group Sessions. Each cohort will have 2 groups of 12-14 WEH. Cohort 8 follow-up will occur month 9. Analyses of earlier data will start month 8.											

6. BASIC DEFINITIONS

Mindful Self Compassion (MSC): is a mind-body integrative health intervention that utilizes meditations, other contemplative practices, home practices, and experiential exercises (including group discussions) to increase SC. To increase feasibility of MSC for use in the RDTS, we will adapt MSC to 7 sessions (6 weekly sessions in alignment with the MSC short course plus the half day retreat included in the full course to facilitate skill consolidation).

Post-traumatic Stress Disorder (PTSD): PTSD is a psychological pathology characterized by re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal after experiencing a traumatic event.

Trauma: According to the DSM-5, must involve actual or threatened death, serious injury, or sexual violence.

Arm: The different groups of the intervention. In this study, Arm 1 is the treatment as usual (TAU) control and Arm 2 is the MSC. Participants are assigned to one Arm or the other, by cohort).

Cohort: The group of people that are doing the interventions at the same time.

Other Acronyms used in the protocol:

WEH: women experiencing homelessness
SUD: substance use disorder
TAU: treatment as usual control group
RDTS: residential drug treatment site

SECTION 1B. INTRODUCTION TO PTSD AND MSC

Subsection 1B.1 PTSD Basics

PTSD

PTSD occurs as the result of direct exposure to experiencing, witnessing, or learning of an event that involves actual or threatened death or serious injury or harm to self of others (American Psychiatric Association, 2013). For a diagnosis of PTSD, symptoms must be present for at least one month prior to diagnosis and must include at least one re-experiencing symptom, one avoidance symptom, two arousal and reactivity symptoms and two cognition and mood symptoms. Re-experiencing symptoms can include flashbacks, nightmares, and invasive thoughts. Avoidance symptoms are related to an individual actively avoiding locations, thoughts,

events, or objects that are reminiscent of the trauma. Arousal and reactivity symptoms include feeling easily frightened, tense, increased anger, and having issues sleeping. Cognitive and mood symptoms include but are not limited to having trouble remembering key features of the trauma, distorted feelings, and loss of interest in previously enjoyable activities. PTSD must be diagnosed by a mental health professional, but a variety of measures have been validated for use as screens or by non-clinical for research purposes. In this study, PTSD symptoms will be measured using the PTSD Checklist for DSM-5 (PCL-5).

DSM-5 Criteria for PTSD

The following text summarizes the diagnostic criteria for PTSD

Criterion A (one required): The person was exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, in the following way(s):

- Direct exposure
- Witnessing the trauma
- Learning that a relative or close friend was exposed to a trauma
- Indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., first responders, medics)

Criterion B (one required): The traumatic event is persistently re-experienced, in the following way(s):

- Unwanted upsetting memories
- Nightmares
- Flashbacks
- Emotional distress after exposure to traumatic reminders
- Physical reactivity after exposure to traumatic reminders

Criterion C (one required): Avoidance of trauma-related stimuli after the trauma, in the following way(s):

- Trauma-related thoughts or feelings
- Trauma-related reminders

Criterion D (two required): Negative thoughts or feelings that began or worsened after the trauma, in the following way(s):

- Inability to recall key features of the trauma
- Overly negative thoughts and assumptions about oneself or the world
- Exaggerated blame of self or others for causing the trauma
- Negative affect
- Decreased interest in activities
- Feeling isolated
- Difficulty experiencing positive affect

Criterion E (two required): Trauma-related arousal and reactivity that began or worsened after the trauma, in the following way(s):

- Irritability or aggression

- Risky or destructive behavior
- Hypervigilance
- Heightened startle reaction
- Difficulty concentrating
- Difficulty sleeping

Criterion F (required): Symptoms last for more than 1 month.

Criterion G (required): Symptoms create distress or functional impairment (e.g., social, occupational).

Criterion H (required): Symptoms are not due to medication, substance use, or other illness.
Two specifications:

1. Dissociative Specification. In addition to meeting criteria for diagnosis, an individual experiences high levels of either of the following in reaction to trauma-related stimuli:
    - Depersonalization. Experience of being an outside observer of or detached from oneself (e.g., feeling as if "this is not happening to me" or one were in a dream).
    - Derealization. Experience of unreality, distance, or distortion (e.g., "things are not real").
2. Delayed Specification. Full diagnostic criteria are not met until at least six months after the trauma(s), although onset of symptoms may occur immediately.

How is PTSD Typically Treated?

CBT, cognitive processing therapy, prolonged exposure therapy (PE), eye movement desensitization and reprocessing (EMDR), stress inoculation training, psychopharmacological treatments are all common treatments for PTSD. Cognitive behavioral therapy (CBT) often occurs once a week and works with the client to reframe thoughts surrounding the event (i.e. feelings of guilt). Similarly, in cognitive processing therapy the client recounts the event and related thoughts to a therapist and subsequently processes and learns new ways to live with the thoughts and trauma. PE takes place in eight to fifteen ninety minute sessions in which the client is taught breathing techniques to combat anxiety before making a list of avoidances and learning to face them. EMDR asks the client to watch or listen to something, such as a light flashing or sound, while concentrating on the traumatic event so that over time, the client can think about something positive while remember the trauma. Stress inoculation training focuses on how the client responds to the stress of the trauma and works to teach them methods to cope such as breathing techniques and thought stopping. Medications frequently prescribed to individuals with PTSD are SSRIs and SNRIs such as Prozac and Zoloft. We are testing whether MSC is an effective complementary treatment for PTSD. Complementary means that it will be used in addition to any other interventions used in standard treatment of PTSD.

