Adaptation of Mindfulness Training to Treat Moral Injury in Veterans

May 22, 2023

NCT Number: NCT05341882

Statistical Design and Power

The goal of the proposed R34 is to adapt the MMCP program for combat wounded veterans with moral injury and compare its acceptability, adherence, and implementation/practicality to an equally intensive online, facilitator-led, interactive education support group comparison condition. We will also collect data to identify potential primary and second outcome measures for a future sufficiently powered RCT.

Design

Aim 1: Adapt MMCP to Address Moral Injury (Study 1)

Study 1 is designed to adapt an existing mindfulness program to be appropriate for moral injury via an iterative developmental process based on existing literature and our previous research. For instance, we will make some key modifications to the mindfulness content to be appropriate for those with moral injury, including a self-compassion/loving kindness exercise based on previous research.[149] We will also obtain information and feedback from stakeholders (veterans, mental health providers). To achieve this objective, the PI and co-Is will have monthly meetings to develop and adapt the program content. We will ask for feedback from moral injury researchers and providers including members of APA's Division 19 Moral Injury Think Tank (chaired by the PI) for which they will receive small renumeration.

As part of Study 1, Dr. Butler (consultant/interventionist) will provide the six 75-minute weekly audiotaped MMMI program sessions to six eligible participants. Upon completion of the MMMI program, semi-structured interviews will be conducted utilizing a post-positivist paradigm,[150] guided by awareness that combat wounded veterans are a diverse population, have different experiences with moral injury, and may have different program reactions. All interviews will be conducted by the PI and GRA. The GRA and graduate and undergraduate lab members (many of whom are student veterans given the PI's focus on veteran mental health and the large student veteran population at the PI's university in Norfolk, VA), will transcript videotapes and develop initial coding themes. These themes will be reviewed by the research team and lead to MMMI refinement and preliminary manualization.

Aim 2: Examine the Intervention's Feasibility, Acceptability, and Preliminary Efficacy (Study 2)

In Study 2, we propose to test our ability to recruit and retain participants, to implement the designed protocol, and to determine treatment adherence of the refined MMMI intervention as compared to a facilitator-led ES comparison group (*N* = 20 combat wounded veterans; 10 MMMI; 10 ES). The two groups (MMMI and ES) will not differ in the delivery (i.e., live facilitator led interactive web-based, number of sessions, length of sessions, and have manualized treatments). Further, some content will be identical (e.g., introductions, icebreakers) or similar (e.g., benchmarks, semi-structured interview). We will gather audiotaped semi-structured interviews and brief benchmark measures to assess the feasibility, acceptability, participant comments and suggestions, as well as and participant acceptance, satisfaction, and compliance data. See Table 1.

Because there is no treatment-as-usual comparable to MMMI, several factors guided our decisions in developing the control group. In a different patient population, co-I Gaylord developed and compared an ES group to a mindfulness training group. Although the mindfulness group developed specific mindfulness skills, the two groups did not differ in their ratings of the credibility of their assigned interventions.[142] Also, an active control condition provides a stronger study design.[151] Third, treatment of the control condition should only differ from the experimental condition in the 'non-receipt' of the 'active ingredient'.[152] Also, 59% of veterans who took part in a Wounded Warrior Project survey reported talking with other veterans "as a top resource for coping with stress".[153] Finally, researchers have provided moral injury treatment in weekly group meetings.[65,99]

Aim 3. To Evaluate the Preliminary Feasibility of the Interventions (Study 3)

In Study 3, we propose to test the refined interventions with a larger group of combat wounded veterans (*N* = 60 combat wounded veterans; 30 MMMI; 30 ES group). After completing the baseline measures, participants will be randomly assigned to program. We will collect information on acceptability, adherence, and implementation/practicality in the two intervention arms, as well as primary moral injury symptoms (e.g., guilt, shame), possible mechanisms of changes (e.g., acceptance, nonjudgment, compassion), and possible secondary outcomes (e.g., mental health symptoms, substance use), which will help inform key variables to include in a large-scale sufficiently powered RCT. See Table 3.

