# Effect of Cognitive Rehabilitation on Outcomes for Persons with Traumatic Brain Injury: A Systematic Review

We evaluated evidence for the effectiveness of cognitive rehabilitation methods to improve outcomes for persons with traumatic brain injury (TBI). A search of MEDLINE, HealthSTAR, CINAHL, PsycINFO, and the Cochrane Library produced 600 potential references. Thirty-two studies met predetermined inclusion criteria and were abstracted; data from 24 were placed into evidence tables. Two randomized controlled trials and one observational study provided evidence that specific forms of cognitive rehabilitation reduce memory failures and anxiety, and improve self-concept and interpersonal relationships for persons with TBI. The durability and clinical relevance of these findings is not established. Future research utilizing control groups and multivariate analysis must incorporate subject variability and must include standard definitions of the intervention and relevant outcome measures that reflect health and function. Key words: *cognitive rehabilitation, evidence based, systematic review* 

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Standards for grading the quality of evidence, consistent with those used by the U.S. Preventive Services Task Force,<sup>2</sup> were used, based on the assumption that the strongest evidence is found in well-designed randomized controlled trials (RCTs).

One class of intervention identified for evaluation was cognitive rehabilitation. The purpose of this article is to present the findings of the evidence report with respect to cognitive rehabilitation. We have three goals:

- To articulate the evidence for effectiveness of this intervention, using methods and standards with demonstrated utility in other areas of medical research<sup>3</sup>;
- 2. To illustrate controversies about the use of such standards in evaluating TBI rehabilitation, particularly when applied to cognitive rehabilitation;
- To compose reasonable recommendations for practice and for future research.

# DEFINITION AND CLASSIFICATION OF COGNITIVE REHABILITATION

A standard, widely used definition of cognitive rehabilitation that serves inter- or transdisciplinary clinical and research purposes does not exist. For this review, a concept founded in Goldstein's<sup>4</sup> schema of cognition was used: Cognition operates as an integrated system consisting of performance fields and various functions within these fields. The fields include attention, memory and learning, thinking or mental organization, affect and expression, and executive functions. Depending on many factors, brain injury may affect overall performance and may have differential effects on performances within these fields. A traditional and perhaps limited<sup>5</sup> definition of cognitive rehabilitation is that it is a set of therapies used to help improve damaged intellectual, perceptual, psychomotor, and behavioral skills.<sup>6</sup> It is a system of interventions designed to increase daily functional abilities by improving or augmenting deficits in processing and interpreting information<sup>7</sup> or by modifying the environment.<sup>5</sup>

Therapeutic strategies of cognitive rehabilitation have been classified as restorative or compensatory. Restorative cognitive rehabilitation (RCR) is based on the theory that repetitive exercise can restore lost function.7 Compensatory cognitive rehabilitation (CCR) strives to develop internal substitutes5 and/or external prosthetic assistance for dysfunctions.<sup>8</sup> Although this distinction is widely used in study publications, it is recognized that, in clinical practice, the two strategies do not exist independent of each other. Ylvisaker<sup>5</sup> argues against the fundamental validity of the distinction, stating that (a) strategic behavior is a component of normal cognition, (b) helping people with TBI to acquire compensatory behaviors and equipment is helping them to become more strategic, and, therefore, (c) the compensatory intervention is restorative, in that it operates to restore this component of normal cognition.

Strategic behavior can be highly individual; its acquisition may involve setting personal goals, specifying methods for meeting the goals, experimenting with methods, and reformulating goals, requiring daily changes in protocol, all of which are a part of the intervention. The question is, What, exactly, is the intervention or set of interventions? Given the apparent necessity for individualized treatment that may change daily, how should cognitive rehabilitation be operationally defined?

# DEFINITION AND CLASSIFICATION OF OUTCOMES

Ylvisaker's<sup>5</sup> argument raises a similar problem with defining and measuring outcomes. The clinical practice of highly individualized treatment in TBI rehabilitation has generated

	lisoq	Number of tests found to have a positive effect or association	nd to have a ssociation	wu bog	Number of tests done without a positive effect or association	ne without a association	Proportion of positive effects found	of positive found
Cognitive domain and	RCTs	Comparative studies	Corr sti	RCTS	Comparative studies	Correlation studies	RCTs & comparative	Correlation studies
associated tests	(a)	(0)	(c)	(e)	(e)	Ð	$\frac{a+b}{a+b+d+e}$	c+f
Attention and orientation								
Digits	0	1	1	ŝ	ю	к	.14	.25
Mental Control	0	0	0	1	0	0	0	0
Trails A & B	0	0	ĉ	1	1	1	0	.75
PASAT	0	1	7	7	1	0	.25	1.0
Test d2	0	0	0	1	0	0	0	0
Continuous Test of Attention	0	0	1	0	0	0	0	1.0
Divided Attention	0	0	0	1	0	0	0	0
Ruff 2 & 7	0	0	0	1	0	0	0	0
Letter Cancellation	0	0	0	0	1	0	0	0
Time Estimation	0	0	0	0	1	0	0	0
Attention to Task	0	1	0	0	0	0	1.0	0
Attention Rating Scale	0	1	0	0	0	0	1.0	0
WMS Attention/Concentration	0	0	0	0	0	2	0	0
Digit Symbol	0	0	1	0	1	1	0	.50
Ruff-Light Trail	0	0	0	2	0	0	0	0
Tactual Performance	0	0	1	0	1	0	0	1.0
Choice Reaction Time	0	1	0	0	0	0	1.0	0
Simple Reaction Time	0	0	0	0	1	0	0	0
Vigilance	0	0	0	0	1	0	0	0
Totals	0	Ś	6	12	11	7	.18	.56
Memory								
WMS General	0	0	0	0	0	2	0	0
WMS Verbal	0	0	0	0	0	2	0	0
WMS Visual	0	0	2	7	1	0	0	1.0
WMS Delayed Recall	0	0	1	0	0	1	0	i
WMS Memory Quotient	0	1	0	0	0	0	1.0	0
WMS I onical Memory	C	0	6	ч	ç	0	0	10

