

## ORIGINAL ARTICLE

# A Trial of Neuropsychologic Rehabilitation in Mild-Spectrum Traumatic Brain Injury

Lana A. Tiersky, PhD, Vera Anselmi, PhD, Mark V. Johnston, PhD, Jonathan Kurtyka, MA, Emily Roosen, MEd, Thomas Schwartz, MA, John DeLuca, PhD

**ABSTRACT.** Tiersky LA, Anselmi V, Johnston MV, Kurtyka J, Roosen E, Schwartz T, DeLuca J. A trial of neuropsychologic rehabilitation in mild-spectrum traumatic brain injury. *Arch Phys Med Rehabil* 2005;86:1565-74.

**Objective:** To test the effectiveness of a neuropsychologic rehabilitation program consisting of psychotherapy and cognitive remediation in the treatment of the affective and neuropsychologic sequelae of mild-spectrum traumatic brain injury (TBI).

**Design:** Single-blind randomized, wait-listed controlled trial, with repeated measures and multiple baselines.

**Setting:** Outpatient clinic in northern New Jersey.

**Participants:** Twenty persons with persisting complaints after mild and moderate TBI (11 in treatment group, 9 controls).

**Interventions:** The experimental group received both 50 minutes of individual cognitive-behavioral psychotherapy and 50 minutes of individual cognitive remediation, 3 times a week for 11 weeks. The control group was wait-listed and received treatment after conclusion of follow-up.

**Main Outcome Measures:** Symptom Check List-90R General Symptom Index, plus scales of depression, anxiety, coping, attention, and neuropsychologic functioning.

**Results:** Compared with the control group, the treatment group showed significantly improved emotional functioning, including lessened anxiety and depression. Most significant improvements in emotional distress were noted at 1 month and 3 months posttreatment. Performance on a measure of divided auditory attention also improved, but no changes were noted in community integration scores.

**Conclusions:** Cognitive behavioral psychotherapy and cognitive remediation appear to diminish psychologic distress and improve cognitive functioning among community-living persons with mild and moderate TBI.

**Key Words:** Brain injuries; Neuropsychology; Psychotherapy; Rehabilitation.

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**M**ILD AND MODERATE BRAIN injuries are a significant health problem in the United States. Each year approximately 2 million people in the United States sustain traumatic brain injuries (TBIs).<sup>1</sup> Of these, approximately 75% to 95% are classified as mild or moderate.<sup>1</sup> Although the majority of people who sustain a mild TBI resume normal functioning fairly quickly, a considerable subset, approximately 5% to 15%, report persistent cognitive, emotional, and somatic symptoms lasting well beyond the initial 3-month "acute" phase (for a review, see Raskin and Mateer<sup>2</sup>). In fact, self-reported symptoms can continue for years postinjury and often seem out of proportion to the severity of the primary trauma (for reviews, see Binder<sup>3</sup> and van der Naalt<sup>4</sup>).

The symptom cluster after mild TBI is diagnosed as postconcussion syndrome (PCS) and is characterized by persisting affective, somatic, cognitive, and sensory symptoms.<sup>5-7</sup> The sequelae of moderate brain injury can also be long-lasting. Survivors of moderate brain injury show symptoms similar to those who sustained a more mild injury, with the exception that the difficulties are noted to be more frequent and severe.<sup>8,9</sup>

Although objective cognitive function has been found to largely improve after a 1-month period in subjects with mild TBI,<sup>10</sup> persisting objective neuropsychologic deficits have been noted in some studies. Most consistently, impairments have been found in attention and concentration, information processing speed, and memory in both mild TBI<sup>11-15</sup> and in moderate TBI.<sup>16-19</sup>

The persisting emotional and cognitive symptoms after mild and moderate TBI can be so disabling for some patients that daily living becomes a challenge.<sup>20,21</sup> Studies have documented a variety of psychiatric disorders in persons who sustain mild and moderate brain injuries.<sup>22</sup> Depression, anxiety, and somatization are common after mild and moderate TBI.<sup>3,16,23-26</sup> Posttraumatic stress disorder also appears to be a consequence of brain injury.<sup>27-29</sup> Emotional disturbances have been found to reduce quality of life in that they are related to chronic social difficulties<sup>30</sup> and possibly even chronic pain<sup>31</sup> in persons with mild head injury. Chronic self-reported anger and impulsivity, mistrust, and poor self-monitoring can reduce life quality in people with moderate TBI who have poor emotional adjustment. Moreover, chronic cognitive impairment has been found to be related to employment difficulties in both mild and moderate TBI.<sup>32</sup> Thus, although psychiatric status appears to play the largest part, both cognitive deficits and emotional distress contribute to the disability sustained by survivors of mild and moderate TBI.<sup>3</sup>

Because emotional and cognitive factors contribute to functional impairment after mild and moderate TBI, effective treatment should address both factors. Early interventions that focus on symptom education and management have been effective in reducing PCS symptoms.<sup>33</sup> Other useful early interventions focus on helping people manage and change dysfunctional thought patterns that lead to prolonged symptoms.<sup>34</sup> In general, brief early interventions that address the patient's psychologic and cognitive needs have been useful in preventing protracted

From the School of Psychology, Fairleigh Dickinson University, Teaneck, NJ (Tiersky, Kurtyka, Roosen, Schwartz); Departments of Physical Medicine and Rehabilitation (Tiersky, Johnston, DeLuca) and Neurosciences (DeLuca), UMDNJ-New Jersey Medical School, Newark, NJ; and Kessler Medical Rehabilitation Research and Education Corp, West Orange, NJ (Anselmi, Johnston, DeLuca).

