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A Randomized Trial of Modified Prolonged Exposure to Prevent the Development of Posttraumatic Stress Disorder in Patients Hospitalized With Traumatic Injuries

Sadie E. Larsen [1,2] Joshua C. Hunt,[3] Tim Geier,[3] Katelyn Heyrman,[4] Nicholas Schumann,[3] Amber Brandolino,[3] Sydney Timmer-Murillo [5] Carisa Bergner,[6] Christine Larson,[7] and Terri A. deRoon-Cassini[3]

[1]Department of Psychiatry and Behavioral Medicine, Medical College of Wisconsin, Wauwatosa, Wisconsin, USA
[2]Milwaukee VA Medical Center, Milwaukee, Wisconsin, USA
[3]Department of Surgery, Division of Trauma & Critical Care, Medical College of Wisconsin, Milwaukee, Wisconsin, USA
[4]Department of Educational Psychology, University of Wisconsin Milwaukee, Milwaukee, Wisconsin, USA
[5]Department of Psychology, Marquette University, Milwaukee, Wisconsin, USA
[6]Medical College of Wisconsin, Comprehensive Injury Center, Milwaukee, WI, USA
[7]Department of Psychology, University of Wisconsin Milwaukee, Milwaukee, Wisconsin, USA

Individuals who require hospitalization after traumatic injuries are at increased risk for developing posttraumatic stress disorder (PTSD); however, few early behavioral interventions have been effective at preventing PTSD within this population. The aim of this pilot study was to assess the feasibility and effectiveness of modified prolonged exposure therapy (mPE) to prevent PTSD and depression symptoms among patients hospitalized after a *DSM-5* single-incident trauma. Hospitalized patients were eligible if they screened positive for PTSD risk. Participants ($N = 74$) were randomly assigned in a parallel-groups design to receive mPE ($n = 38$) or standard of care treatment (SoC; $n = 36$) while admitted to the hospital after a traumatic injury. Individuals randomized to the intervention condition received one (42.1%), two (36.8%), or three sessions (15.8%) of mPE, mainly depending on length of stay. There were no significant differences between groups regarding PTSD or depression severity at 1- or 3-months posttrauma, except for more PTSD diagnoses in the intervention group after 1 month, $\phi = -.326$. Intervention differences were nonsignificant when we took baseline PTSD symptoms and the nonindependence of the repeated measurements within the data into account. No adverse events were reported. Overall, mPE was no more effective than SoC for hospitalized, traumatic injury survivors with a high PTSD risk. The results may point to a need for a stepped-care approach, where intervention protocols focus on first briefly treating individuals who are actively exhibiting acute stress reactions, then extensively treating those whose symptoms do not decrease over time.

According to the Centers for Disease Control and Prevention (2017), approximately 2.9 million adults in the United States were hospitalized in 2017 due to a single incident traumatic injury. Individuals who require hospitalization after a traumatic injury are at an increased risk for distress and reduction in overall quality of life, and the prevalence rate of posttraumatic stress disorder (PTSD) among these individuals is three times the rate found in the general population (O'Donnell et al., 2004). Recognizing this increased risk, researchers have begun to develop secondary preventative interventions to avert the development of PTSD following traumatic injuries. Further, the American College of Surgeons has recommended providing treatment to the individuals most at risk of developing PTSD (Rotondo et al., 2014). Despite top-down support, there is still a clear need for early interventions to be evaluated, as few have garnered significant support, especially when they are administered shortly after trauma exposure (International Society for Traumatic Stress Studies [ISTSS] Guidelines Committee, 2018; Shalev, n.d.). These evaluations will inform best practices for at-risk patients

Nicholas Schumann is now at the Department of Surgery, The Queen's Medical Center, Honolulu, Hawaii.

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Correspondence concerning this article should be addressed to Sadie E. Larsen, Medical College of Wisconsin, 8701 W Watertown Plank Rd., Wauwatosa, WI 53226. E-mail: selarsen@mcw.edu

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who have been identified early in their hospital course as well as for other trauma survivors who can be identified soon after a traumatic event.

One of the first preventative interventions used after traumatic injuries was critical incident stress debriefing (CISD), in which trauma survivors are led through a single 1–3 hr debriefing session soon after a traumatic experience (i.e., typically within 1 week to 1 month). The CISD protocol involves discussion of the details of the critical incident as well as associated thoughts and feelings and is sometimes conducted at the site of the event. However, researchers have now concluded that CISD is, at best, ineffective in preventing PTSD (van Emmerik et al., 2002) and, at worst, may be harmful to some individuals by exacerbating PTSD symptoms (Sijbrandij et al., 2006). Researchers have also examined more independent interventions, such as the provision of self-help or informational materials, and found these to be ineffective as well (Scholes et al., 2007; Turpin et al., 2005). Pharmacological interventions, such as propranolol, morphine, selective serotonin reuptake inhibitors, and, in particular, hydrocortisone, demonstrated initial promise when examined (ISTSS, 2018; Sijbrandij et al., 2015). However, the findings from a literature review showed that when only randomized controlled trials were examined, these pharmacological interventions showed no effect (Sijbrandij et al., 2015). In addition, the results suggested that it is unclear whether patients would accept pharmacological intervention, given higher dropout rates in intervention versus placebo conditions and the possibility of adverse side effects.

Some types of psychosocial prevention interventions have shown initial promise. Giummarra and colleagues (2018) conducted a meta-analysis of early psychological interventions after traumatic injury. Generally, cognitive behavioral therapy (CBT)- or exposure-based interventions administered within 3 months following injury showed small-to-large effect sizes on PTSD symptoms, with the largest effects for interventions delivered within the first month. However, interventions that incorporated a stepped-care paradigm targeting high-acuity patients demonstrated the largest overall population impact, despite smaller effect sizes (Giummarra et al., 2018). These findings are balanced by those from another recent meta-analysis with somewhat overlapping populations, which demonstrated that CBT interventions showed promise for preventing PTSD in a narrative analysis but no significant effect in a quantitative meta-analysis (Pham et al., 2019). As discussed by Giummarra and colleagues (2018), potentially biased methodology in study designs may lead to discrepant findings; thus, high-quality intervention studies are needed.