Table 1. Summary of results of intermediate measures of cognitive function

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Table	

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uditory Verbal Learning         0         0         1         0 <td>Rey Complex Figure</td> <td>0</td> <td>0</td> <td>1</td> <td>1</td> <td>1</td> <td>0</td> <td>0</td> <td>1.0</td>	Rey Complex Figure	0	0	1	1	1	0	0	1.0
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n Visual Memory Test         0         0         1         0	Block Span Learning	0	0	0	1	0	0	0	0
Complex Figure         0         0         1         1         0         0           ke selective Reminding         0         0         1         1         0         1         0         0           ing Sentences         1         1         0         0         0         0         10         10           ing Sentences         1         1         1         8         12         7         6         10           Ke fab and Language         0         0         0         0         1         0         0         10           Ke formation         0         0         0         0         0         0         1         0         10           R Information         0         0         0         0         0         0         10         0         10           R Vocabulary         0         0         0         0         0         10         0         10           R Vocabulary         0         0         0         0         0         10         0         10           R Competence         1         0         0         0         0         10         0         10 <td>Benton Visual Memory Test</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td>	Benton Visual Memory Test	0	0	0	1	0	0	0	0
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	<b>Buschke Selective Reminding</b>	0	0	1	0	1	0	0	1.0
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Cognitive domain and sesociated tests       RCTs associated tests         associated tests       (a)         WAIS-R Picture Completion       0         WAIS-R Arithmetic       0         Making Inferences       0         Raven's Progressive Matrices       0         Category Test       0         Wisconsin Card Sorting       0	-					-		
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essive Matrices d Sorting		0	0	1	0	0	0	0
d Sorting		1	0	0	0	0	1.0	0
d Sorting		0	1	0	0	2	0	.33
		0	0	0	1	1	0	0
Comprehension 0		0	1	0	1	0	0	1.0
Total 0		æ	4	1	ŝ	v	.43	.44
<b>Executive functions and motor</b>								
performance								
WISC-R Mazes 0		0	1	0	0	1	0	.50
Austin Maze 0		0	0	0	1	0	0	0
Halstead Reitan Finger Tapping 0		0	0	0	2	1	0	0
Grooved Pegboard 0		0	1	0	0	0	0	1.0
Grip Strength 0		0	0	0	0	1	0	0
Total 0		0	2	0	ŝ	ŝ	0	.44
Batteries and global tests								
WAIS-R Full Scale I.Q. 0		0	1	0	0	1	0	νċ
WAIS-R Verbal I.Q. 0		0	1	0	7	1	0	v
WAIS-R Performance I.Q. 0		1	æ	0	1	1	.33	.75
Russell Neurenger Average								
Impairment Rating 0		0	0	0	1	0	0	0
San Diego Neurological Test Battery 0		0	0	1	0	0	0	0
Wide Range Achivement Test 0		0	0	0	0	1	0	0
Impairment Index 0		0	1	0	0	0	0	1.0
Total 0		1	9	1	4	4	.17	.60
Miscellaneous and clinic-specific								
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Adolescent Word Test A 1		0	0	0	0	0	1.0	1.0
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Table	

	posi	positive effect or association	issociation	od	positive effect or association	positive effect or association	effects found	found
Cognitive domain and associated tests	RCTs (a)	Comparative studies (b)	Correlation studies (c)	RCTs (d)	Comparative studies (e)	Correlation studies (f)	RCTs & comparative $\frac{a+b}{a+b+d+e}$	Correlation studies <u>c</u> <del>c</del>
Adolescent Word Test B	0	0	0	-	0	0	0	1.0
Adolescent Word Test C	1	0	0	0	0	0	1.0	1.0
Adolescent Word Test D	0	0	0	1	0	0	0	1.0
Picture Vocabulary Test	1	0	0	0	0	0	1.0	1.0
Word Association Subtest	1	0	0	0	0	0	1.0	1.0
Understanding Metaphors	0	0	0	1	0	0	0	1.0
Peabody Picture Vocabulary	0	0	0	1	0	0	0	1.0
Ambiguous Sentences	1	0	0	0	0	0	1.0	1.0
Listening to Paragraphs	0	0	0	1	0	0	0	1.0
Neale Analysis of Reading	0	0	0	0	1	0	0	1.0
Pursuit Rotor	0	0	0	0	1	0	0	1.0
Sentence Assembly	0	0	0	1	0	0	0	1.0
Recreating Sentences	0	0	0	1	0	0	0	1.0
Single Reaction Time	0	0	0	1	0	0	0	1.0
Choice Reaction Time	0	0	0	-	0	0	0	1.0
NYUMT Acq. Rec. Scaled	1	0	0	0	0	0	1.0	1.0
NYUMT Acq. Rec. Standard	0	0	0	1	0	0	0	1.0
Memory Index Scaled	1	0	0	0	0	0	1.0	1.0
Memory Index Standard	1	0	0	0	0	0	1.0	1.0
VerPa	1	0	0	0	0	0	1.0	1.0
VisPA	1	0	0	0	0	0	1.0	1.0
TeachWare Screening Module	1	0	0	0	0	0	1.0	1.0
Name Writing	0	0	1	0	0	0	0	1.0
Total	11	0	1	10	2	0	.48	1.0
Totale	14	12	33	37	33	31	.27	52

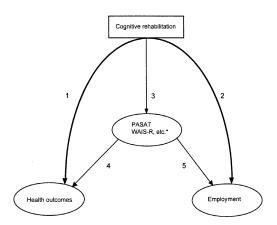
a vast catalog of outcomes and their measures. Table 1 summarizes the results of the studies in this review that used laboratory tests of cognition to measure treatment effects. Tests are organized within six cognitive domains, as defined by Lezak,9 as well as a category for test batteries, one for miscellaneous tests and those developed by a clinic for the purpose of program evaluation (clinic-specific tests). In 23 studies, 91 individual measures of outcome were used, of which approximately 25% are clinic-specific. This simple tabulation suggests that, as with the definition of the intervention, there is no standard set of outcome measures for TBI rehabilitation that can be used across clinics to evaluate both patient progress and program effectiveness.

Note that the category with the highest proportion of positive effects is clinic-specific tests, suggesting that a study conducted in a practice setting that has generated a unique protocol for program evaluation is more likely to show a positive result of its treatment. Such studies, if they met the predetermined inclusion criteria, were used as evidence in this review, contrary to the advice of members of the Aspen Neurobehavioral Conference,<sup>10</sup> who requested that studies be excluded if the clinicians who designed and operate the practice are also the researchers who designed and conducted the evaluation.

Although practitioners agree that the desired outcome of cognitive rehabilitation is improvement in daily function, many of the commonly used outcome indicators, represented in Table 1, are intermediate measures, rather than health outcomes. For example, a cognitive rehabilitation study may identify "attention" as the primary dysfunction for patients, apply an intervention designed to improve attention, and use a common laboratory test, such as the Paced Auditory Serial Attention Task, or PASAT,<sup>11</sup> as a measure of improvement. The question is, Do high scores on the PASAT accurately predict whether the patients' attention performances will function adequately in the context of work or social situations in which distraction and other demands are present? More generally, do the measures used to assess the effectiveness of cognitive rehabilitation predict improvement in real-life function?

