ORIGINAL ARTICLE

A Randomized Controlled Trial of Cognitive Therapy, a Self-help Booklet, and Repeated Assessments as Early Interventions for Posttraumatic Stress Disorder

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Background: It is unclear what psychological help should be offered in the aftermath of traumatic events. Similarly, there is a lack of clarity about the best way of identifying people who are unlikely to recover from early posttraumatic symptoms without intervention.

Objective: To determine whether cognitive therapy or a self-help booklet given in the initial months after a traumatic event is more effective in preventing chronic posttraumatic stress disorder (PTSD) than repeated assessments.

Design: Randomized controlled trial.

Patients: Motor vehicle accident survivors (n=97) who had PTSD in the initial months after the accident and met symptom criteria that had predicted persistent PTSD in a large naturalistic prospective study of a comparable population.

Setting: Patients were recruited from attendees at local accident and emergency departments.

Interventions: Patients completed a 3-week self-monitoring phase. Those who did not recover with self-monitoring (n=85) were randomly assigned to receive cognitive therapy (n=28), a self-help booklet based on principles of cognitive behavioral therapy (n=28), or repeated assessments (n=29).

Main Outcome Measures: Symptoms of PTSD as assessed by self-report and independent assessors unaware of the patient's allocation. Main assessments were at 3 months (posttreatment, n=80) and 9 months (follow-up, n=79).

Results: Twelve percent (n=12) of patients recovered with self-monitoring. Cognitive therapy was more effective in reducing symptoms of PTSD, depression, anxiety, and disability than the self-help booklet or repeated assessments. At follow-up, fewer cognitive therapy patients (3 [11%]) had PTSD compared with those receiving the self-help booklet (17 [61%]; odds ratio, 12.9; 95% confidence interval, 3.1-53.1) or repeated assessments (16 [55%]; odds ratio, 10.3; 95% confidence interval, 2.5-41.7). There was no indication that the self-help booklet was superior to repeated assessments. On 2 measures, high end-state functioning at follow-up and request for treatment, the outcome for the self-help group was worse than for the repeated assessments group.

Conclusions: Cognitive therapy is an effective intervention for recent-onset PTSD. A self-help booklet was not effective. The combination of an elevated initial symptom score and failure to improve with self-monitoring was effective in identifying a group of patients with early PTSD symptoms who were unlikely to recover without intervention.

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IT IS UNCLEAR what type of psychological help should be offered in the aftermath of traumatic events such as assault, severe accidents, or disaster. Critical incident debriefing is frequently advocated. However, existing randomized controlled trials (RCTs) have reported that single-session individual debriefing does not reduce psychological distress in the short term or reduce the probability that an individual will develop chronic posttraumatic stress disorder (PTSD).[1] In addition, some trials have found that, although debriefed patients improved over time, they improved to a lesser extent than individuals who had not been debriefed.[2,3] Group debriefing, which is perhaps more common, has not been examined in RCTs, to our knowledge. The available data on the efficacy of cognitive behavioral therapy (CBT) are somewhat more encouraging. Several RCTs have found that CBT is superior to supportive counseling in preventing the development of chronic PTSD in patients with

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acute stress disorder.[4-6] However, none of these RCTs included an untreated control group, so it cannot be unambiguously concluded that CBT was effective. It is conceivable that supportive counseling leads to a smaller reduction in PTSD symptoms than natural recovery or repeated assessments (RA) alone, parallel to the findings for debriefing.[2,3] Indeed, a recent evaluation of early interventions for PTSD found that, although CBT was superior to supportive counseling, RA by a clinician was as effective as CBT.[7]

Therefore, it has not yet been demonstrated that early psychological treatments are superior to RA in the prevention of chronic PTSD. The present RCT compared the efficacy of a new version of CBT, cognitive therapy (CT) for PTSD as described by Ehlers and Clark,[8] with RA alone and with a self-help condition consisting of a single session with a clinician and a self-help booklet (SH).

The RCT focused on individuals who developed PTSD in the first 3 months after a motor vehicle accident (MVA) and were considered at risk for chronic PTSD. Epidemiological investigations have shown that MVAs are among the most common causes of PTSD in Western society.[9] A 2-fold strategy was used to select individuals in whom PTSD was likely to have a chronic course in the absence of effective treatment. First, a large-scale prospective investigation of MVA survivors in the local catchment area had identified early symptom criteria that predicted persistent PTSD,[10,11] and these criteria were used to select individuals for inclusion in the study. Second, before randomization, all patients entered a 3-week symptom-monitoring phase, and individuals who responded to this simple intervention were excluded from the trial. Tarrier et al[12] found that 11% of patients with chronic PTSD recovered with clinical assessment and self-monitoring alone.