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Reprint requests to Lana Tiersky, PhD, Sch of Psychology, Fairleigh Dickinson University, Williams Hall (T-WH1-01), 1000 River Rd, Teaneck, NJ 07666, e-mail: tiersky@fd.edu.

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postconcussive disorders (for a review see Mittenberg et al<sup>35,36,37</sup>).

For those patients who develop prolonged symptoms after mild or moderate TBI, other types of treatment are necessary. Neuropsychologic rehabilitation programs that address subjective symptoms, emotional distress, objective neuropsychologic deficits, and general functional disability after mild TBI have been used for at least 15 years. Based on programs designed for more severe injuries,<sup>38-40</sup> many of these programs integrate cognitive remediation techniques with psychotherapeutic treatment to help people better adapt to life postinjury.<sup>41</sup>

Despite their common use, only a handful of studies have explored the efficacy of neuropsychologic rehabilitation programs in the treatment of the sequelae of mild and moderate brain injuries (for a review, see Cicerone et al<sup>42</sup>). These studies suffer from methodologic limitations. Some lack adequate controls to assess efficacy properly.<sup>43,44</sup> Other topical studies<sup>45,46</sup> have been limited because they use incompletely defined and inconsistently applied intervention procedures.

For instance, Cicerone et al<sup>45</sup> tested the efficacy of a neuropsychologic rehabilitation program comprised of education, psychotherapy, and cognitive remediation in 20 patients with persistent PCS symptoms. Cicerone reported variable outcomes. However, limited information is available on the consistency with which treatment was applied across subjects. In fact, it is noted that subjects received "various components of a rehabilitation program."<sup>45(p279)</sup> Ho and Bennett<sup>46</sup> found support for the effectiveness of neuropsychologic rehabilitation, but they describe a rehabilitation program that is "individualized" and does not appear to be consistently applied across subjects. Ferguson and Mittenberg<sup>47</sup> and Miller and Mittenberg<sup>48</sup> describe a cognitive-behavioral outpatient treatment of PCS using a structured therapist's manual. Their approach aims to help patients understand how symptoms are maintained by anxiety related to the catastrophic misinterpretation of symptoms. Although their studies provide a more structured and reliable approach to treatment, only 4 case studies are available to suggest the intervention is effective.

## Objectives and Hypotheses

The primary objective of our investigation was to test the efficacy of a comprehensive outpatient neuropsychologic rehabilitation program in the treatment of persistent neuropsychologic dysfunction, emotional distress, and accompanying functional disability after mild and moderate TBI. The program was comprised of individual cognitive-behavioral psychotherapy (CBT) and individual cognitive remediation. By including a well-defined client population, using a randomized no-treatment control group, and using a clearly defined treatment protocol, many of the methodologic limitations of previous studies were addressed.

We hypothesized that subjects in the neuropsychologic rehabilitation program would experience greater improvements than subjects in the no-treatment control group on measures of psychologic well-being and subjective and objective neuropsychologic functioning at the end of treatment and at subsequent 1- and 3-month follow-up. The main hypothesis was that subjects in the treatment group would show a significantly greater reduction in overall emotional distress than those in the control group. We also hypothesized that, after treatment, participants would report less anxiety and depression and would perform better on a test of divided auditory attention skills. Outcomes in terms of community participation and other psychologic and neuropsychologic measures were also examined.

## METHODS

This clinical trial used a randomized, individual baseline design by using repeated measures with 2 groups.<sup>49</sup> The experimental group received both individual CBT and individual cognitive remediation. The no-treatment control group was wait-listed for treatment.

### Participants

The final study sample consisted of 20 subjects (9 in the control group, 11 in the treatment group), ranging from 19 to 62 years of age.

