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A Randomized Controlled Trial of Cognitive-Behavioral Treatment of Posttraumatic Stress Disorder in Severe Mental Illness

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Abstract

A cognitive-behavioral therapy (CBT) program for PTSD was developed to address its high prevalence in persons with severe mental illness receiving treatment at community mental health centers. CBT was compared to treatment as usual (TAU) in a randomized controlled trial with 108 clients with PTSD and either major mood disorder (85%) or schizophrenia or schizoaffective disorder (15%), of whom 25% also had borderline personality disorder. Eighty-one percent of clients assigned to CBT participated in the program. Intent-to-treat analyses showed that CBT clients improved significantly more than clients in TAU at blinded post-treatment and 3- and 6-month follow-up assessments in PTSD symptoms, other symptoms, perceived health, negative trauma-related beliefs, knowledge about PTSD, and case manager working alliance. The effects of CBT on PTSD were strongest in clients with severe PTSD. Homework completion in CBT predicted greater reductions in symptoms. Changes in trauma-related beliefs in CBT mediated improvements in PTSD. The findings suggest that clients with severe mental illness and PTSD can benefit from CBT, despite severe symptoms, suicidal thinking, psychosis, and vulnerability to hospitalizations.

Keywords

posttraumatic stress disorder; severe mental illness; cognitive behavioral therapy; mood disorder; schizophrenia

People with severe mental illnesses such as schizophrenia, bipolar disorder, and treatment-refractory major depression are more likely to have experienced adverse events in childhood such as sexual and physical abuse, and to be victimized in adulthood, compared to the general population (Bebbington et al., 2004; Goodman, Rosenberg, Mueser, & Drake, 1997; Shevlin, Dorahy, & Adamson, 2007). As a presumed result of this high vulnerability to trauma, surveys of posttraumatic stress disorder (PTSD) in treatment samples of people with prolonged and severe mental illness have reported rates of current PTSD ranging between 29% and 48% (Calhoun et al., 2007; Cascardi, Mueser, DeGiralomo, & Murrin, 1996; Craine, Henson, Colliver, & MacLean, 1988; Howgego et al., 2005; Mueser et al., 1998; Mueser et al., 2001; Mueser et al., 2004c; Switzer et al., 1999). These rates far exceed the prevalence of PTSD in the general population, estimated to be 3.5% over 12-months (Kessler, Chiu, Demler, & Walters, 2005b) and 7 to 12% over the lifetime (Breslau, Davis, Andreski, & Peterson, 1991; Breslau, Peterson, Poisson, Schultz, & Lucia, 2004; Kessler et al., 2005a; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995; Resnick, Kilpatrick, Dansky, Saunders, & Best, 1993).

Persons with severe mental illness may experience psychotic distortions or delusions with themes involving sexual or physical abuse (Coverdale & Grunebaum, 1998), raising questions about the reliability and validity of self-reports of trauma and PTSD in this population. However, research addressing this question supports the validity of self-reports (Read, van Os, Morrison, & Ross, 2005). Self-reports of trauma in clients with severe mental illness are reliable over time (Goodman et al., 1999; Meyer, Muenzenmaier, Cancienne, & Struening, 1996; Mueser et al., 2001), have been reported to have high rates of external corroboration (Herman & Schatzow, 1987; Read, Agar, Argyle, & Aderhold, 2003), and are more likely to be under-reported than over-reported (Briere & Zaidi, 1989; Read, 1997). In addition, standardized measures of PTSD for the general population have been shown to have high internal and test-retest reliability in people with severe mental illness (Goodman et al., 1999; Mueser et al., 2001). Finally, the relationship between trauma characteristics and PTSD does not appear to be affected by the presence of psychosis, with severity of trauma exposure and childhood sexual abuse most strongly predictive of PTSD in

both persons with severe mental illness (Mueser et al., 1998; Mueser et al., 2004c) and the general population (Astin, Ogland-Hand, Coleman, & Foy, 1995; King, King, Foy, & Gudanowski, 1996; Rodriguez, Ryan, Van De Kemp, & Foy, 1997).

PTSD in clients with severe mental illness is associated with more severe symptoms, worse functioning, and more frequent hospitalizations (Mueser, Essock, Haines, Wolfe, & Xie, 2004a; Switzer et al., 1999). These findings have led to the hypothesis that PTSD may interact with severe mental illness, through both the direct effects of PTSD symptoms such as over-arousal exacerbating other psychiatric symptoms, and indirect effects such as problems with interpersonal trust leading to a poor working alliance with the case manager and receipt of fewer illness management services (Mueser, Rosenberg, Goodman, & Trumbetta, 2002). Because of the high prevalence of PTSD in this population and its association with a worse course of illness, attention has turned to implementing routine screening of trauma and PTSD in community mental health center settings (Cusack, Frueh, & Brady, 2004; Eilenberg, Fullilove, Goldman, & Mellman, 1996), exploring obstacles to such assessment (Frueh et al., 2002; Salyers, Evans, Bond, & Meyer, 2004), and developing treatments to address this problem (Frueh, Cusack, Grubaugh, Sauvageot, & Wells, 2006; Rosenberg et al., 2001).

Cognitive-behavior therapy (CBT) is an effective treatment for PTSD (Bradley, Greene, Russ, Dutra, & Westen, 2005). However, research on CBT for PTSD has mainly focused on people in the general or veteran population who are either seeking help or are referred to treatment related to specific traumatic experiences (e.g., combat, rape, childhood sexual abuse, auto accidents, disaster/terrorist attacks). These individuals differ from persons with severe mental illness who are already in treatment for another psychiatric disorder (e.g., at community mental health centers), who are not usually seeking treatment for their traumatic experiences, and whose chronic PTSD has gone unrecognized despite years of mental health treatment (Craine et al., 1988; Mueser et al., 1998; Switzer et al., 1999).

Individuals with severe mental illness present several challenges to treatment. Clinically, common symptoms such as suicidal ideation, self-injurious behavior, psychosis, and mood swings can often be only tenuously stabilized, and exacerbations may require hospitalization, rendering it difficult to provide consistent therapy (Corrigan, Mueser, Bond, Drake, & Solomon, in press). Furthermore, persistent symptoms often lead to functional impairments in self-care and the ability to work, culminating in permanent disability (Waghorn, Chant, White, & Whiteford, 2004). The net result is that clients often have poor housing, lack of economic resources and social support, and chronically unstable lifestyles prone to frequent crises. Treatment programs for PTSD in clients with severe mental illness must accommodate to the high vulnerability and special needs of these individuals.

