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INCENTIVIZING ATTENDANCE TO PROLONGED EXPOSURE FOR PTSD IN OPIOID USE DISORDER PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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Abstract

OBJECTIVE—To determine whether contingent monetary incentives increase opioid use disorder patients' attendance to Prolonged Exposure (PE) therapy and whether attendance is associated with improvement in posttraumatic stress disorder (PTSD) and substance use disorder (SUD) outcomes.

METHOD—Patients (N = 58) with PTSD were offered PE or PE with incentives (PE+I; max $480) to attend PE sessions. Participants were assessed at baseline and weeks 6, 12, and 24 post-randomization.

RESULTS—Participants were mostly women (79%) and Caucasian (71%); mean age 37.43 years (SD = 11.33). PE+I participants attended a median of 9 (of 12) sessions compared to 1 session for PE participants (p < 0.001), which included more exposure sessions (PE+I mdn = 6; PE mdn = 0; p < .001). A time × treatment condition interaction indicated that PE+I participants exhibited a greater decrease in PTSD severity over time than PE participants (OR = 3.1; 95% CI = 0.4–5.7; p = 0.024). PE+I participants remained in substance use treatment longer than PE participants (mdn days = 262 vs. 192; p = 0.039). There were no group differences in drug use.

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CONCLUSIONS—Monetary incentives increased SUD patients' attendance to an otherwise poorly-attended treatment for PTSD. Better attendance in the incentivized group was associated with greater PTSD improvement, better SUD treatment retention, and no increased drug use. Incentives are well supported for improving adherence to substance use treatment goals and promising as a means to improve therapy attendance, which may improve the effectiveness of existing psychotherapies in difficult-to-treat populations.

Keywords

attendance; PTSD; Prolonged Exposure Therapy; methadone maintenance; contingency management

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About 25% of patients in substance use disorder (SUD) treatment have current posttraumatic stress disorder (PTSD) (Back et al., 2000; Hien, Nunes, Levin, & Fraser, 2000; Peirce, Burke, Stoller, Neufeld, & Brooner, 2009; Reynolds et al., 2005). Despite this high prevalence, effective treatment for PTSD in this population remains elusive. Failure to treat comorbid PTSD results in patients with much greater impairment than their SUD-only peers in social functioning and mental health (Mills, Teesson, Ross, & Darke, 2007; Ouimette, Finney, & Moos, 1999; Peirce, Kindbom, Waesche, Yuscavage, & Brooner, 2008; Reynolds et al., 2005), and worse substance use and treatment retention outcomes (Hien et al., 2009; Read, Brown, & Kahler, 2004). Some popular PTSD treatments for SUD patients are not trauma-focused, although non-trauma-focused therapies in both non-SUD (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013) and SUD populations (Hien et al., 2009; McGovern et al., 2015) have consistently low efficacy on PTSD outcomes (Roberts, Roberts, Jones, & Bisson, 2015).

Prolonged Exposure therapy (PE), which uses exposure to decondition fear responses to trauma-related stimuli, is a well-supported manualized cognitive behavioral therapy for PTSD that was developed for non-SUD populations (Cukor, Olden, Lee, & Difede, 2010; Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010). Early work with exposure-based therapies explicitly excluded patients with comorbid SUD due to concerns about possible substance use exacerbation (Pitman et al., 1991). However, recent trials of exposure-based treatments for comorbid PTSD and SUD have produced modest improvements in PTSD symptomology (Berenz, Rowe, Schumacher, Stasiewicz, & Coffey, 2012; Brady, Dansky, Back, Foa, & Carroll, 2001; Coffey, Stasiewicz, Hughes, & Brimo, 2006; Foa et al., 2013; Mills et al., 2012; Sannibale, Teesson, Creamer, Sitharthan, Bryant et al., 2013) and, importantly, have not produced increases in substance use. Nevertheless, significant clinical concerns regarding SUD patients' tolerance for exposure-based PTSD treatments have persisted (Najavits, 2015).

Another barrier to providing PTSD-focused treatment for individuals with comorbid substance use disorders is that the traditional structure of PTSD treatment may not easily lend itself to integration into SUD treatment settings. Most current PTSD treatments with an integrated SUD component are stand-alone therapies structured to include one Master's or Doctoral-level therapist and one patient who meet for up to 20 weeks in individual psychotherapy sessions, during which both SUD skills and PTSD exposure and skills are

learned and practiced (Brady et al., 2001; Foa et al., 2013; Mills et al., 2012; Sannibale et al., 2013; Triffleman, Carroll, & Kellogg, 1999). This structure conflicts with most existing SUD treatment approaches in the U.S., which are offered typically in a clinic-based setting where psychotherapy groups are the primary form of counseling. In addition, between one-half and two-thirds of addiction treatment staff lack postgraduate degrees (Mangrum & Spence, 2008; Mulvey, Hubbard & Hayashi, 2003; Rieckmann, Farentinos, Tillotson, Kocarnik, & McCarty, 2011) and may receive little formal training in psychotherapy principles and practice, leaving them ill-equipped to provide effective treatment for PTSD without considerable additional training.

Almost all individuals with an opioid use disorder have experienced one or more traumatic events (Peirce et al., 2009). PTSD rates are very high in this group and are higher than those found in other SUD populations (Cottler, Compton, Mager, Spitznagel, & Janca, 1992; Mills, Teesson, Ross, & Peters, 2006; Peirce et al., 2009). However, existing trials of exposure-based therapy for SUD patients with PTSD rarely include patients with opioid use disorders (e.g., Mills et al., 2012). With heroin and other opioid use rising to epidemic proportions in the past few years, effective treatment for PTSD in opioid use disorder populations is of increasing importance.

The most serious limitation to the use of exposure-based treatments in SUD patients is poor attendance. High treatment dropout rates are routinely observed in SUD patients generally, and particularly those with comorbid PTSD. Completion rates are low (< 20%) even in non-trauma-focused treatments for this population (e.g., McGovern et al., 2015; Hien et al., 2009). Indeed, exposure-based treatments appear to be effective for SUD patients who are retained in treatment (Brady et al., 2001), although some trials that suffered from poor attendance found no benefit (e.g., Foa et al., 2013). As many as one-quarter of participants drop out before therapy starts (Coffey et al., 2006; Foa et al., 2013; Mills et al., 2012), and the average or median number of sessions attended ranges from 33% to 50% of scheduled sessions (Brady et al., 2001; Foa et al., 2013; Mills et al., 2012; Triffleman, 2000). Half or fewer of participants attend at least one imaginal exposure session (Brady et al., 2001; Mills et al., 2012; Sannibale et al., 2013) and the rate of true completion is typically less than 18% (Mills et al., 2012; Triffleman, 2000). Citing the above studies, some investigators have concluded that exposure-based therapies for PTSD are ineffective for SUD populations (Najavits & Hien, 2013). An alternative interpretation is that the effectiveness of exposure-based treatments for PTSD-SUD patients is significantly limited by poor treatment attendance.

Contingent monetary incentives have been used for years in SUD populations to increase abstinence quickly and effectively (Stitzer & Petry, 2006). The approach is based on operant conditioning principles: provide a reinforcer (i.e., monetary vouchers) when a patient exhibits a desired healthy behavior (i.e., a drug-free urine sample). More recent work has expanded the use of contingent monetary incentives to other health behaviors, including attendance to individual and group counseling in SUD programs (Brooner et al., 2007; Ledgerwood, Alessi, Hanson, Godley, & Petry, 2008). Incentives may be effective for increasing attendance to PE in this population.