#### CAUSAL PATHWAY

Fig 1 shows a causal pathway linking cognitive rehabilitation to potential benefits. We used this causal pathway to circumscribe our search for evidence of effectiveness of an intervention in the face of little or no definition of the intervention and no standard measure of effectiveness. Arc 1 represents the direct effect of cognitive rehabilitation on health outcomes—outcomes that can be felt or experienced by the patient in daily life. In the context of a systematic review, "direct" evidence comes from comparative studies that examine the effect of cognitive rehabilitation on measures of these outcomes. Arc 2



**Fig 1.** Causal pathway for cognitive rehabilitation. Note: \*PASAT, Paced Auditory Serial Addition Task; WAIS-R, Wechsler Adult Intelligence Scale— Revised; See Table 1 for measures of cognitive abilities.

represents the direct effect of cognitive rehabilitation on measures of employment, such as return to work and job retention. "Indirect" evidence refers to a causal chain that relies on intermediate measures. In Fig 1, the first link in this chain is between the intervention and intermediate measures of improvement (Arc 3); this link corresponds to the question, Does cognitive rehabilitation improve scores on intermediate measures of cognitive function, such as the PASAT, the Wechsler Adult Intelligence Scale-Revised (WAIS-R), etc.? The next links in the causal chain correspond to the question, Do intermediate measures used to assess the effectiveness of cognitive rehabilitation predict improvement in real-life function (Arc 4) and employment (Arc 5)?

### METHODS

A previous publication<sup>12</sup> documents the methods used to conduct the review. The following summarizes the important aspects of the process:

- 1. Two panels of technical experts, one local and one national, worked with the research team to define key questions, research parameters, and outcome measures, and to specify the causal pathways. Relevant health outcomes were:
  - Activities of daily living (ADL)
  - Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being)
  - Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function)
  - Independence, relationships, family life, satisfaction
  - Long-term financial burden

- 2. Search strategies derived from the questions were used to acquire relevant literature from MEDLINE (1976-1997), HealthSTAR (1995-1997), CINAHL (1982-1997), PsycINFO (1984-1997), and the Cochrane Library.
- 3. Of 3,098 abstracts read by two independent reviewers, 600 applied to the question of cognitive rehabilitation.
- 4. Exclusion criteria were:
  - not TBI (eg, carbon monoxide poisoning),
  - pediatric,
  - pharmacological intervention,
  - case report,
  - instrument development,
  - alcohol/drug abuse as an outcome,
  - stroke,
  - editorial or no data,
  - acute care intervention (eg, surgical), and
  - foreign language.

One hundred fourteen articles passed this screen.

- 5. Inclusion criteria were:
  - data specific to the question,
  - sound scientific methods,
  - rehabilitation as an intervention,
  - independent variable specific to the question,
  - dependent variable specific to the question.
- 6. Level of evidence was determined, using the following system:
  - Class I—Well-designed randomized controlled trials (RCTs)
  - Class II[a]—RCTs with design flaws and multicenter or population-based longitudinal (cohort) studies
  - Class II[b]—Nonrandomized controlled trials, case-control studies, and well-designed case series
  - Class III—Case reports, uncontrolled case series, and expert or consensus opinion

7. Key studies were critically appraised, and data from them were abstracted and placed into evidence tables.

# **1**S

Of the 114 potential references identified for inclusion by the literature search, 53 met the predetermined eligibility criteria. From reference lists of reviewed articles and peer recommendations, an additional 20 articles were identified, resulting in a total of 73 fulltext articles that were retrieved and read. Of those, 41 were excluded. Of the excluded articles, 3 were reviews, 5 were studies with fewer than 5 subjects, 1 was retrospective, and 25 studies were descriptive. Five studies measured independent or dependent variables outside the scope of this research question, and two studies compared clients who were referred for treatment with those referred for testing. Although excluded as evidence about effectiveness, the descriptive and observational data from these research efforts were used in the review process to provide a foundation for understanding and interpreting the evidence.

The remaining 32 articles were abstracted and are presented in the following categories:

- 11 randomized controlled trials
- 5 measuring relevant health outcomes (Table 2)
- 6 measuring intermediate outcomes (Table 3)
- 4 comparative studies
- 1 measuring employment outcomes (Table 4)
- 3 measuring intermediate outcomes (Table 5)

8 studies of the relationship between intermediate tests and employment (Table 6)

9 observational studies

- 1 measuring relevant health outcomes (Table 7)
- 8 measuring intermediate outcomes

### DIRECT EVIDENCE

# Does cognitive rehabilitation improve health outcomes (Arc 1)?

## Randomized controlled trials

Five randomized controlled trials<sup>13-17</sup> used measures of relevant health outcomes to compare the effects of specific forms of cognitive rehabilitation with alternative treatments or with no treatment (see Table 2). Comparison groups were provided with unstructured sessions, computer game sessions, or nontherapeutic attention. In one study,14 two distinct interventions were compared; each group was trained in one of the skills and was tested for both. Treatment time in four of the studies ranged from 10 to 20 hours; the fifth<sup>16</sup> provided 96 hours of treatment. Follow-up for one study<sup>17</sup> occurred at 6 months and for a second study<sup>13</sup> at 1 month for 6 of the subjects; the other studies did not include followup testing.

As seen in Table 2, the studies varied in setting, populations, size, client chronicity, and measures of severity of injury. One hundred thirty-seven clients were observed in these trials; 69 received the targeted treatments.

Measures used in these studies, which approximated important health outcomes, were the Functional Independence Measure (FIM),<sup>15</sup> Observed Everyday Memory Failures (EMFs), Rabideau Kitchen Evaluation Revised (RKE-R),<sup>14</sup> Katz Adjustment Scale (KAS),<sup>16</sup> and a variety of inventories designed to measure anxiety, communication, and relationships.<sup>13</sup> In addition, these studies used neuropsychological test batteries and other intermediate measures of cognitive function to evaluate treatment effect.