An additional consideration is the heterogeneity of this population. Although people with severe mental illness represent several different diagnostic groups, most frequently schizophrenia and mood disorders, they often share many important clinical and social characteristics, such as high levels of distress, poor functioning, and poverty (Corrigan et al., in press). As a result of their disability, many such individuals receive entitlements (e.g., Social Security Disability Income) and are served in the public community mental health system by multi-disciplinary treatment teams that employ the same psychosocial interventions to treat specific problems areas (e.g., vocational rehabilitation, substance abuse, housing supports, symptom management), regardless of clients' psychiatric diagnoses. Thus, in order to maximize the adoption of interventions for PTSD at community mental health centers, there is a pragmatic need for treatments that are sufficiently flexible to be effective across a variety of different psychiatric disorders.

To address this need, several interventions have been developed in recent years that focus on either the broad array of trauma sequelae (Harris, 1998) or specifically on PTSD (Frueh et al., 2004; Mueser et al., 2007) in persons with severe mental illness. To this end, we developed, standardized, and pilot tested a 12-16 session individual CBT program for PTSD in severe mental illness (Mueser, Rosenberg, Jankowski, Hamblen, & Descamps, 2004b; Rosenberg, Mueser, Jankowski, Salyers, & Acker, 2004). The program includes teaching breathing retraining, education about the PTSD, and cognitive restructuring. Both cognitive restructuring (i.e., identifying and challenging inaccurate trauma-related beliefs that lead to negative emotions) and exposure therapy (i.e., planned exposure to feared but safe trauma-related stimuli, such as memories and situations) have strong empirical support for the treatment of PTSD in the general population (Marks, Lovell, Noshirvani, Livanou, & Thrasher, 1998; Resick, Nishith, Weaver, Astin, & Feuer, 2002; Tarrier et al., 1999), with the combination no more effective than either approach alone (Bryant, Moulds, Guthrie, Dang, & Nixon, 2003; Foa et al., 2005; Marks et al., 1998). We chose cognitive restructuring as the primary technique for treating PTSD for two practical reasons.

First, there is extensive clinical and research experience with the use of cognitive restructuring for clients with severe mental illness, including schizophrenia (Turkington, Kingdon, & Weiden, 2006), severe depression (Hollon, DeRubeis, & Shelton, 2005), and bipolar disorder (Lam, Hayward, Watkins, Wright, & Sham, 2005; Scott et al., 2006) suggesting its feasibility for treating PTSD in this population. Much less is known about the feasibility of exposure therapy for people with severe mental illness, with only a few published case studies or non-controlled trials (Arlow, Moran, Bermanzohn, Stronger, & Siris, 1997; Hofmann, Bufka, Brady, DuRand, & Goff, 2000; Mueser & Taylor, 1997; Nishith, Hearst, Mueser, & Foa, 1995). Second, clients with severe mental illness are highly sensitive to stress (Butzlaff & Hooley, 1998; Myin-Germeys, van Os, Schwartz, Stone, & Delespaul, 2001; Nuechterlein & Dawson, 1984), suggesting that cognitive restructuring may be more acceptable and more readily tolerated than exposure therapy.

We report here the results of a controlled evaluation of our CBT program, which is the first randomized controlled trial to evaluate an intervention specifically designed to treat PTSD in individuals with severe mental illness. We compared the CBT for PTSD program to treatment as usual (TAU) and evaluated the following hypotheses:

1. CBT will be more effective than TAU at eliminating PTSD diagnosis, reducing PTSD symptoms and negative trauma-related cognitions, and improving knowledge of PTSD.
2. CBT will be more effective than TAU at reducing depression, anxiety, other psychiatric symptoms, and health-related concerns.
3. CBT will be more effective than TAU at improving the working alliance between the client and case manager.

We also evaluated whether homework completion contributed to treatment response in the CBT program, based on prior research linking homework to outcomes in CBT (Kazantzis, Deane, & Ronan, 2000). Finally, we examined whether changes in negative trauma-related beliefs about the world mediated improvements in PTSD symptoms following participation in the program.

Methods

A randomized controlled trial was conducted comparing the CBT for PTSD program with comprehensive mental health treatment as usual in clients with severe mental illness who were receiving services at four publicly funded community mental health centers in the

northeastern U.S. Assessments were conducted by blinded interviewers at baseline, following the 4-6 months treatment period for the CBT program, and 3- and 6-months later. Recruitment for the study began in May of 2002 and the last interview was conducted in February of 2006.

Study Participants

Inclusion criteria for participation in the study were: 1) minimum age 18 years old; 2) designated by the states of New Hampshire or Vermont as having a severe mental illness, defined as a DSM-IV Axis I disorder and persistent impairment in the areas of work, school, or ability to care for oneself; 3) DSM-IV diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia; 4) current DSM-IV diagnosis of PTSD; and 5) legally able and willing to provide informed consent to participate in the study. We initially planned to enroll and treat only clients who met criteria for “severe” PTSD based on the Clinician Administered PTSD Scale (CAPS; see below), defined by Weathers et al. (1999) as a CAPS total score ≥ 65 . However, due to lower than expected recruitment rates we modified this criterion to include all clients with PTSD based on the CAPS. For this reason, we conducted separate exploratory analyses examining changes in PTSD diagnosis and severity on the subgroups of clients with severe or mild-moderate PTSD at baseline.

Exclusion criteria for participation in the study were: 1) psychiatric hospitalization or suicide attempt within the past 3 months; and 2) current DSM-IV substance dependence. All study procedures were approved by the Institutional Review Boards of Dartmouth College and the State of New Hampshire.

Measures

Axis I psychiatric disorders other than PTSD were assessed with the *Structured Clinical Interview for DSM-IV* (SCID-I) (First, Spitzer, Gibbon, & Williams, 1996). Because of the extensive literature on borderline personality disorder and PTSD (Connor et al., 2002; Gunderson & Sabo, 1993; McLean & Gallop, 2003), we evaluated Axis II diagnosis of borderline personality disorder with the *SCID-II* (First, Spitzer, Gibbon, Williams, & Benjamin, 1994). SCID assessments and trauma history were administered only at baseline, with the remaining assessments repeated at post-treatment, 3- and 6-month follow-ups. The primary outcome measures were PTSD severity and diagnosis, and the secondary outcomes were measures of knowledge about PTSD, trauma-related cognitions, depression, anxiety, perceived health and mental health functioning, and working alliance with the case manager.