METHODS

PATIENTS

Patients had been involved in an MVA that required attendance at the accident and emergency services of the John Radcliffe Hospital, Oxford, or the Northampton General Hospital, Northampton, England, between February 1, 1998, and January 31, 2001. To be accepted into the trial, patients had to meet the following criteria: 18 to 65 years old; meeting diagnostic criteria for PTSD as determined by the Structured Clinical Interview for the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*,[13] with PTSD being the main problem; scoring 20 or higher on the Posttraumatic Diagnostic Scale (PDS),[14] indicating moderate to severe symptom severity; and intervention starting within 6 months after the accident. A prospective investigation drawn from the same population had shown that people who met trial criteria at 3 months after the accident had a 71% chance of still having PTSD at 1 year after the accident (positive predictive power).[10,11] The negative predictive power of the cutoff score was 93%, and the overall efficiency was 90%.

Exclusion criteria were unconsciousness for more than 15 minutes after the accident or having no memory of the accident, history of psychosis, current alcohol or other substance dependence, borderline personality disorder, severe depression needing immediate treatment in its own right (suicide risk), and treatment or assessments that could not be conducted without the aid of an interpreter.

Accepted patients entered a 3-week self-monitoring phase before random allocation. Patients who scored below 14 on the PDS after the self-monitoring phase were excluded, as the prospective investigation indicated that they had only a 5% probability of having PTSD 1 year after the accident. The cutoff score is similar to the cutoff of 15 on the PDS recently recommended by Foa et al[15] as the minimum score for diagnosing PTSD.

PROCEDURE

Approximately 4 weeks after the accident, patients received an information leaflet describing symptoms of PTSD and indicating that help might be available. If interested, they sent in a reply form to request further information about the study. They also completed the PDS and answered a few questions about the accident. Patients who scored 14 or more on the PDS and did not report having been unconscious for more than 15 minutes after the accident were invited for an assessment.

Trained psychologists or research nurses conducted the Structured Clinical Interview for *DSM-IV*[13] for Axis I disorders and borderline personality disorder. A random sample of 40 interviews (by 8 interviewers) was coded by a second clinician (6 raters). Interrater reliabilities were good (PTSD diagnosis, $\kappa=0.95$; distress, $r=0.84$; and interference, $r=0.96$). If patients met the inclusion criteria and were interested in participating, they signed the informed consent form. **Figure 1** summarizes the patient flow. The 20 patients who did not enroll in the study were significantly younger than participants (mean, 29.8 vs 39.4 years; $P<.003$) but did not differ on any other measure.

The assessor explained the monitoring form for intrusions developed by Tarrier et al[12] and asked the patient to fill it in every day for 3 weeks. A telephone session a week later was used to discuss progress with the self-monitoring and to answer any questions. Twelve patients (12% of the 97 suitable participants) no longer met trial criteria after self-monitoring and did not enter the RCT.

The remaining 85 patients were randomly allocated to CT (n=28), SH (n=28), or RA (n=29). Randomization was stratified by sex and severity of PTSD symptoms using the random permuted blocks within strata algorithm.[16] Assessors who decided whether patients were suitable for inclusion in the study could not predict what treatment condition would be assigned to the patient, as (1) the allocation list was kept locked in a separate central office and the patient's allocation was only revealed 3 weeks later, following the self-monitoring assessment, and (2) the study was conducted at 2 sites. There were no group differences in demographics (eg, sex, age, education, profession, previous trauma, and comorbid depression); accident characteristics (eg, time since accident, injury severity, and severity of ongoing health problems); or initial symptom severity between the 3 groups (for details, see http://www.iop.kcl.ac.uk/IoP/Departments/Psycholo/staff/prEhlers.shtml).

Patients in all treatment conditions met with the assessor just before random allocation and 3 and 9 months afterward to discuss their current symptoms and the effect the trauma presently had on their lives. These sessions took about 45 minutes each. In addition, they completed self-report measures on several occasions as described herein. If patients were still suitable for the trial after the self-monitoring phase, they met with a clinician (other than the assessor) who informed them about their allocation and conducted the first session of their respective treatment condition. Patients in the SH and RA conditions were reminded that they would be offered CT 9 months later if they still needed help with their symptoms. They were also informed that

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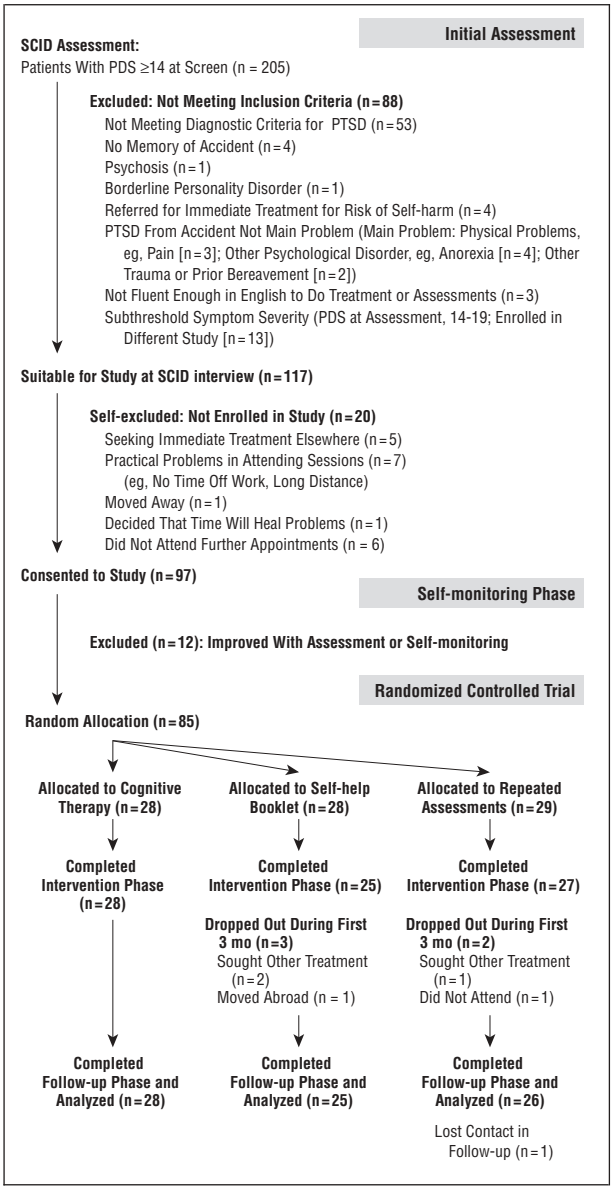

