



## Open trial of exposure therapy for PTSD among patients with severe and persistent mental illness



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### ABSTRACT

**Objective:** There are few empirical data regarding effective treatment of trauma-related symptoms among individuals with severe mental illness (SMI; e.g., bipolar disorder, schizophrenia). This under-examined clinical issue is significant because rates of trauma and PTSD are higher among individuals with SMI relative to the general population, and there are sufficient data to suggest that PTSD symptoms exacerbate the overall course and prognosis of SMI.

**Method:** 34 veterans with SMI received prolonged exposure (PE) for PTSD using an open trial study design.

**Results:** Data suggest that PE is feasible to implement, well-tolerated, and results in clinically significant decreases in PTSD severity in patients with SMI. Mean CAPS scores improved 27.2 points from baseline to immediate post [95% CI for mean change: -44.3, -10.1;  $p = 0.002$ , paired t-test, and treatment gains were maintained at 6 months [mean change from baseline to 6-months, -16.1; 95% CI: -31.0, -1.2;  $p = 0.034$ , paired t-test].

**Conclusions:** The current data support the use of exposure-based interventions for PTSD among individuals with SMI and highlight the need for rigorous randomized efficacy trials investigating frontline PTSD interventions in this patient population.

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Individuals with severe and persistent forms of mental illness are among the most vulnerable individuals in our society with regards to lifetime traumatic event exposure and the subsequent development of posttraumatic stress disorder (PTSD). That is, rates of trauma exposure and PTSD are significantly elevated among individuals with SMI (SMI; i.e., individuals with severe forms of a psychotic disorder, bipolar disorder, or major depressive disorder) relative to the general population (see Grubaugh, Zinzow, Paul, Egede, & Frueh, 2011 for review). More specifically, rates of current PTSD among individuals with SMI range from 13 to 46% and lifetime rates range between 14 and 53%, depending on the

assessment measure used and the characteristics of the study sample (Grubaugh et al., 2011). Although outcomes are variable across studies, they collectively suggest that rates of *current* PTSD among individuals with SMI are consistently higher than *lifetime* rates in the general population (i.e., 7–12%; Kessler, 2000; Kessler et al., 2005) and are comparable to or higher than *lifetime* rates found in individuals with combat exposure (Richardson, Frueh, & Acierno, 2010).

As in the general population, the presence of PTSD among individuals with SMI is strongly correlated with impaired functioning, decreased quality of life, and alcohol or drug use (e.g., Fan et al., 2008; Ford & Fournier, 2007; Grubaugh et al., 2011; Mueser, Essock, Haines, Wolfe, & Xie, 2004; Mueser, Salyers, et al., 2004). The presence of PTSD among individuals with SMI has also been linked to transient living conditions, homelessness, worse disability

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and illness severity indicators, suicidal ideation, and poorer psychosocial functioning across a variety of settings and samples (e.g., Mueser, Essock, et al., 2004; Mueser, Salyers, et al., 2004; Newman, Turnbull, Berman, Rodrigues, & Serper, 2010; Sautter et al., 1999; Strauss et al., 2006); as well as increased health services use (e.g., Calhoun, Bosworth, Stechuchak, Strauss, & Butterfield, 2006; Lu, Mueser, Rosenberg, & Jankowski, 2008; Rosenberg, Lu, Mueser, Jankowski, & Cournos, 2007; Thatcher, Marchland, Thatcher, Jacobs, & Jensen, 2007). Finally, there are also data to suggest that the presence of trauma and/or PTSD among individuals with SMI are associated with exacerbations in the primary symptoms of SMI (e.g., Kilcommons & Morrison, 2005; Lysaker & LaRocco, 2008; Lysaker, Beattie, Strasburger, & Davis, 2005; Meade et al., 2009; Schenkel, Spaulding, DiLillo, & Silverstein, 2005; Ucoc & Bikmaz, 2007).

Despite high rates of trauma and PTSD among individuals with SMI, the literature on the efficacy of PTSD-specific interventions in this patient population is severely underdeveloped, as individuals with psychotic symptoms, recent histories of suicidal or unstable behavior, and severe illness burden have historically been excluded from PTSD clinical trials (Spinazzola, Blaustein, & van der Kolk, 2005). In research contexts, this exclusion has mostly been guided by the desire to limit the impact of confounding factors on outcomes (i.e., an emphasis on internal over external validity). However, in clinical settings, frontline clinicians also have expressed concerns that some interventions for PTSD may be 'overstimulating' for patients with SMI and could potentially exacerbate their primary symptoms and/or cause relapse (Braiterman, 2004; Fowler, 2004). Our own research with public-sector clinicians yielded similar concerns and were coupled with additional fears regarding their perceived competence to effectively address trauma-related issues in this patient population (Frueh, Cusack, Grubaugh, Sauvageot, & Wells, 2006).