Exposure-based interventions have been some of the most promising with regard to PTSD prevention (Giummarra et al., 2018). Modified prolonged exposure (mPE) has been trialed in the immediate aftermath of a traumatic event requiring treatment in the emergency department (ED). This treatment was found to have a significant positive effect on PTSD and depression symptoms (Rothbaum et al., 2012). Standard prolonged exposure (PE) therapy has gained significant empirical support in treating chronic PTSD and is considered a front-line treatment (American Psychological Association [APA], 2017). This treatment is based on an emotional processing model of PTSD, with the understanding that classical fear conditioning and maladaptive beliefs contribute to the development of PTSD. The mPE tested by Rothbaum and colleagues (2008) is likely effective for several reasons. Specifically, it was designed to address the theoretical mechanisms underlying PTSD development (i.e., fear conditioning and avoidance); involves individual rather than group-based delivery; includes other useful components, such as breathing relaxation, in vivo exposure, self-care, and attention to cognitions; and most importantly, involves multiple, repeated exposures to the trauma narrative to allow for fear extinction within and between sessions (Rothbaum et al., 2012). Although standard PE has demonstrated positive outcomes, early mPE has only been used in one setting, where it was offered to all patients who presented to the ED (Rothbaum et al., 2012).

In the present study, we chose to administer mPE to patients during their hospital stay after admission for traumatic injuries for two reasons. First, we reasoned that this population often struggles to return for appointments after discharge; thus, we reasoned that administering the intervention while individuals were in the hospital should increase adherence and reach. Second, there is some evidence that interventions that occur earlier rather than later may be more effective. For instance, one translational study of fear conditioning found that individuals who received extinction training 10 min after fear conditioning demonstrated significantly lower fear-potentiated startle than individuals who received extinction training after 72 hr (Norrholm et al., 2008), indicating that timing of intervention plays a significant role in the trajectory of psychological distress following fear conditioning and, perhaps, trauma exposure. The early days after a traumatic experience have been considered a "sensitive" period during which neuronal plasticity is intensified, and aversive or adaptive learning develops (Shalev, 1999; Shalev et al., 1992). Acute stress responses within the wake of trauma exposure are common and can arguably be considered a healthy response to a traumatic event; however, these reactions can also be considered a "prelude to mental disorders" (Shalev, 2002, p. 532). With regard to preventive studies conducted within the first 3 months following trauma exposure, those administered within the first month posttrauma have appeared to demonstrate the largest effect sizes (Giummarra et al., 2018). Thus, there is some evidence that early interventions may be more effective than those administered later.

The challenge of intervening early, however, is that most people are resilient and will not go on to develop a mental health disorder after a traumatic event, even if they initially have some symptoms (deRoon-Cassini et al., 2010). As such, one systematic review found that administering interventions to all trauma-exposed individuals was generally ineffective, and even evidence-based CBT approaches were not consistently effective (Roberts et al., 2019). Thus, it is crucial, though difficult, to identify individuals who would likely benefit from early

intervention. Therefore, for the present study, we chose to intervene early but enroll only those participants who were judged to be at a higher risk for later PTSD development.

The aim of the current pilot study was to assess the feasibility and effectiveness of an mPE intervention for hospitalized trauma survivors given their high risk of PTSD development. We further adapted mPE by aiming to administer the three sessions while the patient was still hospitalized to increase the feasibility of attendance in a population with transportation difficulties who often have trouble returning for postdischarge healthcare. In this specific population, we targeted individuals who were most at risk of developing chronic PTSD by using a predictive screen, as only approximately 22% of trauma survivors are at high risk for developing chronic PTSD (deRoon-Cassini et al., 2010). We assessed both the feasibility (i.e., number of participants who agreed to treatment, number of sessions completed, number of participants who complied with therapy elements, and patient satisfaction) as well as the effectiveness of the treatment (i.e., PTSD and depression symptom severity).

Method

Participants

Participants were drawn from hospital admissions at an urban, Midwest U.S. Level 1 trauma center (see Figure 1 for the CONSORT diagram). Participants were eligible if they had experienced a single-incident traumatic injury that met the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*) definition of a traumatic stressor for PTSD, including, though not limited to, motor vehicle crashes (MVC), industrial injuries, and blunt or penetrating assault (i.e., gunshot wounds, stab wounds). To reach a larger portion of the population, all injured adult patients admitted to the trauma service were considered for enrollment in the study. To identify individuals who were most at risk for developing PTSD, participants were screened using the Injured Trauma Survivor Screen (ITSS; Hunt et al., 2017). This screen is intended to identify individuals who are most at risk for later development of PTSD and a major depressive episode following a traumatic injury event and subsequent admission to a trauma service. Participants were excluded from the study based on the following criteria: (a) nonpositive screening for later PTSD development risk, based on an ITSS score under 2; (b) presence of a moderate-to-severe traumatic brain injury, as determined by a Glasgow Coma score below 13 upon arrival to the ED and more than 30 min of peritraumatic amnesia; (c) self-inflicted injuries; (d) injuries that resulted in the inability to communicate; (e) non-English speaking; (f) more than 2 weeks posttrauma; (g) age younger than 18 years or older than 75 years; (h) positive screen for current disordered substance use; or (i) not medically stable. A total of 74 eligible participants consented to the study (for a demographic summary, see Table 1). The mean age of the sample was 35.01 years ($SD = 14.57$), with the majority identifying as male ($n = 42$) and African American ($n = 51$). The mechanisms of injury for the sample were MVC (25.0%), gunshot wound (39.5%), stab wound (9.2%), struck by a vehicle as a pedestrian (9.2%), motorcycle crash (2.6%), crush injury (2.6%), and "other" (9.2%), including falls and sports-related incidents (e.g., bicycle crash). Given the evidence regarding differential outcomes across trauma types (Creamer et al., 2001), we classified trauma types into assaultive (gunshot wound, stab wound) versus nonassaultive (all other types) traumas.