Figure 1. Overview of participant progress. PDS indicates Posttraumatic Diagnostic Scale[14]; PTSD, posttraumatic stress disorder; and SCID, Structured Clinical Interview for *DSM-IV*.[13]

they could contact the research group at any time if they believed that they could no longer wait for treatment.

TREATMENT CONDITIONS

Cognitive Therapy

Patients received up to 12 weekly sessions of CT[8,17] during 3 months and up to 3 monthly booster sessions. Session duration was approximately 90 minutes for the initial sessions and 60 minutes thereafter. Patients received a mean of 9.0 (range, 2-12) weekly sessions and 2.4 (range, 0-3) booster sessions. Each case was discussed in weekly group supervision meetings to ensure adherence to the treatment protocol.[17] The treatment is based on the model by Ehlers and Clark,[8] suggesting that PTSD becomes persistent when individuals process the trauma in a way that leads to a sense of serious current threat. The sense of threat arises as a consequence of (1) excessively negative appraisals of the trauma and/or its sequelae and (2) a disturbance of the autobiographical memory of the trauma, characterized by poor elaboration and contextualization, strong associative memory, and strong perceptual priming. Changes in negative appraisals and trauma memory are prevented by a series of problematic behavioral and cognitive strategies. Accordingly, the treatment aims to modify excessively negative appraisals, correct the autobiographical memory disturbance, and remove the problematic behavior and cognitive responses (for details, see http://www.iop.kcl.ac.uk/IoP/Departments/Psycholo/staff/prEhlers.shtml).

Self-help Booklet

Patients received a 64-page booklet (about 18 000 words) entitled *Understanding Your Reactions to Trauma*.[18] The booklet follows cognitive behavioral principles for the treatment of PTSD. Pilot testing showed that the booklet was rated as helpful by most (88%-95%) trauma survivors.[19] An additional 4-page sheet was inserted that was specifically written for the purposes of the study and focused on common avoidance behaviors and safety-seeking behaviors after MVAs. A clinician met with the patients for 40-minute sessions to explain the use of the booklet and to motivate them to follow the advice given in it. The session followed a standardized protocol.

Repeated Assessments

Patients were informed about the rationale and procedure for the RA in a 20-minute session with a trained clinician, who followed a standardized protocol. Clinicians explained that symptoms may decline without intervention, that some people may not need specialist intervention, and that for those who needed treatment it was unknown whether immediate or delayed treatment was more effective. They reiterated that patients would be regularly monitored and explained the timing and nature of the future assessments.

OUTCOME MEASURES

The main outcome measure was change in the severity of PTSD symptoms. In addition, we assessed changes in anxiety and depression as measures of associated symptoms and changes in the disability caused by the PTSD symptoms.

Severity of PTSD Symptoms

Self-Report. Patients completed the PDS,[14,20,21] which asks patients to rate how much they were bothered by each of the PTSD symptoms specified in *DSM-IV*, ranging from 0 ("never") to 3 ("5 times per week or more or almost always"). In addition, patients were asked to indicate how distressing they found each of the PDS symptoms on a scale from 0 ("not at all") to 3 ("very distressing"), yielding an additional score for the patients' distress associated with their PTSD symptoms (parallel to the clinician-rated symptom scales).[22,23]

Clinician-Rated Symptoms. Independent assessors (trained clinical psychologists or research nurses) who were not aware of the treatment condition gave the Clinician-Administered PTSD Scale (CAPS-SX) interview.[24] A random sample of 38 CAPS interviews (8 different interviewers) was rated by a second clinician (7 different raters). Results indicated good reliability for the PTSD diagnosis ($\kappa = 0.94$) and total severity score ($r = 0.96$).

Associated Symptoms

Symptoms of anxiety and depression were assessed with the Beck Anxiety Inventory[25] and the Beck Depression Inventory.[26]

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Disability

Self-report. Patients completed the Sheehan Disability Scale.[27] Patients rated the interference caused by the PTSD symptoms in their (1) work, (2) social life or leisure activities, and (3) family life or home responsibilities on 3 scales from 0 ("not at all") to 10 ("very severe"). The disability score was the mean of these ratings.