In two studies, treatment produced statistically significant effects on relevant outcome measures. In one,<sup>17</sup> individuals trained in the use of notebooks and equipped with wristwatch alarm cues had fewer EMFs than

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	Setting/population	Acute inpatient rehabilita- tion Consecutive admissions over 3 yr	Outpatient volunteers	Boston School of Occupational Therapy, Tufts University. Subjects recruited from 10 head-injury programs, 8 residential, 2 outpatient	University of San Diego Outpatients Population not specified	Brain Injury Project Woodrow Wilson Rehabilitation Center <i>continues</i>
	Follow- up	None	6 months	None	None	1 mo (on 6 subjects)
,	Duration of intervention	30 min sessions 5 d/wk 20 sessions 10 hr total	60 min sessions 2 d/wk 8 wks 16 sessions 16 hr total	30 min sessions 3 d/wk 6 wks 9 hr total	3 hr/d 4 d/wk 8 wk 96 hr total	1 hr/d 20 d 20 hr total
	Comparison group/ 2nd treatment group	Unstructured. Memory/reasoning tasks, games, computer games	Group sessions for problem solving, discussion of social isolation, frustrations	Perceptual Skills Group (T2) trained in parquetry block assembly. Each group trained in one skill, tested for both skills	Psychosocial functioning and ADLs	Nontherapeutic attention (with no feedback on interpersonal function- ing)
)	Intervention/treatment group	Restorative and compensatory Hierarchical, structured CACR with therapist support and external cues	Compensatory Notebook training with wristwatch alarm cue	Restorative Functional Skills Group (T1) trained in food preparation	Restorative and compensatory CACR and external aids (notebooks, calendars, schedules, timers, etc.)	Compensatory Interpersonal Process Recall (IPR) Videotape of social interaction, viewing of tape, feedback, corrections and practice
	Source	Novack (1996)	Schmitter- Edgecombe (1995)	Neistadt (1992)	Ruff (1990)	Helffenstein (1982)

 Table 2.
 Randomized controlled trials of cognitive rehabilitation-health outcomes (Arc 1)

1		I	I	I	I	II (a)
Doculto		No Treatment Effect $\Delta$ for FIM ADLs T = 29.3 C = 29.2	No treatment effect on 4 or 5 measures. Treatment group had fewer EMFs than control group at posttreatment. $\Delta$ for mean no. of EMFs T = -23.37 C = -7.75 No treatment effect at follow-up	No treatment effect on RKE-R \Delta for RKE-R T1 = 7.92 T2 = 2.68 Perceptual Skills Group (T2) scored significantly higher than Functional Skills Group (T1) on Parquetry Block Design	No treatment effect $\Delta$ for means on KAS global scale scores ranged from: T = 4, C = 1 (Social Obstreperous- ness, Self-Report) to: T = -0.6, C = -0.4 (Acute Psychoticism, Family/Report).	Treatment effect on 1 variable from STAS and 3 variables from TSCS. Treatment effect on IRRS scale, and Independent Observer Report Scale (group means not provided)
Cutorence (and and and	Outcourtes/ attaiyers	Digit Span & Mental Control subtests of WMS Computer-based measures of reaction time (RT) Neuropsychological Battery FIM on 24 of 44 subjects MANOVA/ANCOVAs, t-tests	Laboratory Recall (Index from WMS Logical Memory 1 & 2, Visual Reproduc- tion 1 & 2) RBMT profile score Everyday Memory Questionnaire Observed Everyday Memory Failures (EMFs) Symptom Checklist 90 ANCOVAS	Parquetry Block Design Rabideau Kitchen Evaluation Revised (RKE-R) WAIS-R Block Design subtest ANOVAs, t-tests	Katz Adjustment Scale (KAS) Self-Report and Family Report MANOVA/ANCOVA	State Trait Anxiety Scale (STAS) Tennessee Self-Concept Scale (TSCS) Interpersonal Communication Inventory (ICI) Interpersonal Relationship Rating Scale (IRRS) Independent Observer Report Scale Videotape Analysis ANCOVAS
Contractor	Sevenus	21-GCS ≤ 8 3-moderate GCS + positive CT 20-8 days coma + positive CT	T - 139.3 DRS (2.2) C - 140.5 DRS (2.6)	≤ 10 WAIS-R Block Design scaled score Less than perfect score on pretest RKE-R	T - 25.5 coma days (16.4) C - 48.3 coma days (28.3)	Estimated to be mild to moderate
	CITTOTICULY	T - 5.9 wk (3.3) C - 6.4 wk (4.9)	T - 77.7 mo (46.8) C - 86.8 mo (67.7)	7.9 yr (6.6)	T - 44.3 mo (25.6) C - 52.2 mo (19.2)	Not specified
Ĩ	N	T - 22 C - 22	T - 4 C - 4	T1 - 23 T2 - 22	T - 12 C - 12	T - 8 C - 8
	source	Novack (1996)	Schmitter- Edgecombe (1995)	Neistadt (1992)	Ruff (1990)	Helffenstein (1982)

Table 2. Continued

Table 3. Randomized controlled trials of cognitive rehabilitation—intermediate outcomes (Arc 3)

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Setting/population	University of Virginia School of Medicine Woodrow Wilson Rehabilitation Center Population not specified	DeAnza College Population not specified	Results	Treatment effect on 8 of 18 neuropsychological subtests. Group means not presented	ores higher than al tasks. Verbal ner than Imagery o uns between magery Group on: call: +8 tion: -2.5 tion: -2.5 tion: -2.25 tion: -2.25 tion: -2.25
Follow- up	None	15 d CMRG only	-	Treatment effect on 8 of 18 neuropsychological subtest means not presented	Treatment effect Imagery group scores highe Verbal on all verbal rasks. Vy group scores higher than In all imagery tasks. Difference in means betwee Immediate recall: +1.5 3. Trials to criterion: -2.5 Difference in means betwee Labeling and No Verbal Lab Group on: 1. Immediate recall: +5 3. Trials to criterion: -2.25 3. Trials to criterion: -2.25
Duration of intervention	5.5 hr/d 4 d/wk 6 wk 24 sessions 132 hr total	45 min sessions 12 sessions 4.5 wk 9 hr total	sis		
Comparison group/ 2nd treatment group	Games, psychosocial support, art, group discussions, self- expression, relaxation exercises	Two comparison groups: 1. Computer Control Group (CCG) Used computers to create graphics. 2. No-Exposure Control Group (NECG)	Outcomes/analysis	TeachWare Screening Module Standardized Neuropsychological Test Battery ANCOVAS used to test group differences	Verbal Task Mean No. Words Recalled, Delayed Recall, & Trials to Perfect Visual Task Mean No. Words Recalled, Delayed Recall, & Trials to Perfect MANOVA
ment group	Restorative and compensatory External mnemonics, encoding strategy practice, personalized emotional techniques, rehearsal, CACR, synthesis of all in group practice	ining Group	Severity	Recovered to 7 or 8 on Rancho scale	≥ 3 weeks coma Average WAIS- R IQ = 80
Intervention/treatment group	Restorative and compensatory External mnemonics, encoding strategy practice, personalized emotional techniques, rehearsal, CACR, synthesis ( all in group practice	Restorative CACR Computer Memory Retraining Group (CMRG)	Chronicity	Ranged from 3 months to 4 years	Average 13.2 months from return to conscious- ness to treatment
Inte	Restorati External practice, techniqu all in gro	Restorative CACR Computer I (CMRG)	N	T - 6 C - 6	T1 - 15 T2 - 15 T3 - 15 T4 - 15
Source	Ryan (1988)	Kerner (1985)	Source	Thomas- Stonell (1994)	Twum (1994)