Trauma and PTSD—History of trauma exposure was evaluated with the *Trauma History Questionnaire* (Green, 1996), which was previously adapted for persons with severe mental illness (Mueser et al., 1998). PTSD diagnoses and symptom severity were based on the *Clinician Administered PTSD Scale* (CAPS) (Blake et al., 1995), a widely used, semi-structured interview for the assessment of PTSD. For each symptom, a frequency and intensity rating is provided, with overall severity scores computed by summing the frequency and intensity scores for all of the PTSD symptoms (CAPS-Total). Prior research indicates that the CAPS is a reliable and valid instrument for assessing PTSD in persons with severe mental illness (Mueser et al., 2001). Information was recorded on whether the traumatic event occurred in childhood or adulthood, but not the specific age nor the chronicity of PTSD symptoms.

Trauma-related cognitions were evaluated with the *Posttraumatic Cognitions Inventory* (Foa, Ehlers, Clark, Tolin, & Orsillo, 1999), a self-report measure of common negative beliefs about oneself, other people, and the world that frequently occur in individuals with PTSD. High scores correspond to greater endorsement of negative beliefs. Understanding of

PTSD was assessed with the *PTSD Knowledge Test*, which contains 15 multiple choice questions about PTSD. This test has been shown to be sensitive to the effects of education about PTSD in clients with severe mental illness (Pratt et al., 2005).

Other Symptoms—Overall psychiatric symptoms were assessed with the Expanded version of the *Brief Psychiatric Rating Scale* (Lukoff, Nuechterlein, & Ventura, 1986), a widely used measure that taps a broad range of psychiatric symptoms (Shafer, 2005). Self-reported depression and anxiety were rated with the *Beck Depression Inventory-II* (Beck, Steer, & Brown, 1996) and the *Beck Anxiety Inventory* (Beck & Steer, 1990). Self-reported mental health and physical functioning were assessed with the *Short Form-12* (Ware, Kosinski, & Keller, 1994), which is reliable and valid in clients with severe mental illness (Salyers, Bosworth, Swanson, Lamb-Pagone, & Osher, 2000).

Working Alliance—The therapeutic alliance with the case manager (i.e., not the therapist providing CBT treatment) was rated using the client version of the *Working Alliance Inventory* (Horvath & Greenberg, 1989). This measure has been shown to be reliable and valid in clients with severe mental illness (Stylianou & Goering, 1989), with high scores corresponding to a stronger alliance.

All assessments were conducted by Masters or Ph.D. level trained clinical interviewers who were blind to treatment assignment. Clients were instructed at the beginning of interviews to not talk about any treatments for trauma-related problems they may have received. Interviewers were requested to inform the project coordinator if the client broke the blind during an interview. Interviewers were not asked to guess clients' treatment assignments to avoid directly encouraging them to formulate hypotheses about how treatment may have affected clients' symptoms, which could have influenced subsequent ratings. No specific instances of blind breaking were noted in the study. Regular reliability checks were conducted based on audiotaped interviews, with intraclass correlation coefficients of .97 for CAPS Total and .97 for BPRS Total, and $\kappa = .91$ for PTSD diagnosis based on the CAPS.

Treatments

All clients were receiving comprehensive treatment for their psychiatric illness at their local community mental health center and continued to receive these services throughout the study period, regardless of which treatment group they were assigned to. Comprehensive mental health treatment at these centers included pharmacological treatment and monitoring, case management, supportive counseling, and access to psychiatric rehabilitation programs such as vocational rehabilitation. No efforts were made to control or modify any of these services provided to study participants.

CBT for PTSD Program—An outline of the 12-16 session program is provided in Table 1. Sessions followed a structured format and included handouts, worksheets, and homework assignments. The content of each session was summarized by therapists using a standardized contact sheet, which was also used to record whether homework was completed (not completed/partially completed/completed). All sessions were conducted at clients' local community mental health center, with regular contact and coordination between the CBT therapist and the treatment teams providing comprehensive mental health treatment. CBT was provided by 7 clinicians, 5 female and 2 male, 6 with a Ph.D. and 1 with a Masters. Weekly supervision was provided. Fifteen percent of all sessions were randomly selected for fidelity monitoring using a standardized scale. Treatment exposure was defined *a priori* as completion of at least 6 sessions so as to ensure that there would be at least 3 sessions of cognitive restructuring, the presumed critical ingredient in the program (Rosenberg et al., 2004).

Treatment as Usual (TAU)—Clients assigned to TAU continued to receive the usual services they had been receiving before enrollment in the program. None of the mental health centers offered either cognitive restructuring or exposure therapy treatments for PTSD, although supportive counseling for trauma-related problems was available.

Procedures

Recruitment of study clients was conducted by providing orientation meetings to case managers and clinical staff at the community mental health centers. At these meetings, the purposes and methods of the study were described, and clinical instruments for screening potentially eligible clients were provided. Clinicians then discussed the project with their clients who met screening eligibility criteria, and referred interested clients to a member of the research team. A research staff member reviewed the study procedures, obtained written informed consent, and scheduled the baseline interview, which was also used to confirm eligibility for the study. Clients who completed the baseline interview were then randomized to the CBT program or TAU. Clients who were randomized to CBT were also scheduled for an additional assessment session to evaluate their neurocognitive functioning. The results of these assessments will be reported elsewhere.

Randomization was conducted at a central location in the research center by a computer-based randomization program with assignments not known in advance by either clinical or research staff. When a client had completed the baseline assessment and his or her eligibility for the study was confirmed, the interviewer called the research center and a member of the research team obtained the randomized assignment from the computer. The client was informed about the assignment by the project coordinator. Randomization to treatment groups was stratified by site and by the following three diagnostic groups: major mood disorder without borderline personality disorder ($N = 64$), major mood disorder and borderline personality disorder ($N = 27$), or schizophrenia or schizoaffective disorder ($N = 17$). In order to minimize large differences in the number of clients randomized to the two treatments, randomization was conducted in blocks of four within each of the 12 strata (e.g., schizophrenia or schizoaffective disorder at site #1).