Subsection 1B.2 MSC Basics

MSC is a mind-body integrative health intervention that utilizes meditations, other contemplative practices, home practices, and experiential exercises (including group discussions) to increase SC. MSC can be done in groups of 10-25. The full program typically consists of eight sessions, approximately 2.5 hours long, and a 4-hour (half-

day) silent retreat. There are a total of 25 practices in MSC (including three core meditations, four other meditations, and 18 informal practices for daily life); all incorporate loving-kindness (e.g., self-compassion). An official MSC adaptation, the MSC short course consists of six sessions and has been increasingly used in healthcare settings.[116] Our prior work with WEH found that the majority of WEH completed 7/9 available sessions (6 sessions or more were considered treatment completion), with most WEH citing early discharge from RDTS as the reason for lower dose of sessions. To increase feasibility of MSC for use in RDTSs, we will aim to adapt MSC to 7 sessions (6 weekly sessions in alignment with the MSC short course plus the half day retreat included in the full course to facilitate skill consolidation). Sessions will be conducted in a group-based format: prior research found group-based formats equivalent to individual-level interventions for PTSD/SUD.

Table 1. Progression of the adapted 6-week MSC intervention

Table 1. Overview of Key MSC Practice by Session		
Session	**Topics**	**Key Practices for PTSD/SUD**
Session 1 What is MSC?	Why Am I Here? How to Approach MSC Guiding Principles 3 components of SC Misgivings	"How do I treat a friend"? Physiology of SC and Criticism SC Break Informal Practice: SC Bracelets
Session 2 Practicing SC	"Resistance & backdraft" How We Cause Ourselves Unnecessary Suffering Development of Safety & Trust Inner Ally	Affectionate Breathing Practicing Loving Kindness Soles of the Feet Mindfulness & SC in Daily life Here and Now Stone
Session 3 Discovering Your Compassionate Voice	Self-Criticism & Safety Core Values Compassionate Conversations with Self	Meeting the Inner Critic Finding Phrases Compassionate Letter to Ourselves
Session 4 SC & Resilience	Applying SC to Difficult Emotions Hidden Values in Suffering Emotion of Shame Described & Demystified	Core Values Exercise Living with a Vow Silver Linings
Session 5 Meeting Difficult Emotions	Self-Forgiveness Challenging Relationships	Compassionate Friend Meeting Unmet Needs SC Break in Relationships SC with Equanimity
Session 6 Making it Count	Integrate Positive Psychology Concepts of Savoring, Gratitude, & Self-Appreciation Tips for Maintaining Practice	Savoring Gratitude Self-Appreciation
"**Living Deeply Retreat**"	Half-day Retreat Conducted between Sessions 5 & 6	Soften Soothe Allow Affectionate Breathing Compassionate Movement

SECTION 2. INTERVENTION DELIVERY

Subsection 2.1 - Phase II Overview

In Phase II, we will assess the benefit of MSC to produce improvements in primary (PTSD, SUD) and secondary outcomes (depression, anxiety, hopelessness, loneliness) compared to Treatment as Usual (TAU) and to explore mechanisms of symptom change over time. We will implement an open-label cluster randomized clinical trial of an adapted MSC course for PTSD/SUD with WEH (N=202), randomized to MSC (n=101) or TAU (n=101). Women will be recruited from Prototypes, a HealthRIGHT 360 RDTS. Inclusion criteria will be: 1) woman age 18 and over; 2) probable PTSD as judged by the PCL-5 (score of 31 or higher, indicated as having optimal signal detection); 3) no cognitive impairment according to a score of < 10 on the Short-Blessed Test; 4) experienced homelessness in the past 6 months or prior to incarceration ("spent night in public or private shelter or on the street"); and 5) able to speak and understand English. We will recruit 8 cohorts of 24-26 WEH and each cohort will be divided into 2 groups. Cohorts of participants will be randomized to an adapted MSC course or TAU prior to enrollment of the first participant and randomization will occur at the level of the cohort rather than the participant. This is to minimized contamination in cohorts as women live together at the RDTS but cycle out after ~3 months. Women receiving MSC or TAU will complete psychosocial questionnaires, demographics, and a Locator Guide at baseline. Women receiving MSC will participate in weekly MSC classes for 6 weeks, followed by a post-intervention follow-up and 4-month follow-up. Women receiving TAU will complete short psychological surveys each week for 6-weeks, followed by a 6-week post-baseline and 4-month follow-up.

Confidentiality and Ethical Issues

All program staff, RAs, GSRs, and MSC trainers must follow confidentiality and ethical procedures throughout this program to ensure that everybody is treated with respect and dignity.

- Communication with study participants must remain confidential. To maintain confidentiality for participants, any personal information provided, such as participants' name, age, etc., will be protected by use of subject code on all data and questionnaires and stored on REDCap on the UCLA server and never anywhere else. Data including subject identifiable information will be linked to a code on RedCap for this study for access and only UCLA-approved staff, RAs, or GSRs will have access though a password-protected login.

Program Team

The Graduate Student Researchers (GSRs) will help the PI (Dr. Garfin) in organizing all aspects of the study. These individuals will be current graduate students in the UCLA Jonathan and Karin Fielding School of Public Health. They will be responsible for tracking recruitment, scheduling research assistants, and ensuring that the site is well-stocked with necessary supplies. Weekly, the GSRs will meet with Dr. Garfin to review all aspects of the study, troubleshoot any obstacles, participate in ongoing training, and create schedules for the other RAs. The RAs will be highly trained undergraduate students from the University of California, Los Angeles.