Assessor. The overall CAPS[24] severity rating (item 24), ranging from 0 ("no clinically significant symptoms, no distress, or no functional impairment") to 4 ("extreme, marked distress, or marked impairment in 2 or more areas of functioning") was used as a global measure of clinician-rated disability.

Measures of Treatment Response

Several dichotomous measures of treatment response were calculated for comparability with previous studies.

Percentage of Patients With PTSD. Patients were considered to meet *DSM-IV* criteria for PTSD on the PDS or CAPS if they reported the minimum number of symptoms in each symptom cluster with a score of at least 1 (for frequency and for distress or intensity). In addition, on the PDS they had to report interference with at least 2 areas of their lives or general interference in all areas of their lives and have a total score of at least 14,[14,15] or on the CAPS they had to have a global severity rating of 2 or greater.

Treatment Responder. Following the guidelines of Foa and Meadows,[28] patients were classified as treatment responders if they showed a reduction in PTSD symptom severity of 50% or greater on the PDS.

High End-State Functioning. High end-state functioning was defined as a PDS score below 14, a CAPS global severity rating below 2, and Beck Depression Inventory and Beck Anxiety Inventory scores below 12.[29]

Treatment Credibility

Patients in the CT and SH conditions completed a self-report measure of treatment credibility[30] after the rationale for the intervention had been explained. The credibility scale asks patients to rate how logical they consider the treatment, how certain they are that the intervention will be successful in treating their symptoms, and with what degree of confidence they would recommend the intervention to a friend with the same problem, each on a scale from 0 ("not at all") to 10 ("completely").

TIMING OF ASSESSMENTS

To assess the effects of self-monitoring, patients completed the self-report measures at the initial assessment (before self-monitoring) and 3 weeks later (at random allocation). To assess the effects of CT, SH, and RA, independent assessors conducted the CAPS[24] interviews at random allocation (ie, immediately before the first session) and at 3 months (end of the weekly sessions for CT) and at 9 months (6-month follow-up for CT, equivalent to the assessment 1 year after the accident in the naturalistic prospective follow-up investigation[10,11]). Self-report measures were also obtained at these time points. Additional self-report assessments took place 3 weeks after random allocation (ie, after 3 sessions of CT) and at 6 months.

DATA ANALYSIS

The data analysis followed a hierarchical approach. To test whether the treatment conditions led to differential outcome, we performed multivariate analyses of covariance for each of the 3 sets of continuous outcome measures (PTSD symptoms, associated symptoms, and disability), using scores at randomization (ie, immediately before the first session of CT, SH, or RA) as covariates. Reported multivariate F values are based on Pillais coefficients. If multivariate effects of condition were significant, we conducted multivariate comparisons between pairs of conditions. If these were significant, univariate analyses followed. As the most conservative estimate of the efficacy of CT, we report a completer analysis for the continuous outcome measures, comparing the full sample of patients allocated to CT (as there were no dropouts) with the completers in the SH and RA conditions.

Changes in symptoms with time were assessed with multivariate repeated measures analyses of variance. Dichotomous criteria of treatment response at 3 months and 9 months in the 3 conditions were compared by means of χ^2 tests. Both completer and intent-to-treat data are reported.

Treatment effect sizes for changes in PTSD symptom scores were calculated using Cohen *d* statistic.[31] Meta-analyses differ in whether the effect sizes are calculated as

$$(1)\ d = M_{initial} - M_{post}/SD_{pooled},$$

$$\text{with } SD_{pooled} = \sqrt{(SD^2_{initial} + SD^2\ p_o st)/2},$$

where M is mean,[32] or as

$$(2)\ d = M_{initial} - M_{post}/SD_{initial}.^{33}$$

We therefore report both indexes. Controlled effect sizes are the differences between the mean 3-month PTSD symptom scores for CT vs RA and SH vs RA, divided by the pooled SD of the 2 conditions compared.[34]

To assess whether time since the accident (at random allocation) or response to self-monitoring (change in PDS scores) affected outcome, these variables were correlated with residual gain scores (residuals of regression of scores at random allocation on 3-month scores) for each treatment condition. These were calculated from a standardized composite of the 4 measures of PTSD symptoms (scores standardized by the mean scores before and after intervention).[35]

RESULTS

CHANGES ASSOCIATED WITH INITIAL ASSESSMENT AND SELF-MONITORING

The mean (SD) decrease in PDS scores with 3 weeks of self-monitoring was 5.2 (7.2), representing a moderate effect size, $d=0.62$ (pooled SD) and $d=0.71$ (SD at initial assessment). All symptom measures showed significant improvement (all $P<.001$). As expected from random allocation, there was no indication of differential responses to initial assessment/self-monitoring for patients who would be allocated to the different treatment conditions (all $P>.32$) (**Table 1**).