The present study was designed to address the above limitations in a sample of opioid use disordered patients enrolled in a community-based methadone maintenance treatment setting. The primary aim was to evaluate the efficacy of incentivizing attendance to Prolonged Exposure for PTSD sessions via contingent monetary incentives. Secondary aims were to evaluate the effects of PE on PTSD symptoms and SUD treatment outcomes of substance use and retention.

Methods

Participants and procedures

Participants (N = 58) were recruited from an outpatient methadone maintenance clinic, in which treatment consisted of medication management and individual and group counseling assigned according to an evidence-based adaptive stepped-care model (Brooner et al., 2004; 2007). Inclusion criteria for randomization to treatment group were: 1) current diagnosis of PTSD; 2) receiving methadone for at least 4 weeks; 3) 18+ years of age; 4) no psychiatric contraindications to PE (e.g., current suicidal/homicidal intent); 5) clear memory for the traumatic event; 6) interest in receiving PE; 7) willing to sign a release of information for current psychiatric treatment providers outside of the clinic; 8) willing to delay taking daily methadone dose on exposure therapy days until after session; 9) no history of prior exposure-based therapy for PTSD; and 10) willing to have therapy sessions audio-recorded. Exclusion criteria were: 1) pregnancy; 2) medical problem requiring immediate and intensive treatment (e.g., end-stage liver disease); 3) presence of formal thought disorder, delusions, or hallucinations. The affiliated Institutional Review Board approved all procedures. Of the 126 consented individuals, 58 met inclusion/exclusion criteria and were randomized to condition (see Fig. 1).

There were no significant treatment group differences on any demographic variables. The intent-to-treat sample was 79% female (n = 46) and 21% male (n = 12) with a mean age of 37.43 years (SD = 11.33). Most were white (71%; n = 41). The remainder were black (22%; n = 13) or multiracial (7%; n = 4). Approximately two-thirds had obtained a high school diploma or GED (66%; n = 38). Mean reported monthly income was $825.90 ($SD$ = $555.63). Mean days in methadone maintenance treatment at the clinic was 738.64 (SD = 1668.78, median = 188.50, range 30-9004). Mean years of drug use was 24.74 (SD = 11.69), including 6.58 years (SD = 6.33) of heroin and 4.27 years (SD = 5.54) of cocaine use. Table 1 provides disaggregated demographic data for each treatment group.

Procedures

Patients who reported trauma exposure, PTSD symptoms, or PTSD treatment were referred by clinic staff or self-referred. In the consent form, potential participants were told that the purpose of the study was to “find ways to help people in substance abuse treatment who have experienced distressing events get even better psychiatric care.” Potential participants were informed that everyone who participated in the study would receive Prolonged Exposure therapy, which was described as “talking about the distressing event many times with a specially trained therapist, [which] has been shown to weaken the upsetting effects of the memory in many people.” They were informed that they would be randomly assigned to

one of two conditions: “Everyone will be offered Prolonged Exposure therapy, but only those assigned to Condition 2 will receive vouchers for coming to therapy. You have a 50/50 chance of being assigned to either condition.” Both conditions were described as entailing attendance to weekly therapy sessions. The per-session voucher amount and the maximum possible voucher amount in the incentivized condition were described. The payment schedule for completing the follow-up assessments, for which both incentivized and non-incentivized participants were eligible, was also described ($80 for the 4-hour baseline assessment and $40 each for the three follow-up assessments).

Participants who screened positive for PTSD completed a 4-hour baseline assessment with a staff psychometrist. Immediately following the assessment, the psychometrist called another study staff member who did not interact with research participants. The study staff member determined which condition had been pre-selected as the next to be assigned and communicated that information to the psychometrist, who told the participant to which condition she or he had been assigned and scheduled the participant for the first PE session with a therapist. Randomization was conducted in blocks of 10 using a randomization website.

Follow-up assessments occurred in Week 6 following randomization (mid-treatment), Week 12 (end of treatment) and Week 24 (3 months post-treatment). Participants who dropped out of substance use treatment at the methadone maintenance clinic were no longer eligible to continue in the PE treatment part of the study but were eligible to complete follow-up assessments for the study. Participants were paid $80 for the baseline assessment and $40 for each follow-up assessment. Those who appeared intoxicated based on clinical judgment and responses to the Mini-Mental Status Exam (Folstein, Folstein, & McHugh, 1975) were rescheduled.

Measures

Screening—The Traumatic Life Events Questionnaire (TLEQ; Kubany et al., 2000) assessed exposure to 23 potential traumatic events. Respondents indicated how many times they experienced each event (“Never” to “5 times”) which was scored as 0 to 5 for each event. A sixth option of “More than 5 times” was scored as 6. The Modified PTSD Symptom Scale-Revised (MPSS-R; Falsetti, Resnick, Resick, & Kilpatrick, 1993) assessed severity (0 = “not at all distressing” to 4 = “extremely distressing”) and frequency (0 = “not at all” to 3 = “5+ times per week) of current PTSD symptoms associated with TLEQ events. A symptom was considered probable if frequency was at least 1 (“once per week”) and severity was at least 1 (“a little bit distressing”). Potential participants screened in if they endorsed at least one event that met DSM-IV criteria (i.e., Criterion A1 and A2) and symptoms that met minimum DSM-IV PTSD criteria (American Psychiatric Association, 2000). (DSM-5 measures were not yet available when data collection began.)

Baseline characteristics—Participants completed a demographics questionnaire created for the study. The Structured Clinical Interview for DSM-IV – Axis I (SCID; First, Spitzer, Gibbon, & Williams, 1998) was used to identify Axis I DSM-IV disorders other than PTSD and to determine whether potential participants met exclusion for a psychotic disorder. The

antisocial and borderline personality disorder modules of the SCID – Axis II (First, Spitzer, Gibbon, & Williams, 1997) assessed the most common personality disorders in people with chronic SUD and PTSD (Friborg, Martinussen, Kaiser, Overgård, & Rosenvinge, 2013; Hasin et al., 2011).

Therapy process factors—The Credibility/Expectancy Questionnaire (Devilly & Borkovec, 2000; 6 items) assessed participants' beliefs and expectancies regarding treatment effectiveness (Cronbach's alpha = 0.85). The Working Alliance Inventory Client Form (WAI; Horvath & Greenberg, 1989; 36 items) assessed participants' perceptions of their alliance with their therapist (Cronbach's alpha = 0.93). We adapted the child-oriented Barriers to Treatment Participation Scale (BTPS; Kazdin, Holland, Crowley, & Breton, 1997) by removing questions about children, billing, and therapeutic relationship and modifying the object in some questions from the child to the participant. We retained questions about treatment demands and issues and perceived irrelevance of treatment. This adapted BTPS has 17 questions scored on a Likert-type scale from 1 (never a problem) to 5 (very often a problem). Cronbach's alpha for the modified scale was good (0.87), and similar to the original 44-item scale (0.86; Kazdin et al., 1997). The CEQ and BTPS were administered at baseline and each follow-up, although only the baseline measures are presented here. The WAI was administered only at follow-ups.