Procedure

Participant Recruitment and Consent

Participants were identified through the use of a daily trauma surgery census (i.e., a daily list of patients admitted to the trauma surgery service), electronic medical records, and referral by patients' treatment teams. On average, within 2 days of hospital admission, patients were clinically administered the ITSS by research staff or a unit social worker assigned to the patient to screen for individuals most at risk for developing PTSD. This was the main inclusion criterion for the study, and it allowed for a broad sampling of all trauma patients to identify those most at risk and thus in need of intervention. Patients whose screenings demonstrated positive risk for PTSD (i.e., a score of 2 or higher) were eligible. Trained research staff then identified individuals who met all inclusion and no exclusion criteria for the study. Eligible patients were approached in the hospital by research staff to assess for interest in the study. Interested patients gave consent for study participation to research staff. This study was approved by the Medical College of Wisconsin Institutional Review Board. Recruitment began on March 8, 2016, and ended on May 31, 2018; the final follow-up assessment was completed on October 17, 2017.

Randomization and Intervention

Following study enrollment, participants were randomly assigned in a 1:1 allocation, parallel-groups design to either the (a) Control arm (i.e., standard of Care [SOC]) or (b) intervention arm (mPE). Randomization was based on a goal sample of 100 patients, with an expected effect size of $d = 0.6$, 45 participants per group would be needed to detect two-sided differences with 80% power. Randomization was created by the research coordinator using a free, online random number generator. The randomization scheme was uploaded electronically to REDCap (Nashville, TN), which acted as the electronic data capture system for the study. All other study team members remained blind until the end of the baseline assessment. Unblinding occurred via REDCap once the study staff completed all baseline assessments with the participant.

Control Arm (SOC). Participants in the control group completed the same assessments as those in the intervention group. Otherwise, they did not receive a standardized intervention. That said, in this setting, the institution's SOC involved requests for psychology consults being placed when deemed