TREATMENT CREDIBILITY

There were no differences between CT and SH conditions in credibility. Both groups rated their intervention as highly logical (mean, 8.4 and 8.2, respectively), were moderately confident that it would be helpful (mean, 6.7

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Table 1. Main Outcome Measures for Completers*

Measure	Cognitive Therapy (n = 28 [100%])				Self-help Booklet (n = 25 [89%])				Repeated Assessments (n = 27 [93%])			
	Initial Assessment	After Self-monitoring	3 mo	9 mo	Initial Assessment	After Self-monitoring	3 mo	9 mo	Initial Assessment	After Self-monitoring	3 mo	9 mo†
PTSD symptoms												
PDS self-report, frequency	30.2 (7.9)	26.2 (7.4)	8.3 (9.8)	8.7 (8.1)	30.9 (7.5)	27.9 (7.1)	19.9 (7.8)	20.0 (7.8)	31.1 (7.5)	27.0 (9.1)	22.6 (11.6)	19.4 (12.5)
PDS self-report, distress	31.6 (9.1)	25.8 (9.2)	7.1 (10.3)	7.3 (8.6)	32.0 (7.2)	27.3 (6.3)	20.3 (8.2)	19.0 (8.8)	31.4 (8.4)	26.2 (10.4)	22.3 (12.2)	20.0 (14.1)
CAPS assessor, frequency	NA	31.7 (9.5)	11.2 (10.3)	10.2 (9.9)	NA	32.6 (8.6)	22.9 (12.9)	21.4 (11.4)	NA	32.8 (11.5)	25.6 (12.9)	21.1 (15.2)
CAPS assessor, intensity	NA	26.7 (7.4)	10.2 (9.4)	9.7 (9.5)	NA	26.7 (7.4)	19.6 (9.0)	18.6 (10.1)	NA	25.9 (10.4)	22.4 (11.9)	17.0 (13.8)
Associated symptoms												
BAI	21.6 (7.9)	19.1 (7.6)	6.0 (5.8)	5.8 (4.9)	22.2 (9.9)	18.3 (9.1)	14.2 (8.9)	14.0 (8.6)	24.4 (7.4)	19.4 (8.3)	15.7 (10.4)	12.6 (8.6)
BDI	18.8 (6.7)	18.1 (5.6)	7.3 (6.3)	6.5 (7.0)	22.9 (9.2)	19.5 (8.9)	16.1 (6.6)	15.2 (6.9)	22.7 (8.9)	19.6 (10.6)	17.1 (9.6)	12.0 (10.0)
Disability												
Self-report	5.9 (2.4)	5.1 (2.4)	2.3 (2.8)	1.8 (2.5)	6.3 (2.0)	5.3 (2.0)	4.3 (2.5)	3.7 (2.2)	6.1 (1.9)	4.8 (1.8)	4.2 (1.9)	3.2 (2.7)
CAPS	NA	2.2 (0.8)	1.1 (0.8)	1.0 (0.8)	NA	2.1 (0.4)	1.8 (0.7)	1.7 (0.7)	NA	2.1 (0.5)	1.8 (0.7)	1.5 (0.9)

Abbreviations: BAI, Beck Anxiety Inventory[15]; BDI, Beck Depression Inventory[26]; CAPS, Clinician-Administered PTSD Scale[24]; NA, not applicable; PDS, Posttraumatic Diagnostic Scale[14] (frequency, original scale; distress, additional distress rating for each symptom); PTSD, posttraumatic stress disorder.
*Data are given as mean (SD).
†n = 26.

Table 2. Results of Analyses of Covariance for Main Outcome Measures*

Measure	Overall Comparison of the 3 Conditions	CT vs SH	CT vs RA	SH vs RA
PTSD symptoms at 3 mo, multivariate	**<.001**	**<.001**	**<.001**	**>.40**
PDS, frequency	<.001	<.001	<.001	
PDS, distress	<.001	<.001	<.001	
CAPS, frequency	<.001	<.001	<.001	
CAPS, intensity	<.001	<.001	<.001	
PTSD symptoms at 9 mo, multivariate	**<.001**	**<.001**	**<.001**	**>.48**
PDS, frequency	<.001	<.001	<.001	
PDS, distress	<.001	<.001	<.001	
CAPS, frequency	<.001	<.001	.001	
CAPS, intensity	.002	.001	.004	
Associated symptoms at 3 mo, multivariate	**<.001**	**<.001**	**<.001**	**>.90**
BAI	<.001	<.001	<.001	
BDI	<.001	<.001	<.001	
Associated symptoms at 9 mo, multivariate	**<.001**	**<.001**	**.002**	**>.28**
BAI	<.001	<.001	.001	
BDI	<.001	<.001	.02	
Disability at 3 mo, multivariate	**<.001**	**<.001**	**<.001**	**>.86**
Self-report	<.001	.001	<.001	
CAPS	<.001	<.001	<.001	
Disability at 9 mo, multivariate	**.007**	**.001**	**.01**	**>.85**
Self-report	.003	.001	.007	
CAPS	.001	<.001	.005	

Abbreviations: BAI, Beck Anxiety Inventory[15]; BDI, Beck Depression Inventory[26]; CAPS, Clinician-Administered PTSD Scale[24]; CT, cognitive therapy; PDS, Posttraumatic Diagnostic Scale[14] (frequency, original scale; distress, additional distress rating for each symptom); PTSD, posttraumatic stress disorder; RA, repeated assessments; SH, self-help booklet.
*Data are given as univariate *P* values unless otherwise indicated. Boldface indicate multivariate values.

and 6.8), and were confident about recommending it to a friend (mean, 7.9 and 7.7).