Sample Size Determination

Prior to determining the sample size for Study 3, we examined the literature on determination of sample size for feasibility studies.[155-157] We specifically examined prior eligibility, refusal, randomization and session and data completion rates. We also considered practical aspects such as eligibility criteria, refusal and dropout rates,

expected interview and data completion rates, therapist hours and length of training, supervision, fidelity coding, and timeline. Overall, the majority of feasibility studies had modest sample sizes with varying rates of participation completion: 57% (n = 21),[107] 81% (n = 33),[97] and 77% (n = 37).[110] Based on averages from previous studies,[97,107,110] we will recruit 60 combat wounded veterans. Furthermore, we expect an ineligible rate/refusal rate of 30% (n = 18) and that an additional 18.8% (n = 8) will attend no sessions and/or not complete the post-training semi-structured interview or other survey measures, for a conservative completion rate of 34 participants. Given that the MMMI and ES support group will be equal in delivery, facilitation, group size, length, home practice burden, we do not anticipate different group completion rates.

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Table 1. Measurable Benchmarks Administered during Study 2 and 3

Area of Interest	Description of Outcome to be Evaluated	Measure and/or Expected Outcome
Acceptability	Participant Satisfaction	Client Satisfaction Questionnaire (CSQ-8)[154] satisfaction of ≥80%
	Intention to continue to use skills	Questionnaire developed for this study
	Training appropriateness	Questionnaire developed for this study
Demand	Completed sessions	~52% of those who meet eligibility criteria will attend 4 to 6 sessions based on previous studies[97,107,110]
	Homework Practice	Gradual increase in minutes of home practice relative to the number of minutes assigned over the 6 weeks ~40% of those who attend 4 to 6 sessions will complete 80% or more homework
Implementation/ Practicality	Screening/eligibility for study/ dropout	Record number of call attempts for each participant and reasons for ineligibility/decision not to participate/dropout
	Recruitment	Recruit, phone screen, and explain study to eligible participants for Study 1 within 2 weeks, Study 2 within 1 month, and Study 3 within 2 months. Obtained signed informed consent from participant.
	Retainment	Among those randomized, 34/42 (81%) will attend 1 or more sessions[97,107,110]
	Assessment completion	For assessments attempted, 90% completion rate

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Aim 2 and 3: Examining the Intervention's Fidelity, Feasibility and Acceptability

Maintenance and Evaluation of Treatment Fidelity. We will provide ongoing assessment of treatment fidelity among facilitators following recommendations made by Borrelli[174]. Specifically, facilitators will utilize a treatment manual that will detail session-specific components and proscribed topics, along with a checklist to ensure completion. Contact minutes per group will be recorded to ensure duration consistency across groups. Deviations from protocol will be recorded by the facilitators. Further, all sessions will be audio-recorded via state-of-the-art Intelligent Video Solutions equipment (see Equipment). Dr. Gaylord or Vinci will listen to at least one session per cohort group to ensure adherence to the manual across time and sessions. If either facilitator falls below a predetermined performance criterion or self-reported checklist indices, two sessions per group for that facilitator will be observed until adherence meets established criteria. Facilitators will be provided feedback during weekly supervision.

Evaluation of Feasibility and Acceptability. To evaluate feasibility and acceptability, we will rely on benchmarks proposed in the extant pilot/feasibility study literature.[176-178] Specifically, we will assess methodological- (screening, recruitment, randomization, retention) and intervention- (treatment adherence) related components of the proposed protocol. Throughout recruitment and administration, we will assess for: (1) the number of veterans screened per week, (2) the number of veterans enrolled per week, (3) the proportion of screened participants who take part in the sessions, (4) the ability to randomize enrolled veterans, (5) the number of battery assessments completed, and (6) the proportion of questionnaires completed. Low rates could indicate a high level of perceived burden, limiting the feasibility of this intervention.

Specific to treatment components, we will: (1) assess the number of sessions completed by participants in each group, (2) assess the percent of completed mindfulness home practice assignments among intervention participants as compared to the home assignments from the ES group, and (3) compare the retention rate of participants assigned to the MMMI group to that of participants assigned to the ES control condition. High retention and homework completion rates will indicate that participants found the intervention acceptable and that, similar to the MMCP program (Brintz et al., in press), six sessions are acceptable. Based on prior studies conducted we anticipate 81% of those who meet study criteria and agree to participate will attend 4 to 6 sessions and complete the post-training semi-structured interview or other survey measures. Forty (40%) of those who attend 4 to 6 sessions will complete 80% or more homework, ~40% who attend 4 to 6 sessions will complete 40% to 80% of homework, and ~20% who attend 4 to 6 sessions will complete less than 40% of the homework. Acceptability will also be evaluated with the Client Satisfaction Questionnaire (≥80%) and via two questionnaires developed for this study: (1) whether individuals intend to continue using the skills learned in the future, and (2) appropriateness of the intervention to treat moral injury.