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# Treating Patients Who Strain the Research Psychotherapy Paradigm

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### Abstract

**Background**—Clinical trials of psychotherapy require diagnostic homogeneity, which implies a convergence of clinical presentations. Yet research study patients present diversely, and patients who do not fit a treatment paradigm may greatly complicate delivery of the study psychotherapy. The research literature has not addressed this issue.

**Methods**—The authors use case illustrations of three psychotherapies – Prolonged Exposure, Relaxation Therapy, and Interpersonal Psychotherapy – from an ongoing psychotherapy outcome trial of posttraumatic stress disorder to describe psychotherapeutic responses to complex, "atypical" patients who strain standard treatment paradigms.

**Results**—Therapists required flexibility, and occasionally deviations from strict protocol, in treating heterodox patients.

**Conclusions**—Such heterogeneity of presentation may have implications for psychotherapy outcome in research trials. Despite lack of discussion in the literature, many trials may face such issues.

#### Keywords

Psychotherapy; treatment paradigm; postraumatic stress disorder (PTSD); deviation

What happens when a clinician conducting a targeted psychotherapy meets a patient who doesn't match the target? In general practice, the therapist might switch therapeutic approach, add "eclectic" elements to the treatment, or refer the patient to another treatment. A psychotherapist in a research protocol, however, lacks such luxuries and must proceed: it's the inevitable consequence of randomized controlled trials (RCTs). Employing clinical vignettes from an RCT of psychotherapies for posttraumatic stress disorder (PTSD), this

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article explores the phenomenon, apparently undocumented in the literature, of how psychotherapists in outcome trials cope with patients whose clinical presentations do not neatly fit their treatment paradigm.

Psychotherapists in research trials face technical pressures such as time limits and fidelity to a treatment manual. They are constrained by the psychotherapy they are using, which may work effectively with a modal, model patient but challenge the therapist when the study patient's presentation does not match the therapy paradigm. The patient appears to meet study inclusion criteria but offers a principal complaint extraneous to the target disorder, misaligning the clinical picture with the treatment approach. Or in some other key area the presentation diverges from the expected treatment model.

Such constraints have provoked debate over the ecological validity of psychotherapies conducted in RCTs (Borkovec and Castonguay, 1998; Chambless and Hollon, 1998; Goldfried and Wolfe, 1998). To maintain internal validity, RCTs must treat a patient sample sufficiently homogeneous to permit conclusions independent of confounding variables, but not so "pure" that cases no longer resemble the disorder as manifested in the community (Wachtel, 2010; Weston and Morrison, 2001; Westen et al., 2004). Treatment must adhere to a defined, manualized protocol. While a literature exists on technical adherence to psychotherapies (e.g., Hill et al., 1992; Markowitz et al., 2000), the experience of psychotherapists attempting to negotiate complex treatment issues in an RCT has received no attention. Studies rarely report psychotherapy protocol deviations. Consultation with a psychiatric research librarian and PubMed searches employing terms (and their combinations) including "comorbid," "comorbidity," "protocol therapy," "treatment outcome," "psychotherapy, "disadvantage/difficulty...therapy," "complex patients," "patient issues," etc., yielded no pertinent results.

We are not simply describing patients whose diagnosis (in our current study, PTSD) is compounded by comorbidity such as major depressive disorder (MDD) or personality disorder, although PTSD comorbidity is common (Kessler et al., 2005) and comorbidity can complicate clinical outcome (e.g., Frank et al., 2000). Nor are we addressing the "difficult" patient who drives the therapist out of treatment adherence through help-rejecting behaviors, complicating the treatment alliance (Foley et al., 1987). Nor the patient lacking insight who requires extensive psychoeducation to grasp the treatment model. We focus on clinically challenging patients meeting study entry criteria whose atypical presentation – a divergent chief complaint, extraneous symptoms, transferential issues – conflict with the therapeutic model, techniques, or treatment goal. This occurs with some frequency in a heterogeneous disorder like PTSD and has implications for research outcome.

#### METHODS

This RCT compares three disparate manualized psychotherapies delivered over 14 weeks for patients with chronic PTSD: Prolonged Exposure (PE; Foa and Rothbaum, 1998), Relaxation Therapy (RT; Jacobsen, 1938), and Interpersonal Psychotherapy (IPT; Weissman et al., 2007; Bleiberg and Markowitz, 2005). PE reconstructs a detailed trauma narrative and provides *in vivo* and imaginal exposure to trauma reminders. In RT, a highly scripted treatment inducing progressive muscle and mental relaxation, the therapist does much of the talking. IPT for PTSD focuses not on the trauma but on its interpersonal aftermath.

