

The problem of dropout from "gold standard" PTSD therapies

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Abstract

Understanding of posttraumatic stress disorder (PTSD) has increased substantially in the past several decades. There is now more awareness of the many different types of trauma that can lead to PTSD, greater refinement of diagnostic criteria, and the development and testing of various treatments for it. As implementation of PTSD therapies has increased, there is also increased attention to the key issues of retention and dropout. Retention refers to the percentage of patients who stay in a treatment for its intended dose, and dropout is the opposite (the percentage who leave prior to the intended dose); both of which have major implications for treatment outcomes. The two PTSD therapies most studied in relation to retention and dropout are Prolonged Exposure and Cognitive Processing Therapy, which have been the subject of massive, formal, multi-year dissemination rollouts. Both of these evidence-based treatments are defined as gold-standard therapies for PTSD and showed positive outcomes and reasonable retention of patients in randomized controlled trials (RCTs). But an emerging picture based on real-world practice indicates substantial dropout. Such real-world studies are distinct from RCTs, which have consistently evidenced far lower dropout rates, but under much more restricted conditions (e.g. a more selective range of patients and clinicians). In this paper, the phenomena of retention and dropout are described based on real-world studies of Prolonged Exposure and Cognitive Processing Therapy, including rates, characteristics of patients, clinicians, and programs in relation to retention and dropout, and identification of clinical issues and future research on these topics. It is suggested that the term "gold-standard" evidence-based treatments should be reserved for treatments that evidence both positive results in RCTs but also feasibility and strong retention in real-world settings.

Introduction

PTSD has increased substantially in the past several decades. First explored as a disorder of military members during wartime, it is now understood as also arising from many other types of trauma, such as natural disasters, terrorist incidents, interpersonal violence, child abuse, car and industrial accidents, and life-threatening illness. Most people are exposed to one or more traumas in their lifetime [1], yet most trauma does not result in PTSD. When PTSD does develop, it is characterized by four clusters of symptoms per DSM-5 [2]: (a) intrusion (e.g. intrusive memories, nightmares, flashbacks); (b) avoidance (e.g. not wanting to talk about the trauma, avoidance

of reminders of the trauma); (c) negative alterations in cognitions and mood (e.g. distorted self-blame, estrangement from others, diminished interest in activities); and (d) alterations in arousal and reactivity (e.g. sleep problems, anger, exaggerated startle response). Additionally, the dissociative subtype of PTSD identifies symptoms such as feeling detached from one's mind or body, and experiences in which the world seems unreal, dreamlike, or distorted. Persistence of symptoms for over a month and marked decline in functioning are also required.

Treatments for PTSD have also expanded both in the different types of treatments now available and in the

level of rigor for studying them. Overall, current research indicates that PTSD treatments work better than treatment as usual; average improvement (effect sizes) are in the moderate to high range; and various treatments are identified as effective, with no one treatment having clear superiority [3].

PTSD treatments generally fall into two broad categories: past-focused and present-focused (or their combination) [4]. Past-focused PTSD models ask clients to explore their trauma in detail to promote "working through" or processing of painful memories, emotions, beliefs and/ or body sensations about the trauma. In contrast, present-focused PTSD models focus on psychoeducation and coping skills to improve current functioning in domains such as interpersonal, cognitive, and behavioral skills. Examples of past-focused models include Prolonged Exposure (PE) Therapy, Cognitive Processing Therapy (CPT), Eye Movement Desensitization and Reprocessing (EMDR), and Narrative Exposure Therapy. Examples of present-focused models include Cognitive Therapy for PTSD, Seeking Safety, and Stress Inoculation Training. Thus far, the preponderance of evidence indicates that both types (past- and present-focused) work, and neither consistently outperforms the other in terms of outcomes based on RCTs [3]. The majority of RCTs have focused on past-focused models, however, thus leading to the term "gold standard therapies" for models such as PE, CPT and EMDR (e.g. [5]).