In order to ensure that post-treatment and follow-up assessments for clients assigned to TAU and CBT occurred at similar time intervals following the baseline assessment, the dates for follow-up assessments for clients in TAU were yoked to the follow-up assessments dates for clients in CBT based on their completion of the program. Clients were reminded of follow-up assessments through a combination of phone calls, letters, and contacts with their case managers. Clients were paid for participating in the assessments.

Statistical Analysis

Based on prior non-controlled research with this treatment model in persons with PTSD and severe mental illness (Rosenberg et al., 2004) and research on cognitive-behavioral treatment of PTSD in the general population (Foa, Keane, & Friedman, 2000), we estimated power to detect a between group effect size on CAPS severity of .70 for a two-tailed, independent-groups *t*-test, with alpha set at .05 (Borenstein, Rothstein, & Cohen, 1997). With an expected 5-10% dropout rate from the CBT for PTSD intervention, we planned to randomize 88 clients in order to have completed data on 80 clients, resulting in power to detect a significant difference between the treatment groups of .87. Because the rate of dropout from the CBT for PTSD program exceeded the anticipated rate we increased the sample size to 108 in order to maintain the same level of power to detect differences between groups in PTSD symptom severity.

Two tailed t -tests and χ^2 analyses were used to compare the CBT and TAU groups on demographic characteristics, psychiatric history, and outcome measures at baseline. Prior to statistical modeling we conducted descriptive statistical analyses and examined the distributions of each variable for skewness and possible outliers.

Intent-to-treat analyses were conducted to determine treatment effects on the primary outcome measures. Because there were no significant differences between CBT and TAU on these variables at baseline, and because there were only 3 follow-up assessment points, rather than fitting parametric curves with random effects we elected to include the baseline as a covariate and fit baseline adjusted mean response profile models (Fitzmaurice, Laird, & Ware, 2004) using the SAS PROC MIXED procedure for continuous outcomes (e.g., CAPS-Total) and SAS PROC GENMOD for dichotomous outcomes (e.g., CAPS PTSD diagnosis). This approach, also referred to as covariance pattern models (Hedeker & Gibbons, 2006), is similar to a traditional analysis of covariance except that it can accommodate correlated data by selecting appropriate covariance structures as well as missing data with maximum likelihood estimation (Jennrich & Schluchter, 1986). Rather than fitting models for different outcomes with possibly different covariance structures, we obtained estimates of standard error in PROC MIXED by using the “empirical” estimate option. This method is based on “sandwich estimation” (Diggle, Liang, & Zeger, 2002), and yields robust and asymptotically consistent estimates of variance and covariance regardless of the data’s actual covariance structure.

For the continuous variables, treatment group (CBT, TAU), diagnosis (mood disorder without borderline personality disorder, mood disorder and borderline, schizophrenia-schizoaffective), time, and their interactions were included in the model, with the baseline score and education level (post high school education vs. not) as covariates, and the post-treatment, and 3- and 6-month scores as the dependent variables. For the categorical variable (CAPS PTSD diagnosis) the same model was fit, except that baseline was not included as a covariate because it was a constant. Site was also included in the initial analyses but dropped from the final model because it did not alter the main group effects. Since the baseline was statistically adjusted, treatment effects were evaluated with group main effects (i.e., differences in group mean response profiles). In line with this approach, effect sizes were computed based on the last observation available using Cohen’s d (Cohen, 1988).

We next evaluated whether clients’ follow up on homework assignments in CBT (i.e., percentage of assignments completed) influenced their outcomes. For the clients who completed the CBT for PTSD program similar mean response profile models as described above were fit using PROC MIXED and PROC GENMOD, with the baseline dependent variable included as a covariate, and homework completion (binary coded as high or low based on a mean split of the sample) and time as independent variables. The effect for homework is a test of whether homework completion influences the mean responses at the follow-up assessments.

Last, we examined whether improvements in PTSD symptoms at post-treatment, 3- and 6-month follow-ups were mediated by changes in negative trauma-related beliefs using Kenny’s (2004) approach, which includes: 1) showing an effect of the intervention on the mediator (PTCI), 2) showing an effect of the intervention on the outcome (CAPS-Total), and 3) showing that the effect of treatment on the outcome is reduced or eliminated when the effect of treatment on the mediator is statistically controlled. We did not compute a Sobel Test because of the limited sample size (Baron & Kenny, 1986). These analyses were conducted using mean response profile models, as described above.

Results

A total of 270 clients were referred to the study, of whom 108 met inclusion criteria, provided consent, and were randomized to CBT or TAU. Figure 1 contains a flow diagram of client recruitment and participation in the study. The characteristics of the clients assigned to CBT or TAU are summarized in Table 2. There were no differences between the groups on any demographic, diagnostic, or baseline measures, nor in the rates of follow-up assessments ($ps > .10$).

The most common traumatic event that clients reported PTSD due to was childhood sexual abuse ($N = 37$, 34%), followed by childhood physical abuse ($N = 19$, 17%), the sudden unexpected death of a loved one ($N = 16$, 15%), adult sexual assault ($N = 14$, 13%), adult physical assault ($N = 12$, 11%), other traumatic event ($N = 4$, 4%), sexual and physical assault ($N = 2$, 2%), witnessing violence ($N = 2$, 2%), motor vehicle accident ($N = 1$, 1%), and combat ($N = 1$, 1%). Among the 54 clients assigned to CBT, 44 (81%) were exposed to six or more treatment sessions and 38 (70%) completed the 12-16 session program.

Primary Outcomes

Examination of the distributions of the primary outcome measures revealed no outliers and indicated approximately normal distributions. The results of analyses comparing the CBT and TAU groups are summarized in Table 3. We report means and standard deviations (or percent for dichotomous variables), and F -test results from the mean response profile models, and between group effect sizes (ES). In terms of our primary hypotheses, CBT was not more effective than TAU at eliminating PTSD diagnosis, but was significantly better in reducing PTSD symptoms and negative trauma-related cognitions, and improving knowledge of PTSD. CBT was also more effective than TAU at reducing depression, anxiety, other psychiatric symptoms, and health-related concerns, as well as improving the working alliance between the client and case manager. In a post-hoc attempt to better understand these results, we restricted the sample to the original target population: clients with severe PTSD (CAPS > 65). In this analysis, effect sizes for both CAPS-Total and CAPS diagnosis increased, from .45 to .59 and from .27 to .40, respectively, whereas for clients with mild-moderate PTSD (CAPS < 65) the effect sizes decreased to .12 and .10, respectively.