Figure 1
CONSORT Study Enrollment Overview

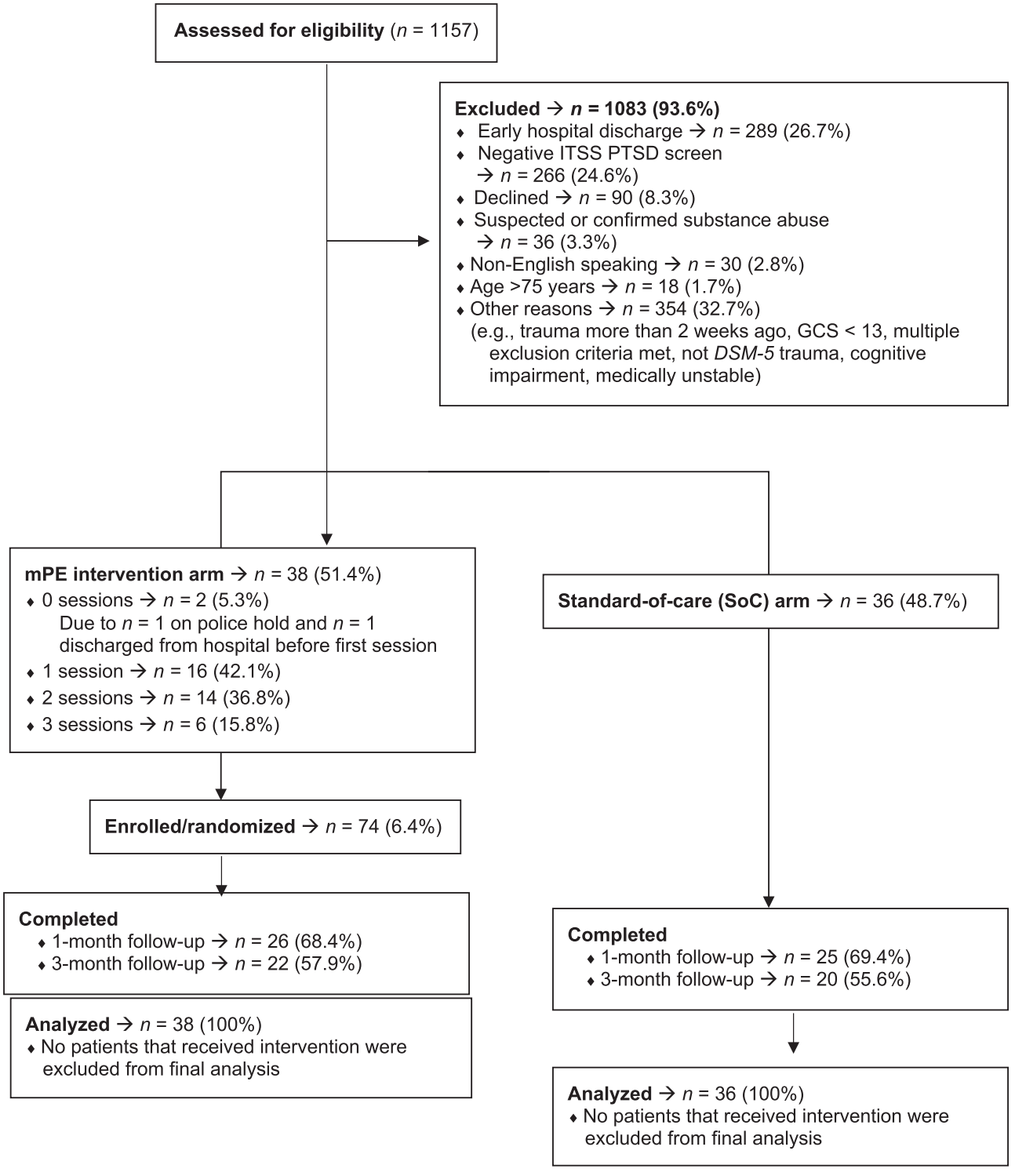

Table 1
Demographic Variables and Symptoms, by Randomized Condition

	Intervention ($n = 38$)				Standard of care ($n = 36$)			
Variable	*n*	%	*M*	*SD*	*n*	%	*M*	*SD*
Male gender	23	60.5			19	52.8		
Assault-related mechanism of injury	22	57.9			19	52.8		
Endorsement of previous history of psychiatric diagnosis or treatment	12	31.6			4	11.1		
Non-White race	31	81.6			27	75.0		
Age (years)			34.95	15.07			35.08	14.24
Time since trauma (days)			3.92	3.07				3.64 3.21
CAPS severity score								
1 month			36.42	13.02			29.92	15.35
3 months			31.27	13.85			22.75	16.50
Met CAPS-5 PTSD criteria[a]								
1 month	22	43.1			15	29.4		
3 months	14	33.3			9	21.4		
PCL-5 score								
Baseline			38.21	18.90			36.14	21.26
1 month			47.50	16.39			39.20	22.17
3 months			41.82	18.88			30.70	19.78
BDI-II								
Baseline			25.07	13.87			24.08	14.71
1 month			25.14	12.67			20.96	14.40
3 months			18.88	11.99			14.64	14.68

Note. PTSD = posttraumatic stress disorder; CAPS-5 = Clinician-Administered PTSD Scale for *DSM-5*; PCL-5 = PTSD Checklist for *DSM-5*; BDI-II = Beck Depression Inventory–Second Edition.
[a]Percentages represent the proportion of participants who completed 1-month follow-up (intervention group: $n = 26$, standard-of-care group: $n = 25$, total: $N = 51$) and 3-month follow-up (intervention group: $n = 22$, standard-of-care group: $n = 20$, total: $N = 42$).

appropriate by the treatment team during the patient's index hospitalization, which did occur for some participants.

Intervention Condition (mPE). Administration of mPE (Rothbaum et al., 2012) was completed by psychology doctoral graduate students or postdoctoral fellows trained in PE and mPE, with weekly clinical supervision. Intervention consisted of up to three 60-min in-person mPE sessions during hospitalization; partway through the study, investigators added the option to conduct the second and third sessions in an outpatient setting in the event of early discharge, although this option was rarely utilized. Standard PE directly addresses avoidance of trauma cues via two types of exposure to facilitate habituation to those cues. In imaginal exposure, the participant discusses the traumatic event in the first-person present tense, with up to three repetitions per session. In vivo exposure involves identifying people, places, or situations that the individual wishes to avoid, creating a hierarchy by ranking those situations in order of difficulty, then systematically approaching the feared situations.

Session 1 focused on psychoeducation, breathing retraining, imaginal exposure (30-45 min), emotional processing (10-15 min), and identification of behavioral exposures to complete as homework prior to Session 2. Session 2 involved reviewing homework, imaginal exposure (30-45 min), emotional processing (10-15 min), and identification of new behavioral

exposures to address continued behavioral avoidance before Session 3. Session 3 involved reviewing homework, imaginal exposure (30-45 min), emotional processing (10-15 min), identification of continual behavioral exposures, and emphasizing self-care techniques. Due to hospitalization, in vivo exposures were adapted to the context, such as having an MVC survivor watch videos of cars similar-looking to those involved in their accident, and encouraged to be practiced daily. Participants were given audio players to listen to the imaginal exposure recordings. The goal was to complete three mPE sessions, but some patients received only one or two because of earlier-than-planned discharge or transportation limitations that prevented outpatient sessions. Individuals in the intervention condition were ineligible for SOC psychology consults.

Assessment

At baseline, we collected information on demographic characteristics, and participants filled out self-report measures of past traumatic experiences (Life Events Checklist [LEC]) and psychological and physical health symptoms (PTSD Checklist for *DSM-5* [PCL-5], Beck Depression Inventory–II [BDI-II]). Participants randomized to the intervention condition were asked to complete the PCL-5 before the second intervention session and the PCL-5 and BDI-II before the third session. At 1- and 3-months posttrauma, individuals in both conditions completed a follow-up assessment, which was conducted either in person or by telephone. At the follow-up assessments, participants completed self-report measures, including the PCL-5 and BDI-II, as well as the LEC to assess for additional traumatic experiences that had occurred since the baseline assessment. Trained clinical psychology graduate students used the past-month version of the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5) to assess diagnostic criteria of PTSD at both follow-ups.

Measures

PTSD Risk

The ITSS (Hunt et al., 2017) is a nine-item screening tool that is used to assess PTSD and depression risk in hospitalized, traumatically injured patients; in the present study, the ITSS was only used to screen for PTSD risk. Each item is assessed with a "yes" or "no" response, and each endorsed item is assigned 1 point. A sum score of 2 or higher indicates that the respondent has screened positive for PTSD risk; lower scores indicate no risk. In the developmental sample, sensitivity and specificity were 75.0% and 93.9%, respectively, at 1-month follow-up and 85.4% and 67.4%, respectively, at 6-month follow-up (Hunt et al., 2018).

Lifetime Trauma History

The LEC (Weathers et al., 2013b) is a validated, 17-item tool used to screen for exposure to unique potentially traumatic events that have demonstrated associations with PTSD development and other posttraumatic symptoms (Gray et al., 2004). For each event, individuals choose from response options "happened to me," "witnessed it," "learned about it," "part of my job," "not sure," and/or "doesn't apply;" multiple options can be endorsed for each item. For the present study, the number of events identified endorsed with the options "happened to me" or "witnessed it" at baseline were summed to create a total score, with higher scores suggesting more exposure to potentially traumatic events (possible score range: 0–34). The LEC was also administered at 1- and 3-month follow-up assessments to evaluate any traumatic experiences that occurred since the index traumatic event; this was coded dichotomously as having experienced or not having experienced a subsequent traumatic event.