Study inclusion criteria include age 18–65 years; primary diagnosis of DSM-IV PTSD determined by Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995); minimum CAPS score of 50, indicating at least moderately severe PTSD (Weathers et al., 2001); informed consent; and English fluency. Exclusion criteria include lifetime diagnosis of

psychosis or bipolar disorder; primary diagnosis of MDD; melancholia; for patients reporting both PTSD and MDD, absence of prominent criterion B (reexperiencing) and criterion C (numbing/avoidance) symptoms; psychiatric disorder due to general medical condition; current substance dependence; acute suicide or homicide risk; unstable medical condition; primary diagnosis of borderline or antisocial personality disorder. The study excludes psychotropic medication and eschews jeopardizing even partial response to extant treatment by requiring its taper.

Patients recruited by clinical referral and media advertisement are serially evaluated by reliable M.D. and Ph.D. independent evaluators in semi-structured interviews that may be spread over several weeks. Evaluators have shown high interrater reliability. Study therapists, psychologists or psychiatrists who first treated pilot cases to ensure clinical expertise, are audiotaped, monitored for treatment adherence, and supervised by experts in the respective treatments to ensure adherence and competence. We asked these experienced study therapists for (disguised) cases that stretched their treatment paradigms.

#### CASE EXAMPLES

**Mr. A**, a 41-year-old single Latino unemployed money manager, lived alone in New York City. Born, raised, and educated in Canada, he worked there until an investment firm located in the World Trade Center recruited him.

On the morning of September 11, 2001, Mr. A was working on the 80th floor in the World Trade Center south tower. Following the terrorist attacks he evacuated, escaping just before the tower collapsed. He recalled feeling scared and confused, believing in the stairwell as the building vibrated that he was going to die. He stopped to help an older, injured man reach safety before walking home, covered in ashes. He crossed the West Village, noticing how beautiful the day was, with birds chirping and people lounging in sidewalk cafes, as if there were no care in the world, while he looked like the "living dead," ash-covered, terror in his eyes. He sat on some stairs and sobbed uncontrollably. He walked to St. Vincent's Hospital to volunteer but was told to return another day. Feeling helpless, he walked uptown to his empty apartment.

Mr. A incurred no physical injuries and required no medical attention. Although he lost no close friends or family, numerous acquaintances died on 9/11 whom he thought about often. Following 9/11, he attended a mandatory debriefing at work and a few psychotherapy sessions offered by the Red Cross. He recalled feeling sad and anxious with intrusive thoughts, increased arousal, avoidance, and numbing. In the following months, he focused on leadership in rebuilding his company, achieving great success.

In 2008 another company recruited Mr. A, offering him a significant promotion and opportunity. After working there for a year, Mr. A began to experience recurrent, unexpected panic attacks with intense fear and discomfort, dyspnea, chest pains, trembling, palpitations, dizziness, derealization, and feeling as if he were going crazy. These panic attacks reportedly popped up "out of the blue." They triggered lengthy fears about having additional panic attacks and worries about the consequences or implications of panic attacks. He thought one such attack, in his office near Ground Zero, was a heart attack and was taken to the emergency room. Following this episode, he felt unable to return to work and began avoiding places that reminded him of where panic attacks occurred: tall buildings, Ground Zero, restaurants in that area, and subways. Around then he turned 40 years old and felt "pressured by life in general," including pressure to marry from his girlfriend of three years and from his parents. He missed his previous coworkers and disliked his current job. As his symptoms worsened, he thought more about 9/11 and attributed his panic attacks to

exposure to the terrorist attacks. He re-experienced intrusive thoughts about 9/11 and had intense psychological distress and physiological reactivity when reminded of 9/11. He increased efforts to avoid reminders of 9/11 and lost interest in many activities he had previously enjoyed. He felt numb and isolated, depressed and hopeless. He had difficulty sleeping, concentrating, and staying attentive. He attended several sessions with a psychologist and was prescribed clonazepam and SSRI by a psychiatrist. He quickly stopped the medications due to side effects.