Safety of Program Staff

While we believe that conducting this study is highly important for public health, it is critical that the research team prioritizes their own safety first. If any member of the research team feels that they are in danger (physically, emotionally, psychologically) in any way, they will be instructed to end the study activities and inform the research coordinator or the PI as soon as it is safe to do so. This is particularly important during COVID-19 and ongoing viral outbreaks. Exposures will be promptly reported to the PI and any applicable UCLA protocols will be strictly followed.

Subsection 2.2 - Phase II Scope of Work & Participant Flow Diagram

1. General Recruitment

a. We will recruit ~8 cohorts of 24-26 WEH from Prototypes, a HealthRIGHT 360 RDTS. The RDTS staff will assist the PI and GSRs in providing a minimum of two informational meetings (advertised through flyers and verbally by staff) for interested women where they will be informed about the opportunity.

b. Dr. Garfin, GSRs, or RAs will administer an eligibility screener to participants using an iPad and will collect the data using REDCap.
    i. Key inclusion criteria are subthreshold or threshold PTSD as measured by the PCL-5 PTSD screener and no cognitive impairment as measured by the Short-Blessed Test.

c. All participants who complete the screener will receive $5.
    i. Note: those who complete the screener must complete the consent to screen, but are not assigned a participant ID at this time as they have not completed the Informed Consent. As such, it is imperative that accurate information be obtained with respect to the individual's name as that will be used to link it to their subsequent data. This will be stored on REDCap on the UCLA secured server and never anywhere else.

d. Eligible WEH who wish to participate will be invited back within the next week for enrollment and baseline assessments. The research team will review the informed consent with the potential participant and provide a copy for them to take for review. Potential participants will be given 24 hours to review the document before enrolling in the study and completing baseline measures; participants are free to waive this waiting period at their own discretion.

2. Group Assignment and Intervention Procedure

a. Cohorts of participants will be randomized to an adapted MSC course or TAU prior to enrollment of the first participant. Consistent with the cluster design, randomization will occur at the level of the cohort rather than the participant. This design was chosen to avoid contamination within the cohorts, since participants

reside at the same RDTS. There will be eight cohorts in total, each with two intervention groups of 12-14 WEH. Each cohort will receive the same intervention (e.g., in Cohort 1 there will be two groups of MSC, in Cohort 2 there will be two groups of TAU). See **Table 2** below:

Table 2: Group Assignment Flowchart

	Intervention	
	MSC	TAU
Cohort 1	Group 1 (12-14 WEH) Group 2 (12-14 WEH)	
Cohort 2		Group 3 (12-14 WEH) Group 4 (12-14 WEH)
Cohort 3	Group 5 (12-14 WEH) Group 6 (12-14 WEH)	
Cohort 4		Group 7 Group 8
Cohort 5	Group 9 Group 10	
Cohort 6		Group 11 Group 12
Cohort 7	Group 13 Group 14	
Cohort 8		Group 15 Group 16

b. Informed Consent: Interested and eligible women will complete informed consent at a private location at the RDTS with the PI, a GSR, or a RA. Only the PI and GSR can sign the informed consent so undergraduate RAs may answer questions about the informed consent but final signatures must be obtained from the PI or GSR.

c. Baseline questionnaire administered:

i. After informed consent, participants will complete an assisted psychosocial interview to measure primary outcomes (PTSD and substance use), secondary outcomes (anxiety, depression, hopelessness,), mediators (emotion-regulation, self-compassion, moral injury, trauma-related guilt, trauma-related shame, craving, mindfulness), and covariates (e.g., negative life

events).

ii. GSRs and RAs will verbally read questions with response options provided both verbally and on a response card and record responses on iPads using REDCap, accessed through a password. Data will be immediately transferred to UCLA's secure server.

iii. Women will receive $15 for completing the baseline assessment.

d. Locator Guide: This is a critical part of maintaining contact with our participants. However, they may not be inclined to provide all the information on the first or second meeting. **NOTE TO RESEARCH ASSISTANTS: PLEASE TAKE THE PICTURE AT THE TIME OF (IMMEDIATELY AFTER) ADMINISTERING INFORMED CONSENT.** Note that the picture (like any measure) is optional and participants can refuse the picture and still participate in the study.

   i. The Locator Guide is stored on REDCap and updated at each contact with participant, beginning with enrollment and baseline. Participants provide their name, date of birth, email, phone number, and social media accounts. We also maintain information on the residence of the participant after they are discharged from treatment: participants nearly all transfer to a sober living home near the Prototypes facility after discharge. In our experience, most participants have a phone and can be reached on their phone or via social media if their phone is disconnected after discharge. On occasion, after discharge, participants live with a friend or family member, but in our prior experience working with this population, this is relatively uncommon.

      1. Participants will provide name, email(s), phone number(s), and social media account(s) for their close friends and relatives. We will prompt the participant for each potential friend or relative, starting with parents (mom, dad, stepmother, stepfather), aunts and uncles, adult children, partners (husband, wife, father of children, etc.), friends, cousins, and other. We update this at each intervention session, as participants will often disclose more information to us over time as they build trust with our team. In our experience, our participants tend to keep in touch with at least one friend or family member, even if they return to using substances and become unhoused after discharge.