Source	N	Chronicity	Severity	Outcomes/analysis	Results	Level
Niemann (1990)	T - 13 C - 13	T - 41.0 C - 37.1	Coma T - 15 days C - 20 days GOAT T - 94.4 (5.5) C - 90.7 (6.8) DRS T - 132.9 (9.0) C - 135.2 (7.0)	Attention Test d2 PASAT Divided Attention Test Trails B RAVLT Block Span Learning SDNTB subtests MANOVA	No treatment effect	
Ruff (1980)	T - 20 C - 20	Ranged from 1 to 7 years	T - 32.1 coma days (21.4) C - 48.8 coma days (26.4)	San Diego Neuropsychological Battery Forms A and B MANOVA	No treatment effect	_
Ryan (1988)	T - 10 C - 10	T - 54.5 months C - 57.3 months	Each group had 5 milds (DRS > 134/ 144) and 5 moderates (DRS ≤ 134/ 144)	BVRT, Rey CFT, Taylor Complex Figure, Selective Reminding Test, Ruff Trail, WMS Logical Memory subtest MANOVA	No treatment effect	
(1985)	CMRG - 12 CCG - 6 NECG - 6	≥3 months	Memory index rating severe to mild	Memory Index (MI) scaled & standard scores Acquisition Recall (AR) scaled & standard scores t-tests	Treatment effect on 5 of 12 measures 1 $\Delta$ AR (scaled) for CMRG = -4.33, for CGG = 0.00 $\Delta$ MI (scaled) for CMRG = -5.92, for CGG = 0.50, for NEGG = 0.66 $\Delta$ MI (standard) for CMRG = -5.58, for CGG = 0.50, for NEGG = 0.33 Significant increase for CMRG was not maintained at follow-up	
T = treatment g	roup, C = c	ontrol group. Num	ıbers in ( ) are stand:	T = treatment group, C = control group. Numbers in () are standard deviations. Negative values indicate gain.		

Table 3. Continued

Source		Intervention/target	/target	Comparison	Duration of intervention	Follow- t up	Setting/population	ų
Prigatano (1984)	Restorative a Intensive, co CR. Stresses, co compensator includes clin speech patho therapist, ph psychologist	Restorative and compensatory Intensive, coordinated, multidisciplinary CR. Stresses awareness of deficits, compensatory skills development. Staff includes clinical neuropsychologist, speech pathologist, occupational therapist, physical therapist, research psychologist	satory inultidisciplinary of deficits, slopment. Staff sychologist, pational bist, research	No neuropsychological rehabilitation program (NRP). Other interventions not specified	4 d/wk 6 hr/d 6 mo 624 hr total	Between 33 mo and depending on when the person entered the program and was discharged	T: TBI clients who entered Presbyterian Hospital NRP between 2/ 80 and 8/82 and stayed at least 6 months. C: TBI files of referrals to NRP between 2/80 and 8/ 82 who did not enter the program were retrospec- tively examined	n 2/ cd at s to id 8/ the vec-
Source	N	Chronicity	Severity	Outcomes/analysis	ysis	Re	Results	Level
Prigatano (1984)	T = 13 C = 17	T - 21.6 months C - 13.6 months	Not specified	<ol> <li>WAIS-R Verbal IQ, Performance IQ, Vocabulary, Block Design, Digit Symbol. WMS Memory Quotient, Logical Memory, Visual Reproduction, Associative Learning, Halstead Reitan Trail Making Test, Finger Tapping, Tactual Performance Test. Russell-Neurenger Average Impairment Scale</li> <li>EMS Relative Scale</li> <li>Employment ANCOVAS</li> </ol>	ol. Jing, ger t	Treatment effect: 1. WAISR performance I.Q. $\Delta$ T = 8.7, C = 4.8 $\Delta$ T = 2, C = 1.4 $\Delta$ T = 2, C = 1.4 3. WMS Memory Quotient $\Delta$ T = 9.5, C = 2	à	(Q)I
= treatment	T = treatment group; c = control group.	ontrol group.						

Table 4. Comparative study of cognitive rehabilitation—employment (Arc 2)

Source	Intervention/treatment group	Comparison group/ 2nd treatment group	Duration of intervention	Follow- up	Setting/population
Gray (1992)	Restorative CACR tasks selected that make demands on alerting, working memory, alternating attention and divided attention. Used feedback, reinforcement, visual stimuli, and cueing	Recreational computing	T - 75 min sessions 14 sessions over 3-9 wk 17.5 hr total C - 60-90 min sessions over 3-9 weeks Mean 12.7 hr total	6 то	Newcastle General Hospital, Cambridge Univ., U.K. Psychologists in outpatient clinics, staff of social services, and support groups in Edinburgh solicited for names of people with attention deficits due to brain injury.
Batchelor (1988)	Restorative CACR directed toward remediation in recent memory, attention/ speed of information processing, and higher cognitive functioning	Restorative cognitive therapy directed toward remediation consistent with treatment group but delivered without computers	4-6 wk 20 hr total	None	Westmead Hospital, Australia Consecutive referrals to rehabilitation medicine unit over 9 month
Wood (1987)	Restorative visual training of information processing using CACR	C1 - Clients in same inpatient rehabilitation center as treatment group who did not receive the CACR intervention C2 - Persons without TBI	1 hr/d 20 d 4 wk 20 hr total	20 d	Inpatient rehabilitation center St. Andrew's Hospital, U.K.
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 Table 5. Comparative studies of cognitive rehabilitation—intermediate outcomes (Arc 3)