Evaluated in 2010 for the study, Mr. A received a primary diagnosis of PTSD (chronic), as well as MDD (moderate, recurrent) and Panic Disorder (PD) with Agoraphobia. His baseline CAPS score was 66, indicating severe PTSD (Weathers et al., 2001); his 24-item Hamilton Depression Rating Scale (Ham-D; Hamilton, 1960) score was 23. He denied a history of suicide attempts, active suicidal intent, but admitted passive death wishes. Meeting study eligibility criteria, Mr. A signed informed consent and was randomized to receive Prolonged Exposure therapy for PTSD.

The clinical challenge was to maintain integrity and adherence to the manualized treatment while addressing Mr. A's comorbid disorders. As PTSD, MDD, and PD share symptoms, one approach was to focus only on PTSD symptoms, presuming that relief of PTSD symptoms would generalize to other, shared symptoms. It was difficult, however, to focus only on PTSD symptoms, as Mr. A's panic attacks increased in frequency and severity soon after treatment began and became increasingly debilitating. This case describes the extent to which a manualized PTSD treatment may both permit and limit treating non-PTSD symptoms.

Mr. A arrived promptly to his first PE session, appearing moderately depressed and anxious. The therapist introduced an outline of the PE program and rationale for treatment. Mr. A acknowledged understanding the rationale. Following protocol, the therapist informed him that PE is a time-limited therapy that focuses on symptoms of PTSD, adding that treating these symptoms with PE might also improve depressive and other anxiety symptoms. Mr. A was cooperative and attentive during the standardized trauma interview. The session concluded with breathing retraining, a relaxation technique that helps patients slow their breathing and feel more relaxed.

The second session entailed discussion of common reactions to trauma, then focused on *in vivo* exposure. Presenting the rationale for *in vivo* exposure in PTSD treatment, the therapist informed Mr. A that it was also a principal technique for treating PD. The cognitive behavioral approach of *in vivo* exposure clearly overlaps in the treatment of PTSD and PD. In creating an *in vivo* hierarchy list, the therapist was able to address avoided situations stemming from PTSD and PD without violating adherence to the treatment protocol.

The challenge of strictly adhering to the treatment manual increased during subsequent sessions with imaginal and *in vivo* exposure homework, even for situations that scored low on the hierarchy of avoided situations. Mr. A's PD was more severe than had been apparent at initial evaluation. As he continued to experience panic attacks "out of the blue," PD became his primary concern and he no longer wanted to focus on his PTSD symptoms related to 9/11. He refused further imaginal exposure and dropped out after seven PE sessions.

In session six, Mr. A reported having experienced a severe panic attack during the week and refused to engage in imaginal exposure. He discussed dropping out of therapy. To help reduce his distress and to encourage his continuing treatment, the therapist focused on the treatment rationale and conducted psychoeducation regarding panic attacks and their relation to trauma exposure. Although session six deviated from the PE manual, a better

understanding of his panic symptoms through the discussions may have contributed to encouraging Mr. A to return for another session and try imaginal exposure again. During the week following the seventh session, however, he reported a series of severe panic attacks and ended treatment. Although his level of distress had decreased slightly during imaginal exposure, his panic attacks had increased. He was unable to complete *in vivo* exposure homework for fear of anxiety and panic. Although reviewing the rationale for PE techniques can motivate many patients with PTSD to engage in treatment, the severity of anxiety sensitivity and fear of panic attacks were too overwhelming for Mr. A.

Including interoceptive exposure, an effective technique integral to cognitive behavioral treatment of PD, might have better addressed Mr. A's anxiety sensitivity and panic symptoms than *in vivo* exposure alone. He might have found it more tolerable to provoke panic symptoms through physical exercises in the relative safety of the therapist's office than to experience panic symptoms *in vivo*. Following interoceptive exposures, Mr. A might have been more likely to employ *in vivo* exposure on his own and have better tolerated increased anxiety response and anticipatory fear of another panic attack. The increased arousal he experienced during imaginal exposure to his trauma experience may have been qualitatively different from his panic symptoms and insufficient to target his panic-related fears. However, as including interoceptive exposure would have violated treatment fidelity, the therapist did not conduct this technique. Although psychoeducation, cognitive restructuring, and *in vivo* exposure addressed PD within the boundaries of PE therapy, they did not suffice to ease the panic attacks and maintain Mr. A's ability to focus on and to tolerate the challenges of PE therapy for PTSD.