Treatment

Prolonged Exposure Therapy—All participants were offered manualized PE Therapy (Foa, Hembree, & Rothbaum, 2007) with modifications to fit the schedule of a community-based clinic: 60 rather than 90 minute sessions once per week rather than twice-weekly. These modifications have been approved by the treatment developers and tested to verify that they produce similar outcomes as the original PE schedule (Coffey et al., 2006; Nacasch et al., 2015; Reger et al., 2013). Session 1 provided an introduction and rationale for PE and breathing retraining for relaxation. The original Session 2 was divided into two sessions to fit the 60-minute format while allowing time to cover all content. Details of the participant's traumatic event were elicited in Session 2 and an exposure hierarchy was developed for imaginal and in vivo exposure in Session 3. Session 4 was the first to include imaginal exposure, in which participants described the traumatic event. This process was repeated until the final session, which also included a review of treatment progress. Participants were given weekly homework assignments to listen to the recorded therapy session once per day and complete assignments from the in vivo hierarchy. Treatment was provided by three doctoral or master's level therapists trained in PE. Therapists met weekly with study team psychologists for supervision, which included case discussion and audio record review. Participants who completed 12 sessions or at least 9 sessions and demonstrated a 70% reduction in PTSD symptoms, based on MPSS-R scores assessed at each therapy session (Falsetti et al., 1993), were considered to have completed treatment (Foa et al., 2005).

Treatment conditions—PE participants received PE therapy as detailed above. PE+I participants received PE and vouchers for attending scheduled PE appointments. Participants chose gift cards or payment of clinic fees to redeem vouchers. Voucher amounts began at $30 for Session 1 and escalated by $10 per session to $60 with consecutive attended

sessions. Missed sessions earned no voucher and the next attended session reset earnings to $30. Because participants could complete treatment at Session 9, sessions 10 to 12 were not incentivized. Participants who attended every session as scheduled received $480. The average amount earned was $307 (*SD* = $187; median = $410) and 93% of PE+I participants earned at least one voucher.

Missed sessions—Participants who missed a session were rescheduled or continued with the next session at their next scheduled appointment. Those who missed two consecutive appointments were reminded of their option to withdraw from PE while still being eligible to participate in follow-up assessments. Those who missed four consecutive weeks were withdrawn from PE but remained eligible to participate in follow-up assessments.

Treatment fidelity—Sixteen percent (*n* = 41) of sessions were rated by the first author for fidelity (i.e., therapists' adherence to the treatment manual) using adherence rating forms from the PE treatment development team, who also provided recommendations regarding how many sessions should be assessed (S. Capaldi, personal communication, January 28, 2013). Therapists delivered PE as prescribed. Mean adherence and competence ratings were 2.95 out of 3 (*SD* = 0.22). To assess interrater reliability, 12% of rated sessions (*n* = 5) were independently rated by the senior author. Interrater agreement was 100%.

Primary outcomes

PE therapy attendance—Attendance was recorded throughout the study (see description of treatment). Treatment completion was coded as noted above.

PTSD severity—The Clinician-Administered PTSD Scale for DSM-IV (CAPS; Blake et al., 1995) is a structured interview that was used to assess the presence, severity, and intensity of the 17 PTSD symptoms in the past month (American Psychiatric Association, 2000). The frequency and intensity of each symptom is measured on a 0–4 scale, with higher scores indicating more frequent and/or intense symptoms. Total scores range from 0 to 136; 40+ is considered positive for PTSD. Scores of 60+ are considered indicative of severe to extreme PTSD (Weathers, Keane, & Davidson, 2001). Clinical improvement was coded based on a decrease of 15 or more points in total score (Weathers et al., 2001). Participants were considered to meet criteria for PTSD based on published guidelines for positive symptoms (frequency ≥ 1 and severity ≥ 2) (Weathers, Ruscio, & Keane, 1999). The CAPS was administered at baseline and each follow-up.

Substance use disorder treatment response—Retention in the original SUD treatment program was recorded as the number of days from consent to discharge. No attempt was made to track whether participants entered other treatment or returned to the original treatment setting after discharge. Participants provided urine samples for drug testing on a bimonthly to monthly schedule determined by the treatment program. Urine samples were tested for opioids (including methadone), cocaine, benzodiazepines, marijuana, and amphetamine. Drug use was measured as a proportion of urine tests provided in the interval between study events (i.e., consent, baseline assessment, follow-ups) that were positive for any drug. Because these data were extracted from the clinical record,

information was only available for the time that participants remained in treatment. Drug use problem severity was measured with the Addiction Severity Index (ASI; 5th edition; McLellan et al., 1992) drug composite score. The ASI was administered at baseline and at each follow-up.

Secondary outcomes (assessed at baseline and each follow-up)

The *Symptom Checklist-90-Revised* (Derogatis, 1994; 90 items) assessed general psychiatric functioning and distress across 9 subscales (Somatization, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, and Psychoticism) and three composite indices (Global Severity Index, Positive Symptom Total, and Positive Symptom Distress Index). Raw scores were converted to t-scores based on outpatient psychiatric patient norms. Internal reliability for subscales are satisfactory to good, with the GSI scale reliability consistently rating as high (Derogatis, 1994; Prinz et al., 2013). Although the scale's multidimensionality has been challenged, it appears to be better supported in patients with high distress (Paap et al., 2012). Given this caution, we report all scale scores but focus on the more reliable GSI scale.

The *Difficulties in Emotion Regulation Scale* (DERS; Gratz & Roemer, 2004; 36 items) assessed emotion regulation and dysregulation (Cronbach's alpha = 0.93; Gratz & Roemer, 2004) via six subscales: Lack of Emotional Awareness, Lack of Emotional Clarity, Difficulties Controlling Impulsive Behaviors when Distressed, Difficulties Engaging in Goal-Directed Behavior when Distressed, Nonacceptance of Negative Emotional Responses, and Limited Access to Emotion Regulation Strategies.

The *Quality of Life Enjoyment and Satisfaction Questionnaire –Short Form* (Q-LES-Q; 16 items; Endicott, Nee, Harrison, & Blumenthal, 1993; Mick, Faraone, Spencer, Zhang, & Biederman, 2008) assessed quality of life across domains (Cronbach's alpha = 0.84), yielding a total score ranging from 14–70 and a single overall satisfaction score.

Statistical analyses

Missing data—The study was designed and implemented to minimize missing data and this was largely successful. No data was missing for the primary outcomes of PE session attendance or substance abuse treatment retention. The primary outcome of objective drug use from urine testing had data present for 73% of 232 possible data points (58 participants × 4 intervals). The primary outcomes of PTSD severity and drug use problem severity (i.e., ASI score) and the secondary outcomes were collected during follow-ups. About 86% of scheduled follow-ups were attended and about 80% of participants attended all 3 follow-ups, with no group difference (80% PE vs. 79% PE+I; $\chi^2(1) = 0.018$; $p = 0.893$.) Some follow-ups were unavoidably missed due to hospitalization (2 PE, 1 PE+I), incarceration (2 PE, 2 PE+I), or death (2 PE).