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Level	II(b)	(4)	(d)II	
Results	Treatment Effect on 2 of 22 tests at posttreatment Treatment effect on 6 of 22 tests at follow-up Group means not presented	No treatment effect	Treatment effect for attention to Task and Attention Rating Scale from baseline to first follow-up Treatment effect for Choice Reaction time from baseline to second follow- up. Group means not presented	
Outcomes/analysis	PASAT No. Correct, Longest String, and Information Processing Rate (IPR) WAIS-R subtests Neuropsychological Battery 22 Total Tests ANCOVAS used for analysis	WAIS-R Russel's WMS Buschke Selective Reminding Test Taylor Figure PASAT Austin Maze ANCOVAs and t-tests used for analysis	Pursuit Rotor, Digit Symbol, Choice Reaction Time, Simple Reaction Time, Visual and Choice Reaction Time for vigilance, attention to task, Attention Rating Scale	ndard deviations
Severity	T - 8 mild to moderate, 9 severe C - 8 mild to moderate, 6 severe	T - 7.3 coma days (6.3) C - 7.0 coma days (8.7)	PTA T - 2.4 months (0.5) CI - 2.7 months (0.4) All required full-time care	T = Treatment Group, C = Control Group. Numbers in ( ) are standard deviations
Chronicity	T - 79 weeks (151) C - 84 weeks (152)	T - 72.7 days (66.5) C - 96.3 days (104.1)	T - 27.5 months (5.8) CI - 36.5 months (15.6)	Control Group. N
N	T - 17 C - 14	T - 17 C - 17	T - 10 10 - 22 10 - 10	Group, C =
Source	Gray (1992)	Batchelor (1988)	WooW (7987)	T = Treatment (

Source	Setting/population	Ν	Chronicity	Severity
Girard (1996)	Current and former clients of a hospital-based, interdisciplinary outpatient TBI program	Initial - 152 6 month follow-up - 114 12 month follow-up - 69	3 years (range 6 mo to 12 yr)	Not specified
Cicerone (1996)	Referrals to neuropsychology clinic of brain injury rehabilitation program. Selected on basis of having participated in neurorchabilitation, having neuropsychological evaluation, and being available for follow-up.	20	7.8 mo (range 3-20 mo)	Mild
Ip (1995)	Consecutive referrals for rehabilitation to brain injury unit of a hospital between 1988 and 1994	70	3.1 yr	20% mild 27% moderate 53% severe (based on GCS)
Fabiano (1995)	Consecutive referrals to 3 postacute rehabilitation facilities Minimum length of coma 24 hr, minimum chronicity 1 yr	94	59 mo (42.6)	Severe 20 days average length of coma (20.2)
Ezrachi (1991)	Consecutive participants in NYU Head Trauma Program over 4 years Sample chosen on basis of not being able to return to work for 1 year postinjury and willingness to partici- pate in program	59	34.65 mo (27.49)	Moderate to severe 36.2 days in coma (31.42)
Fraser (1988)	Consecutive outpatient referrals who were employed prior to injury	48	Not specified	Average GCS for 35 who returned to work = 13 Average BCS for 13 who did not return to work = 11
Brooks (1987)	Consecutive admissions to Department of Neurosur- gery, Institute of Neurological Sciences, Glasgow, UK	134	Ranged from 2 to 7 years	Coma duration ≥ 6 hours, or PTA > 2 days, or surgery for intracranial hematoma <i>continues</i>

Table 6. Studies of the relationship between intermediate tests and employment (Arc 5)

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Severity	Coma duration ranged from $\leq 1$ day ( $n = 21$ ) to $\geq$ 30 days ( $n = 21$ )	Results	67% of sample was productive at follow-up, 33% not produc- tive. 6 scores significantly related to outcome at first follow-up, 8 at second With regression analysis, 9 test with regression analysis, 9 test scores (WAIS-R Block Design, Digit Symbol, Picture Comple- tion, and Full Scale IQ; Symbol Digit Written and Oral; Trails B; WAIS-R Arithmetic and WRAT-R WAIS-R Arithmetic and WRAT-R Characteristics (mechanism of injury, insurance funding, and premorbid substance abuse) accounted for 30% of the variance in outcome	GO clients had significant improvement on 6 of 13 neuropsychological tests PO clients had significant improvement on 1 neuropsy- chological test	00
Chronicity	Not specified		67% of sa at follow- tive. 6 scores s outcome with regr second With regr scores (W MAIS-R A Digit Sym Digit Writ WAIS-R A Arithmeti character injury, ins premorbi accounter	GO clients had improvement ( neuropsycholo PO clients had improvement ( chological test	
N	Not	Design/analysis	Prospective case series ANOVAs and Stepwise Multiple Regression used for analysis	Retrospective T-tests	
pulation	Lowenstein Rehabilitation 147 viv University School of to 1/4/7	Health/employment outcomes	McAuley Outcome Scale Measures productive outcome in home, school, work. Scale ranges from 1 (not productive) to 6 (more produc- tive than premorbid level)	Good Outcome Group (GO): Clients who resumed responsibili- ties equivalent to premorbid status, or other, less demanding, productive activity ( $n = 10$ ). Poor Outcome Group (PO): Poor Outcome Group (PO): premorbid level of activity/ responsibility ( $n = 10$ )	
Setting/population	Consecutive discharges from Lowenstein Rehabilitation Hospital, Ra'anana, and Tel Aviv University School of Medicine, Israel from 1/11/74 to 1/4/7	Intermediate tests	28 tests and subtests: Symbol Digit Written and Oral Halstead-Reitan Trails A & B WAIS-R Verbal subtests (6) Performance subtests (5) WMS-R Verbal Memory, Visual Memory, General Memory, Attention/Concentration, Delayed Recall Wisconsin Card Sorting Test The Booklet Category Test Wide Range Achievement Test (WRAT-R)	Gicerone 13 neuropsychological tests (1996) Digit Span Forward & Backward Trails A & B Continuous Performance Test of Attention PASAT Logical Memory 1 & II CVLT Rey CFT Inmediate and Delayed Recall WCST Perseveration Category Test Mazes Verbal Fluency	
Source	Najenson (1980)	Source	Girard (1996)	Cicerone (1996)	