Accordingly, few PTSD treatment trials have focused on or even included patients with SMI. To date, only a handful of PTSD treatment outcome studies with this population have been completed, the majority of which consist of small open-trial study designs (Frueh et al., 2009; Lu et al., 2009; Mueser et al., 2007; Rosenberg, Mueser, Jankowski, Salyers, & Acher, 2004), which generally tested the same cognitive restructuring intervention delivered in either group or individual format (Mueser et al., 2007; Rosenberg et al., 2004). One of two published randomized controlled trials for PTSD in an SMI patient population ( $n = 108$ ; Mueser et al., 2008), compared the cognitive intervention tested in the open trials above to treatment as usual (TAU) among 108 community mental health center (CMHC) patients and found statistically significant decreases in symptom severity in the CBT group relative to the TAU group. A second RCT, again by the same group, examined whether cognitive restructuring had a significant impact on outcomes above and beyond breathing retaining and psychoeducation among 201 patients enrolled in a University Behavioral Healthcare System (Mueser et al., 2015). These authors found that the group that received all three components improved significantly more on PTSD severity, PTSD diagnostic status, and PTSD-related social functioning relative to the group that received only breathing retraining and psychoeducation. The three pilot studies referenced above (Lu et al., 2009; Mueser et al., 2007; Rosenberg et al., 2004) used a similar cognitive behavioral intervention and likewise yielded statistically significant reductions in PTSD severity.

To our knowledge, there are only two published treatment outcome studies using an exposure-based intervention for PTSD in a sample of individuals with SMI. Frueh and colleagues conducted an open trial of 20 patients enrolled in a regular program of care within two CMHCs (Frueh et al., 2009). Their combined intervention, which was developed previously for the treatment of complex

PTSD, consisted of 22-sessions: 14 sessions of group therapy focused initially on education and relaxation training and later on social skills building, followed by eight sessions of individual exposure therapy (Frueh et al., 2004). Findings from this pilot suggest that the treatment was effective—92% of treatment completers (12/13) no longer met criteria for PTSD post treatment and gains were maintained at the 3-month follow-up. Another study conducted in the Netherlands compared the efficacy of Prolonged Exposure (PE) to Eye Movement Desensitization and Reprocessing (EMDR) in a sample of 10 outpatients with psychosis (De Bont, van Minnen, & de Jongh, 2013). Study findings indicated that both PE and EMDR resulted in statistically significant decreases in PTSD severity and general psychopathology. These study findings, as well as results from cognitive restructuring interventions (e.g., Mueser et al., 2007, 2008; Rosenberg et al., 2004), suggest that intensive PTSD interventions are feasible to implement with patients with SMI and are well tolerated by this patient population. Furthermore, despite being few in number, these studies also suggest that the majority of patients with SMI can benefit significantly from such interventions with regard to either symptom reduction and/or loss of PTSD diagnostic status.

Currently, there are few PTSD treatment outcome studies for individuals with SMI by which to inform practice guidelines. Additionally, there are few published studies testing the efficacy of exposure-based interventions for PTSD such as PE. There are likewise no published clinical trials using Veteran samples or treating combat-related PTSD. As such, we tested the efficacy of PE using an open trial study design of 34 veterans enrolled in a program of care at a Southeastern Veterans Affairs Medical Center (VAMC). It was hypothesized that PE would result in statistically significant decreases in PTSD severity from baseline to post-intervention. These data are timely as there is both a significant need for and growing movement within the trauma field to expand empirically supported PTSD interventions to more complicated, yet often times more representative patient populations (Grubaugh, Egede, Frueh, & Knapp, 2010; Spinazzola et al., 2005). This need is all the more striking among individuals with SMI who represent one of the highest risk patient populations with regard to trauma exposure and the subsequent development of PTSD.

## 1. Method

### 1.1. Overview of study

The current study was an open trial evaluation of an exposure-based intervention for PTSD among 34 veterans with a co-occurring diagnosis of a severe mental illness. Treatment included 10 to 15 weekly sessions of individual exposure therapy for PTSD consistent with Prolonged Exposure (PE), a widely disseminated manualized exposure-based intervention (Foa & Rothbaum, 1998). Participants completed a baseline assessment prior to enrollment, a post assessment immediately after treatment, and a final assessment 6 months after completing treatment.

### 1.2. Participants

Fifty-eight veterans were referred to the study and screened for eligibility. Thirty-six (36) veterans met study inclusion/exclusion criteria and were enrolled in the study. Of these, one participant was subsequently removed from the study protocol due to improbable PTSD and one never started treatment, yielding an intent-to-treat (i.e., analysis) sample of 34 veterans.

Enrolled patients had notable histories of psychiatric hospitalization and typically required assistance (either at the time of study participation or in the past) with independent living skills,

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