Depressive Symptoms

The BDI-II (Beck et al., 1996) is a validated 21-item measure of depressive symptoms. Items are rated on a 4-point Likert scale ranging from 0 to 3, with participants rating the degree to which they have experienced each symptom within the previous 2 weeks. The total score is summed (possible score range: 0–63), with higher sum scores indicating a higher level of symptom severity. The BDI-II is widely used to assess depressive symptoms and has demonstrated good construct validity and test–retest reliability (Pearson's $r = .93$; Beck et al., 1996). A BDI-II score of 14.5 is optimal for differentiating between those with and without depression (von Glischinski, von Brachel & Hirschfeld, 2019). In the present sample, Cronbach's alpha values were .92 at baseline, .94 at 1-month follow-up, and .94 at 3-months follow-up.

PTSD Symptom Severity

The PCL-5 (Weathers, Litz, et al., 2013) is a 20-item measure that is used to assess *DSM-5* PTSD symptom severity. At baseline, participants were asked to rate their symptoms using the time since the traumatic event as a reference point; for follow-up assessments, the past month was used as the reference point. Respondents rate each *DSM-5* PTSD symptom–related item using a 5-point Likert scale ranging from 0 (*not at all)* to 4 (*extremely*). Sum scores are calculated for a total score (possible score range: 0–80), with higher scores indicating a higher level of symptom severity. The PCL-5 has demonstrated good internal consistency (Cronbach's $\alpha = 0.94$), test-–retest reliability (Pearson's $r = .82$), and validity ($rs = .31$–$.60$; Blevins et al., 2015). A PCL-5 score of 31 or higher has been shown to indicate a likely PTSD diagnosis in a traumatically injured population (Geier et al., 2019); however, we did not use the PCL-5 as a diagnostic tool in the current study. In the present sample, Cronbach's alpha values were .93 at baseline, .91 at 1-month follow-up, and .94 at 3-month follow-up.

PTSD Diagnosis and Severity

The CAPS-5 (Weathers et al., 2013a) is a structured interview considered to be the gold standard for PTSD diagnosis. The CAPS-5 is a 30-item clinical interview that is used to evaluate each *DSM-5* PTSD symptom cluster to determine whether

an individual meets the diagnostic criteria for PTSD 1 month after a potentially traumatic experience. Each symptom is rated on a scale of 0 (*absent)* to 4 (*extreme*), and the 20 PTSD symptom items can be summed to create a total severity rating (possible score range: 0–80), with higher scores indicating a higher level of symptom severity. The CAPS-5 has shown excellent interrater reliability for diagnosis of PTSD (Pearson's $r = 1.00$) and good interrater reliability for frequency and intensity of symptoms (Pearson's *r*s = .83–1.00; Forbes et al., 2015). In the present sample, Cronbach's alpha was .91 at both 1-month and 3-month follow-ups. To assess interrater reliability, 20% of the CAPS-5 assessments were audio-recorded and scored by two independent raters. A kappa score of 1.00 was found when comparing diagnoses between the raters.

Data Analysis

All analyses were intent to treat, including all participants who were randomized to a condition, regardless of the number of sessions received. At 1 month, 31.1% of participants could not be reached for follow-up and thus had missing data; at 3 months, the rate was 43.2%. Completion of follow-up assessment was unrelated to demographic characteristics, baseline symptoms, or randomization. Missing data were handled via the use of mixed-level modeling, which estimates parameters via restricted maximum likelihood and utilizes any data available from any time point.

We first compared treatment conditions with regard to baseline demographic characteristics, symptoms, and traumatic experiences, both at baseline and between baseline and follow-up. We next assessed feasibility by examining (a) the number of participants who met the inclusion criteria and agreed to participate; (b) the number of sessions completed; (C) fidelity of sessions in terms of necessary elements administered, protocol deviations, homework compliance, and expert review of audio recordings; and (d) patient satisfaction.

A multilevel modeling framework was employed to examine the effectiveness of the treatment. Specifically, we utilized the lme4 package in R (Version 3.4.2) and R studio (Version 1.1.383 (R Core Team; 2017) to fit a linear mixed model, accounting for both fixed- and random-effects terms. The "lmer" function within the lme4 package, which determines linear model parameters using restricted maximum likelihood (REML) estimates, was selected for the analysis. Two models were constructed: (a) a null model with random intercepts grouped by both subject and time point and (b) a model with random intercepts grouped by both subject and time point as well as the fixed predictor of interest (i.e., treatment). Intraclass correlation coefficients (ICC) were computed to extract the variances for each random-effects term, and an analysis of variance (ANOVA) was used to compare models. Separate pairs of models were fit for the outcomes of PTSD (i.e., PCL-5 score) and depression (i.e., BDI-II score), given that we had data for these variables at all three time points as opposed to the CAPS-5, which was only administered at follow-up assessment. Differences in symptoms are also presented descriptively for each time point, using PCL-5, CAPS-5, and BDI-II scores, to allow for further interpretation.

To better understand predictors of change, we conducted two linear regressions predicting nonimputed CAPS-5 total severity scores at 1- and 3-month follow-ups, with baseline PCL-5 symptoms and intervention group entered as independent variables. We utilized the CAPS-5 for this analysis as it is considered to be the gold-standard diagnostic assessment. Effect size interpretations are presented for group differences but should be interpreted with caution given that this was a pilot study with a small sample size (Leon et al., 2011).