      2. During follow-ups, GSRs will be responsible for contacting participants to schedule their follow-up appointments. We first try to contact the participant several times via phone, email, and social media accounts. If we are unable to reach the participant, we use the Locator Guide and begin to contact their friends and family members. We take detailed notes in the Locator Guide on REDCap, including dates of contact, who we talked to, and what information we obtained. If we can not reach a participant, we continue to re-contact the participant and their family until we reach the individual or unless the participant, friend, or family member requests us not to contact them again.

         a. Another strategy we use is to track unreachable participants is to ask other participants in the program if they have spoken to the unreachable participant. Frequently, someone else in the

study will have updated contact information, know where the individual is residing, or is able to pass along our contact information so the unreachable participant can reach out to us.

e. Intervention
    i. Participants will participate in a seven session (six sessions + retreat) adapted MSC short course administered over a 6-week timeframe or TAU. WEH will be compensated $10 per session.

f. Post-Intervention Follow-up
    i. Following the MSC or TAU sessions, participants will complete the psychosocial metrics that were assessed at baseline again and be compensated $20. Psychosocial assessments for women who leave the RDTS will be administered at a location convenient for the participant (e.g., sober living home) or by Zoom.
    ii. Women in the MSC group will also be invited to participate in-depth interviews (approximately 20 minutes in length) to share their experiences with the intervention and be compensated $10 for the interview.

g. 4-Month Follow-Up
    i. Four months after baseline (approximately 2 months after post-assessment), primary and secondary outcomes will be re-assessed, in addition to key covariates and recent negative life events. Participants will be contacted using the Locator Guide and compensated $30. These sessions will occur in person (at a private location convenient for the participant) or over Zoom as requested by participant.

3. Phase II Reimbursement

a. Women will receive $5 for the eligibility screener; $15 for completing baseline measures; $10 per session in the intervention; $20 for the post-intervention follow-up and $10 if they complete an additional interview; and $30 for the 4-month follow-up.
    i. Women are paid in cash or a Visa gift card and must sign on the iPad (via REDCap) that they have received the payment. If a virtual follow-up, the individual who provides compensation will sign. This must also be initiated, signed, and dated by the RA or GSR in charge of payment.

Subsection 2.3 - Phase II Recruitment & Treatment Overview

Table 3. Overview of Phase II Assessments

Intervention	Recruitment	Eligibility Screen	Baseline	Weekly	Post-Intervention Follow-up	4-Month Follow-up

MSC	Info meetings with PI at RDTS	PTSD SBT[a]	Psychosocial questionnaires[b,c,d] Demographics Locator Guide[e]	Home practice adherence Accept & feasibility activities[f]	Psychosocial questionnaires[b,c,d] ~20-minute interview	Psychosocial questionnaires[b,c,d]
TAU	Info meetings with PI at RDTS	PTSD SBT[a]	Psychosocial questionnaires[b,c,d] Demographics Locator Guide[e]	Short psych surveys[g]	Psycho-social questionnaires[b,c,d]	Psycho-social questionnaires[b,c,d]

[a]PTSD, SBT=Short Blessed Test (cognitive impairment screen; >9=likely cognitive impairment); [b]Primary (PTSD, substance use) & Secondary (anxiety, depression, hopelessness, loneliness) Outcomes, [c]Mediators: emotion-regulation, self-compassion, moral injury, trauma-related guilt, trauma-related shame, craving, mindfulness; [d]Covariates: negative life events; [e]Locator Guide will be updated regularly; [f]Used to provide detailed feedback on acceptability & feasibility of MSC intervention; [g]Surveys on attitudes, personality, other non-clinical factors. MSC=Mindful Self Compassion; TAU=Treatment as Usual

Subsection 2.4 - Phase II Recruitment & Screening

Women will be recruited from Prototypes, a HealthRIGHT 360 RDTS. The RDTS staff will assist the PI and GSR in providing approximately two informational meetings (advertised through UCLA IRB-approved flyers and verbally by staff) for interested women where they will be informed about the opportunity. Recruitment flyers will also be posted around the RDTS. GSRs and RAs will help recruit women and conduct the initial screening in a private room or in an area onsite where the interview can not be overheard by others after completing the Consent to Screen Script. Progress will be monitored closely by Dr. Garfin the Lab Management team.

There will be eight cohorts in total, each with two intervention groups of 12-14 WEH (see Table 2). Each cohort will receive the same intervention (e.g., in Cohort 1 there will be two groups of MSC, in Cohort 2 there will be two groups of TAU). The cohorts will be divided into two smaller groups of 12-14 WEH (24-26 per cohort) rather than one large group of 24-26 WEH. Recruitment and the intervention for each cohort will take approximately 6-8 weeks to complete.

Dr. Garfin and/or lead GSR(s) will explain the study during an initial meeting with potential participants and answer any questions. Then women will be screened for eligibility. Prior to obtaining any data, the women will provide a "consent to screen". This is because we need to obtain data from the women to determine if they are eligible, but they are not officially enrolled as human subjects. By providing their "consent to screen", we are obtaining verbal consent/permission to ask them questions. Their data will not be used by the research team if they are not eligible.

A member of the research team will read the consent to screen script exactly as written on REDCap. Potential participants are free to stop at any time – remind them that all procedures are completely voluntary. Dr. Garfin and/or someone from the Lab Management team (e.g., GSR) will always be onsite to help answer questions.

The RA or GSR will then administer the eligibility screener to participants via iPad. The screener will first assess age, prior homelessness, and cognitive impairment. Cognitive impairment will be determined by a score greater than 9 on the Short Blessed Test. The screener then screens for PTSD using the PTSD Checklist for DSM-5 (PCL-5) for the worst event in their life. We will assess PTSD to their most recent event (in the past year) during the baseline and follow-up assessments. The standard PCL-5 initially starts with the identification of the presence of exposure to a DSM-5 traumatic event and then assesses whether it involved actual or threatened death, serious injury or sexual violence. The RA may need to prompt the potential participant with examples to keep them on track and to ensure that the participant is responding to an actual DSM-5 traumatic event. The next 20 items on the PCL-5 assess all four B-E PTSD criterion (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale 0 "not at all", 1 "a little bit", 2 "moderately", 3 "quite a bit", 4 "extremely". Subthreshold PTSD will be defined as endorsing "moderately" or more to at least 2 B-E criteria; probable-PTSD will be measured by meeting criteria A-G for PTSD.