EFFECTS OF CT, SH, AND RA

Changes in Symptoms and Disability

Table 1 shows symptom changes over time for the 3 conditions, and **Table 2** presents the results of the multivariate analyses of covariance. **Figure 2** illustrates changes in the PDS score, the main outcome measure that was included in all assessments. The multivariate analyses of covariance for each set of measures indicated differential outcome for the 3 conditions [at 3 months: PTSD symptoms, $F(8,142)=5.072$, $P<.001$; associated symptoms, $F(4,150)=7.333$, $P<.001$; disability, $F(4,150)=6.269$, $P<.001$; at 9 months: PTSD symptoms, $F(8,140)=4.473$, $P<.001$; associated symptoms, $F(4,148)=5.591$, $P<.001$; disability, $F(4,148)=3.670$, $P<.001$].

On all measures, the CT group showed better outcome than RA at posttreatment and follow-up [at

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3 months: PTSD symptoms, $F(4,46)=9.474$, $P<.001$; associated symptoms, $F(2,50)=13.136$, $P<.001$; disability, $F(2,50)=13.054$, $P<.001$; at 9 months: PTSD symptoms, $F(2,45)=7.602$, $P<.001$; associated symptoms, $F(2,49)=6.897$, $P=.002$; disability, $F(2,49)=4.840$, $P=.01$].

On all measures, the CT group also showed better outcome than SH at posttreatment and follow-up [at 3 months: PTSD symptoms, $F(4,44)=8.044$, $P<.001$; associated symptoms, $F(2,48)=14.189$, $P<.001$; disability, $F(2,48)=9.042$, $P<.001$; at 9 months: PTSD symptoms, $F(4,44)=7.674$, $P<.001$; associated symptoms, $F(2,48)=12.509$, $P<.001$; disability, $F(2,48)=7.887$, $P=.001$]. RA and SH did not differ at either time point, with all F tests being far from significant.

Multivariate repeated measures analyses of variance showed significant changes between random allocation and the 3-month assessment on all measures for the CT condition (all $P<.001$) and all measures except for depression for SH (all $P<.05$). For RA, the changes in PTSD symptoms ($P<.06$) and associated symptoms ($P=.09$) failed to reach significance in the multivariate tests, although the univariate tests for both PDS scales, the CAPS frequency scale, and the Beck Anxiety Inventory demonstrated significant differences (all $P<.05$). Changes between random allocation and the 9-month assessment were significant on all continuous measures for CT (all $P<.001$), SH (all $P<.05$), and RA (all $P<.01$).

Treatment Responders

Table 3 presents the results for dichotomous measures of treatment response. At 3 and 9 months, fewer patients in the CT condition had PTSD than in the SH and RA conditions. There were no significant differences between the SH and RA groups. The results for completer and intent-to-treat analyses were identical. The odd ratios for intent-to-treat CAPS diagnoses for CT vs SH were 13.4 (95% confidence interval, 3.8-48.2) at 3 months and 12.9 (95% confidence interval, 3.1-53.1) at 9 months. For CT vs RA, the values were 9.6 (95% confidence interval, 2.9-32.5) at 3 months and 10.3 (95% confidence interval, 2.5-41.7) at 9 months.

The same pattern of results was found for the number of responders. For high end-state functioning, CT was superior to SH and RA at 3 and 9 months. The SH and RA groups did not differ at 3 months, but fewer SH patients had reached high end-state functioning at 9 months than RA patients. Similarly, more SH than RA patients requested treatment at 9 months.

Effect Sizes

Table 4 shows the effect sizes on PTSD symptoms for the treatment conditions. The comparison of initial assessment and 3-month assessments on the PDS is most relevant, as these are the time points that are comparable to recent meta-analyses of PTSD treatment[32,34] and other investigations of treatment efficacy in PTSD. The effect sizes for CT were very large. The SH and RA conditions also led to a large improvement (Cohen[31] classifies effect sizes of $d\geq0.80$ as large). In addition, we report the effect sizes for changes in PDS and CAPS scores from random allocation to the 3 months' assessment. These underestimate the true effect sizes, as effects of initial assessments and self-monitoring that are usually part of CBT treatments are removed.

