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<b>14. ABSTRACT</b> This study seeks to address the problem of dropout from evidence-based treatment for PTSD. We will evaluate whether the opportunity to receive social support during in vivo exposure therapy assignments from Veterans who themselves have successfully completed PE (i.e., the therapeutic equivalent of an exposure therapy 'workout buddy') is effective in reversing dropout and improving PTSD outcomes. To achieve this objective, we will use a between group, randomized controlled repeated measures design comparing PE + Exposure Workout Buddy vs. PE + Peer General Support (i.e., the standard VA Peer Support program methods involving a peer who does NOT engage in any support during in vivo homework) to evaluate the 'PE + Exposure Workout Buddy' adjunctive therapy component in terms of its ability to increase likelihood that Veterans will (a) return to and complete treatment & (b) evince reduced PTSD symptomatology at post-treatment and 3- & 6-month follow-up. An exploratory objective is to determine whether the hypothesized differential advantage of the workout buddy program is more pronounced for Veterans who receive PE via telehealth vs. receiving PE in person, as data from previous studies indicate that this may be the case.					
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## 1. Introduction

Posttraumatic stress disorder (PTSD) is a debilitating mental health condition characterized by a sense of imminent threat, hypervigilance, persistent avoidance, and intense reactions when reminded of the traumatic event (Shalev et al., 2017). Military Veterans across eras report higher lifetime prevalence of PTSD (ranging from 10 to 29% depending on era; Na et al., 2023) compared to the general United States population (6%; Goldstein et al., 2016). Fortunately, there are effective treatments for PTSD available from both the Departments of Veterans Affairs (VA) and Defense (Ostacher & Cifu, 2019).

Prolonged exposure (PE; Foa et al., 2007) is among the most highly researched and strongly recommended treatments for PTSD (Ostacher & Cifu, 2019). Specifically, PE is a manualized intervention that includes the following components: (a) psychological education about the common reactions to traumatic events and presentation of the treatment rationale (sessions 1 and 2), (b) repeated in vivo exposure to trauma-related stimuli such as people, places, things, or situations that trigger memories of the traumatic event but are realistically safe (assigned as homework during sessions 3-11), (c) repeated, prolonged, imaginal exposure to traumatic memories (implemented during sessions 3-11; patients listen to session audiotapes for homework between sessions), and (d) relapse prevention strategies and further treatment planning (session 12).

PE is based on emotional processing theory, which suggests that traumatic events are incompletely and inaccurately encoded in memory as “fear networks.” Gradual exposure to corrective information via the confrontation of (i.e., exposure to)

conditioned trauma-related stimuli within a safe and therapeutic environment results in a competing and antithetical memory structure that inhibits the conditioned fear response. PE relies on two primary therapeutic tools: in vivo exposure and imaginal exposure. During in vivo exposure, the patient gradually confronts feared, but safe, stimuli or cues that elicit trauma-related distress. During imaginal exposure, patients are guided by therapists and “relive” the traumatic event, providing a detailed, present-tense verbal account that includes sensory information, thoughts, feelings, and reactions experienced during the traumatic event.

Studies of PE outcomes routinely show large effect sizes. For example, Powers and colleagues (2010) found the average patient treated with PE fared better than 86% of control group patients on PTSD measures. Unfortunately, dropout from PE often exceeds 30% (Hernandez-Tejada et al., 2020), and efforts to help patients begin PE and see treatment to completion are ongoing. Hoge et al. (2014) identified reasons why Veterans leave therapy prematurely, and among the most common were problems surrounding logistics of attending therapy (i.e., transportation to a clinician’s office), questions of confidentiality, and concerns about stigma. In response, researchers studied telemedicine’s ability to overcome these barriers, meeting Veterans literally and figuratively “where they’re at” (Shore, Goranson, Ward, & Lu, 2014), to help retain them in PE therapy. However, retention rates of PE delivered in-person vs. via home-based telemedicine were similar, even though virtually all logistical and stigma-related barriers were eliminated (Acierno et al., 2017). Hernandez-Tejada et al. (2021) followed PE dropouts from telemedicine to ascertain reasons for leaving treatment, and found that, while telemedicine options did relieve issues of transportation, parking, work and family

obligations, in vivo homework central to PE were too difficult or anxiety provoking. Specifically, both groups reported significant difficulty (as expected given the role of avoidance in maintaining PTSD) with 40% of in-person and 58% of telemedicine Veterans who dropped out reporting that they, “could not tolerate assignments to go out in public” (Hernandez-Tejada et al., 2021). Perhaps most relevant, about 50% of those who dropped out of PE reported that they would have continued treatment if they had the support of a fellow Veteran *during the in vivo exposures* (Hernandez-Tejada et al., 2021).

Leveraging social support to boost psychotherapy outcomes is not a new idea, with peer support groups being commonplace in other health specialties like cancer or diabetes. In PTSD specifically, social support has a reciprocal relationship to PTSD symptom severity, where more social support buffers against PTSD, and more PTSD symptoms deplete social support (Wang, 2021). The VA has implemented “Peer Support Programs” (Money et al., 2011) that report high acceptability and success. The intended effects of peer support are to increase treatment engagement and boost patient adherence to treatment protocols by increasing perceived empowerment and sense of hope (Jain et al., 2016). Under this framework (and current VA protocols), the peers providing support do not participate in any aspect of therapy, but rather provide support and advice for the patient, which many Veterans find meaningful and helpful in increasing their overall wellness (Brown et al., 2016).

However, social support can be further refined, and specific functional aspects of social support impact patients in different ways. For example, in Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) Veterans, more positive social

interactions correlated with lessened pretreatment symptom severity (Price et al., 2013). Further, in line with the Veterans who had dropped out of PE but said they would return if a fellow Veteran who had “been there” would help them with their in vivo homework (Hernandez-Tejada et al., 2014), Price and colleagues (2013) found that emotional and informational support positively correlated to increased treatment response. In other words, it might be helpful to actually engage peer social support *directly* in difficult PTSD treatment components, such as in vivo exposure.