There was only one significant interaction between psychiatric diagnosis and treatment group, for the SF-12 Physical, $F = 4.83$, $df = 2, 73$, $p = .01$. Post hoc within diagnostic group analyses indicated significant treatment effects on the SF-12 Physical for clients with borderline personality disorder and major mood disorder, $F = 16.61$, $df = 1, 15$, $p = .001$, and schizophrenia, $F = 5.24$, $df = 1, 10$, $p = .05$, but not for clients with major mood disorder only. For both diagnostic groups, clients who received CBT improved more in perceived physical health than clients who received TAU.

Effect of Homework Completion on Treatment Outcomes

The average rate of homework completion across all sessions was 50% (range: 0-92%). Analyses of homework completion indicated significant effects for CAPS-Total, $F = 5.81$, $df = 1, 37$, $p = .02$, $ES = .93$, CAPS-Diagnosis, $F = 4.71$, $df = 1, p = .03$, $ES = .47$, BDI-II, $F = 15.21$, $df = 1, 37$, $p = .0004$, $ES = .97$, BAI, $F = 6.60$, $df = 1, 37$, $p = .01$, $ES = .65$, SF-12 Mental Component, $F = 6.19$, $df = 1, 34$, $p = .02$, $ES = .68$, and PTCL, $F = 6.10$, $df = 1, 37$, $p = .02$, $ES = .44$, but not for PTSD Knowledge, SF-12 Physical Component, BPRS Total, or the WAI Total. Higher rates of homework completion were associated with greater improvements in symptoms, perceived mental health, and negative trauma-related beliefs.

Tarrier and colleagues (2000) have reported that duration to complete therapy and missed appointments were associated with worse response to CBT for PTSD in the general population. These problems could reflect lack of engagement and motivation in therapy, and might also be expected to be associated with poor follow-through on homework assignments. We did not obtain information on missed sessions, but did on duration of therapy. To explore whether homework completion was related to duration of therapy we computed a Spearman's rho correlation coefficient in the subgroup of clients who completed the CBT for PTSD program. This correlation was significant ($\rho = -.34$, $N = 48$, $p = .02$), and as expected lower rates of homework completion were related to a longer time to complete therapy.

Mediation Analysis

The steps of the analysis testing whether changes in negative trauma-related beliefs (PTCI) mediated improvements in PTSD symptom severity (CAPS-Total) following CBT are summarized in Table 4. CBT had a significant effect on trauma-related beliefs (Step 1) and on PTSD severity (Step 2). Finally, when trauma-related beliefs was added to the statistical model, the effect of CBT on PTSD severity was no longer significant, whereas trauma-related beliefs and PTSD severity were highly significantly related (Step 3). The results are consistent with the hypothesis that changes in trauma-related beliefs over the course of CBT mediated reductions in PTSD symptom severity.

Discussion

The setting and client population for this study differed from those of most prior studies of PTSD. Treatment took place at several community mental health centers that provided long-term care to clients with severe mood or schizophrenia-spectrum disorders, and whose comorbid PTSD had only been recently identified through screening for the purposes of the study. Over 90% of the clients had prior psychiatric hospitalizations, and most were receiving Social Security entitlements because of their mental illness. In contrast, most other research in this area has focused on general or veteran population samples, recruited either by referrals or advertisements for treatment of psychological distress related to traumatic events. Despite the chronic and disabled nature of this study population, clients were successfully engaged in the CBT program, with a comparable dropout rate (19%) to PTSD treatment studies in the general population (Bradley et al., 2005). Furthermore, clients in CBT improved significantly more than those in treatment as usual (TAU) on PTSD symptoms and a range of other outcomes. The results suggest that despite the multitude of challenges faced by clients with severe mental illness and PTSD, CBT can be effective at reducing the severity of their symptoms.

Although clients assigned to CBT improved more on most outcomes, those in TAU nevertheless also improved, despite the lack of CBT treatment for PTSD in usual care. It is possible that the comprehensive mental health care available to everyone in this study, including supportive counseling, afforded some benefit to clients in TAU for managing trauma-related problems such as PTSD. Alternatively, the severity of PTSD symptoms may covary with other psychiatric symptoms in clients with severe mental illness, resulting in some clients meeting diagnostic criteria for PTSD intermittently as symptoms fluctuate over time. In line with this, severe PTSD (based on CAPS-Total scores ≥ 65) has been shown to be more stable over brief periods of time (1-2 weeks) than mild to moderate PTSD (Mueser et al., 2001). In the present study, clients with severe PTSD benefited more from the CBT program in terms of PTSD severity and diagnosis than those with mild to moderate symptoms. The findings suggest that the CBT program might better be directed at clients

with severe PTSD, who according to this and one previous study (Mueser et al., 2001) represent approximately three-quarters of clients with severe mental illness and PTSD.

Clients who received CBT also reported more improvement in their working alliance with their case manager than clients in TAU, as hypothesized. These results could have been due to the effects of cognitive restructuring on challenging beliefs related to the pervasive interpersonal distrust often present in clients with PTSD (American Psychiatric Association, 1994; Carmen, Rieker, & Mills, 1984; Figley, 1985), leading to improved trust of the case manager. The working alliance may have also improved because the therapist providing CBT maintained ongoing contact with the case manager during the program, and one session focused on fostering collaboration by having the client explain cognitive restructuring to the case manager in order to elicit his or her support for when the program ended (see Table 1). Therapeutic alliance with the case manager has been shown to predict outcome in clients with severe mental illness (Gehrs & Goering, 1994; Neale & Rosenheck, 1995; Priebe & Gruyters, 1993). The findings suggest that the CBT program could improve working alliance with the case manager, which in turn could improve the course of the psychiatric illness, as hypothesized in our interactive model of PTSD and severe mental illness (Mueser et al., 2002).