Yet an important issue in relation to such PTSD "gold standard therapies" is their level of retention and dropout. Retention refers to the percentage of patients who stay in a treatment for its intended dose. Dropout is the opposite: the percentage who leave a treatment prior to its intended dose. An emerging literature on realworld practice indicates substantial dropout from the PTSD therapies that are currently most studied: PE and CPT. Such real-world studies are distinct from RCTs, which have consistently evidenced far lower dropout rates for these therapies. This paper explores the phenomena of retention and dropout in relation to PE and CPT. For clinicians, these topics are highly relevant to practice. For researchers, these topics are highly relevant to implementation science, which is the study of how treatments fare when they are used in treatment programs.

A poignant example is described by David Morris, a former Marine officer, in a New York Times article [6]. He writes about his experience with PE: "...after a month of therapy, I began to have problems. When I think back on that time, the word that comes to mind is 'nausea'. I felt sick inside, the blood hot in my veins. Never a good

sleeper, I became an insomniac of the highest order. I couldn't read, let alone write...One day, my cellphone failed to dial out and I stabbed it repeatedly with a stainless steel knife until I bent the blade 90 degrees. When I mentioned all this to my therapist, he seemed unsurprised...Following a heated discussion, in which I declared the therapy 'insane and dangerous' and my therapist ardently defended it, we decided to call it quits. Before I left, he admonished me: 'P.E. has worked for many, many people, so I would be careful about saying that it doesn't work just because it didn't work for you'. Within a few weeks, my body returned to normal. My agitation subsided to the lower, simmering level it had been at before I went to the V.A. I began once more to sleep, read and write...My own disappointment is that after waiting three months [to start therapy], after completing endless forms, I was offered an overhyped therapy built on the premise that the best way to escape the aftereffects of hell was to go through hell again". The patient later did group CPT without exposure and had more positive results.

PE and CPT

PE and CPT share a common focus on having the patient bring to light memories and emotions associated with trauma. A brief description of each model is offered here, as well as citations for further reading on them.

PE [7] begins with preparation of the patient over several sessions, after which the patient is to engage in "imaginal exposure" (the patient is asked to bring the trauma to mind, in detail, using all senses, as if it were in the present so as to evoke the intense memories and emotions related to the trauma and work them through). There is also *in vivo* exposure, in which the patient faces reminders of the trauma. Breathing retraining is also recommended. There is a strong focus on repeated exposure homework, including writing or audiotaping a trauma narrative to review between sessions.

CPT [8] was first developed for female rape victims [9], but has since been tested in other populations. The model draws heavily on McCann and Pearlman's 1990 trauma themes of safety, trust, power, esteem, and intimacy [10]. A major focus is on cognitive restructuring to address overly generalized beliefs ("the world is unsafe") and overly constricted beliefs ("it's all my fault"). The patient is also typically asked to write a trauma narrative as homework outside of therapy sessions although a modified version of the original CPT leaves this as an option.

Both PE and CPT were designed and tested as short-term treatments: 12 sessions for CPT and typically

8–15 sessions for PE [11]. The definition of "completers", those who obtain an adequate dose, of these evidence-based treatments (EBTs), is seven sessions or more [12]. Yet an emerging literature based on the recent large-scale implementation projects of the models indicates that most patients with PTSD do not stay in these treatments for their intended lengths. The issue of dropout from PE and CPT has been studied most in the Veterans Affairs (VA) system, which is the largest healthcare system in the US, and which formally "rolled out" both treatments in the largest implementation of the models thus far [11]. The Department of Defense (DoD) also rolled out both treatments.

In the largest study to date, Watts *et al.* [13] found that of 1924 VA patients newly enrolled in a PTSD clinic who attended at least one session of CPT or PE, the median number of sessions attended was five (with a range of two to nine sessions across sites studied). They remark, "Typically, in clinical trials, a full course of CPT was 12 sessions, and a full course of PE ranged from eight to 18 sessions. Although a full course may not be necessary for all patients, it is unlikely that fewer than five sessions of either psychotherapy would constitute an adequate dose". They also analyzed an "adequate dose", which they defined as eight sessions or more, and found that just 2% of their sample received an adequate dose of either CPT or PE.