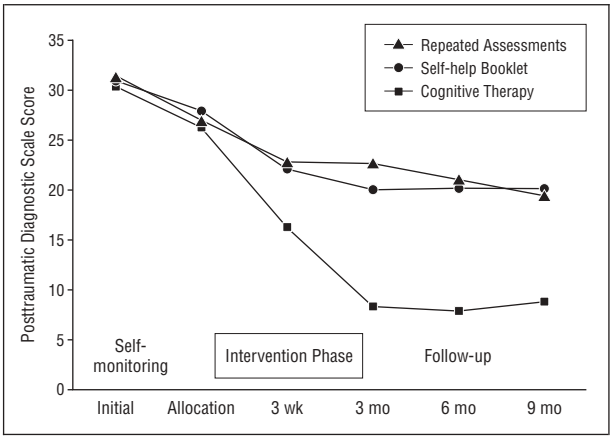

Figure 2. Changes in posttraumatic stress disorder (PTSD) symptoms across assessment points as measured by the Posttraumatic Diagnostic Scale.[14]

The controlled effect sizes comparing CT with RA were large, $d=1.34$ for the PDS and $d=1.24$ for the CAPS at 3 months, and $d=1.01$ for the PDS and $d=0.74$ for the CAPS at 9 months. The controlled effect sizes for comparisons between SH and RA were small ($d=0.27$ for the PDS and $d=0.24$ for the CAPS at 3 months, and near zero for both measures at 9 months).

Additional Analyses

Neither time since the accident nor the degree of change in PTSD severity (PDS score) with self-monitoring predicted outcome in any of the conditions. There were no site effects (Oxford vs Northampton) or interactions with site for any of the measures.

COMMENT

The study demonstrated that CT for PTSD[8] is an effective treatment in the initial months after a traumatic event. In line with previous epidemiological and naturalistic follow-up studies,[36,37] all conditions were associated with improvement in symptoms of PTSD, depression, anxiety, and disability during the 9 months of the study. The greatest improvement, however, occurred in the CT group. On all measures, CT was superior to SH and RA at posttreatment (3 months) and at follow-up (9 months). The superiority of CT over SH was not related to differences in the extent to which patients considered the interventions to be credible, as both interventions received high and equivalent credibility ratings. Outcome for patients who had received CT was also much better than for comparable participants of a naturalistic prospective study,[10,11] with 11% (3/28) as opposed to 71% (65/91) still having PTSD at follow-up (approximately 1 year after the accident). The large effect size for CT of $d=2.46$ for pre-

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Table 3. Dichotomous Measures of Treatment Response*

Measure	CT	SH		RA		Statistics for Completer Analysis			
	Intent to Treat and Completer (n = 28)	Intent to Treat (n = 28)	Completer Only (n = 25)	Intent to Treat (n = 29)	Completer Only (n = 27)	χ^2 Test Comparing 3 Conditions	*P* Value		
							CT vs SH	CT vs RA	SH vs RA
PTSD diagnosis at 3 mo									
PDS, self-report	14.3	78.6	76.0	72.4	70.4	$\chi^2_{2,80} = 25.39$, $P<.001$	<.001	<.001	>.64
CAPS, assessor	21.4	78.6	76.0	72.4	70.4	$\chi^2_{2,80} = 19.78$, $P<.001$	<.001	<.001	>.64
PTSD diagnosis at 9 mo									
PDS, self-report	14.3	75.0	72.0	55.2	53.8†	$\chi^2_{2,79} = 18.81$, $P<.001$	<.001	.002	>.17
CAPS, assessor	10.7	60.7	56.0	55.2	53.8†	$\chi^2_{2,79} = 14.83$, $P<.001$	<.001	.001	>.87
Treatment responders									
At 3 mo	82.1	25.0	28.0	20.7	22.2	$\chi^2_{2,80} = 24.19$, $P<.001$	<.001	<.001	>.63
At 9 mo	89.3	25.0	28.0	41.4	42.3†	$\chi^2_{2,79} = 22.30$, $P<.001$	<.001	<.005	>.29
High end-state functioning									
At 3 mo	67.9	7.1	8.0	10.3	11.1	$\chi^2_{2,80} = 29.46$, $P<.001$	<.001	<.001	>.70
At 9 mo	75.0	3.6	4.0	27.6	23.1†	$\chi^2_{2,79} = 31.69$, $P<.001$	<.001	<.001	.048
Requested further treatment at 9 mo or earlier	0	84.6		60.7		NA	NA	NA	$\chi^2_{1,52} = 3.87$, $P = .049$

Abbreviations: CAPS, Clinician-Administered PTSD Scale[24]; CT, cognitive therapy; NA, not applicable; PDS, Posttraumatic Diagnostic Scale[14]; PTSD, posttraumatic stress disorder; RA, repeated assessments; SH, self-help booklet.

*Data are given as percentages of patients unless otherwise indicated.

†n = 26. One patient was rated as a responder in the intent-to-treat analysis because of good outcome at 3 months.