Higher rates of homework completion contributed to better outcomes in the CBT program, including greater improvements in PTSD symptoms and diagnosis, post-traumatic cognitions, depression, anxiety, and perceived mental health functioning, with effect sizes of .95 for PTSD severity, .97 for depression, and .65 for anxiety. These effect sizes are considerably higher than those reported in a meta-analysis of the effects of homework on depression (.38), anxiety (.27), and other outpatient problems (.40) (Kazantzis et al., 2000). The assignment of homework to practice skills taught in therapy is a central tenet of CBT (Beck, 1995). Homework completion has previously been reported to be associated with gains in CBT for depression (Coon & Thompson, 2003; Startup & Edmonds, 1994), social phobia (Edelman & Chambless, 1995), and agoraphobia (Edelman & Chambless, 1993). To our knowledge, the effects of homework completion on outcomes of CBT in either PTSD or severe mental illness have not been reported. Considering the magnitude of the effect sizes for homework, strategies for increasing homework adherence could be an important approach to maximizing the treatment gains of clients in the CBT for PTSD program.

The mediation analysis was consistent with the hypothesis that changes in negative trauma-related beliefs in CBT improved PTSD symptoms. This finding is consistent with cognitive theories that posit trauma-related schemas underlie PTSD symptoms (Dalgleish, 2004; Ehlers & Clark, 2000; Ehlers, Mayou, & Bryant, 2003). Research on CBT suggests that changes in cognition mediate treatment response for depression (Burns & Spangler, 2001; DeRubeis, Tang, Gelfand, & Freely, 2000), anxiety (Burns & Spangler, 2001), and panic disorder (Smits, Powers, Cho, & M.J., 2004). Research on PTSD has shown that both cognitive restructuring and exposure therapy result in improvements in negative trauma-related beliefs (Ehlers, Clark, Hackmann, McManus, & Fennell, 2005; Foa & Rauch, 2004; Resick et al., 2002), although mediation analyses have not been reported.

While the CBT program led to significant improvements in PTSD and other symptoms, in the overall sample it did not result in a significantly greater reduction in PTSD diagnosis, and symptoms remained in the moderate to severe range at post-treatment and follow-up for clients who received CBT. For example, in the total sample 63-73% of clients who received CBT continued to meet criteria for PTSD at post-treatment or follow-up compared to 77-85% of those in TAU, whereas among clients with severe PTSD at baseline the respective rates of PTSD caseness were 68-78% compared to 88-92%. The findings suggest that CBT results in clinically significant improvements for some clients, but many still

experience persistent and severe symptoms. Further work is needed to explore whether the CBT for PTSD model could be modified to make it more effective, such as by providing additional sessions for clients whose PTSD does not remit in 12-16 sessions or incorporating exposure therapy into the approach.

The results of other treatment approaches for trauma-related problems in persons with severe mental illness, such as Harris's (1998) broad-based Trauma Recovery and Empowerment group therapy model and Frueh et al's (2004) individual and group model that combines anxiety reduction methods with exposure therapy and social skills training, have not been reported. We have also developed a 21-session group-based CBT program for clients with severe mental illness that incorporates the major components of the individual-based program studied here, as well as several sessions that address coping with persistent symptoms and developing a personal recovery plan (Mueser et al., 2007). Non-controlled research on 41 clients who participated in this program indicated post-treatment and follow-up PTSD rates for the CBT group participants of 73%, compared to 88-100% for dropouts, suggesting comparable effects to those reported here for the individual CBT program. Research is needed to evaluate different treatment formats and programs for PTSD in clients with severe mental illness.

Despite the high rates of PTSD in borderline personality disorder (Golier et al., 2003; Mueser et al., 1998; Zanarini et al., 1998), very limited research has evaluated the treatment of PTSD in this population. Two randomized controlled trials of CBT programs for the general population, both involving exposure therapy and either stress inoculation training (Feeny, Zoellner, & Foa, 2002) or cognitive restructuring (Hembree, Cahill, & Foa, 2004), reported similar effects for respective subgroups of nine and three clients with borderline personality disorder compared to other clients. In addition, case studies have demonstrated the feasibility and promise of combining exposure therapy with either stress inoculation and social skills training (Mueser & Taylor, 1997) or dialectical behavior therapy (Harned & Linehan, in press) for PTSD in borderline personality disorder. The present study is unique both in the number of clients included and its evaluation of a non-exposure approach to PTSD. The finding that the 27 clients with borderline personality disorder in this study did not differ in treatment response from the 81 clients without it suggests that the burden of PTSD can be reduced in this population, and that exposure therapy may not be a necessary ingredient.

Several limitations of this study should be noted. First, the use of TAU as a control condition leaves open the question of whether an attention control group would have yielded weaker results. However, research on the treatment of PTSD in the general population has consistently found that CBT is more effective than non-specific "supportive" therapies (Bradley et al., 2005). Nevertheless, future research should consider comparing the CBT for PTSD program to more active comparison treatments, such as interventions designed to address the broad range of trauma sequelae (Harris, 1998) or exposure-based approaches (Frueh et al., 2004). Second, the study was conducted in relatively rural northern New England where there are lower rates of poverty, homelessness, and crime, and less representation of racial and ethnic minority groups, pointing to the need to evaluate the CBT program in more urban settings with more disadvantaged clients. Third, the measures focused primarily on PTSD and other psychiatric symptoms, leaving open the question of the broader impact of the CBT program on functional outcomes, course of psychiatric disorder, and service utilization and costs. Fourth, information on prescribed medications was not obtained, raising the question of whether differences in medication could account for some of the differences between groups. Finally, a heterogeneous group of clients with severe mental illness was studied, leading to low statistical power to detect possible differences between diagnostic groups in response to the CBT program, and potentially

spurious findings for the few interactions that were found. A related concern is that only 15% of the sample had schizophrenia or schizoaffective disorder, despite the high rate of PTSD in this population (Calhoun et al., 2007; Mueser et al., 2004c), suggesting that more research is needed to evaluate the program in this population.

Several strengths of the study are also noteworthy. Despite the high rates of PTSD in clients with severe mental illness (Mueser et al., 2002), this study is the first to evaluate a standardized treatment for PTSD in this population in a randomized controlled trial. The CBT program was successfully implemented across four centers providing comprehensive mental health services, with excellent retention of clients in treatment, and positive effects of the program on PTSD and other outcomes. The findings support the feasibility and clinical benefits of treating PTSD in clients with severe mental illness, which is encouraging in light of recent initiatives to develop trauma services for this population (Harris & Fallot, 2001; Jennings, 2004). Further research is needed to evaluate the CBT for PTSD program in other settings, and to determine its longer term impact on both mental health and service utilization outcomes.