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Results	At follow-up, 42% had returned to work/school, 58% had not 5 of 16 neuropsychological tests significantly related to RTW/S	At follow-up, 8 subtests predicted employment status as follows: Full-time employed: 62% accurate Part-time employed: 58% accurate Not competitively employed: 67% accurate
Design/analysis	Retrospective evaluation of medical charts and follow-up phone calls to obtain RTW/S data t-tests used for continuous scales chi-square used for mominal scales Wilcoxon rank sum test used for ordinal scales logistic regression used to evaluate association of neuropsychological tests with RTW/S	Retrospective evaluation of medical charts and follow-up phone calls to obtain current employ- ment data Discriminant analysis used to specify strongest used to specify strongest ment
Health/employment outcomes	Dichotomous measures of return to work or school (RTW/S), either full or part time, following hospital discharge	Full-time employment $(n = 20)$ Part-time employment $(n = 15)$ Successful college attendance $(n = 8)$ Supported/sheltcred employment $(n = 11)$ Unemployed $(n = 40)$
Intermediate tests	Ip (1995) 16 neuropsychological tests: WAIS-R Performance IQ Verbal IQ, Full Scale IQ WMS-R Delayed Recall Attention/Concentration General Memory Index Verbal Memory Index Visual Memory Index Visual Memory Index Tapping dominant & nondominant Grooved Pegboard Test dominant & nondominant	8 subtests of WAIS-R Picture Arrangement Full Scale IQ Performance IQ Similarities Block Design Digit Symbol Prediction Points Verbal IQ Length of Coma
Source	Ip (1995)	Fabiano (1995)

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Results	At 6-month follow-up, factors from pretreatment data with strongest association to VSTAT were: Adaptation to community Verbal Aptitude Self-Appraisal Coma Factors from posttreatment data with strongest association to VSTAT were: Acceptance of program Verbal aptitude Involvement with others Psychomotor dexterity Self-appraisal Coma	At 1-year follow-up, 35 had returned to work, 13 had not returned to work 6 of 9 neuropsychological tests significantly related to employment
Design/analysis	Prospective case series Factor analysis was used to reduce data for neuropsychological tests and BCI, with pretreat- ment scores to ment scores to and determine factors Data reduction resulted in 12 neuropsychologi- factors and 4 BCI factors After generating factor structures, factor scores were calculated separately from pretreatment data for each factor to serve as predictors for VSTAT Stepwise multiple regressions were dron evaluate association of factors derived from neuropsychological tests and BCI with VSTAT	Prospective case series Binary data analyzed with chi-square tests of association All other data analyzed with Wilcoxon rank sum tests
Health/employment outcomes	Vocational Status (VSTAT) 6 mo after completion of program, rated on a 10-point scale from 1 (remains unemployable in any capacity) to 10 (returned to academic level position; no qualifications) qualifications)	chological tests: Dichotomous measure of Performance Test (TPT), returned to work or did not ory Test, Trails B, return to work ad's Impairment Index, IQ (Verbal, Perfor- 2, Full Scale), WAIS Digit J, and Name Writing dures
Intermediate tests	38 neuropsychological subtests from 7 instruments: Orientation Remedial Module (ORM) Purdue Pegboard Visual measures from Rusk Institute of Rehabilitation Medicine (RIRM) Academic measures from MAT and WRAT WAISA Higher order verbal and conceptual skills from RIRM 19 tests of functional behavior- Behavioral Competence Index (BCI)	9 neuropsychological tests: Tactual Performance Test (TPT), Category Test, Trails B, Halstead's Impairment Index, WAIS IQ (Verbal, Perfor- mance, Full Scale), WAIS Digit Symbol, and Name Writing Procedures
Source	Ezrachi (1991)	Fraser (1988)

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Results	At follow-up, 34 clients were employed full or part time, 85 were unemployed, 13 had other status, ie, homemaker, retired, 2 were unknown Groups differed significantly on 6 of 9 neuropsychological tests	At ≥ 6 months follow-up (skilled and unskilled work groups were combined to constitute "working"): For Raven Matrices Test, 10 of 14 who scored above average were working (55%); 17 of 48 who scored below average were working (55%); 18 of 48 who scored below average were working (55%); 18 of 40 who scored below average were working (55%); 18 of 62 who scored below mormal were working (29%); 16 who scored severe rigidity were working (19%).
Design/analysis	Retrospective evaluation of medical charts and follow-up interview of client and informant 2-7 years pottrauma t-tests used to compare neuropsychological tests scores between groups	Prospective case series Frequencies reported, and statistical signifi- cance (p < .005) reported; method of analysis not reported
Health/employment outcomes	Dichotomous measure of employed or not	Four employment categories: Skilled work Sheltered workshop Unemployed
Intermediate tests	9 neuropsychological tests: Progressive Matrices and Mill Hill Vocabulary Scale, WMS Logical Memory, Verbal Paired Associates, Buschke Procedure, Rey Complex Figure Copy, PASAT, Borkowski Word Fluency Test, Token Test, and a structured interview	<ul> <li>Najenson 2 neuropsychological tests:</li> <li>(1980) Raven Matrices Test and Wisconsin Card Sorting Test</li> </ul>
Source	Brooks (1987)	Najenson (1980)

 Table 7. Observational study of cognitive rehabilitation—health outcomes (Arc 1)

Source	Int	Intervention	Duration of intervention Follow-up	Follow-up	Setting/population	N
Vilson (1997)	Compensatory c provide remind <i>neuropage</i>	Wilson (1997) Compensatory device programmed to baseline 2-6 wk provide reminders of daily activities treatment-12 wk <i>neuropage</i> baseline-3 wk	<ul> <li>baseline 2-6 wk</li> <li>treatment-12 wk</li> <li>baseline-3 wk</li> </ul>	none	Cambridge University, UK Referrals from hospital, therapists, psychiat- ric clinics, support group	15
Source	Chronicity	Severity	Outcomes/analysis		Results	Level
Wilson (1997)	Ranged from 6 mo to 13 yr	RBMT ranges from severe to moderate or mild	Everyday Memory Failures maximum sc individually determined, based on num of target reminders Mean % success used to measure effect	a number 6 a number 6 effect A F	<ul> <li>Wilson (1997) Ranged from 6 RBMT ranges from Everyday Memory Failures maximum score Significant increase in scores for all subjects mo to 13 yr severe to individually determined, based on number during treatment. Scores decreased for 11 of 15 during second baseline. Mean % success used to measure effect Mean % success: Baseline-37,08% (24,86) Treatment-85,6% (18,58) Baseline-74,46% (28,23)</li> </ul>	⊟
lumbers in ( ) are	Numbers in ( ) are standard deviations.	ls.				

did those who did not have the compensatory devices. However, the effect was not present at 6-month follow-up. In the second study,<sup>13</sup> clients who received compensatory training had better results than did those given nontherapeutic attention on one variable from an anxiety scale and three variables from a communication scale, and had better performance on the Interpersonal Relationship Rating Scale and Independent Observer Report Scale. Six scales were used in this study. The numbers of variables per scale were not provided, nor were the group means.