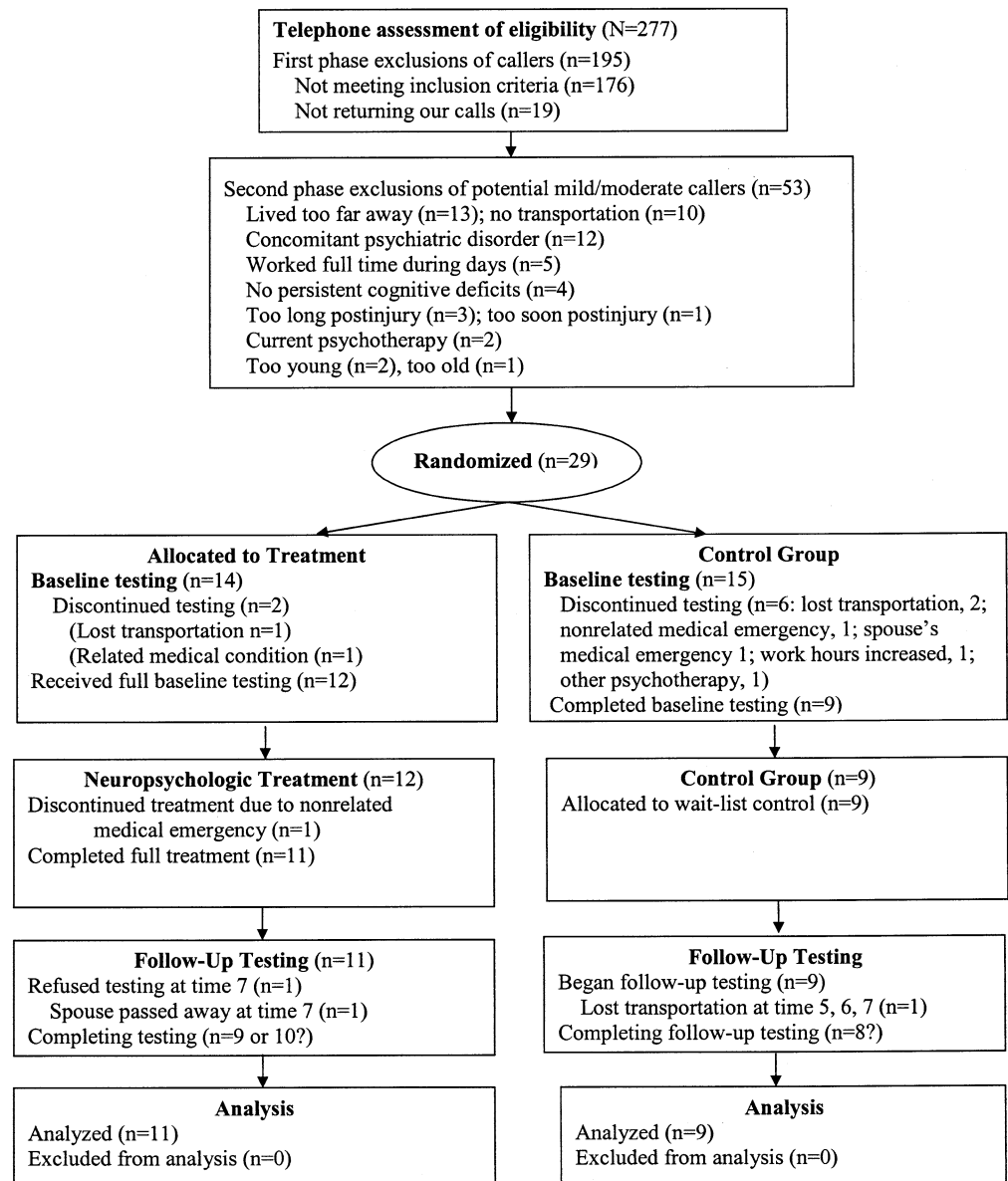
**Criteria.** Participants' head injury severity was categorized as "mild" or "moderate" based on the following inclusion criteria. Subjects with mild TBI met the definition proposed by the Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine (ACRM).<sup>50</sup> Those with moderate TBI must have had a Glasgow Coma Scale (GCS) score between 9 and 12 at the time of injury and a loss of consciousness (LOC) between 30 minutes and 4 hours.<sup>51</sup> Determination whether the previously described criteria were met was based on patient self-report, review of medical documentation (available for 16 subjects [80% of the sample]), and the patients' general clinical history and presentation.

All participants in the study were also required to meet the following inclusion criteria: (1) fluency in the English language; (2) no current or prior history of bipolar disorder, mania, or schizophrenia; (3) no current history of substance abuse; (4) no concurrent history of neurologic disease known to affect cognitive functioning; (5) no evidence of a behavioral disorder as the primary diagnosis; (6) 1 to 20 years postinjury; (7) a Disability Rating Scale (DRS) score between 1 and 5 at study inclusion; (8) complaints of cognitive dysfunction in the areas of attention and memory<sup>52</sup> (as determined by the Assessment of Client Functioning Inventory [ACFI]) as well as complaints of emotional distress<sup>53</sup> (as determined by the Symptom Checklist-90 Revised [SCL-90R]) at study inclusion; (9) no involvement in other ongoing services to address present issues; and (10) on a stable dosage of any psychotropic medication.

**Recruitment procedures.** Participants were recruited by using several methods. Direct mailings announcing the study and inviting participation were sent to (1) health care practitioners (neurologists, psychiatrists, neuropsychologists, psychologists, family medicine and general medicine practitioners, emergency medicine and trauma room physicians, psychiatrists), (2) members of the New Jersey Brain Injury Association, and (3) discharged outpatients from a large regional TBI rehabilitation program. Advertisements were also placed in the local Brain Injury Association print and on-line newsletters.

**Flow through the study.** Potential subjects were screened by using a brief telephone interview to determine if they met basic eligibility requirements. Those who were willing to participate and who met basic selection criteria were then scheduled for a full intake assessment at the Kessler Institute, East Orange, NJ.

Participant flow and dropout numbers are reported in figure 1 and are presented according to the CONSORT standards for reporting of clinical trials.<sup>54</sup> From April 1999 to May 2002, 277 telephone inquiries were made about the study. Of these individuals, 176 of 277 (63%) were determined to have suffered severe or other brain injuries that disqualified them from participation. Nineteen of the 277 (7%) subjects did not follow-through for further telephone evaluation. Of the remaining subjects, 82 of the 277 (30%) were identified as suffering from mild and moderate injuries. Of those 82 subjects, 29 were determined to meet full



**Fig 1. Flow diagram of subject progress through the phases of the randomized trial.**

inclusion criteria and were invited for an intake session. Twenty subjects completed the trial, and 9 dropped out (3 from the treatment group, 6 from the control group).

**Comparisons between completers and dropouts.** At baseline, there were no differences between the subjects who completed the study and those who dropped out on almost all key demographic variables (all  $P \leq .05$ ). The mean age  $\pm$  standard deviation (SD) of the dropout group was  $43.75 \pm 8.92$ , 78% (n=7) of the people were women, 89% (n=8) were white, 100% (n=9) suffered from mild brain injuries, and the median DRS score was 3.25 (range, 2–5). Moreover, the dropouts did not differ from completers on initial SCL-90R scores (eg, mean General Symptom Index [GSI] score,  $1.73 \pm 1.30$ ;  $P \leq .05$ ). However, those who dropped out were significantly less educated than those who completed the study ( $P \leq .05$ ; median, General Education Development degree/high school education; range, grade 9–11 to bachelor's level). Thus, those who completed the study seem representative of those that did not complete the trial with the exception of being more educated.

## Study Procedures

The chronologic ordering of the investigation is depicted in table 1. Multiple repeated tests were performed to obtain a stable measure of baseline, pretreatment functioning, and of outcomes over time.