Therefore, the present study was conducted to determine the relative impact of applying peer support directly into PE in vivo exposure homework assignments (i.e., peers accompany patients during in vivo exposure as a type of exposure “workout buddy”) compared to standard Peer support (i.e., peer supportive phone calls or meeting at non-exposure locations) measured in terms of both number of sessions completed and in terms of overall treatment completion. COVID and logistical considerations allowed us to define peer support either virtually (e.g., via Facetime during in vivo exposures) or in person. We hypothesized that peer-accompanied in vivo exposures would result in greater treatment completion, and that this relationship would be linear, with greater numbers of peer-accompanied in vivo exposure trials associated with greater numbers of completed treatment sessions.

## **2. KEYWORDS**

PTSD; social support; exposure therapy; peer support

### **3. ACCOMPLISHMENTS**

#### **Participants**

Participants were 109 Veterans aged 18 and over who were recruited from a southeastern Veterans Affairs Health Care System and its satellite Community Based Outpatient Clinics. All participants were currently or recently engaged in evidence-based PTSD treatment (PE or Cognitive Processing Therapy) but had either dropped out or indicated to their provider that they intended to drop out of treatment. Specific inclusion criterion for patient-participants was a current diagnosis of PTSD as determined by the Clinician Administered PTSD Scale 5 (CAPS-5) or a CAPS-5 severity score  $\geq 25$ , and a PTSD Checklist 5 (PCL-5) score of  $\geq 25$ . Specific exclusion criteria were active psychosis or dementia, suicidal ideation with clear intent, and/or concurrent enrollment in another trial for PTSD or depression treatment. Eligibility criteria for peer supports included Veterans aged 18 or over, successful completion of evidence-based treatment involving in vivo exposure in the past, PCL-5 score of 32 or lower, and no psychosis, dementia, or suicidality with intent.

The average age of patient-participants was 43.9 years, 62.4% were female, 56.9% were employed, 43.1% were White, 47.7% were Black, and 8.3% reported more than one race, 7.1% reported Hispanic ethnicity, and 59.6% reported having a VA disability classification. Fully 63.3% ( $n = 69$ ) were seeking services for PTSD following military sexual trauma; 31.2% ( $n = 34$ ) were seeking treatment for PTSD following combat trauma, and 5.5% ( $n = 6$ ) were seeking treatment for PTSD following other criterion A qualifying events. Additional demographic data for the sample are given in

Table 1.

## **Procedures**

### ***Experimental Condition: PE+Peer-Accompanied In Vivo Exposure***

The experimental treatment was a modified version of PE insofar as social support in the form of “workout buddies” for in vivo exposure homework is added to the protocol. Consistent with the spirit of the new VA mandate to use peers in specialty clinics (such as PTSD clinics), we offered those individuals who indicated that they had decided to drop out / did drop out of treatment (e.g., stopped attending sessions) the opportunity to have a peer (see description of peer and training below) who has been through treatment successfully, and no longer holds a PTSD diagnosis, help them to complete in vivo exposure trials as an “exposure workout buddy,” who would offer social support directly during exposure homework, much as a “workout buddy” might do in a gym environment.

**Peer Selection.** VA PTSD therapists were asked if they had any patients who completed treatment with in vivo exposure therapy components. Therapists were then asked to contact these patients, inform them about the peer-accompanied in vivo exposure study, and ask them if they would like to hear more about the program, at which time Dr. Melba Hernandez-Tejada outlined the nature of expectations and research characteristics, and scheduled a training session. Thus, initial nominations for the program were based on therapist impressions of successful candidates *after* they had completed treatment. Peers who were candidates for the program were consented, evaluated for presence of PTSD diagnosis via the PCL-5, and only those who scored

below the exclusion cutoff were permitted to participate in this study. The same peers also served in the capacity of general peer support for the comparison condition and were explicitly directed *not* to meet the Veteran during in vivo exposure assignments.

**Peer Exposure Assignment “Workout Buddy” Training.** Peers are not therapists or therapist replacements, and the major activities of the peers were to simply meet Veterans at in vivo exposure homework sites and offer encouragement and support. Thus, logistics and *limits* of responsibility, not skills, were the primary focus of training. Much time was spent emphasizing appropriate boundaries and safety procedures. Two analogies were very helpful: that peer and participants were like “workout buddies,” and that peer and participant have the same relationship and responsibilities to one another as group therapy patients (e.g., with respect to confidentiality).

Each peer attended a 2-hour training meeting with the Dr. Melba Hernandez-Tejada. During this meeting, the rationale for in vivo exposure was reviewed, and the benefits of having a supportive partner, friend, or “exposure workout buddy” during in vivo exposure was outlined. Training explicitly included content wherein peers were clearly informed that they were *not* engaging in the role of therapist or providing therapy. Rather, their role was equivalent to that of a supportive group member in traditional group counseling (with which many Veterans are familiar), but that this support was given in the context of exposure exercises. In such a situation, group members offer each other advice and support on how to achieve stated goals. In the present case, the stated and agreed upon goal was the completion of the in vivo exposure therapy assignment. As with group counseling members, peers were trained in the importance

of confidentiality, and were *not* paid or compensated for their time (they were reimbursed for fuel). This clarified that they were not operating in the role of a compensated therapist, and speaks to the sustainability of the program, a position underscored by the fact that we had such a high peer volunteer rate (85% of those approached). Limits to personal responsibility were clearly outlined, and peers were well educated that neither the outcome of the treatment, nor the disposition of the patient was their responsibility. Moreover, we made it explicitly clear that exactly and only those roles and responsibilities found in group counseling sessions, including support, respect, and confidentiality, were in place here, with the exception that meeting locations were offsite and without therapist direction.