Data collection method: All data will be collected via iPads using REDCap and will be immediately transferred to UCLA's secure server.

All participants who complete the screener will receive $5. It is very important to compensate all individuals who participate in the screening, even if they are not eligible!!!

Subsection 2.5 - Phase II Eligibility Criteria

Inclusion Criteria:

1) Unhoused women or individual who identifies as a woman (N=202; 101 in each group)
   a. Women over 18 years of age
   b. Able to speak English
   c. Experienced homelessness in the last 6 months: a homeless person is defined as anyone who spent the previous night in a public or private shelter, or on the street.
   e. Likely subthreshold or threshold PTSD, as measured by the PCL-5.
   f. No cognitive impairment according to a score of < 10 on the Short-Blessed Test

Exclusion Criteria:

The following will not be eligible for participating:

1) Persons who are:
   a. Not able to speak English
   b. Judged to be cognitively impaired, as indicated by score > 10 on the Short-Blessed Screener
   c. Do not meet other inclusion criteria

Subsection 2.6 - Phase II Intervention Program Description

General Description: Among 202 eligible trauma-exposed WEH, assess the

impact of the MSC intervention at improving primary (PTSD, substance use) and secondary outcomes (depression, anxiety, suicidality) in WEH at a RDTS.

Data Collection Time points: Baseline, Post-Intervention follow-up, 4-month follow-up

Total Duration: 4 months

The following sections will outline the intervention process:

- Pre-intervention Assessments
- MSC Intervention
- Treatment as Usual
- Post-Assessment
- Dealing with Program Attrition
- Follow-up

Subsection 2.7 - Phase II Pre-Intervention Assessments

After Informed Consent, participants will complete a series of self-report measures. These measures will be administered by Research Staff at a private location at the site. Responses options to each question will be provided to the participant, organized in a clearly labeled binder. The Research Staff will display the response options for each measure, read the options out loud, and then record the response on the tablet. At the end of each measure, the RA will "lock" the measure. There will be a prompt if any items have been missed. Please check that there is no missing data. The participant may take a break at any time.

Assessments

Primary outcomes:

- PTSD PCL-5 (lifetime, past year)

  PTSD symptoms will be measured using the PTSD Checklist for DSM-5 (PCL-5),[1,2] which will be scored continuously and according to diagnostic criteria.[2] The PCL-5 initially starts with the identification of the presence of exposure to a DSM-V traumatic event; assesses actual or threatened death, serious injury or sexual violence; and whether the person directly experienced it. Twenty additional items assess all four B-E criteria (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale from 0 (not at all) to 4 (extremely). Treatment response will be defined as a $\geq$ 5-point reduction in symptoms and clinically meaningful improvement as $\geq$ 10-point reduction in symptoms. PTSD will be assessed for worse lifetime event and (if applicable) worst event in the past year.

- Alcohol Use Disorders Identification Test (AUDIT)[3]

  The AUDIT is part of the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) Common Data Elements for use in

clinical trials. The Audit is a 10-item alcohol screen that helps identify persons who are hazardous drinkers or who have active alcohol use disorders. It can be calculated as a sum score and will be analyzed as a continuous and categorical (yes/no used alcohol) outcome.

- Drug Abuse Screening Test-10 item (DAST)[3]

  The AUDIT is part of the NIDA CTN Common Data Elements for use in clinical trials. The DAST is a 10-item brief, self-report instrument for population screening, clinical case finding and treatment evaluation research. It can be used with adults and older youth. The DAST-10 yields a quantitative index of the degree of consequences related to drug abuse. The instrument takes approximately 5 minutes to administer and may be given in either a self-report or interview format. The DAST may be used in a variety of settings to provide a quick index of drug abuse problems. It will be evaluated continuously and as a categorical outcome (yes/no).

Secondary outcomes:

- Beck hopelessness inventory[4]

  This twenty-item measure has been widely used[5,6] to assess hopelessness through a series of true/false statements (1, 0) that create a sum score.
- PROMIS – anxiety[7]

  This clinically valid, 7 item measure has been developed as part of the National Institute of Health (NIH) toolkit to assess anxiety in individuals 18 and older. Endpoints range from 1=never to 5=always. It can be used as a sum score and categorizes responses as “none to slight”, “mild”, “moderate,” and “severe”.
- PROMIS - depression[7]

  This clinically valid, 8 item measure has been developed as part of the NIH toolkit to assess depression in the past two weeks. It assesses symptoms ranging from 1=never to 5=always and can be used in individuals 18 and older. It can be used as a sum score and categorizes responses as “none to slight”, “mild”, “moderate,” and “severe”.

- PROMIS – loneliness

  This clinically valid, five item measure was developed as part of the NIH toolkit to assesses feelings of social isolation on a five-point scale from 1=never to 5=not at all.

Mediators & additional outcomes

- Self Compassion Scale (SCS)[8]

This twelve-item scale assesses self compassion on a scale of 1=almost never to 5=almost always. Items will be summed and used as a continuous measure.

- Difficulties in Emotion Regulation Scale[9]

  This 18-item scale assesses emotion dysregulation on a scale from 1=almost never (0-10%) to 5=almost always (91-100%). It can be summed up (several items reverse coded) and also has six subscales: Nonacceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity.