**Ms. B** had endured 16 years of chronic nightmares, insomnia, flashbacks, and other PTSD symptoms. She presented at age 33, working as a receptionist and living with her two children and her husband; but they were no longer intimate, and talked of divorce. Ten years before she had left her Korean homeland, where she had lived for most of her life with her mother, sister, and aunt. Seventeen years earlier she had visited her father, whom she had rarely seen previously and would never see afterwards. During that visit, her father sexually assaulted Ms. B. She developed severe, chronic PTSD, which remained untreated until her current presentation. Her initial CAPS score was 75, indicating severe PTSD.

Though physically strong, outspoken, intelligent, and fluently polylingual, Ms. B had vulnerabilities from her traumatic past that complicated her Relaxation treatment from the outset. Having requested a male therapist, she seemed to misinterpret the body-focused relaxation narrative he read her as crossing personal boundaries. Nonetheless, she quietly endured this discomfort without letting on or expressing her needs. Her compliance and passivity before male authority imposed a delicate task upon her therapist: to ensure that treatment would not feel like a repetition of her trauma.

Ms. B's symptoms of hypervigilance and re-experiencing were the primary concerns. The therapist, trained in helping trauma survivors to better advocate for themselves, felt restricted by the research protocol in how much he could use talk therapy to address her feelings. The highly structured, lengthy RT script bound what he said, when he said it, and how treatment unfolded. What if the script triggered traumatic memories, for example when asking Ms. B to tighten and relax her stomach area, her thighs? RT initially seemed a bad idea for this patient.

In the first session, the therapist intuited that Ms. B felt, but could not overtly express, anxieties about the protocol. He therefore reframed the first session as an "exploratory" session to determine whether RT would be helpful for her or not, encouraging her to consider whether she would feel comfortable proceeding, and expressing his own doubts. He

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read a shortened version of the first Relaxation script, editing certain words (e.g., substituting "lungs" for "chest"), and skipping others (e.g., "thighs'). That is, he accommodated the first stage of treatment to allow Ms. B to test the boundaries of treatment compliance, tempering the protocol's structure to provide space for her to contemplate whether treatment was tolerable and, importantly, to instill a sense of choice in her. The therapist felt unable to relax without knowing that Ms. B could refuse treatment if she desired.

Ms. B engaged in this process, describing in the second session some of her fears about the RT protocol. She expressed specific discomfort with the body-focused nature of RT, yet feared that stopping therapy would waste an opportunity. After this session, the therapist considered discontinuing treatment and referring her out of the protocol. Having consulted the RT supervisor, he tried once more to encourage treatment, with the understanding that he would edit the script as necessary, allow slightly more time for talking, and stop the protocol if he sensed harmful outcomes. Contacting Ms. B by phone to invite her to continue, the therapist learned she had already decided to proceed. The third session felt more relaxed in both alliance and treatment procedure. Within two further sessions, Ms. B was fully engaged and showing signs of remission, including improved sleep, fewer nightmares, and positive shifts in interpersonal behaviors. Ms. B's final CAPS score was 0. The efficacy of RT stems from its relaxation procedures; however, it likely also required appropriately graded exposure of this incest survivor to the stimulus of a male therapist reading a body-focused relaxation script, in the context of safety, control, and freedom of choice.

**Mr. C**, a 28 year old divorced unemployed white man who met study entry criteria for PTSD, had a history of childhood physical abuse. He reported having felt physically and sexually harassed by minority co-workers at a job in another city and threatened by a coworker's family when he said he would complain about the harassment. Leaving that job, he continued to feel threatened, eventually moving to New York to escape pursuit by minority individuals. He lost subsequent jobs due to perceived racial and sexual harassment in brief stints in other work settings. Mr. C's presenting CAPS score was 63, indicating severe symptomatology (Weathers et al., 2001).

Like many patients with chronic PTSD, Mr. C presented with a paranoid stance, mistrusting his environment and the people in it. He met SCID-II criteria (First et al., 1997) for paranoid personality disorder. This is commonplace: traumatized patients anticipate further trauma and have difficulty trusting others. In the setting of chronic trauma, even expert evaluators may have trouble distinguishing PTSD "state" from personality "trait." Such paranoid pathology generally dissipates as affective detachment and other PTSD symptoms fade. Here, however, they did not. As Mr. C became more attuned to his emotions and trusted his IPT therapist more, he reported referential, paranoid ideas about minorities and delusional concerns about minority networks conspiring against his career. He denied other frank psychotic symptoms, but his delusional paranoid outlook exceeded study exclusion criteria in retrospect.