**Peer-Accompanied In Vivo Exposure Logistics & Supervision: Getting Started.** Once patients agreed to re-initiate treatment, the available peer in closest proximity to the patient was asked by the project coordinator to call in to the next therapy session. (This geographic factor was eliminated during COVID, when peers also accompanied patients via televideo, such as on Facetime.) During the session, the therapist made introductions and the peer listened to the patient and therapist review the next item of the in vivo exposure hierarchy in depth. The location, timing, outline, description, and parameters of the in vivo exposure therapy assignment were reviewed and were made clear to patient, peer, and therapist. Once this clarity was achieved, peer and patient finalized arrangements to meet at a set time and place to engage in this exposure trial and were directed to arrange about three such meetings per week for about three to four weeks. The analogy of a workout buddy was used, insofar as the role of the peer was to be present and encourage the Veteran during his or her

exposure efforts. As a final check, after the participant, peer, and therapist held this conference call to review logistics of in vivo exposure trials, therapists spoke with only the participant to assure that he or she continued to want to participate with a peer “exposure workout buddy.”

Peers were not matched on gender or age, except in cases of military sexual trauma, for which peers were matched on gender. Over the following weeks, “check-ins” with participants were repeated each week, with the therapist asking the patient to comment on any problems or benefits associated with in vivo exposures that were accompanied by a peer workout buddy to obtain a progress report of how exposure trials were going, and to determine if there were any issues that should be discussed and resolved.

Only exposure activities from a patient’s hierarchy, conducted in clearly safe places, were included in the in vivo exposure participation events with peers. This was determined by review with therapist and peer. If either party felt there was more than minimal risk, the activity was not included. Of note, risk of anxiety on the part of the participant was not a justifiable reason to exclude an activity. Indeed, producing and dealing with such anxiety in a supportive environment is the point of in vivo exercises. It is impossible to list every possible activity that was to be avoided versus included. However, several common activities, listed below, were excluded. For example: (1) activities involving driving together on the part of either the exposure workout buddy or the peer as driver (public transportation, such as taking a bus together, was permitted); (2) activities in or around private residences of the participant or exposure workout buddy; (3) activities involving weapons (e.g., shooting range); (4) new or previously

unlisted or unscheduled activities; and (5) activities that are associated with risk or danger as defined per therapist and or peer workout buddy.

Peers and participants were told that the program was only in place for a given patient for three to four weeks, three to four times per week, and was a means by which to allow participants to progress to their own, independently conducted in vivo exposure trials. Thus, “phase out” of the program was built in from the beginning. Workout buddies focused on helping participants engage in those exposure exercises that typically are social in nature.

***Control Condition: PE+Peer General Support.***

Participants in this condition received PE and were assigned a peer support volunteer who did *not* engage in any support during the in vivo homework. The primary purpose of the peer in this condition was to emulate standard VA PTSD peer support procedures. Therefore, in this condition, peers provided general support, such as reminding and encouraging participants to attend appointments, meeting with them online or at the VA two to four times per month to assess general progress, checking up on them once per week via telephone and asking about current treatment progress, life stresses, opportunities, problems and successes, and offering general support with VA programs. The PE component of this treatment was the same as the experimental condition in terms of session number, length, and duration (12-15 sessions; 90 minutes).

**Measures**

***Demographics.***

See Table 1 for demographic data for the sample. All participants were asked to report their age, gender, income bracket, employment status, disability rating assigned by the VA, race, and ethnicity. Patient participants completed at baseline, post-treatment, and 3-, 6-month follow-up to assess change in symptoms. Peers were only assessed at baseline to determine lack of a PTSD diagnosis.

***Clinician Administered PTSD Scale-5 (CAPS-5; Weathers, Blake, et al., 2013).***

PTSD diagnoses were ascertained using the CAPS-5, which is considered the gold standard in PTSD assessment. The CAPS is a 30-item, structured interview that corresponds to the DSM-5 criteria for PTSD. For each diagnostic item, standardized questions and probes are provided. Questions focus on symptom presence, the onset and duration of symptoms, subjective distress, impact of symptoms on social, and occupational functioning and improvement in symptoms.

***PTSD Checklist-5 (PCL-5; Weathers, Liz, et al., 2013).***

The PCL-5 is a new version of the PCL, among the most frequently used self-report measures of PTSD symptoms and intensity. The PCL-5 is structured to correspond to the DSM-5 PTSD criteria. The 20-items are scored on a 0-4 Likert scale for each symptom corresponding to “Not at all” to “Extremely.” Total scores range from 0 to 80. Initial psychometric data are encouraging. With college student samples, Blevins et al. (2015) found PCL-5 scores exhibited strong internal consistency ( $\alpha = .94$ ), test-retest reliability ( $r = .82$ ), and convergent ( $r_s = .74$  to  $.85$ ) and discriminant ( $r_s = .31$  to  $.60$ ) validity. With Veteran samples, Bovin et al. (2015) found that the PCL-5 had good internal consistency ( $\alpha = .96$ ) and test-retest reliability ( $r = .84$ ). Moreover, signal detection analyses using CAPS-5 indicated a cutoff score of 31-33 on the PCL-5

optimally categorized PTSD diagnosis.

***Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001).***

The PHQ-9 is a widely used, well-validated measure of depression severity with high internal consistency (alpha .83 to .92; Cameron, Crawford, et al, 2008), and is correlated strongly with other depression measures (Kroenke et al., 2001). Its nine items assess affective and somatic symptoms and correspond to diagnostic criteria for major depressive disorder.

***Treatment Completion Data.***

The primary outcome measure, number of treatment sessions completed, was a simple count of sessions attended, ranging from 0-15. Number of peer-accompanied in vivo exposure homework trials completed was also a simple count of the number of times the “exposure workout buddy” was present, in person or virtually, for in vivo exposures. Finally, we defined treatment completion as at least 14 sessions completed OR at least 8 sessions completed AND two consecutive PCL-5 scores below 30 AND therapist AND patient concurrence that treatment was completed.