Results

Baseline Assessment

We first compared the intervention ($n = 38$) and control ($n = 36$) groups across a variety of demographic and clinical variables to identify any baseline group differences (see Table 1). There were no significant differences with regard to gender, $\chi^2(1, N = 74) = .45$, $p = .501$; ITSS PTSD risk, $t(72) = 1.29$, $p = .620$; ITSS depression risk, $t(72) = -.26$, $p = .90$; baseline depressive symptoms, $t(72) = .284$, $p = .777$; baseline PTSD symptoms, $t(72) = .444$, $p = .659$; assaultive versus nonassaultive trauma exposure, $\chi^2(1, N = 74) = .196$, $p = .658$; or total LEC score, $t(72) = .744$, $p = .459$. Although not significant, marginally more people in the control group had a previous history of psychiatric diagnosis or treatment, $\chi^2(1, N = 74) = 3.41$, $p = .065$. Likewise, the numbers of participants who experienced a further trauma exposure within 1 or 3 months of the index traumatic event were not significantly different between groups: 1-month follow-up, $\chi^2(1, N = 41) = 0.26$, $p = .613$; 3-month follow-up, $\chi^2(1, N = 36) = 1.00$, $p = .317$. On average, participants were approached 3.78 days ($SD = 3.12$) after their index traumatic event and completed their 1-month follow up 54.22 ($SD = 20.64$) days posttrauma. No adverse events were reported.

Feasibility

Of the individuals assessed for study eligibility ($N = 1{,}083$), a small subset declined ($n = 90$, 8.3%), and some were discharged from the hospital before they were able to start the treatment ($n = 289$, 26.7%; see Figure 1). Of the patients randomized to the intervention condition, most had only one ($n = 16$, 42.1%) or two sessions ($n = 14$, 36.8%), with few completing all three sessions ($n = 6$, 15.8%); this was mainly due to hospital discharge as opposed to declining participation. Two participants were randomized to intervention but did not complete any intervention sessions (5.3%; one because they were placed on police hold and one who was discharged unexpectedly before completing any sessions). All participants were included in the intent-to-treat analyses. Three participants returned to the hospital to receive an outpatient session, one of

whom returned for both the second and third sessions on an outpatient basis.

Regarding necessary session elements, for the first session, seven elements were supposed to be present; in all sessions, therapists self-reported that all elements were present except for one session, in which the "wrap-up and consolidate learning" and "breathing" sections were reported as not present for one patient. For three patients, between one and six session elements were missing data. Therapists also recorded any protocol deviations; in the first session, three protocol deviations were reported: One therapist forgot the subjective units of distress (SUDS) explanation until midway through imaginal exposure, one therapist interrupted imaginal exposure to ground a patient having a panic attack before reengaging, and one patient did not engage in the full imaginal exposure session. Thus, for 32 of 36 first sessions, 32 (88.9%), no missing elements or deviations were reported.

For the second session, four protocol deviations were noted: One therapist forgot the SUDS initially, one patient started to process during imaginal exposure and took some redirection to return to the exposure, and two patients quit before or during the exposure portion of Session 2. All five session elements were present in all sessions except for the two previously noted protocol deviations, which led to all session elements except the initial "review homework" element reported as missing for two participants. Two additional patients were missing data for one Session 2 element. Thus, in 16 of 20 second sessions (80.0%), no protocol deviations or missing elements were reported. During Session 2, therapists also assessed patient homework compliance. All participants reported practicing breathing, 68.4% reported listening to the imaginal exposure tape, and 52.6% reported practicing in vivo exposure.

For the third session, all six session elements were present. One protocol deviation was noted, in which the patient was somewhat sedated and sleepy, and both imaginal exposure and processing were somewhat minimal; thus, 5 of 6 sessions (83.0%) were fully adherent and had no missing data. Regarding homework compliance, 83.3% of participants practiced breathing, 50.0% listened to the imaginal exposure tape, and 83.3% reported completing imaginal exposure.

Rates of follow-up assessment completion were similar. At 1 month, 68.4% of participants in the intervention group ($n = 26$) and 69.4% of participants in the control group ($n = 25$) completed follow-up; at 3 months, the rates were 57.9% ($n = 22$) and 55.6% ($n = 20$), respectively. The rates were not significantly different between intervention and control groups. Patient satisfaction was also briefly assessed at 1- and 3-month follow-ups by asking patients to evaluate how difficult the treatment was and how helpful it was. At 1-month follow-up, 25.0% of patients asked how difficult treatment was said "neutral," 50.0% said "somewhat difficult" or "very difficult," and 25.0% said "somewhat easy" or "very easy." With regard to how helpful treatment was, 10.0% of patients asked said "neutral," whereas 90.0% said "somewhat helpful" or "very helpful;" no participants rated the treatment as "unhelpful." Anecdotally, some themes that emerged were an appreciation for the therapists but a dislike of the repetition involved in the imaginal exposure. A few participants indicated at the 3-month follow up that this intervention may have been more helpful later on in their physical recovery.

Expert clinician review was conducted on 10 sessions via listening to audio recordings of the sessions across all interventionists. A treatment integrity checklist was utilized to evaluate six treatment components for adherence and competency separately, with the rating ranging from 1 (*very poor*) to 7 (*excellent*). Overall, interventionists reached 96% adherence and 92% overall competency across the 10 sessions, out of the total possible points on adherence and competency separately.

Effectiveness

We next utilized multilevel modeling to analyze the effect of treatment on PTSD (i.e., PCL-5) and depression (i.e., BDI-II) symptoms while accounting for the nonindependence of the repeated measurements within the data. For the model predicting PTSD, the intraclass correlation coefficients indicated that the differences between subjects accounted for a substantial portion of the variance (63.8%), whereas the differences between time points had little impact (1.6%). A comparison of the null PTSD model to the model including the fixed predictor (i.e., treatment) showed that there was not a significant improvement of model fit, $p = .413$. The lack of model fit improvement when treatment was included suggests that the intervention was not effective. Descriptively, these results were consistent with simple t tests comparing both CAPS-5 and PCL-5 symptom severity totals at each follow-up time point (see Table 1), which indicated no significant differences between groups, although, in contrast to our hypotheses, participants in the intervention group reported higher levels of PTS severity at follow-up, $d =$ 0.46 at 1 month and 0.56 at 3 months (medium effect sizes). The results of a chi-square test demonstrated a significant difference for CAPS PTSD diagnosis at 1 month, $p = .020$, but not 3 months, such that individuals in the intervention group were significantly more likely to have a PTSD diagnosis at that time point.