- Mindful Attention Awareness Scale[10]

  This is a 15-item scale that assesses mindfulness on a scale of 1=almost always to 6=almost never. It is summed and used as a continuous measure.

- Moral Injury and Distress Scale[11]

  This six item scale measures moral injury on a scale from 0=not at all to 4=extremely. It is coded categorically (yes moral injury=1, no moral injury=0) and as a continuous outcome.

- Craving[12]

  Craving will be measured for alcohol, opioids, methamphetamine, marijuana, psychedelics or other substances (provide name) from 0=no craving at all to 100=maximum possible.

- Trauma-related Shame Inventory[13]

  This 24-item measure assesses trauma-related shame from 0=not true of me to 4=completely true for me. It is summed and analyzed as a continuous outcome.

Covariates:

- Negative life events[14–16]

  This measure assesses exposure to 31 possible negative life events and assesses if they occurred before age 18, after age 18 or in the past year. Seven additional adverse childhood experiences[17] will also be specifically assessed.

- Interpersonal Violence Short Form/Revised Conflicts Tactics -Short form

  This twenty-item measure is designed to capture intimate partner violence. Specifically, it assesses three tactics used when there is conflict in the relationships of dating, cohabiting, or marital couples: Negotiation, Physical Assault, and Psychological Aggression. Questions are answered in terms of frequency of occurrence. Scoring can occur in a variety of ways as outlined here

- Demographics

Subsection 2.8 - Phase II MSC Intervention

(MSC) is a mind-body integrative health intervention that utilizes meditations, other contemplative practices, home practices, and experiential exercises (including group

discussions) to increase SC. MSC can be done in groups of 10-25. To increase feasibility of MSC for use in RDTSs, we will aim to adapt MSC to 7 sessions (6 weekly sessions in alignment with the MSC short course plus the half day retreat included in the full course to facilitate skill consolidation). Sessions will be conducted in a group-based format: prior research found group-based formats equivalent to individual-level interventions for PTSD/SUD.

The MSC sessions are as follows:

Session 1: What is MSC?

- **Topics:** Why am I here? How to approach MSC. Guiding Principles. 3 components of SC. Misgivings.
- **Key Practices for PTSD/SUD:** How do I treat a friend? Physiology of SC and Criticism SC Break. Informal Practice: SC Bracelets

Session 2: Practicing SC

- **Topics:** "Resistance & backdraft". How we cause ourselves unnecessary suffering. Development of Safety & Trust. Inner Ally
- **Key Practices:** Affectionate Breathing. Practicing Loving Kindness. Soles of the Feet. Mindfulness & SC in Daily Life. Here and Now Stone.

Session 3: Discovering Your Compassionate Voice

- **Topics:** Self Criticism & Safety. Core Values. Compassionate Conversations with Self.
- **Key Practices:** Meeting the Inner Critic. Finding Phrases. Compassionate Letter to Ourselves.

Session 4: SC & Resilience

- **Topics:** Applying SC to Difficult Emotions. Hidden Values in Suffering. Emotion of Shame Described & Demystified.
- **Key Practices:** Core Values Exercise. Living with a Vow. Silver Linings.

Session 5: Meeting Difficult Emotions

- **Topics:** Self-forgiveness. Challenging Relationships.
- **Key Practices:** Compassionate Friend. Meeting Unmet Needs. SC Break in Relationships. SC with Equanimity.

Living Deeply Half-Day Retreat:

- **Key Practices:** Soft Soothe Allow. Affectionate Breathing. Compassionate Movement.

Session 6: Making it Count

- **Topics:** Integrate Positive Psychology. Concepts of Savoring, Gratitude, Self-Appreciation. Tips for Maintaining Practice.
- **Key Practices:** Savoring. Gratitude. Self-Appreciation.

Subsection 2.9 - Phase II Treatment as Usual

Selecting appropriate attention control groups for behavioral intervention research, particularly for mindfulness-based interventions, can be problematic. Comparator groups often also improve as they tend to target related mechanisms (e.g., social support, health behaviors, improved attention). After weighing the pros and cons, a "treatment as usual" (TAU) approach was selected, whereby the MSC will be compared to TAU at the RDTS. However, to control for the confound of weekly compensation, TAU participants will meet with study staff seven times over the 6-week period and fill out short psychosocial surveys on non-distressing topics (e.g., personality tests, attitudes surveys) in exchange for compensation commensurate with the MSC group. We believe this will also help with retention of the TAU group over time and strike an appropriate balance between controlling for the effects of study participation while minimizing confounds that often occur with active control groups in behavioral interventions.

Subsection 2.10 - Phase II Post Assessment

After the seventh session (of either MSC or TAU), a post-assessment will be administered via tablet.

Assessments (see detailed description above)

Primary outcomes:

- PTSD PCL-5 (lifetime, past year):

- Substance use
  - AUDIT
  - DAST

Secondary outcomes:

- Beck hopelessness inventory
- PROMIS - anxiety
- PROMIS - depression
- PROMIS - loneliness

Mediators & additional outcomes

- Self Compassion Scale (SCS)
- Difficulties in Emotion Regulation Scale
- Mindful Attention Awareness Scale
- Moral Injury and Distress Scale
- Craving
- Trauma-related Shame

Covariates:

- Negative life events (updated)
- Interpersonal Violence Short Form
- Demographics

Women in the MSC group will also be invited to participate in-depth, semi-structured interviews (approximately 20 minutes in length) to share their experiences with the intervention. They will be compensated $10 for the interview.