**Data Analysis and Statistical Plan**

SPSS version 28 statistical software was used for all analyses. First, descriptive demographic and baseline psychological symptom data were derived. Second, the key study variable of treatment retainment was measured continuously in terms of number of completed sessions, and dichotomously in terms of overall treatment completed. The correlation between number of sessions completed and continuous demographic variables, baseline psychological symptom variables, and the number of peer-

accompanied in vivo exposures was determined to illustrate potential presence of a dose effect of the intervention on session completion. This was then followed by a stepwise linear regression analysis to determine relative impact of demographic (step 1), baseline psychological symptom variables (step 2), and number of peer-accompanied in vivo exposures (step 3) on predicting number of sessions completed. Third, we compared rates and likelihood of overall treatment completion in terms of treatment condition and key study variables (demographic, psychological symptoms, treatment condition). We also derived a treatment manipulation check variable (e.g., whether a peer-accompanied in vivo exposure was actually completed at least once), and repeated rates of treatment completion analyses, this time comparing those who actually experienced peer-accompanied in vivo exposure vs. those who did not, irrespective of assigned treatment condition, through two-tailed bivariate  $\chi^2$  analyses, followed by a logistic regression analyses with  $\alpha$  set *a priori* at  $p < .05$ , so as to illustrate the impact of peer-accompanied in vivo exposure on treatment completion likelihood, over and above the impact of demographic variables.

## **Results**

Table 1 provides relevant demographic and psychopathology variable means, standard deviations, and percentages for treatment completion in terms of experimental group (*assigned to standard supportive peer vs. in vivo exposure peer accompaniment*) as well as in terms of the experimental manipulation check: (*completed at least 1 peer-accompanied in vivo exposure vs no peer-accompanied in vivo exposures*). With the exception of a larger proportion of minority race/ethnicity participants in the in vivo peer

condition (67.3% vs. 46.3%), there were no significant differences between groups in terms of baseline demographic or psychopathology variables.

There was a significant time effect for the PCL-5, the study measure of PTSD, with both groups evincing significant improvement over baseline PCL-5 scores (PCL-5  $\bar{x}$  = 54.7,  $SD$  = 14.5) at all time points ( $F_{(3, 321)} = 75.24, p < .001$ ), including post treatment, (PCL-5  $\bar{x}$  = 33.5,  $SD$  = 18.6), 3-month follow-up (PCL-5  $\bar{x}$  = 35.8,  $SD$  = 16.6), and 6 month follow-up (PCL-5  $\bar{x}$  = 38.7,  $SD$  = 16.3). However, there was no significant effect for treatment condition on PCL-5 score reductions ( $F_{(1, 107)} = 0.26, p = .61$ ), as both peer support groups showed similar overall improvement. There was no significant effect for treatment condition on number of sessions completed (in vivo peer condition  $\bar{x}$  = 8.5 sessions,  $SD$  = 4.3 vs. general peer support condition  $\bar{x}$  = 8.7 sessions,  $SD$  = 4.8) ( $F_{(1, 108)} = 0.03, p = .86$ ). Consistent with study objectives, we also examined whether there was a condition effect of the different type of peer support when historically relevant covariates (i.e., race, gender, age, substance use, or social support) were considered. Controlling for these covariates also did not reveal between group differences across peer support types in terms of minority racial status ( $F_{(1, 106)} = 0.01, p = .99$ ); gender ( $F_{(1, 106)} = 0.24, p = .63$ ); age ( $F_{(1, 106)} = 0.28, p = .60$ ); substance use ( $F_{(1, 106)} = 0.23, p = .64$ ); or social support ( $F_{(1, 106)} = 0.41, p = .52$ ).

There was no significant treatment condition effect on the dichotomous variable of treatment completion (in vivo peer condition = 70.9% vs. general peer support condition 63%,  $\chi^2 = 0.78, p = .25, OR = 0.70, CI: 0.31 - 1.56$ ). However, with respect to the key study concept of treatment retainment, a linear relationship was observed between number of treatment sessions completed and number of peer-accompanied in

vivo exposure homework trials completed ( $r = 0.34, p < .001$ ), whereas no relationship was noted between number of treatment sessions completed and any other continuous variable, including baseline PCL-5 score ( $r = -.06, p = .52$ ); baseline PHQ-9 score ( $r = -.11, p = .24$ ); age ( $r = .02, p = .41$ ); or income ( $r = -.13, p = .09$ ). Considering the independent effects of number of peer-accompanied in vivo exposure homework trials over and above the aforementioned variables (i.e., demographic, baseline, and psychological symptoms) on number of treatment sessions completed, linear regression indicated significantly improved variance accounted for only in the final step for number of peer-accompanied in vivo exposures (R-square change 12%). See Table 2 for linear regression statistics.

Fully 30.9% ( $n = 17$ ) of those assigned to the peer in vivo condition failed to actually engage in any peer-accompanied in vivo exposures. Therefore, we created a conservative dichotomous treatment manipulation check variable defined as having completed at least 1 peer-accompanied in vivo exposure, either virtual or in person, and analyzed treatment retention outcomes in terms of this manipulation check independent variable. These results are also given in Table 1, which provides information regarding the dichotomous variable of treatment completion in terms of study variables (dichotomized age, gender, income, employment status, minority race/ethnicity status, disability status).

There were no significant differences among demographic variables between those who engaged in at least 1 peer-accompanied in vivo exposure vs. those who did not; however, a larger proportion of those reporting that they were classified by the VA as disabled (66.2%) did not engage in any peer-accompanied in vivo exposures compared

to those that did engage with peers (47.4%). With respect to the primary outcome variable of interest, these analyses demonstrated that likelihood of treatment completion was not affected by any demographic variable, but rates were significantly increased among those completing even one peer-accompanied in vivo exposure homework trial to 86.8%, compared to 56.3% among those who had not completed peer-accompanied in vivo exposure ( $\chi^2 = 10.41$ ,  $p < .001$ , OR = 5.10, CI: 1.79 – 14.63). Moreover, there was a dose – effect relationship between these variables, with completion of two or more peer-accompanied in vivo exposure trials increasing rate of treatment completion to about 93%, and completion of five or more peer-accompanied in vivo exposure trials increasing rate of treatment completion to approximately 97%. To demonstrate the unique contribution of demographic variables and the treatment manipulation check variable on treatment completion rates, logistic regression was conducted and showed that the independent effects of having completed at least one peer-accompanied in vivo exposure were sustained, insofar as likelihood of treatment completion was increased 653% (see Table 3 for logistic regression statistics).