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Appendix: CONSORT Checklist Items to include when reporting a randomized trial

<i>PAPER SECTION and topic</i>	<i>Item</i>	<i>Descriptor</i>	<i>Reported on Page #</i>
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., “random allocation”, “randomized”, or “randomly assigned”).	1,2
<i>INTRODUCTION</i> Background	2	Scientific background and explanation of rationale.	3-7
<i>METHODS</i> Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	8-9
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	12-13
Objectives	5	Specific objectives and hypotheses.	10
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	9-12
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	14-15
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)	13-14
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	14

PAPER SECTION and topic	Item	Descriptor	Reported on Page #
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	13-14
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	11
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	15-17
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	Figure 1
Recruitment	14	Dates defining the periods of recruitment and follow-up.	8
Baseline data	15	Baseline demographic and clinical characteristics of each group.	Table 2
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	15, Figure 1
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	19, Table 3
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	9, 16-17
Adverse events	19	All important adverse events or side effects in each intervention group.	None
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	20-27
Generalizability	21	Generalizability (external validity) of the trial findings.	20-21
Overall evidence	22	General interpretation of the results in the context of current evidence.	26-27

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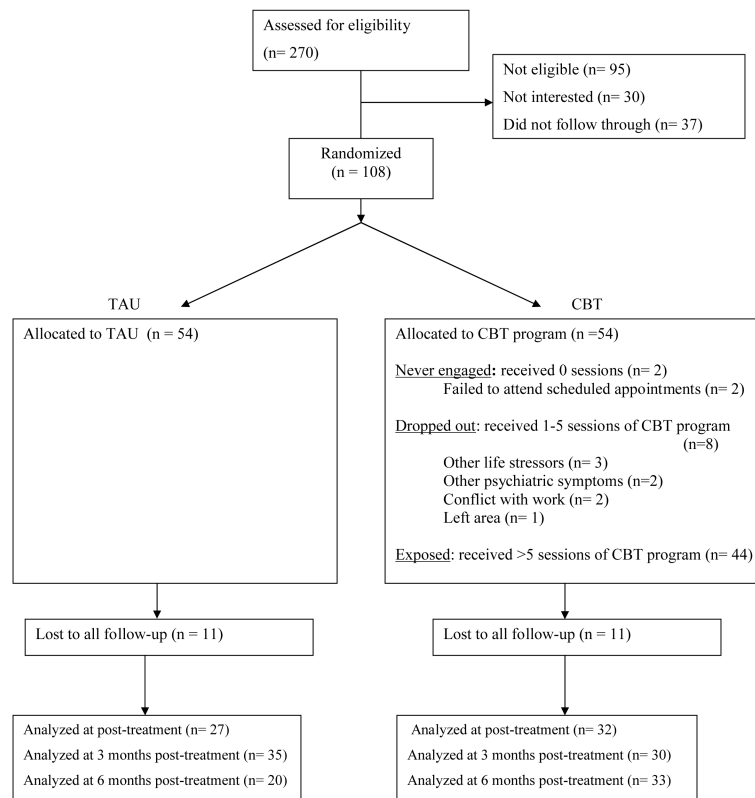
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1. .
Flow of participants through the study.

Table 1

Overview of Cognitive-Behavioral Therapy Program for PTSD

Module	Topic	Goals	# of Sessions
1	Introduction	<ul style="list-style-type: none"> Engage client in program Provide treatment overview 	1
2	Crisis Plan Review	<ul style="list-style-type: none"> Decide on a crisis plan with client Clarify with client's treatment team plan for managing any crises 	1
3	Psychoeducation Part I: Core Symptoms of PTSD	<ul style="list-style-type: none"> Help client understand the nature of PTSD Make information relevant to client's own experience of symptoms 	1-2
4	Breathing Retraining	<ul style="list-style-type: none"> Improve client's ability to manage tension and anxiety associated with PTSD 	1+
5	Psychoeducation Part II: Associated Symptoms of PTSD	<ul style="list-style-type: none"> Help client understand how other problems and symptoms are related to PTSD & trauma 	1-2
6	Cognitive Restructuring Part I: Common Styles of Thinking	<ul style="list-style-type: none"> Establish relationship between thoughts and feelings Discuss role of life experiences, including trauma, in causing thoughts and beliefs Teach client how to recognize common but incorrect thinking patterns that lead to distress 	1-3
7	Cognitive Restructuring Part II: The Five Steps of Cognitive Restructuring	<ul style="list-style-type: none"> Teach client step-by-step process for using cognitive restructuring when distressed: <ol style="list-style-type: none"> Describe situation Identify strongest feeling, Identify thought underlying feeling, Challenge thought Take action by either changing thought or making a plan to deal with the situation Help client first practice using cognitive restructuring to deal with distressing feelings Then help client use cognitive restructuring to deal with trauma-related thoughts and beliefs 	7+
8	Generalization Training & Termination	<ul style="list-style-type: none"> Bring treatment to closure Conduct session where client explains cognitive restructuring to case manager Ease transition from PTSD treatment to care as usual with treatment team 	2

Table 2

Baseline Characteristics of the Sample*

	<i>CBT</i> (N = 54)	<i>TAU</i> (N = 54)	<i>Total</i> (N = 108)
Demographics			
Male	13 (24.1)	10 (18.5)	23 (21.3)
White	46 (85.2)	45 (83.3)	91 (84.3)
Education (High School Grad.)	41 (75.9)	36 (66.7)	77 (71.3)
Never Married	17 (31.5)	21 (38.9)	38 (35.2)
Age, mean (SD), y	45.13 (9.83)	43.30 (11.41)	44.21 (10.64)
Currently Employed	3 (5.6)	6 (11.1)	9 (8.3)
Primary Diagnosis			
Schizophrenia	5 (9.3)	3 (5.6)	8 (7.4)
Schizoaffective Disorder	5 (9.3)	4 (7.4)	9 (8.3)
Major Depression	30 (55.6)	36 (66.7)	66 (61.1)
Bipolar Disorder	14 (25.9)	11 (20.4)	25 (23.1)
Secondary Diagnoses			
Borderline Personality Disorder	15 (27.8)	12 (22.2)	27 (25.0)
Substance Use Disorder	17 (31.5)	27 (50.0)	44 (40.7)
Psychiatric History			
Prior Psychiatric Hospitalization	46 [†] (93.9)	42 [†] (89.4)	88 [†] (89.8)
# of Prior Hospitalizations, median (range)	4 (0-100)	5 (0-100)	4 (0-100)
Age at 1 st hospitalization, mean (SD), y	27.85 (12.03)	22.98 (11.70)	25.49 (12.05)
Months since last hospitalization, mean (SD)	49.11 (73.54)	31.95 (54.31)	41.01 (65.39)

Abbreviations: CBT, Cognitive Behavioral Therapy; TAU, Treatment as Usual.