Refusal Subsection 2.11 - Phase II Dealing with Program Attrition

Based on the team's prior research, we conservatively estimate 80% retention over time for a target enrollment of 202, for a total of 8 cohorts of 24-26 participants (divided equally into two groups per cohort). In the team's prior work, 82% of those screened were eligible for participation: thus, we will aim to screen 246 WEH.

We will work hard to ensure retention of participants during the study. The Locator Guide is key to maintaining effective follow-up. RAs, GSRs, and the PI will work to ensure maximum retention.

Subsection 2.12 - Phase II Follow-up

At four-month follow-up, we will contact the women with assistance from the site supervisor or by using our Locator Guide. These sessions will occur in person (at a private location convenient for the participant) or over Zoom on an encrypted UCLA device as requested by the participant.

Subsection 2.13 - Phase II Compensation

The Phase II compensation is listed below. Each participant will receive a total of up to $150 over the course of the study.

$5 – screener (after completing screener)
$15 – baseline measures (after completing)
$10 – per session in the intervention (at the end of each session; for a total of 7 sessions)
$20 – immediate post-intervention follow-up measures (after the final session)
*$10 - if they complete an additional qualitative interview
$30 – 4-month follow-up (after completion)

Both the MSC and TAU groups will receive a certificate of completion at the end of the 6-week (7 session) program.

Subsection 2.14 - Program Fidelity

To ensure program fidelity, all procedures will be closely supervised by the PI, Dr. Garfin. Detailed training materials will be provided to all staff, and staff will be required to complete a quiz prior to working on site. For those involved in administering the interventions, a detailed teachers manual will be provided, and all staff will be expected to adhere to the manual, with some flexibility allowed depending on the needs of the group, as is typical with MSC programs. All trainers will be certified in MSC and have an interest in working with unhoused persons.

Subsection 2.15 - Research Staff Competencies & Training

UCLA has implemented an educational program on the protection of human research

subjects. All study personnel who are responsible for the design and conduct of this project must complete the Collaborative Institutional Training Initiative Human Research Curriculum (CITI program), with the confirmation of completion of the training on file. The following courses should be completed by all staff prior to engaging in study activities.

- Human Research - Social & Behavioral Researchers & Staff
- Good Clinical Practices (GCP) courses (mandatory for RAs & GSRs)
- Refresher courses are also available on CITI website

  https://about.citiprogram.org/en/homepage/) as needed.

Further, all research staff will be highly trained by the PI in the following:

- Trained in specific protocols for dealing with emotional and mental distress (e.g., remaining calm, immediately finding appropriate onsite clinical staff).
- Trained in observational and communication skills, and in providing psychosocial support, particularly as it relates to emotional and information support.
- Trained in the California Mandatory Reporting Laws governing reporting of child abuse, domestic violence, and elder/dependent abuse. Protocols governing reports to the California Department of Family and Child Protective Services, or (in the case of domestic violence) local police, will be carefully followed. Study participants will receive full disclosure regarding mandatory reporting laws during the informed consent process and discussion of confidentiality. In terms of current or recent abuse experience, research staff will refer the participants to the onsite Prototypes clinical staff.
- Trained in our "RED FLAG" protocol and in reporting adverse events. Any adverse event will be documented in REDCap and reported to the IRB if appropriate.
- During research study training, the research team will be supervised by the PI as they practice the scripts for the screener, psychosocial questionnaires, and collecting data using REDCap.

Subsection 2.16 - Data Entry, Management, & Confidentiality

In Phase 2, secure and encrypted platforms will be used:

- **REDCap:** Interview data will be captured electronically using REDCap (Research Electronic Data Capture; http://project-redcap.org/), a secure, web-based application designed to support data entry and storage for research studies. Participants will answer surveys via an electronic tablet and the data will be uploaded in real-time. Possible errors, including incomplete responses, logic checks, and data range checks will be flagged by the RedCap software during input so that they can be corrected immediately.
- The GSRs, as supervised by Dr. Garfin, will routinely check to ensure data is accurately entered.

Procedures to safeguard confidentiality

Confidentiality of data will be protected by use of subject code on all data and questionnaires.

Any forms that link participant with their codes will be stored electronically on UCLA's secure server and only senior research staff and the PI will have access. All self-report data will be immediately uploaded onto UCLA's secure server via REDCap.

- Participants will be reminded that their interview questions will be provided over a tablet that will immediately transfer the data to the UCLA secure server and site staff will not see their data.

- We will minimize the risk by strictly adhering to confidentiality procedures. All study staff will be rigorously trained in methods to promote confidentiality. The staff will also be taught to treat participants in a non-judgmental, professional and confidential manner.

- Confidentiality of data will be protected by use of subject code on all data and questionnaires. Data including subject identifiable information (eg: locator form etc) will be linked to a code on REDCap for access in real time to track participants and only research staff will have access. REDCap also allows for participant's names and IDs to be viewed without access to their responses to the other items in the survey. Tracking of participants for their follow-ups will be based upon the information the participant reveals on their Locator Guide. When contacting people over the phone, we will use their preferred method and the research staff will identify themselves per participants' wishes.

- To protect confidentiality and reassure subjects, the research staff will be providing explicit explanations in the beginning of the program that they will share no confidential information. The trained research staff will administer the questionnaires individually to the participants.

- Subject identifiable data will be destroyed upon completion of the study. All the data will be stripped off any identifiable information and only de-identified database will be kept for analysis and dissemination.

Subsection 2.17 - Using REDCap

- For electronic data electronic data entry, log onto REDCap with you user ID and password: (https://gpsslvpn.mednet.ucla.edu/https/ctrcapps.medsch.ucla.edu/redcap/)

- RedCap also incorporates suitable validity checks at the point of data entry to prevent "out of range," "missing" or other checkable data entry errors.