Data analytic approach—Groups (randomized to treatment vs. not; PE vs. PE+I) were compared on dichotomous variables with chi-square or likelihood ratios for larger samples, or Fisher's Exact test for small samples. Groups were compared on continuous variables with t-tests, using adjusted degrees of freedom where variances were unequal. Group

medians on the count variable of PE sessions attended (all and exposure sessions) were compared using Mann-Whitney U. Simple bivariate correlations between PTSD severity change and number of sessions used Pearson's *r*. For primary outcomes of PTSD severity and drug use (% positive, ASI composite score) and secondary outcomes of psychiatric distress, emotional regulation, and quality of life, we fit longitudinal linear mixed-effects models with random intercepts that examined the pattern of changes from baseline to the Week 6, Week 12, and Week 24 follow-ups. Mixed-effects models are particularly useful in longitudinal studies with sporadic missing data because the analysis takes advantage of all available data without imputation while accounting for within-subject correlation. The interaction term time × treatment condition was of primary interest, with main effect of time a secondary focus. There were no significant main effects of condition. Results are presented as odds ratios (OR) with 95% confidence intervals (CI). For most outcomes, a condition × time OR greater than 1 represents the difference in the improvement per 6-week period for PE+I participants relative to PE participants. For the DERS scales, a decrease represents improvement in emotional regulation so an OR less than 1 represents improvement in the PE +I participants relative to the PE participants. Substance use disorder treatment retention across conditions was analyzed with Kaplan-Meier survival analysis with the Log-Rank chi square statistic. Data from participants who remained in SUD treatment at the end of their study participation were right-censored.

Results

Baseline characteristics

Intent-to-treat groups did not differ on any demographic variables (Table 1). Participants reported exposure to at least 32 lifetime traumatic events based on the TLEQ (Kubany et al., 2000), which caps the number of possible events for each answer at 6 for "more than 5 times" (PE+I = 33, $SD = 16$; PE = 32, $SD = 15$; $t[56] = -0.416$, $p = 0.679$). Baseline PTSD severity scores on the CAPS were also the same across groups (PE+I $M = 72.29$, $SD = 18.78$ vs. PE $M = 72.77$, $SD = 15.52$; $t(56)=0.11$, $p = 0.915$), and indicate PTSD symptomology in the severe to extreme range (Weathers et al., 2001). The most common index traumatic events were child sexual assault (35%, $n = 20$), intimate partner violence (16%, $n = 9$), child physical assault (12%, $n = 7$), and unexpected death of loved one (12%, $n = 7$). There was no group difference in index event categories (Likelihood ratio = 9.112, $df = 8$; $p = 0.333$). Groups had similar rates of the most common comorbid psychiatric diagnoses: major depressive disorder (PE 47% vs. PE+I 50%; χ^2 (1) = .064; $p = 0.800$); antisocial personality disorder (PE 40% vs. PE+I 29%, χ^2 (1) = .837; $p = 0.360$); borderline personality disorder (PE 20% vs. PE+I 43%, χ^2 (1) = 3.535; $p = 0.060$); bipolar I disorder (PE 17% vs. PE+I 14%, Fisher's Exact; $p = 1.000$); and obsessive-compulsive disorder (PE 14% vs. PE+I 18%; Fisher's Exact; $p = 0.730$).

Serious Adverse Events

Serious adverse events (SAE) included hospitalizations, suicide attempts, and death, and were tracked from consent to the last follow-up. Seven events were reported by consented participants who were not randomized: 5 medical; 1 psychiatric; and 1 drug-related hospitalization. PE participants had 10 SAEs: 9 hospitalizations (4 medical; 1 psychiatric;

and 4 drug-related); and 1 death. The medical examiner determined the cause of that participant's death was drug overdose. The participant attended the first introductory session, which focused on rationale for the treatment, then voluntarily withdrew from the treatment phase of the study approximately one month prior to death. PE+I participants had 6 SAEs: 5 hospitalizations (2 medical; 3 psychiatric); and 1 suicide attempt not requiring hospitalization. The suicide attempt was self-reported several days after it occurred, which was approximately 2 months after the last attended PE session (session 8) and 6 weeks after voluntary withdrawal from the treatment phase. None of the SAEs were determined to be related to study participation.

Primary outcomes

Prolonged Exposure therapy attendance—The majority of both groups attended at least one PE session (60% PE; 93% PE+I). PE+I participants attended more therapy sessions (see Table 1; Mann-Whitney U = 704; $p < .001$; Hodges-Lehman median difference = 6; 95% CI = 4 – 8); were more likely to attend at least one exposure session (75%, n=21 vs. 17% n=5; $\chi^2(1) = 19.926$, $p < 0.001$; $\varphi = 0.586$); and attended more total exposure sessions than PE participants (Table 1; Mann-Whitney U = 690, $p < 0.001$, Hodges-Lehman median difference = 5; 95% CI = 3 – 6). PE+I participants were also more likely to be treatment completers (36%, $n = 10$ vs. 3%, $n = 1$; $\chi^2(1) = 9.881$, $p = 0.002$; $\varphi = 0.413$). Two PE and four PE+I participants missed two consecutive weeks. Twenty-eight PE and 14 PE+I participants missed four consecutive weeks and were withdrawn from the study, per study protocol.

PTSD severity—Across groups, participants demonstrated a decrease in PTSD severity on the CAPS of about 7 points per 6-week period (OR = −6.8; 95% CI = −8.7 – −4.9; $p < 0.001$). As predicted, there was also a time × treatment condition interaction such that PE+I participants exhibited a greater decrease in PTSD symptom severity over time than PE participants (OR = 3.1; 95% CI = 0.4 – 5.7; $p = 0.024$). Figure 2 shows each participant's raw CAPS data with the estimated regression line for each condition superimposed. A greater proportion of PE+I participants met criteria for clinical improvement at the Week 12 follow-up ($n = 50$; PE+I 78% [$n = 18$] vs. PE 48% [$n = 13$]; $\chi^2[1] = 4.78$; $p = 0.029$) and at the Week 24 follow-up ($n = 47$; PE+I 74% [$n = 17$] vs. PE 38% [$n = 9$]; $\chi^2[1] = 6.30$; $p = 0.012$). To explore whether it was incentives alone or attendance to PE sessions that was associated with PTSD response, correlational analyses were conducted across conditions. Improvement in PTSD severity by the Week 12 follow-up was positively correlated with attending more PE sessions ($r = 0.349$; $n = 50$; $p = 0.013$) and attending more PE sessions with exposure content ($r = 0.356$; $n = 50$; $p = 0.011$). Changes in Week 24 CAPS scores were similarly positively associated with sessions attended ($r = 0.377$, $n = 47$; $p = 0.009$) and with exposure sessions attended ($r = 0.370$; $n = 47$; $p = 0.010$). Participants in both groups were less likely to meet diagnostic criteria for PTSD over time ($OR = 0.86$; 95% CI = 0.78 – 0.95; $p = 0.004$), but the time × condition interaction was nonsignificant ($OR = 1.057$; 95% CI = 0.936 – 1.194; $p = 0.374$).

Substance use disorder treatment response—PE+I participants were retained in SUD treatment longer than PE participants (median days = 262 vs. 192; Log-Rank $\chi^2(1) =$

4.3; $p = 0.039$; see Figure 3). There was a main effect of time for drug use such that across groups participants had 4% fewer drug-positive urine results per 6-week period (*OR* = −0.04; 95% *CI* = −0.08 – −0.0003; $p = 0.048$), although the time × condition interaction was not significant (OR = 0.013; 95% CI = −0.046 – 0.073; p = 0.654). There was no main effect of time or time × condition interaction on the ASI drug composite score (data not shown).