**Pretest assessments.** The initial baseline session was broken down into 2 visits. During the first visit, demographic data were collected and eligibility was confirmed. Informed consent was also obtained at this point. Historical and/or medical information were corroborated by a review of the person's medical records, which were available for 16 (80%) of the subjects. Subjects with moderate brain injuries presented with medical documentation that helped corroborate severity.

Approximately 1 week later, subjects returned for the second session during which they completed the psychometric testing. For simplicity, the first 2 visits are referred to as pretest 0. The subsequent pretesting sessions took place approximately 1, 3, and 6 weeks after completion of pretest 0.

Table 1: Chronologic Ordering of the Investigation

Group	Baseline Testing (wk)				Intervention (11wk)	Outcomes Assessment (mo)		
	0	1	3	6		0	1	3*
Group I (CBT/neuro)	X	X	X	X	CBT and cognitive remediation	X	X	X
Group II (control)	X	X	X	X	No intervention	X	X	X

Abbreviation: neuro, neuropsychotherapy; X, measurement point.

\*Months after termination of treatment.

After pretest 0 was completed and it was determined that the person was eligible to participate, randomization took place. Each participant was randomly assigned to the treatment or control group by a clerical staff member who was not directly involved in the study. This staff member was blind to information collected during the evaluation process. A random numbers table was used to make the group assignments. Randomization was completed after pretest 0 to facilitate scheduling. However, subjects were not informed of their group status until all pretesting was completed. The examiners completing the testing were not aware of the participants' group membership. The only person on the research team who knew individual group assignment was the clinical psychologist (VA), who had no contact with participants from the point of randomization until she informed participants of their group membership.

After the final pretest session, subjects were informed of their group status and were either scheduled to begin treatment or told of the wait. All subjects in the experimental group underwent an 11-week treatment program. Subjects in the control condition received no intervention other than follow-along interviews during the control period but were offered full treatment once they completed the study.

**Follow-up testing.** Subsequent to the 11-week treatment or the waiting period, participants received 3 follow-up evaluations. The first posttest took place immediately after treatment (the 11-wk point). Additional posttest evaluations took place at 1 and 3 months after the intervention/waiting phase. These follow-up intervals allowed us to detect short-term immediate effects of treatment as well as the durability of treatment for a moderate period. This procedure improved on most previous investigations, which only examined immediate clinical or posttreatment changes (for a review, see Cicerone et al<sup>42</sup>). Pre- and posttesting was completed by 2 researchers (TS, JK) who were blinded to each individual's group membership. The initial and follow-up evaluations covered 3 specific areas: (1) objective and subjective cognitive functioning, (2) psychosocial and affective functioning, and (3) functional status. All testing sessions were approximately 2 hours long.

## Measures

Background demographic data were collected through the Northern New Jersey Traumatic Brain Injury Model System dataset, an augmented database based on the national Traumatic Brain Injury Model Systems dataset. Unless otherwise cited, descriptions for measures are available in Lezak,<sup>55</sup> Hannay,<sup>56</sup> or Johnston<sup>57</sup> and colleagues. Measures of objective and subjective neuropsychologic functioning included the Paced Auditory Serial Addition Task (PASAT), the Rey Auditory Verbal Learning Test (RAVLT), the ACFI (to assess complaints of memory dysfunction),<sup>52</sup> and the Attention Questionnaire.<sup>58</sup> Measures of psychosocial and affective functioning included the Coping Response Inventory (CRI)<sup>59</sup> and the SCL-90R.<sup>53</sup> Community participation was assessed by using the Community Integration Questionnaire (CIQ). All testing was completed according to standard procedures.

## Treatment Methods: Protocol for the Neuropsychologic Rehabilitation Group

Participants in the treatment group received a neuropsychologic rehabilitation program, which consisted of 2 primary components: (1) a structured program of cognitive remediation and (2) CBT. All treatment was provided by the same licensed psychologist (VA) who had expertise in the treatment of brain injury. Before study initiation, a treatment manual was created, and all components of treatment were administered according to its specifications. Some details of the manualized protocol are presented later. Additional information pertaining to the treatment manual is available from the authors.

The dual treatment method was based on models of neuropsychologic rehabilitation, reported by Mateer,<sup>44</sup> Ben-Yishay and Prigatano,<sup>60</sup> and Prigatano et al,<sup>39</sup> that are widely used by rehabilitation programs across the United States. These 3 models complement each other and are based on an overall goal of improving neuropsychologic functioning, emotional well-being, and functional status through integration of the remedial and psychotherapeutic interventions.

Participants in the treatment group received two 50-minute periods of one-on-one individualized treatment, 3 days per week, for an 11-week period. Both sessions were completed in the same day. In addition, participants were assigned daily half-hour homework assignments after each therapy session. The 11-week period of intervention was chosen because it is equivalent to the treatment duration reported by previous studies<sup>44,61</sup> that used similar training strategies and materials as our investigation.

**Cognitive remediation.** Cognitive remedial training focused on 2 domains of cognitive functioning: (1) attention and information processing and (2) memory. Organization and problem-solving skills were addressed throughout the remedial training because these abilities are a corollary of memory and attentional skills.

The cognitive remediation interventions were based on a process-specific approach to cognitive rehabilitation.<sup>62</sup> Consistent with this model, cognitive remediation interventions used in our study consisted of 2 types of tasks: retraining or remediation exercises and exercises designed to improve compensatory skills.

The retraining tasks were drawn from the Attention Process Training II materials.<sup>58</sup> Several single-subject, multiple-baseline across-behavior studies have suggested the effectiveness of this program in the treatment of attention deficits associated with mild brain injury<sup>61,63</sup> and moderate to severe brain injury.<sup>64</sup> Training involves a series of multimodal techniques focusing on auditory and visual attention and concentration skills. Training was conducted according to the instructions provided within the treatment manual.