Similarly, Mott et al. [12] in another recent VA study, analyzed data on 796 patients in a large VA PTSD and anxiety clinic who attended at least one individual psychotherapy appointment with 1 of 8 providers trained in CPT or PE. Only 11.4% (n = 91 patients) began either CPT or PE and only 7.9% (n = 59 patients) completed either CPT or PE. Moreover, CPT dropouts most commonly discontinued treatment after three CPT sessions, and PE patients most commonly discontinued after two PE sessions. They add that their results are convergent with other veteran studies that "consistently" indicate that, "...less than 10% of veterans with PTSD could have feasibly completed an EBP" [14,15]. Garcia et al. [16] studied 117 Iraq/Afghanistan veterans being treated in a VA PTSD clinic and found 68% dropped out prematurely. Cook et al. [17], studying 38 residential VA programs, found that among the subset of patients who began an EBT, their average attendance was 10 sessions, though they found that they also participated at the same time in an average of 7 non-EBT sessions. They noted that it is unclear how the combining of EBT and non-EBT treatments may have affected retention. DeViva [18] studied 200 consecutive admissions to PTSD specialty therapy in a VA, in which "The long-term goal for all referrals was the completion of evidence-based therapy for PTSD". He found that of 33 patients referred to trauma-focused CBT (a term used for PE and CPT) and who attended at least one session, only 21% were completers. In contrast, 50% of those referred to CBT for anxiety were completers, and 43% those referred to non-PTSD symptom-focused therapies completed. He attempted a chi-square comparing four different types of treatment and found no difference, but it was underpowered to evaluate the question and, moreover, confounded individual versus group modalities.

In the DoD, Hoge et al. [19] studied PTSD treatment (psychotherapy and/or pharmacotherapy) and found that of 229 soldiers who screened positive for PTSD and received treatment, "the median number of visits in six months was four; 22% had only one visit, 52% received minimally adequate care (four or more visits in six months), and 24% dropped out of care". Although these data are not focused exclusively on PE and CPT, these are the two PTSD psychotherapies that were rolled out in the DoD as its evidence-based PTSD therapies, and thus the study speaks to challenges with these models as well as to other issues related to PTSD treatment in DoD settings, such as attitudes toward treatment and practical obstacles. These studies are especially important in identifying dropout and retention in real-world conditions rather than RCTs. RCTs of CPT and PE have always evidenced more positive results, averaging around 28% dropout [13,20]. But real-world conditions consistently have much higher dropout rates than RCTs, both for PTSD and also other mental health disorders [21,22]. RCT samples are not representative of front-line programs in terms of either patients or clinicians. The PTSD EBT literature is documented to have consistently excluded highly complex, severe patients, notably those with substance dependence, as well as problems such as homelessness, suicidality, violence potential, bipolar and psychotic disorders, major cognitive impairment, current domestic violence, and other challenges [23]. In this paper, the term "real-world" is used for naturalistic, front-line studies from RCTs, in keeping with published writing on this issue [21,22]. In an early study on this topic, Zayfert et al. [21] found that a university-based PTSD clinic designed specifically to deliver PE showed that of 115 clinic patients, 42% began PE and only 28% completed it. However, in that study, completion was defined differently than in the current era in that both patient and clinician agreed that the patient no longer needed treatment for the PTSD, rather than current definitions, which are based on an a priori number of sessions (either 7 or 8, per Mott et al. and Watts et al., respectively) [12,13].