The depression (i.e., BDI-II) linear mixed model showed similar results. Intraclass correlation coefficients for participants (63.6%) and time points (3.1%) closely resembled those found for the PTSD model, thus demonstrating a strong effect of individual participants on model variance. Again, a comparison of the null BDI-II model without fixed effects with the model that included the treatment variable did not yield statistical significance, $p = .743$, signaling that the intervention was not effective in reducing depressive symptoms. Again, the results fit descriptively with t tests for the BDI-II, which demonstrated no significant differences between groups, although participants in the intervention group reported a higher level of depressive symptoms at follow-up, $d = 0.31$ at 1 month and 0.32 at 3 months (small-to-medium effects).

We also conducted a linear regression predicting CAPS-5 total severity at 1-month follow-up, with baseline PCL-5 symptoms and intervention group entered as independent variables. In this regression, baseline symptom severity was significantly related to 1-month CAPS-5 score, $\beta = .398$, $p = .004$, whereas condition was not, $\beta = -.153$, $p = .249$. The results were similar at 3 months posttreatment, $\beta = .596$, $p < .001$ for baseline PCL; $\beta = -.143$, $p = .263$ for treatment condition.

Post Hoc Analyses

To better understand the experience of participants in the control group, we conducted a chart review to document any mental health contact among individuals in the control group. All of these participants were eligible for psychological consults, which are part of the SOC at this trauma center. Of the 36 control participants, 12 had no mental health treatment, but 24 individuals reported some. A majority of those participants ($n = 23$) had one or more inpatient mental health sessions, and three individuals had outpatient mental health sessions. These consisted of the following non–mutually-exclusive elements: psychiatry consult ($n = 1$), psychoeducation on trauma responses ($n = 18$), discussions of avoidance ($n = 13$), teaching deep breathing ($n = 10$), discussing social support ($n = 7$), utilizing CBT techniques ($n = 8$), utilizing exposure therapy ($n = 1$), and utilizing other practical interventions ($n = 6$).

Discussion

The goal of the present study was to evaluate the feasibility and effectiveness of mPE, delivered in-hospital to patients admitted for a traumatic injury, for reducing PTSD symptom severity as assessed 1 and 3 months posttrauma. Overall, mPE was no more effective than SOC for hospitalized traumatic injury survivors admitted to a Level I trauma center who were identified as having a high risk of developing PTSD. Specifically, participants who received mPE did not significantly differ regarding PTSD or depression severity at 1- and 3-months postinjury when compared to their counterparts assigned to a control condition; however, individuals in the intervention group were more likely to have a PTSD diagnosis at 1-month follow-up but not 3-month follow-up. The results of multilevel modeling and regression analyses indicate that any such group differences at single time points became nonsignificant after initial symptoms were taken into account.

Several differences may explain the null results found in the current study compared to previous findings in a study of mPE among injured patients recruited from the hospital. Rothbaum and colleagues (2008, 2012) found that a brief mPE intervention helped reduce the development of psychological maladjustment following traumatic injury; participants were recruited from the ER, where the first session took place, and completed the second and third sessions 1 week later on an outpatient basis. With regard to potential meaningful differences, there are several differences in setting. First, whereas the intervention in Rothbaum and colleagues' (2008, 2012) study consisted of outpatients returning to the hospital weekly for the second and third sessions, the current study largely consisted of participants who were still in the hospital for all three sessions, which took place within the first week after the traumatic injury occurred. This difference in setting could have resulted in the hospitalized participants not being able to generalize the exposure learning to their daily lives or to see the impact the traumatic experience would have on their day-to-day lives, thereby potentially impacting treatment effectiveness and motivation to engage in treatment. Moreover, this midwestern United States Level I trauma center includes a psychological consult service as part of its surgical intervention model. In line with this model, a chart review revealed that most control participants received at least some psychological intervention, which may be similar to other such trials (Sise et al., 2018). The most common factors included in this service consisted of psychoeducation on common posttraumatic reactions and the importance of minimizing or reducing avoidance behaviors, discussions around the patient's experience of the traumatic event (i.e., peritraumatic reactions), and relaxation training, such as diaphragmatic breathing; therefore, there is arguably much overlap between interventions received by both groups.

In addition to the setting, some patient characteristics may have contributed to different findings compared to those reported by Rothbaum and colleagues (2012). First, Rothbaum and colleagues noted that their mPE intervention was most efficacious for individuals whose index traumatic event was a sexual assault, whereas the intervention produced a nonsignificant effect size for physical assault victims and a marginally significant effect size for MVC victims. The current investigation had no participants who reported sexual assault as their index traumatic event, which could have yielded the effect differences between the two studies. The injury severity of the patient population also differed. In the current study, participants were hospitalized patients, whereas the sample consisted of individuals who had been discharged from the ED in the Rothbaum et al. (2012) study. This difference in severity could suggest that the current sample would require more extensive psychological intervention to be effective or that effects would perhaps be larger by identifying individuals with both a high PTSD risk and elevated symptoms to target a larger "dose" of treatment, similar to other effective early interventions administered slightly later (i.e., 2–4 weeks posttrauma; Bryant et al., 2003; O'Donnell et al., 2012; Zatzick et al., 2009). Future researchers may also want to ensure that trauma exposure is not ongoing. Traumatic injury experiences can serve as the beginning of a very challenging period of several months to years, which includes recovery from physical injuries. Participants in the present study often returned to the same dangerous neighborhoods where they were assaulted or were incapacitated physically. When returning to their respective communities, participants may continue to suffer from chronic pain, family disruptions, and stressors related to employment, finances, and their community. Taken together, these factors not only increase cumulative stress but

also lead to devastating impacts on economic status, especially when engaged with compensation systems that can be stressful themselves. Finally, differences in treatment compliance may have contributed to differences across studies. Specifically, although most participants in the current investigation completed the diaphragmatic breathing exercises, compliance with exposure tasks as well as subsequent treatment sessions appeared lower in this sample when compared to those cited in Rothbaum and colleagues (2012) study, in which compliance was reported to be roughly 85%.