Treatment group participants were also trained to use the following compensatory strategies to improve attention and concentration skills: (1) single task completion, (2) removal of distractions, and (3) planning and problem-solving tech-



Table 2: Individual Demographics and Injury Characteristics at Baseline

Characteristic	Experimental Group (n=11)	Control Group (n=9)	Total Sample (N=20)	P*
Age	47.55±11.78	46.00±9.35	46.85±10.51	.859
Sex				.456
Female	45.5 (5)	66.7 (6)	55.0 (11)	
Education				.814
HS/GED	9.1 (1)	11.1 (1)	10.0 (2)	
Some college	18.2 (2)	11.1 (1)	15.0 (3)	
Associate's degree	9.1 (1)	0.0 (0)	5.0 (1)	
Bachelor's degree	45.5 (5)	66.7 (6)	55.0 (11)	
Master's degree	18.2 (2)	11.1 (1)	15.0 (3)	
Race/ethnicity				.881
White	90.9 (10)	88.9 (8)	90.0 (18)	
Employment status				.353
Student	9.1 (1)	11.1 (1)	10.0 (2)	
Employed	9.1 (1)	33.3 (3)	20.0 (4)	
Retired	9.1 (1)	0.0 (0)	5.0 (1)	
Unemployed	72.7 (8)	55.6 (5)	65.0 (13)	
Marital status				.104
Married (7)	54.5 (6)	11.1 (1)	35.0 (7)	
Single (9)	36.4 (4)	55.6 (5)	45.0 (9)	
Divorced (4)	9.1 (1)	33.3 (3)	20.0 (4)	
Severity of injury				.099
Mild	100.0 (11)	77.8 (7)	90.0 (18)	
LOC				.199
Yes	72.7 (8)	44.4% (4)	60.0 (12)	
Duration of unconsciousness (min)				.503
0	27.3 (3)	55.6 (5)	40.0 (8)	
1-29	72.8 (8)	33.3 (3)	55.0 (11)	
>29	0.0 (0)	11.1 (1)	5.0 (1)	
Subjects in active litigation				.197
Yes	54.5 (6)	22.2 (2)	40.0 (8)	
Duration postinjury				.503
Years	5.01±5.46	5.47±4.09	6.25±6.02	
DRS total				.366
0	0 (0)	0 (0)	0 (0)	
1	9.1 (1)	0.0 (0)	5.0 (1)	
2	36.4 (4)	22.2 (2)	30.0 (6)	
3	0.0 (0)	22.2 (2)	10.0 (2)	
3.5	18.2 (2)	11.1 (1)	15.0 (3)	
4	9.1 (1)	0.0 (0)	5.0 (1)	
4.5	9.1 (1)	0.0 (0)	5.0 (1)	
5	18.2 (2)	44.4 (4)	30.0 (6)	
Total score (median)	3.5	3.5	3.5	.370

NOTE. Values are mean ± SD, percentage (n), or as otherwise indicated.

Abbreviations: GED, General Education Development diploma; HS, high school.

\*For continuous variables, significance levels of *t* test are given; for ordinal variables, the Mann-Whitney *U*; for categorical variables, the chi-square test.

niques. Each subject was trained in how to use a 5-step problem-solving technique to help him/her overcome personal difficulties in attention and concentration. Homework tasks were completed in concert with the cognitive remediation exercises. Subjects received daily assignments that required them to use the new techniques learned in each session in their daily lives. This was done to facilitate generalization of skills.

Remediation of behavioral memory deficits involved tasks designed to improve compensatory skills. Tasks were drawn from the memory rehabilitation literature focusing on memory book training.<sup>65,66</sup> Specifically, the following external compensatory and environmental modification strategies were taught: notebook use, note taking, and environmental modification.

**Cognitive-behavioral psychotherapy.** The CBT treatment techniques used were based on the work of Beck<sup>67,68</sup> and

Hawton<sup>69</sup> and colleagues. The goals of the CBT protocol for each client were (1) to increase the use of effective coping behaviors, (2) to reduce levels of stress, (3) to teach skills for preventing relapse (ie, return of emotional distress), and (4) to help subjects cope with feelings of loss related to decreased cognitive and physical functioning. Treatment was educative, collaborative, and tailored to each person's needs. All treatment was individually provided across 3 phases: (1) engagement, (2) active treatment, and (3) prevention of relapse and planning for discharge.

Phase 1 was engagement, and the goals of this phase included establishing a therapeutic relationship and developing mutually agreed on treatment targets, ensuring that the subject understood the rationale and principles of CBT, and beginning to help the client recognize illness-perpetuating behaviors and cognitions. Homework for this phase involved helping subjects

**Table 3: Cause of Injury**

Cause	% of Total Sample (N=20)
MVC (occupant or driver)	65 (13)
Falling object	15 (3)
Falls	10 (2)
Sports related	5 (1)
Pedestrian in MVC	5 (1)

NOTE. Values are % (n).

Abbreviation: MVC, motor vehicle collision.

begin to learn how to use automatic thought records (see later for a more complete description).

Phase 2 was active treatment. During this phase, treatment focused on improving coping skills and decreasing levels of stress. All interventions conducted during this phase were adapted to each person's level of cognitive functioning. The 3 primary forms of treatment included (1) detection of automatic thoughts and use of thought records, (2) behavioral experiments, and (3) cognitive rehearsal. Homework for the active treatment phase focused on having subjects sequentially apply the 3 noted treatment techniques in their daily lives.