* Data are given as number (percentage) unless otherwise indicated. No values between two groups were statistically different using χ^2 -test or *t*-test as appropriate.

[†] Data on prior hospitalization were missing for 3 clients in CBT and 7 clients in TAU.

Table 3
Results of Mean Response Profile Analyses and Effect Sizes (*ES*) with Baseline and Education as Covariates for Primary Outcomes

Outcome	Condition	Base	Post	3 Month	6 Month	df	F	P	ES
Continuous Variables[*]									
CAPS-Total	CBT	74.46 (17.56)	55.53 (27.92)	55.10 (25.96)	57.48 (25.34)	1,78	8.30	.005	.45
	TAU	76.15 (17.07)	67.78 (26.84)	64.80 (28.25)	70.90 (24.15)				
CAPS-Total (>65)	CBT	82.05 (14.46)	59.68 (29.12)	57.23 (26.92)	62.78 (25.01)	1,57	9.16	.004	.59
	TAU	83.87 (12.45)	79.65 (18.41)	74.50 (22.17)	74.24 (23.54)				
CAPS- Total (<65) [§]	CBT	54.73 (4.74)	40.71 (17.56)	49.25 (23.77)	45.30 (22.73)	1,18	.08	.77	.12
	TAU	56.07 (9.16)	33.86 (15.40)	36.78 (25.83)	52.00 (21.93)				
PTSD Knowledge	CBT	9.57 (3.20)	10.55 (2.53)	10.87 (2.29)	10.75 (2.45)	1,76	12.73	<.001	.30
	TAU	10.00 (2.45)	10.00 (2.59)	9.35 (2.63)	10.21 (2.49)				
PTCI-Total	CBT	3.88 (0.99)	3.26 (1.10)	2.87 (0.99)	3.05 (1.03)	1,78	14.19	<.001	.51
	TAU	3.76 (0.99)	3.54 (1.23)	3.54 (1.27)	3.58 (1.15)				
BDI-II	CBT	31.48 (13.24)	21.91 (11.52)	21.67 (13.32)	25.02 (12.85)	1,78	14.89	<.001	.51
	TAU	31.76 (13.79)	27.70 (14.75)	30.66 (15.26)	31.30 (13.50)				
BAI	CBT	48.29 (13.04)	42.59 (12.95)	41.10 (14.29)	43.58 (12.03)	1,78	5.14	.03	.23
	TAU	49.68 (13.26)	45.81 (14.16)	48.04 (15.62)	47.84 (13.73)				
BPRS-Total	CBT	43.92 (7.69)	39.63 (10.00)	40.57 (7.33)	41.78 (6.81)	1,74	5.69	.02	.45
	TAU	43.77 (7.42)	42.25 (7.59)	43.97 (10.37)	46.60 (11.56)				
WAI-Total	CBT	59.84 (16.23)	61.33 (17.04)	65.27 (9.21)	63.75 (9.92)	1,69	7.14	.009	.55
	TAU	60.33 (13.85)	57.11 (18.38)	58.45 (17.24)	59.10 (13.59)				
SF-12 Physical	CBT	39.81 (11.63)	39.23 (11.26)	39.17 (13.61)	38.89 (13.44)	1,73	10.27	.002	.07
	TAU	40.74 (11.54)	39.34 (12.98)	38.14 (11.59)	35.81 (10.72)				
SF-12 Mental	CBT	29.35 (9.57)	33.81 (11.02)	33.92 (11.03)	31.19 (9.12)	1,73	2.38	.1275	.33
	TAU	29.37 (9.05)	33.75 (10.93)	29.99 (11.44)	26.66 (10.01)				
Categorical Variables[†]									
Condition									
CAPS-Dx.	CBT	54 (100.0)	21 (67.7)	19 (63.3)	24 (72.7)	1	.23	.63	.27
	TAU	54 (100.0)	21 (77.8)	27 (77.1)	17 (85.0)				
CAPS-Dx. (>65) [‡]	CBT	39 (100.0)	17 (70.8)	15 (68.2)	18 (78.3)	1	5.19	.02	.40

Outcome	Condition	Base	Post	3 Month	6 Month	Group Effect		
Continuous Variables*						df	F	P ES
CAPS-Dx(<65) [‡]	TAU	39 (100.0)	18 (90.0)	24 (92.3)	15 (88.2)			
	CBT	15 (100.0)	4 (57.1)	4 (50.0)	6 (60.0)			
	TAU	15 (100.0)	3 (42.9)	3 (33.3)	2 (66.7)	1	.18	.67 .10

Abbreviations: CBT, Cognitive Behavioral Therapy; TAU, Treatment as Usual; BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; BPRS, Brief Psychiatric Rating Scale; CAPS, Clinician Administered PTSD Scale; PTCI, Posttraumatic Cognitions Inventory; SF-12, Short Form; WAI, Working Alliance Inventory

* Values are given as mean (SD). ES = effect size comparing change from baseline to last assessment in CBT with change in TAU

[§] Full model unestimable; tested includes baseline as covariate and treatment group as independent variable.

[‡] Values are given as number (%).

[‡] Full model unestimable; tested includes treatment group as independent variable.

Table 4

Mediation Analysis: PTSD Symptoms (CAPS-Total) as Outcome and Trauma-Related Beliefs (PTCI) as Mediator

Variables	<i>F</i>	<i>se</i>	<i>P</i>
For entire study period (baseline, post-treatment, 3-, and 6-month follow-ups)*			
1. Treatment effect on mediator (PTCI)	10.19	0.10	.002
2. Treatment effect on outcome (CAPS-Total) without mediator	6.23	2.23	.01
3. Treatment effect on outcome after adding mediator [†]	3.05	2.15	.08
Effect of mediator on outcome	41.75	1.21	<.001

Abbreviations: CAPS, Clinician Administered PTSD Scale; PTCI, Posttraumatic Cognitions Inventory.

* Treatment effect is measured by main group effect in mean response profile model including baseline as covariate.

[†] Mediator reduced treatment effect from 10.19 to 3.05, and treatment effect became non-significant.