#### **4. IMPACT**

This study involved Veterans who had either dropped out of PE therapy for PTSD, or who had indicated their intention to do so. As such, any intervention to enhance retention in this evidence-based treatment for PTSD was positioned against significant headwinds. Moreover, the active experimental manipulation, peer assisted in vivo exposure, was compared to another active form of treatment augmentation, general peer support. In other words, the impact of peers during the in vivo exposure

homework was juxtaposed against significant peer support, rather than no support during PE treatment, among a group of Veterans who had already decided to withdraw from treatment. As such, it is striking that Veterans who completed even one in vivo exposure homework assignment accompanied by a peer (virtually or in person), completed treatment at significantly increased rates: 87%, compared to 56% of those who did not complete in vivo exposure with a peer. The dose effect of peer accompanied in vivo exposure was telling, with treatment completion rates increasing to 93% with 2 or more peer accompanied exposures, and 97% with 3 or more peer accompanied exposures. This dose effect was also evident from the strong positive correlation between number of peer exposures and number of sessions completed ( $r = .33$ ). No other factors, including demographic or baseline symptom intensity scores, significantly predicted either session number or treatment completion.

Of course, involving peers directly in therapy homework assignments such as in vivo exposure requires additional coordinating and supervising effort on the part of the clinical staff. Nonetheless, benefits of such effort appear to significantly outweigh costs of the additional work. Indeed, exerting extra effort helping Veterans with PTSD complete highly effective treatment may save both time and money in the future, given the long term personal and system costs of PTSD.

Often, patients do not convey to their therapists just how much they may be struggling during therapies that require exposure to feared or anxiety provoking stimuli, particularly during the beginning stages of treatment, when treatment attrition is greatest (Kleiven, Hjeltnes, Råbu, & Moltu, 2020). Peer support during precisely these initial, difficult assignments may serve as a buffer to mitigate those struggles and concerns,

and/or motivate patients to complete homework. Indeed, even patients in the supportive peer telephone call condition reported that these calls were a positive aspect of treatment, and that having someone who had been through military trauma and subsequent treatment checking up on them was helpful. As mentioned, results obtained here for both groups were derived from patients who had already decided to drop out of treatment, and effects of a similar program implemented as preventive measure might be even more impactful.

The international health emergency produced by the COVID-19 pandemic actually provided an opportunity for the research team to accommodate requests made by some patients and peers who resided in extremely rural areas: specifically, using televideo technology to allow virtual peer video and audio observation of, and partnership during in vivo exposure homework assignments. Of note, this format of peer support also made some of the 'dos and don'ts' of peer training easier to guarantee (i.e., the prohibition of driving together to the exposure site, or meeting at each other's residence). Additionally, the virtual nature of peer assisted in vivo homework seemed to allow an even easier 'titration' of peer support, insofar as this format actually did involve relatively greater independent work on the part of the patient. Although peer support titration was prescribed from the beginning of the program by limiting the number of weeks and sessions that peers were available, we can envision future work wherein peers begin meeting patients during exposure homework in person, and then transition to virtual accompaniment as a step-down approach to fostering patient independence.

An important strength to highlight of this study is the strong representation of women in the sample. In most PTSD research on Veteran populations, women

represent about 10-15% of the sample. In the present study, about 66% of the sample were women who experienced military sexual trauma (MST), a trauma subtype associated with extremely high treatment attrition (Galovski et al., 2022; Kimerling et al., 2015). As such, results are even more impressive.

### Limitations

Perhaps the most notable limitation was along the lines of implementation: nearly a third of those assigned to the peer-accompanied in vivo exposure condition never met with the peer during exposure homework events. Although our pilot research indicated that our proposed schedule and frequency of peer assisted in vivo exposure homework events was feasible, it may actually be the case that 3-4 times per week for 3-4 weeks is both unwieldy and unnecessary, particularly in light of aforementioned findings that 97% of those completing 3 or more in vivo exposures in the presence (virtual or in person) of a peer completed treatment. Perhaps 1-3 peer assisted exposures overall is a reasonable target.

A second limitation is that we used peer support as a means to retrieve Veterans back into treatment, after they had decided to terminate. Thus, the actual impact of instrumental peer support during in vivo exposure homework, per se, is unknown. Giving patients the option to have peer support during a limited number of in vivo homework assignments from the beginning of treatment would allow those who find such exposure overwhelming to leverage social support precisely when they need it most and represents a design improvement over the current study.

### **5. CHANGES/PROBLEMS**

No changes or problems to report.

## 6. PRODUCTS (MORE PUBLICATIONS FORTHCOMING)

Hernandez-Tejada, M. A., Muzzy, W., Price, M., Hamski, S., Hart, S., Foa, E., & Acierno, R. (2020). Peer support during in vivo exposure homework to reverse attrition from Prolonged Exposure therapy for posttraumatic stress disorder (PTSD): Description of a randomized controlled trial. *Trials*, 21(1), 366.

<https://doi.org/10.1186/s13063-020-04302-5>

Hernandez-Tejada, M. A., Acierno, R., & Sánchez-Carracedo, D. (2021). Re-engaging dropouts of Prolonged Exposure for PTSD delivered via home-based telemedicine or in person: Satisfaction with Veteran-to-Veteran support. *The Journal of Behavioral Health Services & Research*, 48(2), 171–182.