Secondary outcomes

Psychiatric distress—There were significant main effects of time for all Symptom Checklist-90-R subscales and composite indices such that symptoms decreased over time for both treatment groups (all *p* values < 0.003; see Table 2). There were also significant time × condition interactions for the Psychoticism and Positive Symptom Distress indices such that PE+I participants exhibited a greater decrease on both subscales than PE participants (OR = 1.21, 95% CI = 0.0008 – 2.4, $p = 0.049$; OR = 1.64, 95% CI = 0.228 – 3.05, $p = 0.023$, respectively). There was a time × condition trend for the Global Severity Index such that PE +I participants exhibited a larger decrease than PE participants (OR = 1.09, 95% CI = −0.193 – 2.376, $p = 0.095$).

Emotion regulation—Across groups, participants reported better emotion regulation skills over time for all subscales of the Difficulties in Emotion Regulation Scale (all *p* values ≤ 0.001) except for the Lack of Emotional Awareness subscale. There was a significant time × condition interaction for the Overall Score (Table 2) and for the Difficulties Engaging in Goal-Directed Behavior subscale such that PE+I participants exhibited a greater improvement over time than PE participants (OR = 0.728, 95% CI = 0.087 – 1.369, $p = 0.026$). Trend-level time × condition interactions were found for the Nonacceptance of Emotional Responses and the Limited Access to Emotion Regulation Strategies such that PE +I participants exhibited greater improvements over time than PE participants (OR = 0.745, 95% CI = −0.025 – 1.515, $p = 0.058$; and OR = 0.960, 95% CI = −0.266 – 1.946, $p = 0.056$, respectively).

Quality of Life—Both groups reported improved quality of life on the total Q-LES-Q-SF scale (Table 2) and overall satisfaction (OR = 0.145, 95% CI = 0.032 – 0.259, $p = 0.012$). There were no significant time × condition interactions.

Therapy Process Factors

Credibility/Expectancy Questionnaire—Groups found the treatment equally credible before treatment began (PE $M = 22.83$, $SD = 3.80$ vs. PE+I $M = 22.54$, $SD = 3.87$, $t(56) = 0.30$, $p = 0.769$) and expected to receive the same level of benefits from treatment (PE $M = 20.40$, $SD = 583$ vs. PE+I $M = 20.07$, $SD = 4.64$, $t(56) = 0.24$, $p = 0.814$).

Working Alliance Inventory—The WAI Total score of participants who attended at least one therapy session was equivalent across groups at the 6-week follow-up (PE $M = 222.88$, $SD = 25.07$ vs. PE+I $M = 230.04$, $SD = 15.15$, $t(24.22) = -1.05$, $p = 0.304$), 12-week follow-up (PE $M = 221.27$, $SD = 24.13$ vs. PE+I $M = 222.19$, $SD = 29.52$, $t(34) = -0.10$, $p = 0.921$), and 24-week follow-up (PE $M = 226.71$, $SD = 21.64$ vs. PE+I $M = 223.57$, $SD = 19.66$, $t(33) = 0.45$, $p = 0.659$).

Barriers to Treatment Participation—Groups anticipated the same severity of potential barriers to participation before treatment began (PE $M = 26.03$, $SD = 7.16$ vs. PE+I $M = 27.14$, $SD = 8.51$; $t(56) = -0.54$; $p = 0.592$), and expected to attend nearly all scheduled sessions (PE $M = 92\%$, $SD = 9.25$ vs. PE+I $M = 93\%$, $SD = 14.30$, $t(56) = -0.16$, $p = 0.874$).

Discussion

The primary hypothesis of this study – that incentivizing methadone maintenance patients' attendance to exposure-based treatment for PTSD would result in improved attendance – was supported. Incentivized participants attended far more Prolonged Exposure (PE) sessions than did non-incentivized participants. Importantly, the difference in attendance occurred despite both groups reporting that they were equally interested in and expecting benefit from treatment and endorsing equivalent rapport with the therapists throughout treatment. Patients with severe substance use disorder (SUD) are often poor attenders to psychosocial treatment. This has been a serious stumbling block for treating PTSD in this population (Pinto, Campbell, Hien, Yu, & Gorroochurn, 2011), and some have concluded that exposure-based therapy is ineffective for this population. However, concluding that treatment is ineffective when a patient receives little to no active intervention is premature. We note that treatment attendance of the non-incentivized participants was similar to one previous study (Foa et al., 2013), but somewhat lower than others (Mills et al., 2012; Sannibale et al., 2013; Coffey et al., 2016). However, concern that this lower than expected rate may have inflated the difference between conditions is ameliorated by the incentivized group's equivalent or higher rate of attendance to at least one session when compared to past published reports (64 – 96%; Mills et al., 2012; Sannibale et a. 2013; Foa et al., 2013; Coffey et al., 2016), and the far higher rate of attendance to at least one imaginal exposure session in comparison to other outpatient-based studies (40–55%; Mills et al, 2012; Sannibale et al., 2013). Treatment completion rates are low (Mills et al., 2012) or not presented (e.g., Sannibale et al., 2013; Foa et al., 2013) in several prior studies, thus limiting possible cross-study comparisons. However, Coffey et al. (2016) reported treatment completion rates for a residential SUD sample. They defined treatment completion as attending eight or more sessions.; Uusing this metric, we find comparable results for the current study (57% completion in the incentivized group, vs. 61% in Coffey et al.), suggesting that incentivizing treatment can improve treatment attendance rates to those found in a residential SUD treatment setting, where participants would have had few treatment barriers like employment, need for childcare and transportation, and active drug use. Results from this study demonstrate that the drop-out and nonattendance rate can be reduced in SUD patients in the community, which gives us an opportunity to appropriately assess whether exposure-based treatment of PTSD in SUD patients is effective. We encourage future investigators to report detailed attendance and completion rates explicitly in order to facilitate comparisons across studies and to better determine the relationship between treatment attendance and outcome.

As expected, participants who were incentivized to attend PE sessions showed greater improvement in PTSD symptoms. Correlational analyses are consistent with the interpretation that it was the improved attendance in the PE+I group, and not just the

presence of incentives, that led to better outcomes. Comparing the pattern of attendance across groups illustrates why this study shows a better response to PE as compared to previous studies. The incentivized group attended a median of six exposure sessions whereas the non-incentivized group attended a median of 0 exposure sessions, the latter number being similar to past findings with exposure-based treatment for comorbid substance use and PTSD (Mills et al., 2012). Since exposure is the putative active component of PE (Foa et al., 2007), it follows that participants who receive more of the active treatment component will demonstrate a greater PTSD response. The findings for PTSD are buttressed by similar differential improvement in general psychiatric distress and some emotional regulation skills, as previous studies in non-SUD populations have shown (van Minnen, Zoellner, Harned, & Mills, 2015). This pattern of findings should be interpreted with caution, however, as more participants in the analysis were in the incentivized group and were therefore driving the positive correlation. Nevertheless, these preliminary findings suggest that previous studies of exposure-based therapy for PTSD in SUD patients that failed to produce consistently positive outcomes may have elicited better responding if participants had attended more of the treatment.

Despite past concerns that men and women with substance use disorders would not tolerate the psychological stress of exposure-based treatments for PTSD (Pitman et al., 1991), the current findings support clinical observations that substance users can respond well to PE with no increase in drug use (Mills et al., 2012; Sannibale et al., 2013; van Minnen et al., 2015). To the contrary, overall drug use decreased in this study and the PE+I participants were retained in substance use disorder treatment longer, which supports feasibility and lack of harm and may even represent better SUD outcomes in those who receive PE treatment. The benefit of PE treatment on SUD outcomes could be direct or mediated through improvement in PTSD symptoms (Morgan-Lopez et al., 2014). Although serious adverse events were fairly frequent, they were unrelated to study participation and are likely more indicative of the serious medical and psychiatric consequences of chronic and severe substance use disorders (Petry et al., 2008). Importantly, SAEs were equivalent in number and type across groups, indicating no greater risk of harm from incentivizing patients for attendance or attending more PE sessions in particular.