It can also be noted that several studies that purport to research drop-out from PE and CPT in "real-world"

conditions are not truly real-world conditions, and thus it will be important to more clearly define what that term means. For example, Eftekhari et al. reported on outcomes of 1931 patients treated as part of the VA roll-out of PE [24]. They found that 72% completed PE, but this roll-out was a hugely expensive one that replicated RCT conditions. Clinicians had to engage in a 6-month intensive process prior to implementation of PE. The process included attending a 4-day training course; required weekly consultation; and the submission of audiotapes of all their sessions with at least two patients, which were rated for fidelity. Moreover, it was a highly selective clinician sample, with 96% psychologists, social workers, or psychiatrists. Patients were excluded if they were in any acute current crisis that needed stabilization or if the clinician decided the patient "wasn't suitable" for PE (no definition was provided for that term) [24,25]. Such exceptional training, fidelity, and monitoring is simply not possible in the vast majority of general practice and in the absence of massive funding. Similarly, Tuerk et al. [26] studied combat-related PTSD dropout among veterans in PE, here too with the same parameters as just described. In sum, it is not a surprise that when studies fully replicate RCT conditions, they find completion rates comparable to RCTs. The problem is that such studies are not generalizable to what is widely understood to be the real world of clinical practice.

Finally, even PTSD RCTs have notable dropout. Per Hoge et al. [19], "Recovery from PTSD in both psychotherapy and pharmacotherapy randomized clinical trials can reach 70–80% among individuals who complete treatment (which usually involves at least eight visits, even for pharmacotherapy trials). However, dropout plagues virtually every treatment trial, leading to average recovery rates in intent-to-treat analyses of only around 40%."

Factors associated with dropout

A natural question is *why* dropout appears to be occurring at such high rates from PE and CPT. Below several major factors are explored—patient characteristics, clinician factors, and factors related to the treatments themselves.

Patient factors associated with dropout from PTSD EBTs

Numerous patient characteristics have been explored in relation to dropout from PE and CPT. The presence of substance use disorder (SUD) appears to be associated with dropout in several RCTs [27,28,29]. Other factors are wide-ranging and it is challenging to discern overall patterns as different studies evaluated different variables. For example, Harpaz-Rotem *et al.* [30] found lower numbers of PTSD-related visits were associated with male gender, Hispanic ethnicity, receiving service-connected

disability benefits, serving during the era of the Korean War, or living in rural areas. Mott et al., also in VA, found Iraq and Afghanistan veteran status, and a history of psychiatric inpatient hospitalization, were associated with decreased likelihood of PTSD EBT completion [12]. In DoD, Hoge et al., [19], found "Reported reasons for dropout included soldiers feeling they could handle problems on their own, work interference, insufficient time with the mental health professional, stigma, treatment ineffectiveness, confidentiality concerns, or discomfort with how the professional interacted". Lester et al., [31], in a study of data from CPT outside of VA, found that African Americans were significantly less likely to complete CPT compared with Caucasians (45% versus. 73%, respectively, P=.001) and that the differences held even after controlling for education and income. Zayfert et al., [21] also outside of VA, found that "Dropouts reported more PTSD avoidance, greater arousal, higher overall PTSD severity, more severe depression, and more impaired social functioning at intake" and "...they were more likely to have met criteria for BPD [borderline personality disorder]". Indeed, patients with BPD had double the dropout rate compared to non-BPD patients. Jaeger et al., [32] found in their analogue study that "high symptom severity or the presence of comorbidity may be somewhat associated with less receptivity to exposure therapy".

In short, greater patient severity may be an underlying pattern that predicts dropout from PE and CPT. This is consistent with the observation that RCTs on these models have historically consistently excluded patients with major complications, such as the following [13,23,33]: homelessness; substance use disorder (especially dependence and drug use disorders); domestic violence; suicidal or homicidal ideation; serious and persistent mental illness; significant medical illnesses such as HIV; mandated treatment; pregnancy; cognitive impairment; current incarceration. Thus, the PTSD literature needs to be understood in light of such major limitations. Greater dropout is expected when a broader range of patients are seen in real-world settings.