Table 4. Preintervention vs Postintervention Effect Sizes for Posttraumatic Stress Symptoms

Intervention	Based on Pooled SDs		Based on Pretreatment SDs	
	3 mo	9 mo	3 mo	9 mo
Cognitive therapy				
PDS, initial assessment	2.46	2.69	2.77	2.72
PDS, after self-monitoring	2.06	2.26	2.42	2.36
CAPS, after self-monitoring	2.07	2.17	2.28	2.37
Self-help booklet				
PDS, initial assessment	1.44	1.42	1.47	1.45
PDS, after self-monitoring	1.08	1.06	1.13	1.11
CAPS, after self-monitoring	0.92	1.03	1.11	1.28
Repeated assessments				
PDS, initial assessment	0.70	1.14	1.13	1.56
PDS, after self-monitoring	0.42	0.70	0.48	0.84
CAPS, after self-monitoring	0.47	0.84	0.52	1.00

Abbreviations: CAPS, Clinician-Administered PTSD Scale[24]; PDS, Posttraumatic Diagnostic Scale[14]; PTSD, posttraumatic stress disorder.

treatment to posttreatment changes in our intent-to-treat analysis compares favorably with the mean effect size of $d=1.27$ for treatment completers of CBT for PTSD reported in a recent meta-analysis.[32] The controlled effect sizes of $d=1.34$ for the PDS and $d=1.24$ for the CAPS also compare favorably with the mean of $d=0.52$ reported for completer analyses of psychotherapeutic treatments in another meta-analysis.[34] The treatment has shown similarly high efficacy in patients with long-standing PTSD following a range of traumas.[38] The present findings are in line with the positive results for CBT in patients with PTSD of at least 6 months' duration following an MVA.[39]

The study demonstrated the feasibility of a 2-stage strategy for identifying traumatized people who are unlikely to recover on their own. A cutoff for the severity of PTSD symptoms at initial assessment identified people at risk for chronic symptoms, based on a previous prospective investigation.[10,11] Second, people who responded to the initial clinical assessment and 3 weeks of self-monitoring of symptoms were excluded before random allocation. At 1 year after the accident, patients in the RA and SH conditions had PTSD rates of 55% (16/29) and 61% (17/28), respectively. This is considerably higher than the general risk of 16.5% (129/781) established in the previous prospective investigation.[10,11]

Twelve percent (n=12) of the patients improved with assessment and self-monitoring alone, replicating the findings of Tarrier et al.[12] This result is potentially of practical relevance as it may help in identifying patients who do not need specialist treatment. It remains unclear whether the improvement was because of the effects of the initial clinical assessment, or because of natural recovery. A controlled trial would be necessary to answer this question.

The available information on the patients who scored below the symptom severity cutoff or who improved with

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assessment/self-monitoring suggested that, as expected, these patients had a good long-term outcome, comparable to findings in the previous naturalistic follow-up investigation.[10,11] Therefore, it appeared justified to withhold treatment from these patients.

Contrary to our expectations, an SH designed to normalize posttraumatic symptoms and to promote self-exposure to memories and reminders of the event did not lead to a better outcome than RA. The outcome for SH was not better than that observed for untreated patients in a large-scale naturalistic follow-up investigation[10,11] or for patients receiving RA in the present randomized controlled trial. Furthermore, 2 measures indicated worse outcome for SH than for RA at 9 months. The latter findings resemble those of 2 RCTs that found adverse long-term effects for psychological debriefing, which has elements in common with the self-help advice given in this study.[2,3] This suggests that use of the booklet should be considered with caution if no follow-up by a clinician is offered.

Among the strengths of the present study was the low number of dropouts. There are several possible reasons for this. First, time-consuming efforts were taken to ensure completeness of data. Second, patients may find CT acceptable as it requires little imaginal reliving[40] of the trauma. Similarly low dropout rates associated with the CT approach were found in another study[38] of patients with long-standing PTSD. One may argue that the low dropout rates may be a reflection of the particular way in which health services are organized in the United Kingdom. We do not think that this is the case, as other UK trials using different versions of CBT have found dropout rates similar to those of US or Australian studies.[41,42]

The study had several limitations. First, although our aim was to recruit patients in the second month after trauma and to start intervention at 3 months, a few patients did not attend their initial appointments, making rescheduling necessary. This had the effect that interventions started on average at 4 months after the accident. This limits the comparability of the data with those of other studies[4-7,43] that started interventions in the first month after trauma. On the other hand, there was no relationship between time since the accident and outcome for any of the treatment conditions in the present study or in other studies.[38,44] Furthermore, the data would have been systematically biased if we had excluded people who found it difficult to attend initial appointments, as they might have been more avoidant or more ambivalent about engaging in treatment. Their inclusion underscores the generalizability of the findings. Nevertheless, the intervention started at a time point at which patients would technically just have qualified for a diagnosis of chronic PTSD. However, as about half of the MVA survivors with PTSD at 3 months recover by a year after the event,[10,45] it is misleading to consider patients as having reached a steady state of chronic PTSD at this time point. Indeed, many of the recent trials of chronic PTSD require a minimum symptom duration of 6 months to minimize the chance of natural recovery in the untreated control groups.[38,39,41,42]

Second, the study focused on PTSD after MVA, and it remains to be tested whether the results generalize to survivors of other traumatic events. Other studies[4-6,38] have not reported differential response rates to CBT for MVA or assault survivors. Third, although the study showed that people at high risk of chronic symptoms benefit from CT, not all patients will want to commit themselves to several sessions of treatment soon after the trauma. Future research will need to investigate ways of increasing patient motivation, such as different methods of introducing patients to early interventions.

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