Participants in this study had severe PTSD and extensive trauma histories, making this sample similar to a treatment-seeking PTSD sample that might be found in a community clinic. Many of these men and women had no previous treatment for their PTSD and none had received exposure-based therapy, despite years of suffering. Anecdotally, several participants said they had never been asked about their traumatic event history or described their index traumatic event in detail to anyone before the intake assessment for the study. Even one episode of describing a traumatic event can be an effective intervention to reduce PTSD symptoms in SUD populations, although there is some question about how strong or persistent the improvement is (Bragdon & Lombardo, 2012; Mills et al., 2014). In addition, every participant was enrolled in an evidence-based adaptive stepped-care methadone maintenance treatment program that systematically and predictably changes the intensity of SUD treatment based on objective indicators of response. This treatment may be at least partly responsible for the overall improvements in PTSD symptoms, drug use, psychiatric distress, emotional regulation, and quality of life seen in both treatment groups.

Enthusiasm for these promising initial findings are moderated somewhat by study limitations. Although attendance in the incentivized group was considerably higher than most previous trials of exposure therapy in SUD populations, the rate in the non-incentivized group was at the low end of the reported range. It is possible that randomization to the non-incentivized condition reduced participants' willingness to attend treatment. Alternative study designs using a yoked noncontingent control or incentives targeted to other behaviors could inform this question. The small sample size in this pilot study also limited statistical power to assess some outcomes; a larger study is planned to address this. We also note that PE+I participants were not universally responsive to the incentive intervention; seven participants attended three or fewer sessions. It is possible that larger incentive amounts or incentivizing other behaviors in addition to attendance may have improved outcomes further. Finally, the use of objective drug use outcomes was a strength, although unexpectedly lower retention in the PE group limited data collection for that group and may have obscured important effects on drug use. Linking objective drug tests to the research procedures or supplementing objective drug use outcomes with self-report data would help to ameliorate this limitation in future work. These limitations notwithstanding, the present study rigorously applied two evidence-based interventions—PE and contingent monetary incentives—to a highly symptomatic population with severe and chronic PTSD, extensive psychiatric comorbidity, and substantial life challenges, with significant benefit and no suggestion of harm.

There is considerable potential for the use of incentives across a wide range of problems that are often considered difficult to treat, although significant barriers remain. The traditional use of contingent monetary incentives to target changes in behaviorally-driven outcomes (e.g., drug abstinence) comes with the problem that when the incentives are removed, the problematic behavior often returns to pre-treatment levels. Targeting adherence to an intervention eliminates this problem because the length of time the incentive needs to be offered is naturally limited and outcomes improve not as a direct result of the incentives but as a result of increased participation in the intervention. Many medical interventions have been targeted in this way, from diabetic glucose monitoring (Petry et al., 2013) to adherence to complicated medication regimens (Petry, Rash, Byrne, Ashraf, White, 2012), but its application to psychotherapy has lagged. The largest barriers are concerns about cost and feasibility and providers' philosophical objections to using contingent incentives, particularly in the context of psychotherapy. As seen in the present study, the median cost of $410 per participant to attend an average of 4 to 8 more treatment sessions would be easily offset by increased insurance reimbursement and better response to treatment (e.g., Olmstead & Petry, 2009). This finding is consistent with another recent study in which financial incentives resulted in improved and highly cost-effective smoking cessation rates, suggesting that contingency management can pay for itself when used in a manner consistent with behavioral economic principles (Halpern et al., 2015). Federal guidelines support the use of contingent monetary incentives in healthcare; they are in fact increasingly used in settings like the U.S. Veterans Affairs Medical System (Petry, DePhilippis, Rash, Drapkin, & McKay, 2014). Changing providers' attitudes toward contingent monetary incentives is difficult, but studies from the SUD treatment field have shown that providing accurate information about and support for the intervention can be effective ways to get buy-

in from front-line providers (Petry et al., 2014; Rash, Dephilippis, McKay, Drapkin, & Petry, 2013). Indeed, data suggest that providers with direct experience using incentives with patients (e.g., contingent abstinence incentives) report more positive opinions of incentives compared to providers with no such experience (Kirby et al., 2012). Many evidence-based brief psychotherapies are limited in their effectiveness simply because patients do not receive an effective dose. The present study demonstrates one more tool at our disposal to help patients receive the maximal benefit of our interventions.

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PUBLIC HEALTH SIGNIFICANCE

Patients with comorbid opioid use disorder and PTSD are much more likely to attend Prolonged Exposure therapy sessions if they are incentivized to do so. Prolonged Exposure is associated with greater improvement in PTSD symptoms and substance use disorder treatment retention when patients attend more sessions.