Additional client factors

Several studies have directly queried patients in relation to dropout from PTSD EBTs. For example, Zayfert and Black's study [34] of 65 patients who dropped out of PE in a medical school-based outpatient clinic found reasons for dropout as follows: "6% said they improved after assessment and did not need treatment, 11% became actively suicidal or engaged in dissociative behavior, 12% were in another active treatment, 27% reported logistical and life problems, 17% refused to engage in imaginal exposure, and 26% gave no reason" [22]. Thus, it is important to

recognize that dropout sometimes indicates that a patient perceives that s/he has improved and no longer needs treatment, yet in other cases may indicate lack of response to the therapy, iatrogenesis, or other clinical worsening. Logistics such as travel, child care, finances, and work schedules can also play a role, which may have no relationship to the treatments themselves. It has been noted in numerous reviews and studies that dropout from PE typically occurs prior to the imaginal exposure [22,21], though this could mean that patients are afraid of engaging in it, or that they are dropping out unrelated to the nature of the treatment. Shottenbauer et al. [22] provide an extensive review of dropout from PTSD EBTs, covering 55 studies. They explore detailed coverage of nonresponse to treatment, exacerbation of symptoms, and other clinical factors, as well as providing a full table of studies with dropout rates identified for each.

Clinician factors

Clinician factors have also been found to play a major role in the use of PTSD EBTs. Clinicians have long expressed concerns that patients will drop out of the PTSD EBTs [35,21,36]. In Zayfert et al.'s study of PE [21], 59% endorsed this belief and it was prominent "even among psychologists with a special interest in PTSD, background in behavior therapy, and a likely affinity for empirically supported, structured psychotherapy". In VA, concern about patient dropout was also mentioned by clinicians as a reason for not implementing PTSD EBTs [17,37]. Per Cook et al., "Staff from some programs expressed a belief that not all veterans should engage in formal trauma processing due to the potential risk of symptom exacerbation, dropout, and presence of other more pressing treatment needs. These programs delivered coping or skill-based treatments only" [38]. In DoD, Borah et al. [39] state, "There also appears to be low provider confidence and even resistance to specific evidence-based treatment approaches for PTSD, and provider perception of patient concerns about potential treatment complications". Borah et al. [39] also note that lack of training was stated as the most common barrier to the use of both CPT and PE.

Further, although numerous scientific reviews and practice guidelines view CPT and PE as equal in their efficacy, clinicians in the DoD report CPT, compared to PE, to have significantly greater likeability, strength of research evidence, and sense that the treatment will not harm patients [39]. Najavits *et al.* [40] also found some PTSD EBTs were clearly preferred by some clinicians over other EBTs

It has also been found that for both CPT and PE, clinicians make major modifications to the treatments to

help make them fit their practice [38]. For example, "CPT was viewed by some as difficult to deliver due to the number of structured sessions, modules, and amount of homework assigned. Instead, specific modules, worksheets, or elements were utilized. This type of 'off-label' integration of treatment elements was noted as appealing to providers" [38]. Cook et al. [17] had also found that providers informally combined PTSD EBTs with non-EBTs. In the DoD, a survey of DoD clinicians 6–18 months after they attended training in CPT or PE explored their use of the models [41]. Supportive therapy (not a PTSD EBT) was identified as the most commonly used by these clinicians, although providers rated their PTSD EBT training positively.

Earlier analogue studies of potential patient treatment preferences have found that potential patients are positive about engaging in PE [42,32,43], and thus the study authors suggest that clinicians may be more of a factor in the adoption or lack of adoption of the model. Yet surveys of clinicians on treatment preferences do show positive endorsement of PE and CPT [40]. It may be that analogue and survey methodologies are not as useful as studying true adoption patterns.

Factors related to the PTSD EBTs themselves

Having explored above various patient and clinician factors related to dropout from PTSD EBTs, it can also be noted that there may be aspects of the treatments themselves that are associated with dropout. A recent meta-analysis covering 42 studies found that traumafocused PTSD treatments resulted in higher dropout compared with present-centered PTSD therapy (PCT) [44,45]. They also found that trauma focused treatments did not differ between themselves with regard to dropout rate. There is no empirical literature at this point, however, to "unpack" what about the two treatment types (trauma-focused *versus* PCT) could explain this difference. A study by Najavits [46] found that clinicians treating PTSD/SUD patients also preferred present-focused over past-focused treatments.