Phase 3 involved planning for discharge and was aimed at the prevention of relapse. During this phase, treatment focused on educating the subject regarding relapse, helping the subject prepare for relapse, summarizing the treatment gains, and highlighting areas for future self-improvement. Subjects prepared for relapse by preparing relapse prevention plans. Homework exercises for this phase involved helping each person develop a personally relevant relapse plan as well as discrete plans for future personal improvement.

### Protocol for the Control Group

Subjects in the control group were placed on a wait list for treatment following the same assessment procedures as the experimental group. During the experimental period, they received minimal follow-up contact. They met with the principal investigator of this study in person for 45 minutes or by telephone, 2 or 3 times over the course of 11 weeks. During these meetings, they were encouraged to engage in a discussion about whatever interested them and no attempt was made to provide psychotherapeutic intervention. Follow-up assessments were performed in person, and, at the end of the total period, treatment was provided to them if requested.

### Precise Hypotheses

With a small sample, it is important to limit the number of main a priori endpoints to avoid inflation of  $\alpha$  (spurious positive findings from repeated testing). The SCL-90R GSI total score was chosen as the first primary (level 1A) endpoint because it was expected that treatment would improve overall level of psychologic distress. It was also anticipated that the neuropsychologic rehabilitation program would reduce depression and anxiety, likely the main symptoms of the participants. Improvement in performance on the PASAT was also hypothesized as a primary outcome. Thus, the total scores on the SCL-90R depression and anxiety subscales as well as the total score on the PASAT were chosen as dependent measures and comprised a hypothesized set of outcomes (level 1B). Effects on self-reported coping (CRI, problem solving-total subscale score) and attention (Attention Questionnaire total score) were also tested a priori (level 1C hypotheses).

Effects of treatment on many other areas of functioning, including community integration, are possible and can be important. These were examined, but given the small sample and

the large number of comparisons at this point, these statistical results at this third level will be interpreted as post hoc, that is, as suggesting effects that particularly need to be tested in future research.

### Statistical Analysis

Although a variety of methods are available for the analysis of repeated measures experimental data, certain relatively simple methods can be appropriate.<sup>70</sup> If variances of baseline measures and their correlations with the outcome measure are the same, "using the mean of baseline measurements turns out to be a reasonable strategy."<sup>70(p868)</sup> In our study, some positive effects at the conclusion of treatment were expected and the durability over time of these effects was of interest. Although trends over time might occur, no definite trend could be plausibly specified a priori. Use of mean values was then conceptually appropriate. Thus, for the final analyses, a summary value for each main outcome variable was constructed by averaging the 4 baseline scores, and then another summary value for each main outcome variable was created by averaging the 3 outcome scores. Hypotheses were then tested by using a standard 1-way analysis of covariance on each summary outcome variable.<sup>71</sup> Trend analyses were completed by using independent samples, 2-tailed *t* tests.

Although high type I error is expected and appropriate in an exploratory study such as ours, which aims at clarifying effects that most need to be tested in future research, results that are likely to be stable must be distinguished from those that should be used only to guide future research. Keselman et al<sup>72</sup> have shown that when 5 or more pairwise comparisons are tested, the Benjamini and Hochberg<sup>73</sup> method of controlling for the false discovery rate is most powerful. The procedure involves ordering probability values of a priori test results  $P_{(i)}$  from least significant to most significant and rejecting the null hypothesis whenever  $P_{(i)} \leq (i/m) \cdot .05$ , where  $m$  is the number of total tests. This method was used on the a priori outcome set.

### RESULTS

Participant demographics and injury characteristics are described in table 2. On average, the sample was middle aged (range, 19–62y), well-educated, white, and female. There were no significant group differences on the demographic variables (all  $P \leq .05$ ). Most subjects suffered from mild brain injuries.

**Table 4: Pretest Values of Major Outcomes Across Control and Treatment Groups**

Outcome Measure	Baseline Averages		<i>P</i> *
	Treatment	Control	
Main measures			
GSI (SCL-90R)	1.16±0.724	1.62±0.75	.19
Depression (SCL-90R)	1.50±0.83	2.07±0.94	.18
Anxiety (SCL-90R)	.921±0.85	1.39±0.70	.22
PASAT	116.07±33.07	112.50±51.02	.85
Problem solving (CRI)	10.75±3.17	13.25±2.86	.08
Attention Questionnaire	31.30±9.88	34.56±6.05	.40
Other measures			
Somatization (SCL-90R)	1.12±0.91	1.53±0.80	.32
RAVLT	47.24±11.84	53.50±15.05	.31
ACFI	88.48±23.24	80.11±21.03	.42
Emotional discharge (CRI)	7.64±3.02	8.36±2.66	.58
CIQ	15.63±3.64	16.22±4.06	.74

NOTE. Values are mean ± SD.

\*From *t* test.

Table 5: Main A Priori Outcomes and Tests of Treatment Effects

Outcome Measure	Treatment Group	Control Group	<i>P</i> *	<i>r</i> (prepost values)	<i>P</i> (treatment effect) <sup>†</sup>
GSI (SCL-90R)	0.86±0.41	1.74±1.00	.045	.81	.046
Depression (SCL-90R)	1.12±0.45	2.11±1.14	.046	.78	.029
Anxiety subscale (SCL-90R)	0.72±0.42	1.53±1.02	.066	.75	.031
PASAT	135.55±30.71	110.88±60.28	.257	.94	.011
Problem solving (CRI)	13.06±2.67	12.58±2.21	.685	.49	.141
Attention Questionnaire	19.42±11.56	29.29±9.94	.082	.67	.096

NOTE. Values are mean ± SD.

\*From *t* test of group differences at the given point in time.

<sup>†</sup>*P* is from univariate analysis of variance with baseline average as covariate.