<https://doi.org/10.1007/s11414-020-09734-0>

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### Participants

<b>Name:</b>	<b>Wendy Muzzy</b>
Project Role:	Principal Investigator
Contribution to Project:	Responsible for conceptual and practical resolution of scientific questions and data analytic decisions
<b>Name:</b>	<b>Ronald Acierno</b>
Project Role:	Co-Principal Investigator
Contribution to Project:	Responsible for all scientific, technical, and financial aspects of the project
<b>Name:</b>	<b>Melba Hernandez</b>
Project Role:	Co-Investigator
Contribution to Project:	Provided expertise around completing exposure activities with a peer, treatment fidelity, and clinical supervision
<b>Name:</b>	<b>Rebecca Knapp</b>
Project Role:	Co-Investigator
Contribution to Project:	Served as statistician
<b>Name:</b>	<b>Daniel Gros</b>
Project Role:	Co-Investigator
Contribution to Project:	Provided guidance in the interpretation, analysis, and publication of data

<b>Name:</b>	<b>Carol Denier</b>
Project Role:	Co-Investigator
Contribution to Project:	Facilitated referrals from patients that have screened positive for PTSD from PTSD Clinic Team (PCT)
<b>Name:</b>	<b>Anna Birks</b>
Project Role:	Clinical Coordinator
Contribution to Project:	Provided overall assessment supervision, including overseeing assessment measure procedures, and assisted with clinic referral flow
<b>Name:</b>	<b>Bethany Wangelin</b>
Project Role:	VAMC Coordinator
Contribution to Project:	Supported recruitment efforts/VA liaison
<b>Name:</b>	<b>Stephanie Hart</b>
Project Role:	Research Assistant
Contribution to Project:	Coordinated the day-to-day aspects of this project
<b>Name:</b>	<b>A. Raquel Vining</b>
Project Role:	Research Assistant
Contribution to Project:	Served as documentation coordinator
<b>Name:</b>	<b>Michelle Pompei</b>
Project Role:	Research Assistant
Contribution to Project:	Served as a participant recruiter
<b>Name:</b>	<b>Linette Dubois</b>
Project Role:	Research Assistant
Contribution to Project:	Served as a participant recruiter
<b>Name:</b>	<b>Gabrielle Frook</b>
Project Role:	Research Assistant
Contribution to Project:	Served as a participant recruiter
<b>Name:</b>	<b>Stephanie Hamski</b>
Project Role:	Study Clinician
Contribution to Project:	Served as a study clinician and participant recruiter
<b>Name:</b>	<b>Sally Murphy</b>
Project Role:	Study Clinician
Contribution to Project:	Served as a study clinician and participant recruiter
<b>Name:</b>	<b>Jonna Vaughn</b>
Project Role:	Study Clinician
Contribution to Project:	Served as a study clinician and participant recruiter
<b>Name:</b>	<b>Martina Radic</b>
Project Role:	Study Clinician
Contribution to Project:	Conducted all interviews/assessments as detailed in the protocol;
<b>Name:</b>	<b>Tracey Rosenlieb</b>
Project Role:	Study Clinician
Contribution to Project:	Conducted all interviews/assessments as detailed in the protocol

## **Partners**

**Organization Name:** Lowcountry Center for Veterans Research  
**Location of Organization:** 22 Westedge Steet Suite 410, Charleston, SC 29403

**Organization Name:** The University of Texas Health Science Center at  
Houston

**Location of Organization:** 7000 Fannin, UCT 1006 Houston, TX 77030-5401

**Partners' contribution to the project:** Collaboration

## **8. SPECIAL REPORTING REQUIREMENTS**

Final Quad Chart and Report of Inventions and Subcontracts continued on next page.

# Peer Social Support During In Vivo Exposure for PTSD: A Program to Address Dropout from Prolonged Exposure

W81XWH-18-1-0081 / BA160297

PI: Wendy A. Muzzy, MRA, MLIS

Org: Medical University of South Carolina

Award Amount: \$2,112,716



## Study/Product Aim(s)

Objective 1: To determine relative differences in treatment dose obtained, measured in terms of the number of sessions completed upon return to treatment, in response to 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' in individuals who have previously dropped out of evidence-based treatment for PTSD. Whether differences are amplified or diminished with respect to prior identified risk factors such as age, race, gender, substance use, or social support will also be determined.

Objective 2: To determine differential effectiveness, measured in terms of therapeutic gains over time on measures of PTSD symptomatology, of 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' with therapy dropouts in (i.e., 'treatment outcome'). Whether differences are amplified or diminished with respect to race, gender, age, substance use, or social support will also be determined.

## Approach

Using a between group, randomized controlled repeated measures design comparing PE + Exposure Workout Buddy vs. PE + Peer General Support (i.e., the standard VA Peer Support program methods involving a peer who does NOT engage in any support during in vivo homework) to evaluate the 'PE + Exposure Workout Buddy' adjunctive therapy component in terms of its ability to increase likelihood that Veterans will (a) return to and complete treatment & (b) evince reduced PTSD symptomatology at post-treatment and 3- & 6-month follow-up.

## Impact

This was a study of Veterans who had either dropped out of PE therapy for PTSD, or who had indicated their intention to do so. As such, any intervention to enhance retention in this evidence-based treatment for PTSD was positioned against significant headwinds. Moreover, the active experimental manipulation, peer-assisted in vivo exposure, was compared to another active form of treatment, general peer support. In other words, the impact of peer in vivo exposure accompaniment was juxtaposed against significant peer support, rather than no treatment, among a group of Veterans who had already decided to withdraw from treatment. As such, it is striking that among those Veterans who completed even one in vivo exposure homework assignment accompanied virtually or in person by a peer, treatment completion rates were dramatically increased to about 87%, compared to 56% of those who did not complete in vivo exposure with a peer. The dose effect of peer-accompanied in vivo exposure was also evident, with treatment completion rates increasing to 93% with 2 or more peer-accompanied exposures, and 97% with 3 or more peer-accompanied exposures. This dose effect was also evident by the strong positive correlation between number of peer exposures and number of sessions completed ( $r = .33$ ). No other factors, including demographic or symptom variables, significantly predicted either session or treatment completion.