Limited adoption of CPT and PE

The issue of patient dropout/retention is all the more important given that the adoption of CPT and PE has been far less than is considered optimal despite both models having existed for decades and the major, formal training and roll-out [11] efforts used to disseminated them [39,41]. For example, Watts *et al.* [13] have identified that among newly diagnosed PTSD patients in VA, only 6% received one or more CPT or PE sessions within six months after entry into a PTSD clinic. Mott *et al.* [12] found that 11.4% received CPT or PE, and note that their slightly higher rate (albeit still very low) is due

to their focus only on clinicians trained in these approaches. Cook et al. [38] found that between 2008 and 2011, in the residential programs they studied, 64% had received training in CPT, 37% had received training in PE, but only 9.5% had completed case consultation in each. Few programs had developed a treatment track for either treatment (13% CPT, 5% PE), or had made the PTSD EBT the core of their program and offered it to every patient (26% CPT, 0% PE). Cook et al. [17] restudied those same programs from 2010 to 2012 and found definite increases on various facets, but still a minority who achieved certification (43% CPT, 36% PE), and most programs reporting no change in their use of either model. A few programs had "de-adopted" them. They also found that "There were numerous adaptations made to the treatments", and "most programs made changes to content, number of sessions, and style of presentation". The most common implementation was to select only some patients for the treatments, averaging just 25% of the patients in the program. Over a decade ago, Smucker, Grunert, and Weis raised "concerns that there has been a tendency in the field to attribute treatment failures largely to inadequate implementation of [PE] as opposed to a focus on systematically identifying factors that may lead to poor outcome" (quoted in Zayfert et al. [21]. Now, with over a decade of exemplary and highly expensive training and roll-out efforts on the largest scale ever conducted, the data indicate that adoption and drop-out remain significant issues.

As DeViva observes about VA PTSD evidence based therapies [18], "...results may indicate that a more useful strategy than broad-based application of trauma focused therapy might be to allow veterans to select the treatments that they believe suit them best".

Future directions

We are at a pivotal historical moment with regard to PTSD therapies. There has now been substantial investment in development of therapies, testing of them in rigorous RCTs, and dissemination of them in large-scale treatment systems. Such efforts indicate that the actual performance of the "gold standard" therapies PE and CPT consistently perform less well in real-world implementation with regard to retention and dropout than in the RCT literature.

As Hoge et al. recently stated in relation to the problem of PTSD patients dropping out of therapy [19]: "Dropping out of care is clearly the most important predictor of treatment failure; therefore the most promising strategies to improve efficacy of evidence-based treatments will be those that address engagement, therapeutic rapport, and retention."

Recently too, there has been debate about how therapies such as PE and CPT were selected for adoption [47-51] and the lack of adequate focus on real-world performance of them. A major lesson learned in this area is that therapies may perform well in the "hothouse" of RCTs: optimal selection and training of clinicians, ongoing high-quality supervision, and selection of less complex patients who do not possess challenging features (such as homelessness, substance dependence, domestic violence, etc.). But in real-world conditions with a broader array of clinicians, patients, and programs, they may have substantial difficulty gaining traction. Indeed, the literature covered in this review indicates that patients appear to "vote with their feet" by dropping out of such treatments at substantial rates, and clinicians appear to be developing ad hoc adaptations of the models to try to make them more suitable for real-world practice. The next generation of clinical research can gain from these phenomena by further exploring such issues prior to wide-scale deployment of therapies. The highest standard for gold-standard therapies would thus be strong performance in RCTs plus evidence of ability to retain patients, and their clinicians, under real-world conditions. In this framework, performance in RCTs alone would be bronze, performance in real-world conditions would be silver, and the gold—the true EBT champions—would have to evidence success at both.

Abbreviations

BPD, borderline personality disorder; CPT, cognitive processing therapy; DoD, Department of Defense; EBT, evidence-based treatment; EMDR, eye movement desensitization and reprocessing; PCT, present-centered therapy; PE, prolonged exposure; PTSD, posttraumatic stress disorder; RCT, randomized controlled trial; SUD, substance use disorder; VA, Veterans Affairs.

Disclosures

The author declares that she is the developer and author of the Seeking Safety model, which is mentioned in this article.

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