The groups did not differ by injury severity (ie, percentage of mild or moderate subjects,  $P \leq .189$ ). As table 3 illustrates, the majority of subjects in both groups sustained their injuries because of falls or car collisions. GCS data are not presented because they were not consistently available.

Baseline values of primary outcomes are described in table 4. There were no statistically significant differences between experimental and control groups on any of these measures at baseline (all  $P \leq .05$ ).

### Effects on Primary Outcome Measures

The main results of the study are presented in table 5. Outcomes are ordered by hypothesized expectation level. Improvement on the SCL-90R GSI total score was the most expected (level 1A) outcome. Improvement on SCL-90R depression and anxiety subtests (total scores) as well as PASAT total score were also main expected effects (level 1B), but we hoped to find an effect on all 6 (level 1C).

A significant treatment effect ( $P \leq .05$ ) was found for the primary endpoint, GSI total score (last column table 5). Subjects in the treatment group reported less emotional distress than those in the control group, at follow-up. As table 4 also shows, subjects in the treatment reported reduced anxiety and depression on the SCL-90R and showed improved PASAT performance after treatment ( $P \leq .05$ ). If one applies the Benjamini-Hochberg<sup>73</sup> criterion to these 4 a priori variables, the set of 4 expected outcomes (level 1B hypothesis set) is then significant, keeping the false discovery rate below .05.

Figure 2 depicts changes in mean GSI scores at each assessment point. Trend analyses indicate that the treatment group reported diminished distress 1 month ( $P \leq .05$ ) and 3 months ( $P \leq .05$ ) later, whereas distress increased for control participants. There was great variability across subjects, so visual results of this post hoc analysis should be interpreted as suggestive.

### Effects on Secondary Measures

Results of planned post hoc analyses of other important outcomes are presented in table 6. Only 1 nominally significant effect was detected: performance on the RAVLT total learning trials 1 through 5 appeared to increase in the treatment group but not in the control group. Given the number of tests at this point, the result should primarily be interpreted as instructive for future research rather than statistically stable. No other significant effects were evident.

## DISCUSSION

Results provide preliminary evidence that intensive outpatient treatment consisting of both CBT and cognitive remediation is beneficial in the treatment of persistent emotional distress and perhaps even cognitive dysfunction after mild and moderate TBI. In this randomized controlled trial (RCT), sub-

jects in the treatment group showed less emotional distress and more improved cognitive functioning at follow-up compared with subjects who did not receive treatment. Moreover, improvement was most significant on a measure of emotional distress at 1 and 3 months posttreatment. These findings are consistent with other studies that suggest comprehensive outpatient rehabilitation helps improve the cognitive and affective sequelae of mild and moderate TBI.<sup>46,48</sup> Outpatient treatment is a viable treatment alternative for those who do not benefit from early effective interventions.<sup>35</sup>

When compared with healthy adults,<sup>53</sup> subjects in the treatment group entered the study showing severe emotional distress. Moreover, at follow-up these subjects improved significantly, but not always to levels that are considered within normative limits. At baseline, the mean SCL-90R GSI T score for the treatment group was 67.5. After the intervention, the mean T score was 63.0, which is still a cutoff for psychiatric "caseness" or a positive likelihood that the subject suffers from some psychiatric illness. Similar clinical findings were observed for the treatment group on the depression subscale of the SCL-90R, with a mean pretest T score of 67.2, and a mean posttest T score of 63.6. However, although the treated group showed significant anxiety at baseline ( $T=61.6$ ), levels of anxiety returned to within normative limits after the intervention ( $T=57.7$ ). Subjects in the control group showed similarly elevated levels of emotional distress at baseline on measures of overall emotional distress, depression, and anxiety (mean average T scores, 72.7, 72.0, 67.6, respectively). As expected, no significant improvements were noted on these measures at posttest (mean average T scores, 73.5 [SCL-90R GSI subtest]; 71.9 [SCL-90R depression subtest]; 68.0 [SCL-90R anxiety subtest]). Similar to the findings of other psychotherapy outcome studies, although improved, the treated subjects were not "cured" at the conclusion of treatment.<sup>74</sup>

In contrast to the lingering emotional distress, neuropsychologic functioning returned to or remained "average" in the

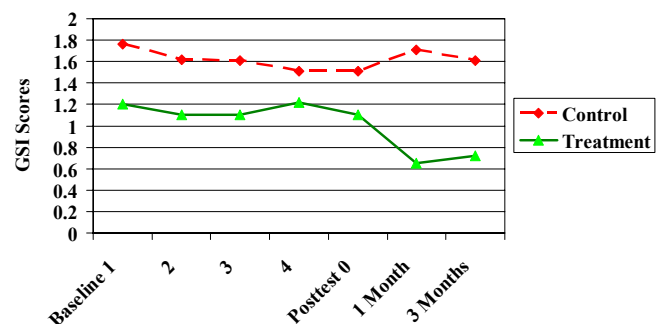


Fig 2. Change in GSI scores over time in the treatment and control groups.

Table 6: Secondary Outcomes: Averages and Tests of Treatment Effects

Outcome Measure (Dependent Variable)	Treatment Group*	Control Group	P	r (pre-post values)	P (treatment effect) <sup>†</sup>
Somatization (SCL-90R) (total score)	1.07±0.84	1.71±0.97	.150	.773	.456
RAVLT (total, trials 1–5)	52.37±13.93	48.77±14.49	.600	.891	.010
ACFI (total score)	63.68±36.91	74.10±21.72	.516	.684	.069
Emotional discharge (CRI) (total score)	6.47±2.94	7.73±4.37	.461	.547	.791
CIQ (total score)	15.90±4.56	15.72±4.30	.931	.851	.715

\*Values are mean ± SD.

\*From t test of group differences at the given point in time.