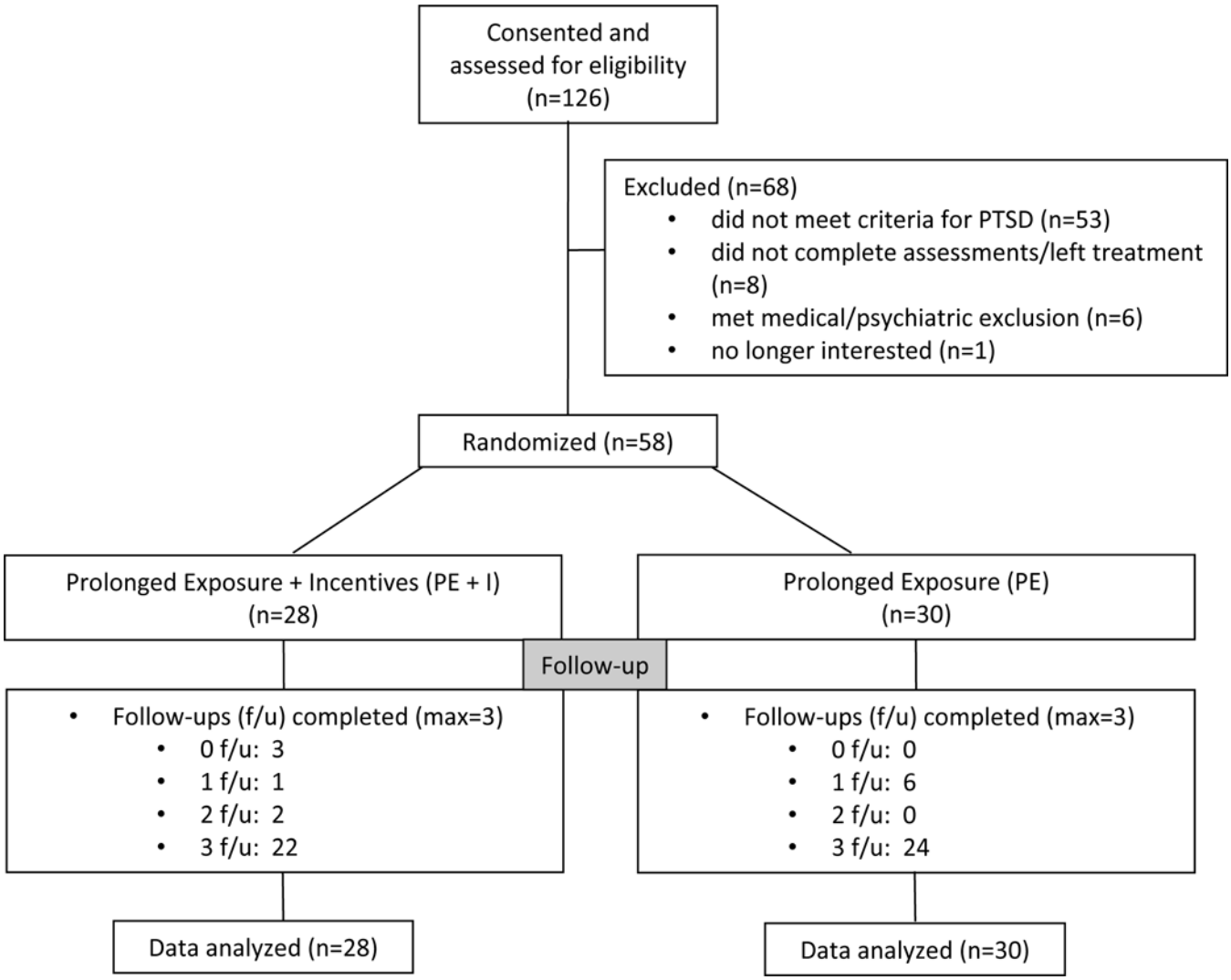

Figure 1.
CONSORT diagram.

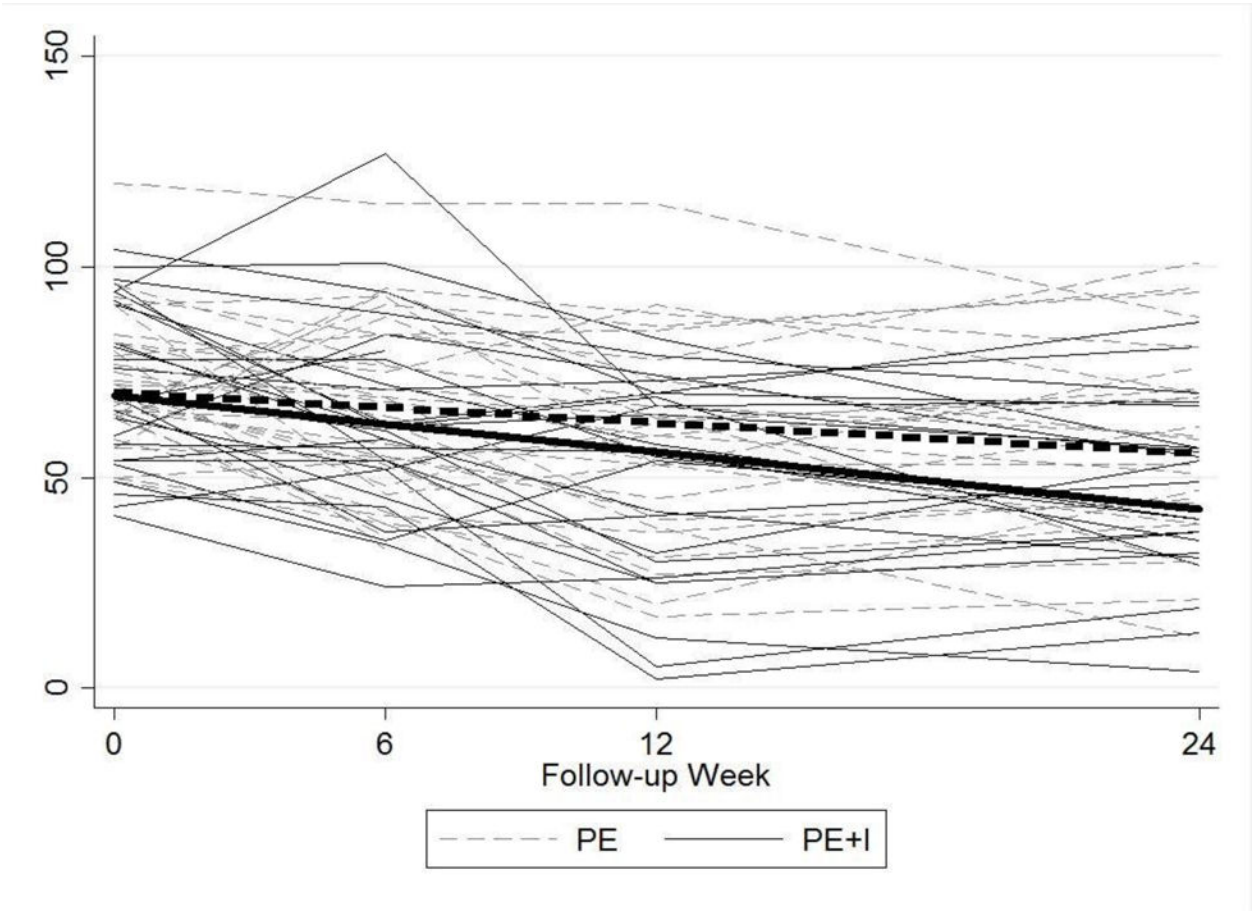

Figure 2.
PTSD symptoms by group over time.