Another possible reason for our null findings is that extinction training and memory reconsolidation processes are not the optimal mechanisms for preventing PTSD at this timing. Some basic research has indicated that there is a brief window after a fear-conditioning event, during which extinction training may prevent the fear memory from being consolidated (e.g., 10 min vs. 72 hr postevent; Myers et al., 2006). Similarly, administering human extinction training 10 min after an event appears to be more effective than administering training 72 hr later (Norrholm et al., 2008). In the present study, exposure therapy, which is analogous to extinction training, began within days after a traumatic event, but this may be already too much elapsed time for brief extinction training to be effective, indicating a need for more extensive exposure, as has been shown to be effective with chronic PTSD.

Regarding feasibility, the present results pointed to some important implications for early intervention efforts. It was difficult for participants to complete three sessions while admitted, partially due to other demands on patients' time and discharges that occurred too quickly for all sessions to take place. This may be part of why Rothbaum et al. (2012) found more benefit from mainly outpatient sessions. Partway through this study, investigators did alter the protocol to allow for subsequent sessions to be administered in outpatient settings, but given the nature of the patient population (e.g., limited transportation, significant injuries limiting mobility), such sessions were still rare. Due to the inpatient setting, we also noticed that in vivo exposure homework was difficult. Although there were modifications, such as using images or Google earth, exposure to the most upsetting trauma cues was not always feasible while patients were confined to the hospital and, in some, cases physically limited due to their injuries. These factors contributed to the lower level of compliance compared to previous studies. It is also possible that compliance was lower because many symptoms are not yet as evident in the immediate aftermath of a trauma, thus decreasing motivation. Despite these drawbacks, patients were largely willing and interested in treatment (i.e., few were excluded due to lack of interest), and participant feedback suggested that most participants found the intervention at least somewhat helpful even though it was challenging; no participants rated the treatment as unhelpful. To date, the findings regarding the effectiveness of early intervention have been quite mixed (Roberts et al., 2019), perhaps pointing to a need for a wait-and-see or stepped-care approach, or a need to identify individuals in need of intervention based on both risk and symptom severity, taking treatment preference into account.

In contrast, the protocol as written for the current study intended to include any injured patients who required hospitalization and were risk-positive for the potential development of PTSD. After an individual was identified as being at risk, the intention was to complete the treatment protocol before patient discharge, potentially increasing the population impact of the intervention. This is similar to other stepped collaborative-care models that start with broad inclusion and then, over the course of risk screenings and assessments, focus on patients who are more symptomatic and/or are at higher risk for poor outcomes (e.g., Zatzick et al., 2015). These stepped collaborative-care interventions then have the potential for high population impact and high treatment effect (Koepsell et al., 2011). However, for the current trial, although the stepped-screen approach was utilized to increase population impact, patients' level of symptom distress was not assessed, potentially limiting the depth of symptom impact. In fact, Koepsell et al. (2011) noted that the reach of an intervention may be smaller when prevention is most broadly targeted, possibly contributing to the lack of observed treatment effects in the current study. We would encourage future researchers to examine and present population impact numbers to be able to compare these across disparate types of early interventions (Koepsell et al., 2011).

Approximately 15% of participants completed all three treatment sessions, with some sessions completed on an outpatient basis due to early patient discharge, bringing the feasibility of three inpatient sessions prior to discharge into question. From the current findings, it is clear that attempting to engage in three sessions of CBT before discharge was challenging. Although, theoretically, the intention was intended to treat at-risk individuals to habituate any fear conditioning that had taken place, the hospital environment and length of stay of traumatic injury survivors may not make this treatment feasible. Instead, the most successful models are the aforementioned stepped collaborative-care models that incorporate risk screening, case management, and embedded motivational interviewing to reduce symptoms of PTSD (Zatzick et al., 2015). It may be that these stepped collaborative-care models, although they do not engage in specific PTSD intervention initially, may be able to identify which specific CBT interventions will be helpful for observed symptoms over time. These models scale intervention toward individuals most in need of care over time, while also having population impact by initially reaching as many patients as possible.

Several additional limitations should be noted. First, as noted previously, the feasibility of delivering three sessions in an inpatient hospital setting appears to be low. Follow-up lasted 3 months, but it may be that the benefits of the early intervention may be evidenced later than 3 months postinjury as participants are physically more able to reengage in life and not avoid the people, places, and circumstances related to their traumatic experience. Additionally, the present study sample was rather small ($n = 74$), thereby reducing power while increasing the

margin for error; indeed, due to an end to study funding, the study ended before we reached the goal number of participants per group as determined by a priori power analysis. Participants were also recruited from a single Level I trauma center in the midwestern United States, which likely differs from other institutions regarding factors such as demographics, mechanisms of injury, and catchment area. This constrained sample ultimately impacts the conclusiveness of our results, and future studies would benefit from larger samples across a heterogeneous group of trauma centers to inform early intervention efforts. In sum, the brief mPE intervention administered in the current investigation was no more effective than SOC. Additionally, these results are in line with the findings of a recent meta-analysis, which showed more efficacy for later interventions that were targeted more toward individuals with prominent symptoms versus earlier intervention targeted toward those with higher risk factors (Roberts et al., 2019).

Open Practices Statement

This study was not formally preregistered. Neither the data nor the materials have been made available on a permanent third-party archive; requests for the data or materials may be sent via email to the lead author at selarsen@mcw.edu

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