†P is from univariate ANOVA with baseline average as covariate.

treatment group, after the intervention. When compared with healthy subjects,<sup>75</sup> at baseline, the treatment group showed severe impairment on the PASAT (mean T score, 29.3). After treatment, however, performance on this measure was within the normative range (mean posttest T score, 44.3). In contrast, the control group remained impaired on this measure at posttest (mean pretest T score, 31.7; mean posttest T score, 32.0). On the RAVLT, both groups initially showed normative performance relative to healthy subjects.<sup>76</sup> The mean T score for the control group was 49.5, and the mean T score for the treated group was 43.8. However, after treatment, the intervention group showed improvement in their mean performance (T score, 49.0), whereas the control group did not significantly change (T=44.4). These data show that cognitive processing can improve significantly in persons with mild and moderate TBI when they are given appropriate interventions.

The subjects with brain injury in our study remained emotionally distressed and functionally impaired despite improvement in cognitive functioning. This suggests that the emotional and functional sequelae of mild and moderate TBI are not primarily maintained by neuropsychologic impairment. These findings support Binder's<sup>3</sup> conclusions and Kay's<sup>77,78</sup> neuropsychologic model of functional disability after mild TBI. According to this model, irrespective of brain "injury," a series of dysfunctional psychologic feedback loops maintain symptoms that contribute to functional impairment. Indeed, no significant improvement was noted on the measures of functional ability in our investigation. This may be because subjects continued to show significant psychologic distress that contributed to functional disability. Interestingly, no improvement was noted on measures of subjective cognitive dysfunction, despite the objective improvement. Again this is likely indicative of a "subjective cognitive dysfunction loop,"<sup>77(p38f)</sup> which is maintained by emotional distress and which then reduces functional ability.

The findings of our study also support a biopsychosocial treatment perspective for mild and moderate TBI.<sup>20</sup> Accordingly, physiologic, cognitive, emotional, and environmental factors interact and contribute to overall symptom presentation. By focusing on cognitive and emotional impairment, some improvement was noted. If environment and physiology were more directly addressed through medication and behavioral interventions, greater improvement may have been noted. This is an area for future research.

### Limitations

Several limitations of our investigation must be recognized. This was a small study, with only 20 participants who were largely highly educated. A larger, multisite study is needed to determine the generalizability of results. Although the difference in educational status of dropouts is a concern, the groups were randomly assigned, so biases because of preexisting differences are probabilistically equalized across groups. Future

research could help determine whether treatment effectiveness is impacted by the level of education of the study participants. Another criticism might be that some participants did not suffer LOC. However, all subjects at least met the ACRM criteria for mild head injury. Those who did not suffer LOC reported some alteration of mental status after their respective injuries. The need for the use of self-report for documentation in this instance, however, remains a limitation.

Another possible limitation is that many of the participants were involved in litigation pertaining to their injuries. There was, however, no significant difference between the groups in litigation status. Litigation may produce a tendency toward nonresponse to treatment or a reporting bias. Because more people in active litigation were in the treatment group, the direction of bias would be against finding a significant effect. This was not found. Thus, litigation status might affect generalizability but did not appear to confound study findings.

### CONCLUSIONS

RCTs are possible in community-living persons with TBI, and even small RCTs can provide important information. Although there are limits to the generalizability of the findings, this study shows that a readily available model for care can be implemented by trained clinicians. The treatment was well tolerated despite its intensity. No subject dropped out because of the intensity of the treatment. No clinical emergencies, such as psychiatric hospitalizations, were observed. Overall, control subjects also tolerated the wait for treatment. One of the most difficult aspects of our investigation was subject recruitment. Had there been additional resources available to transport patients, the sample would also likely have been larger. Any future investigation should address this difficulty to ensure inclusion of a representative sample of mild-spectrum TBI survivors.

Over half of the subjects who participated in our investigation were women (55%). This might be an unexpected finding because the incidence of TBI is greater in men.<sup>1</sup> However, there is some suggestion in the literature that women are at greater risk for suffering prolonged symptoms after mild TBI.<sup>3</sup> A larger study with more diverse sampling techniques could help determine whether the current results support the contention that women are at greater risk for developing protracted postconcussive disorders.

The present study provides definite directions for future research. A study with a longer duration of treatment will help determine if greater improvement can be achieved. It is suggested that longer-term treatment is more beneficial than short-term interventions.<sup>79</sup> Moreover, "booster sessions" might improve durability of treatment effect (eg, Ball et al<sup>80</sup>). Also, a design that includes longer-term follow-up will help determine if symptom amelioration is noted over time.

Another investigation could also help determine what part of the intervention was most effective or if both CBT and cognitive remediation are necessary components of a rehabilitation



program. Our suspicion is that both treatments are needed to see positive effects of neuropsychologic rehabilitation. This view is consistent with traditional holistic and comprehensive approaches to TBI rehabilitation.<sup>38,39,81</sup>

Although manualized, the CBT protocol was flexible enough to allow for some individualization for each subject. Each intervention was made contextually relevant to the subject (eg, each behavioral experiment was customized so that it would be therapeutically relevant to a specific person). There is much evidence supporting the need for individualization and contextual variation when designing treatment protocols to remediate neuropsychologic dysfunction.<sup>82</sup> Additional research is needed to clarify the needed balance between more rigid protocols and those that allow for more individualized contextual variations in treatment.

In sum, a neuropsychologic rehabilitation program consisting of CBT and cognitive-remediation showed promise in the treatment of psychologic distress, including depression and anxiety, among well-educated persons with TBI in the community. Divided auditory attention also appeared to improve after treatment. The findings from this study can be used to help develop treatment recommendations for the cognitive and affective sequelae of mild and moderate TBI.

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