## Timeline and Cost

Activities	YEAR	1	2	3	4	5
Approvals: IRB / VA / DoD		[Green bar spanning years 1-5]				
Recruit and Treat Participants		[Green bar spanning years 1-5]				
Data Analysis and Reports						[Green bar in year 5]
Dissemination					[Green bar in year 4]	[Green bar in year 5]
<b>Budget (Direct and Indirect Costs)</b>		\$354,676	\$609,015	\$603,289	\$545,736	NCE

Updated: 31-MAY-2023

## Goals/Milestones

**YR1 Goal** – Institutional Human Subject Approvals Submitted  
 IRB, VA Research, DoD HRPO approvals obtained

**YR2 Goals** – Recruitment, Reports  
 Establish recruitment protocols and procedures  
 Recruit and consent participants

**YR3 & YR4 Goal** – Recruitment, Reports  
 Continue to recruit and consent participants

**YR5 Goal** – Complete Recruitment, Analyze Data, Submit Publications  
 Submit final report and presentations to DoD

## Comments/Challenges/Issues/Concerns

- None at this time

**REPORT OF INVENTIONS AND SUBCONTRACTS**  
*(Pursuant to "Patent Rights" Contract Clause) (See Instructions on back)*

*Form Approved  
 OMB No. 5000-0095  
 Expires Jan 31, 2008*

The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (5000-0095). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO THE CONTRACTING OFFICER.**

1.a. NAME OF CONTRACTOR/SUBCONTRACTOR Medical University of South Carolina		c. CONTRACT NUMBER W81XWH-18-1-0081		2.a. NAME OF GOVERNMENT PRIME CONTRACTOR		c. CONTRACT NUMBER		3. TYPE OF REPORT <i>(X one)</i> <input type="checkbox"/> a. INTERIM <input checked="" type="checkbox"/> b. FINAL			
b. ADDRESS <i>(Include ZIP Code)</i> 179 Ashley Avenue Charleston, SC 29425			d. AWARD DATE <i>(YYYYMMDD)</i> 20180315		b. ADDRESS <i>(Include ZIP Code)</i>			d. AWARD DATE <i>(YYYYMMDD)</i>		4. REPORTING PERIOD <i>(YYYYMMDD)</i> a. FROM 20180315 b. TO 20230314	

**SECTION I - SUBJECT INVENTIONS**

5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR *(If "None," so state)*

a. NAME(S) OF INVENTOR(S) <i>(Last, First, Middle Initial)</i>	b. TITLE OF INVENTION(S)	c. DISCLOSURE NUMBER, PATENT APPLICATION SERIAL NUMBER OR PATENT NUMBER	d. ELECTION TO FILE PATENT APPLICATIONS <i>(X)</i>				e. CONFIRMATORY INSTRUMENT OR ASSIGNMENT FORWARDED TO CONTRACTING OFFICER <i>(X)</i>	
			(1) UNITED STATES		(2) FOREIGN		(a) YES	(b) NO
			(a) YES	(b) NO	(a) YES	(b) NO		
NONE	NONE							

f. EMPLOYER OF INVENTOR(S) NOT EMPLOYED BY CONTRACTOR/SUBCONTRACTOR

(1) (a) NAME OF INVENTOR <i>(Last, First, Middle Initial)</i>	(2) (a) NAME OF INVENTOR <i>(Last, First, Middle Initial)</i>	(1) TITLE OF INVENTION	(2) FOREIGN COUNTRIES OF PATENT APPLICATION
(b) NAME OF EMPLOYER	(b) NAME OF EMPLOYER		
(c) ADDRESS OF EMPLOYER <i>(Include ZIP Code)</i>	(c) ADDRESS OF EMPLOYER <i>(Include ZIP Code)</i>		

g. ELECTED FOREIGN COUNTRIES IN WHICH A PATENT APPLICATION WILL BE FILED

**SECTION II - SUBCONTRACTS *(Containing a "Patent Rights" clause)***

6. SUBCONTRACTS AWARDED BY CONTRACTOR/SUBCONTRACTOR *(If "None," so state)*

a. NAME OF SUBCONTRACTOR(S)	b. ADDRESS <i>(Include ZIP Code)</i>	c. SUBCONTRACT NUMBER(S)	d. FAR "PATENT RIGHTS"		e. DESCRIPTION OF WORK TO BE PERFORMED UNDER SUBCONTRACT(S)	f. SUBCONTRACT DATES <i>(YYYYMMDD)</i>	
			(1) CLAUSE NUMBER	(2) DATE <i>(YYYYMM)</i>		(1) AWARD	(2) ESTIMATED COMPLETION
Lowcountry Center for Veterans Research - LCVR	22 Westedge St Suite 410, Charleston, SC 29403	A00-3520-S002			Clinical activities (recruitment, treatment, follow up assessment)	20180315	20230314
University of Texas Health Science Center at Houston	7000 Fannin St, Ste 1006 Houston, TX 77030-5400	A00-3520-S001			Scientific activities (clinical supervision, dissemination of research findings)	20190901	20220314

**SECTION III - CERTIFICATION**

7. CERTIFICATION OF REPORT BY CONTRACTOR/SUBCONTRACTOR *(Not required if *(X)* as appropriate)*

SMALL BUSINESS or  NONPROFIT ORGANIZATION

I certify that the reporting party has procedures for prompt identification and timely disclosure of "Subject Inventions," that such procedures have been followed and that all "Subject Inventions" have been reported.

a. NAME OF AUTHORIZED CONTRACTOR/SUBCONTRACTOR OFFICIAL <i>(Last, First, Middle Initial)</i> Ferguson, Heather A.	b. TITLE Program Mgr, Research & Sponsored Programs	c. SIGNATURE <i>Heather A Ferguson</i>	d. DATE SIGNED 05/23/23
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## **9. APPENDICES**

### **References**

**Table 1.** Baseline Demographics

**Table 2.** Stepwise Hierarchical Regression

**Table 3.** Logistic Regression

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**Table 1.** Baseline demographic and psychological symptom variables in terms of (1) randomly assigned treatment condition and (2) treatment manipulation check (i.e., having completed at least 1 peer-accompanied in vivo exposure).