What to do? Deciding to make the best of the situation, the therapist incorporated the referential/paranoid thinking into the IPT definition of PTSD as a treatable medical illness. The patient readily accepted this and began to report in sessions, "My PTSD was acting up again" in describing the racist conspiracy theories he obsessed over in the workplace. The IPT framework of categorizing symptoms as treatable illness that was not the patient's fault seemed to help Mr. C deem his delusions ego-dystonic. At termination, Mr. C had improved considerably (CAPS = 37, a 41% reduction), meeting study response criteria. His referential thinking persisted but interfered far less. He had found and was holding a job despite having

minority co-workers. Post-study disposition included discussing the option of low dose antipsychotic medication, which Mr. C agreed to consider.

#### DISCUSSION

How psychotherapists handle "atypical" cases in the context of a psychotherapy clinical trial has received too little attention. These case examples illustrate themes of working in such complex clinical situations, illustrating the tension therapists may experience between maintaining the protocol's internal validity while responding to an individual patient's clinical needs. Mr. A's case was complicated by comorbidity the patient grew to consider primary; Ms. B evoked transference/countertransference issues in a therapy that does not discuss them; and treating Mr. C unmasked psychotic symptoms the psychotherapy is not designed to address.

Although most of our study cases have not strained the treatment paradigms, PTSD is highly heterogeneous and comorbid. The therapist must recognize the clinical presentation and decide how best to respond, building an alliance and improvising without grossly violating protocol. The case of Mr. A demonstrates the intricacies of addressing serious, distracting comorbidity with a constrained armamentarium. Distinguishing between expectable paranoid ideation and quiet psychotic symptoms can sometimes be difficult (Mr. C). We speculate that therapist experience helps: a veteran therapist will less likely be thrown by an atypical presentation, more likely maintain therapeutic composure (Greenacre, 1957), perhaps have less anxiety in stretching study protocol, and hence will more likely optimally employ a therapeutic approach under such difficult circumstances (Chambless and Hollon, 1998).

These cases required therapists to respond flexibly, bending if not frankly deviating from study protocol. Such flexibility may benefit the therapeutic alliance and ultimately contribute to positive outcome (Castonguay et al., 1996). The case of Ms. B, whose therapist creatively oriented the protocol to promote their alliance, illustrates this. All three highly competent therapists maintained treatment allegiance and were not considered inadherent by supervisors or independent adherence raters. The case of Mr. A suggests that psychotherapy narrowly focused on specific symptoms may have disadvantages with "atypical" patients. When their manual limits specific techniques that might address particular symptoms, therapists may have to rely more on non-specific "common factors" of psychotherapy to help their patients (Markowitz and Milrod, 2011). As a less focused, less structured psychotherapy, IPT may have flexible advantages for atypically presenting PTSD patients (Rafaeli and Markowitz, 2011) – if it proves efficacious for PTSD.

Even in carefully conducted trials, despite the most careful intakes, atypical and even occasionally ineligible patients slip in. The examples we provide in this article are intentionally the "problem" cases, *not* typical study patients. That such cases do appear in randomized controlled efficacy studies, however, helps to counter the belief that patients in such trials are rarified, "ivory tower" patients not generalizable to the larger treatment population.

This exploratory article has manifold limitations. A handful of cases in three psychotherapies clearly cannot fully comprehend the phenomenon under discussion, neither exhausting potential therapeutic dilemmas nor how therapists may respond to them. They do provide a sampling of the richness of psychotherapeutic work and an initial foray into this territory.

How do such cases affect psychotherapy research outcome? These are instances that beg discussion with supervisors and fellow therapists, cases supervisors should look for and

highlight in research protocols. It is possible that such "atypical" cases affect outcome in some therapies more than others. How often patients in research and in community clinical settings do not neatly fit a psychotherapy treatment paradigm is a researchable question. How important a factor such presentations may be relative to other clinical variables is unclear. Psychotherapy outcome research should report protocol deviations and attend to the inevitable deviations "atypical" patients produce, even when such therapeutic shifts do not result in treatment infidelity.

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