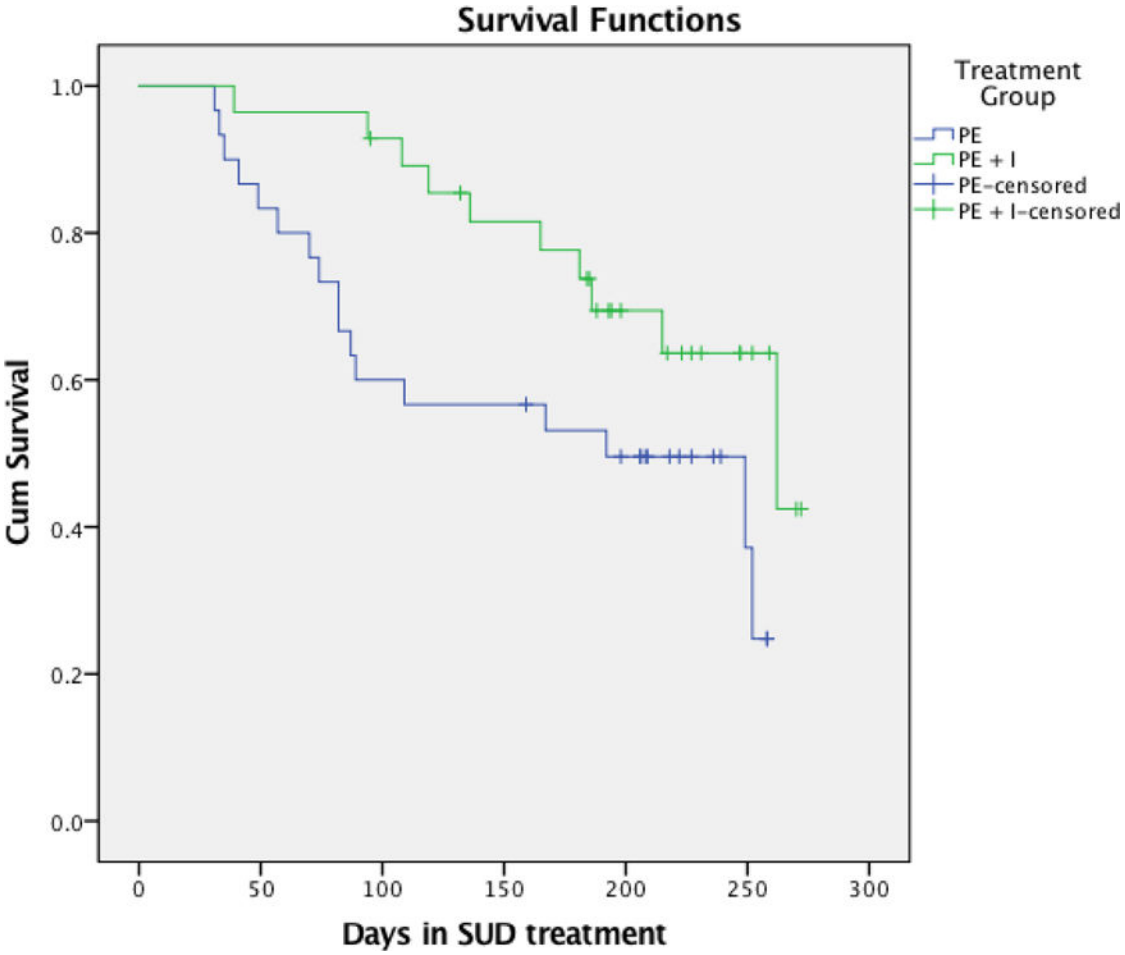

Figure 3.
Retention in substance use disorder treatment by group.

Table 1

Demographic and treatment adherence data.

Variable		PE (*n* = 30)	PE+I (*n* = 28)
Demographics		***M* (*SD*) or % (*n*)**	
Age in years		35.95 (10.16)	39.02 (12.45)
Gender	Women	77% (23)	82% (23)
	Men	23% (7)	18% (5)
Race/ethnicity	White	70% (21)	71% (20)
	African American	23% (7)	21% (6)
	Multiracial or other	7% (2)	7% (2)
Years of education		11.30 (2.51)	12.43 (1.95)
Monthly income		$724.87 (505.58)	$934.14 (594.74)
Substance use history			
Days in methadone maintenance treatment		488.77 (852.33)	1006.36 (2226.00)
Years of substance use	Any drug use	23.39 (10.54)	26.09 (12.83)
	Heroin	6.99 (7.34)	6.13 (5.14)
	Cocaine	4.39 (5.24)	4.15 (5.83)
Trauma history			
Mean number of traumatic events *		32 (15)	33 (16)
Most common traumatic events (% reporting)			
	Child sexual assault	27% (8)	43% (12)
	Partner violence	20% (6)	11% (3)
	Child physical assault	10% (3)	14% (4)
	Adult sexual assault	17% (5)	4% (1)
	Unexpected death of loved one	10% (3)	14% (4)
Current comorbid diagnoses (most common)			
	Major depressive disorder	47% (14)	50% (14)
	Antisocial personality disorder	40% (12)	29% (8)
	Borderline personality disorder	20% (6)	43% (12)
	Bipolar I disorder	17% (5)	14% (4)
	Obsessive-compulsive disorder	14% (4)	18% (5)
Course of Prolonged Exposure Therapy			
Mean sessions attended **		1.80 (2.57)	7.11 (4.10)
Median sessions attended **		1	9
Mean exposure sessions attended **		0.57 (1.74)	4.57 (3.38)
Median exposure sessions attended **		0	6
Treatment completer **†		3.3% (1)	36% (10)

Notes.

[*] Based on the Traumatic Life Events Questionnaire, which truncates the number of possible exposures per type of event at six, allowing up to 138 events across 23 types of events to be reported.

[**] indicates differences significant at $p < 0.005$ based on chi-squared or *t*-test analyses.

[†] Participants were considered to have completed treatment if they attended at least 12 sessions or at least 9 sessions with a 70% reduction in PTSD symptoms based on Modified PTSD Scale-Revised scores assessed at each PE session (Falsetti et al., 1993).

Table 2

Descriptive data by group for primary and secondary outcome variables across time.

Construct (measure)	Baseline		Week 6		Week 12		Week 24		Time	Condition × Time
	PE n=30	PE+I n=28	PE n=27	PE+I n=26	PE n=27	PE+I n=23	PE n=24	PE+I n=23		
PTSD severity (CAPS score)	72.77 (15.52)	72.29 (18.78)	65.93 (22.05)	63.42 (23.06)	58.33 (23.41)	48.09 (24.26)	58.54 (23.98)	46.13 (20.84)	−6.80 (−8.71 – −4.90)*	3.06 (0.41 – 5.72)*
Psychiatric distress (SCL−90−R)										
Global Severity Index	54.23 (8.50)	55.86 (11.93)	51.19 (9.51)	51.15 (12.50)	48.04 (9.35)	46.48 (13.05)	48.29 (10.05)	45.78 (10.92)	−2.50 (−3.42 – −1.58)*	1.09 (−0.19 – 2.38)
Positive Symptom Distress Index	52.20 (10.06)	53.29 (12.65)	50.70 (11.21)	48.73 (13.21)	47.96 (10.88)	44.91 (11.71)	49.17 (8.67)	44.52 (10.50)	−2.22 (−3.23 – −1.21)*	1.64 (0.23 – 3.05)*
Positive Symptom Total	55.07 (7.37)	56.61 (10.44)	51.85 (9.16)	53.04 (11.08)	49.33 (10.26)	49.17 (12.93)	49.42 (11.55)	48.22 (12.24)	−2.01 (−2.91 – −1.12)*	0.57 (−0.68 – 1.82)
Emotion regulation (DERS total score)	99.70 (21.50)	108.54 (28.02)	93.41 (26.57)	95.50 (30.35)	95.48 (26.55)	87.39 (27.49)	88.88 (24.51)	85.26 (28.28)	−5.59 (−8.02 – −3.76)*	3.19 (0.22 – 6.16)*
Quality of life (Q−LES−Q)										
Total score	47.86 (18.99)	46.88 (16.82)	53.17 (18.39)	48.21 (18.68)	51.06 (20.92)	55.82 (18.79)	56.40 (17.45)	53.42 (19.80)	1.88 (0.14 – 3.61)*	−0.28 (−2.7 – 2.14)
Overall satisfaction [+]	2.93 (1.08)	2.79 (1.07)	3.11 (1.16)	3.19 (1.10)	3.19 (1.04)	3.52 (0.90)	3.25 (0.94)	3.39 (0.94)	0.15 (0.03 – 0.26)*	−0.07 (−0.23 – 0.09)
Drug use (% mean positive drug screen)[≠]	45.54 (46.79) (*n* = 29)	49.36 (44.41) (*n* = 26)	43.59 (39.96) (*n* = 20)	41.18 (42.50) (*n* = 27)	48.44 (48.71) (*n* = 16)	35.73 (38.58) (*n* = 22)	32.99 (30.69) (*n* = 14)	26.42 (29.26) (*n* = 19)	−0.040 (−0.080 – −0.0003)*	0.013 (−0.046 – 0.073)

Notes. All columns indicate means and standard deviations with the exception of the last two, which contain odds ratios with 95% confidence intervals; ps <= .05 are marked with an asterisk. Change across time and the interaction of condition and time were analyzed with linear mixed-effect models with random intercept specified.

[+] This is a single-item score.

[≠] Drug use data were not collected from participants who left treatment at the methadone clinic. Therefore, results should be interpreted with caution because of attrition.