Variable	Assigned In Vivo Peer ( <i>n</i> = 55)	Assigned General Peer ( <i>n</i> = 54)	$F_{(1, 108)}/\chi^2, p$	Completed 1+Peer Exposure ( <i>n</i> = 38)	Completed No Peer Exposure ( <i>n</i> = 71)	$F_{(1, 108)}/\chi^2, p$
<b>Age Years</b> ( $\bar{x}$ , SD)	43.6 (11.8)	44.2 (12.8)	0.08, .77	42.6 (12.0)	44.6 (12.4)	0.61, .44
<b>Age Dichotomous</b>			0.00, .97			0.01, .59
< 60 years (%)	89.1	88.9		89.5	88.7	
60+ years (%)	10.9	11.0		10.5	11.3	
<b>Gender</b>			0.45, .32			1.87, .12
Male (%)	34.5	40.7		28.9	42.3	
Female (%)	65.5	59.3		71.1	57.7	
<b>Income</b>			3.60, .83			7.12, .42
1: <\$10k (%)	7.3	7.4		5.3	8.5	
2: \$10k-\$15k (%)	1.8	3.7		0.0	4.2	
3: \$15k-\$20k (%)	5.5	3.7		7.9	2.8	
4: \$20k-\$25k (%)	9.1	7.4		7.9	8.5	
5: \$25k-\$35k (%)	20.0	9.3		23.7	9.9	
6: \$35k-\$50k (%)	23.6	27.8		23.7	26.8	
7: \$50k-\$75k (%)	18.2	20.4		15.8	21.1	
8: \$75k-\$80k (%)	14.5	20.4		15.8	18.3	
<b>Unemployed (%)</b>	38.2	48.1	1.13, .20	65.8	52.1	1.89, .12
<b>Race</b>			6.49, .09			1.73, .63
1: White (ref) (%)	32.7	53.7		36.8	46.5	
2: Black (%)	56.4	38.9		52.6	45.1	
3: Asian (%)	0.0	1.9		0.0	1.4	
4: American Indian/ Alaskan Native	0.0	0.0		0.0	0.0	
5: Pacific Islander/ Hawaiian	0.0	0.0		0.0	0.0	
6: More than one race or Other	10.9	5.6		10.5	7.0	
<b>+ Hispanic (%)</b>	11.5	2.1	3.43, .07	11.1	4.7	1.46, .21
<b>+ Minority Status (%)</b>	67.3	46.3	4.89, .02	63.2	53.5	0.94, .22
<b>+ Disability Dichotomous (%)</b>	54.5	64.8	1.19, .19	47.4	66.2	3.65, .045
<b>Disability Rating</b> ( $\bar{x}$ , SD)	60.2 (37.0)	69.6 (33.4)	1.68, .20	63.8 (35.9)	65.4 (35.4)	0.05, .83

<b>Baseline PCL-5</b>	56.2 (16.4)	53.2 (12.2)	1.16, .29	58.2 (15.6)	52.9 (13.6)	3.36, .07
<b>Baseline PHQ9</b>	17.0 (5.8)	16.7 (5.3)	0.01, .78	17.6 (6.0)	16.5 (5.3)	0.98, .33

*Notes.* Mean (standard deviation) or percent (*n*) are presented.

Presence of statistically significant differences were assessed between groups using one-way ANOVA and chi-square analyses. Reference values for chi square analyses: below age 60, male gender, annual income below \$10,000; unemployed, White, non-Hispanic race/ethnicity, not-disabled).

**Table 2.** Stepwise Hierarchical Regression of age, income (step 1), baseline PCL, baseline PHQ9 (step 2), and number of peer-accompanied in vivo exposures (step 3) on number of treatment sessions completed.

Variable	B	$\beta$	$t$	$R$	$R^2$	$\Delta R^2$
Step 1 $F_{(2,106)} = 0.93, p = .40$				.13	.02	.02
Constant			4.90**			
Age	.01	.03	0.30			
Income	-.30	-.13	-1.34			
Step 2 $F_{(2,104)} = 0.80, p = .53$				.17	.03	.01
Constant			4.11**			
Age	.01	.03	0.35			
Income	-.28	-.12	-1.26			
Baseline PCL	.02	.05	0.35			
Baseline PHQ9	-.12	-.15	-0.98			
Step 3 $F_{(1,103)} = 3.56, p < .001$				.38	.15	.12**
Constant			4.29**			
Age	.01	.02	0.12			
Income	-.22	-.09	-1.03			
Baseline PCL-5	.01	.02	0.14			
Baseline PHQ9	-.13	-.16	0.26			
# Peer In Vivo	.80	.35	3.76**			

Note.  $N=109$ ; \* $p < .05$ , \*\* $p < .01$

**Table 3.** Logistic Regression of predicting treatment completion in terms of age, gender, income, employment status, minority status, disability status and completing at least one peer-accompanied in vivo exposure.

Variable	OR	95% CI	<i>B</i>	<i>W</i>	<i>p</i>
<i>Treatment Completion</i>					
Age	1.01	0.97 – 1.05	0.01	0.20	.66
Gender (Female)	0.55	0.21 – 1.42	-0.60	1.55	.21
Income (low)	0.82	0.63 – 1.06	-0.21	2.39	.12
Unemployed	1.37	0.49 – 3.87	0.32	0.36	.55
+Minority Status	0.61	0.23 – 1.61	0.61	1.00	.32
+Disabled	1.68	0.62 – 4.58	0.52	1.02	.31
Peer-Accompanied In Vivo	6.53	2.15 – 19.80	1.88	11.00	.00

*Note.* Reference values for logistic regression analyses: below age 60, male gender, annual income below \$10,000; unemployed, White/non-Hispanic race/ethnicity, not-disabled.