Subsection 2.18 - Data Security

- All questionnaires must be identified by a code number (Study ID) only and patient identifier information will also be linked on REDCap through this code.
- The informed consent with the participants' names and signature will be on REDCap.

- All databases are accessible only to key investigators and research assistants on the project though password-protected login. Each member of the research team has their own personal password and login (administered through UCLA Mednet).
- The electronic data files are stored on the secure, password-protected UCLA server.
- This data is available for access on the UCLA server to authorized users through a password-protected web application.
- Authorized users can export deidentified data into Excel or other statistical software sheets for further analyses.
- The de-identified database will be archived for future analyses and all other identifying data will be destroyed at the end of the study**.**

Subsection 2.19 - Post Data Collection

- Validity checks on REDCap will be done right after any interview or other data collection is completed.
- Routine statistical validity checks should identify missing or suspect entries at agreed defined intervals (twice per month or as needed) by approved study staff, so that correct data can be obtained from the research staff, participants or their records if needed.
- Thorough data cleaning should be performed before any data analysis.

Subsection 2.20 - End of Study

- De-identified electronic data will be maintained for the period agreed in the study protocol (indefinitely).
- Final cleaned electronic data will be used for all statistical analyses.

Section 3 – Data analytic plan

- ***Power analysis***. Sample size was estimated using G*Power[18,19] and standard guidelines for testing mediation,[20] with α=.05, β=.80, and the standard deviation bound at ±1.91. Effect size estimates were derived from prior research on SC interventions for PTSD, which found a small-medium effect size (Cohen's d=0.2-0.5).[21] Particularly since the effect of MSC to reduce PTSD symptoms is emerging research, findings have been mixed regarding effect sizes for direct and indirect effects of SC interventions on PTSD, with some studies finding large effects of reduced PTSD due to SC interventions,[22,23] and others finding medium effect sizes.[24] (Of note, few randomized trials have been conducted).[21] To account for additional covariates, the clustering design,[25] and Type 1 error due to multiple tests, a small-medium effect size of .3 was conservatively estimated. Sample size appropriate for mediation was derived from a percentile bootstrap method, which simulations consistently show to be the most powerful test compared to similar methods (e.g., Sobel, bias-corrected bootstrap).[20] This yielded a final sample size of 162. Based on the team's prior research, we conservatively estimate 80% retention over time for a target enrollment of 202, for a total of 8 cohorts of 24-26 participants (divided equally into two groups per cohort). In the

team's prior work, 82% of those screened were eligible for participation: thus, we will aim to screen 246 WEH.

- ***Statistical analysis***. Initial analysis will include descriptive statistics. Data will be screened for outliers and deviations from normality; results will be considered in subsequent analyses. Patterns of missing data will be examined using logistic regression (0=missing; 1=complete) and will be reported in results. Based on prior research, very little missing data on key independent or dependent variables is expected.[26,27] Any missing data on independent variables or continuous dependent variables will be imputed using multiple imputation and related methods.[28] Although cohorts should be comparable in terms of demographics (e.g., age, ethnicity) and other risk factors (e.g., type of drug use, history of recidivism), propensity score methods and/or multilevel analyses (with cohort/cluster as a random effect[25]) will be utilized to account for these or any other covariates statistically different between cohorts at baseline. Reliability for computed scores will be assessed using Cronbach's alpha. Next, a series of t-tests and chi-squares will examine differences between groups (MSC vs. TAU). Then, for each dependent variable of interest, key predictors and covariates will be examined using a series of t-tests, chi-squares, and ordinary least squares (for continuous outcomes) and logistic (for dichotomous outcomes) bivariate regression models. Type, timing and amount of trauma exposure will be examined as covariates, given their link with PTSD incidence, severity,[29,30] substance use,[31–33] and distress.

- To evaluate reductions in *PTSD symptoms*, first, treatment response (≥ 5-point reduction in symptoms) and clinically meaningful improvement (≥ 10-point reduction in symptoms) will be calculated for both immediate and 4-month follow-up. Potential covariates (e.g., demographic indicators; type, timing and amount of trauma exposure, including history of incarceration) will be screened for inclusion (included if $p<.05$). Change over time will be analyzed, using data from the three time points, using a mixed-effects repeated measures approach. This will also allow for a test of fixed (e.g., treatment group) and random (e.g., cohort) effects over time and conserves power by capitalizing on the longitudinal design. Reductions in PTSD will be examined using a modified Poisson distribution with robust variance, which tends to be less biased than a logit-based approach. Reductions in symptoms (measured continuously) will also be evaluated using a Gaussian distribution. *Substance use* will be evaluated using the TLFB, quantified as *time to first use*, *days of use* and *relapse status* (abstinent [did not use], lapse [used after study intervention but did not revert to regular use], or relapse [used substances for more than one third of days]).[34,35] Group x time contrasts will be tested. Identical analytic approaches will be used to examine secondary outcomes (suicidality, depression, and anxiety).

- To test for mediation effects, AGReMA (A Guideline for Reporting Mediation Analyses of Randomized Trials and Observational Studies)[36] will be followed. A series of longitudinal structural equation models (SEM)[37] will examine both direct and indirect effects by which change in mediators (emotion regulation, trauma-related guilt, trauma-related shame, moral injury and craving) are associated with change in PTSD, substance use, and secondary outcomes over time. Confidence intervals for indirect effects will be obtained through percentile bootstrap.[37] SEM has the capacity to test for bidirectional

effects between PTSD symptoms and substance use. Model fit (e.g., Root Mean Square Error of Approximation) will be compared to find hypothesized paths that best fit the data.[37]

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