In the other three studies described in Table 2, the cognitive rehabilitation intervention was not more effective than were the alternatives. The predominantly negative results of these small, Class I and II[a] trials may be mitigated by three important factors. First, in general, both groups in these studies improved from pre- to posttreatment, producing no treatment effect in the statistical analysis. This raises the question, What is operating to cause general improvement-stimulation or spontaneous recovery, or both? In each study, the comparison group received equal hours of some form of stimulation, some of which was therapy of an unstructured nature. Second, four of the five studies provided 20 hours or less of treatment time. With the pervasive and lifelong cognitive deficits that result from TBI, results from interventions of such limited duration should not be generalized to more sustained interventions. Third, it isn't clear whether the patients included in these studies are representative of patients who might undergo cognitive rehabilitation in current practice. Along with the small size of the studies and the narrow range of interventions studied, the lack of information about the representation of included patients makes it difficult to apply the findings of these studies to cognitive rehabilitation practice in general.

# Does cognitive rehabilitation improve employment outcomes (Arc 2)?

There is no direct evidence from randomized trials of the effect of cognitive rehabilitation on employment.

#### **Comparative studies**

One study<sup>18</sup> compared employment outcomes for clients of an intensive cognitive rehabilitation program (NRP) with those of people who were referred to the program but who did not participate (see Table 4). The intervention involved RCR and CCR in a coordinated multidisciplinary program. Participants were provided a minimum of 624 hours of treatment (4 days a week for 6 hours a day) over 6 months. The treatment group consisted of patients who entered NRP between February 1980 and August 1982, and who stayed in the program at least 6 months. Files for patients referred to NRP during the same time period and who did not enter the program were retrospectively evaluated to provide control group data. Follow-up took place approximately 3 months after the last client was discharged; consequently, follow-up varies from 3 months to 33 months. Eighteen people received the treatment; 17 were the nontreatment referrals. Chronicity for the control group was shorter (13.6 months) than that of the treatment group (21.6 months). Severity was not specified.

Participants were evaluated with 13 neuropsychological tests, the KAS Relative Scale, and a measure of employment. People who were gainfully employed, either part time or full time, or who were actively engaged in a realistic school program were considered to be employed. There were treatment effects on 3 of the 13 neuropsychological tests. Client attrition resulted in a reduction of participants at the time of follow-up. Of 18 people in the treatment group, 9 were employed at follow-up (50%). Of 13 in the control group, 5

were employed (38%). The statistical significance of this difference was not reported.

Because of the potential and unknown differences between treatment and control groups, interpretation of these results is difficult. Authors did not specify why clients in the control group, although referred to NRP, did not participate. It is possible that the same factor or factors that caused them not to participate in NRP operated to influence their employment outcomes (in either direction). This Class II(b) study does not provide evidence for or against the effect of cognitive rehabilitation on employment. However, it provides limited evidence of the effect of the intervention on some intermediate measures of cognitive function.

#### **INDIRECT EVIDENCE**

# Does cognitive rehabilitation improve performance on intermediate measures of cognitive function (Arc 3)?

# Randomized controlled trials

Six randomized controlled trials<sup>19-24</sup> used a variety of neuropsychological tests and other intermediate measures to compare the effects of different forms of cognitive rehabilitation with each other and with other forms of therapy and stimulation (see Table 3). Duration of treatment ranged from a single training session to a total of 160 hours of intervention. Two studies<sup>19,20</sup> conducted follow-up testing at 2 weeks. The other studies did not follow up participants. The studies varied in setting, client populations, sample size, client chronicity, and measures of severity of injury. One hundred eighty-two clients were observed; 106 received the targeted treatments.

A number of individual tests of cognition, such as the PASAT, was used in the six RCTs. In addition, three of the studies also used a full battery of neuropsychological subtests. Three studies produced treatment effects. Outcomes for one<sup>23</sup> were a computerized screening module and a neuropsychological battery. No follow-up testing was conducted. Outcomes for the second study<sup>24</sup> were number of words and colors recalled immediately after practicing mnemonic techniques with the words and colors. No follow-up testing was conducted. Outcomes for the third study<sup>19</sup> were a Memory Index (MI) task and an Acquisition Recall (AR) task, measured in scaled and standard forms. The treatment group received computer-assisted cognitive rehabilitation (CACR) targeting memory retraining. A control group used computers to create graphics, and a second control group had no intervention. With three groups and two forms of measuring each of the two tests, twelve effects were possible. Treatment effects were produced on 5 of the 12 measures at posttreatment. Improvement by the treatment group was not maintained at 2-week follow-up; however, the two control groups did not receive a follow-up test. Therefore, group differences in the decline were not assessed.

Two of the three studies for which there were no treatment effects<sup>21,22</sup> compared equal amounts of structured cognitive rehabilitation programs with unstructured activities. The third<sup>20</sup> compared equal hours (36 total) of attention remediation with memory remediation. For all three studies, clients in both treatment and comparison groups improved from pre- to posttreatment. This result underlines the previous suggestion that more may be learned about treatment effects by comparing intervention with no intervention, rather than by comparing one form of intervention (ie, structured) with another form (unstructured) in a design that provides equal amounts of time and stimulation. Also, this result suggests that there may be a general effect of stimulation, perhaps interacting with spontaneous recovery, that exceeds the effect of the intervention.

To conclude, there is evidence from three small Class I trials that practice, both with and without the aid of a computer, operates to improve short-term recall on laboratory tests of memory for persons with TBI. However, it is not known whether these improvements were clinically meaningful to the individuals tested.

#### **Comparative studies**

Three studies with comparison groups to which participants were not randomly assigned used laboratory tests to evaluate the effect of cognitive rehabilitation on cognition<sup>25-27</sup> (see Table 5). All three used CACR to enhance the intervention. One<sup>26</sup> compared the effect of CACR with that of recreational computing; the other two compared CACR to therapy that did not make use of computers. Treatment time ranged from 17.5 to 20 hours. Two studies<sup>26,27</sup> performed follow-up testing at 6 months and 20 days, respectively. Samples included both inpatients and outpatients; the populations from which they were drawn varied. Ninety-five people were observed in these studies; 44 received the targeted interventions.

Measures used to evaluate treatment effect included tests developed by the clinic or research project, as well as established neuropsychological tests. Of 36 intermediate tests performed, two of the three studies produced treatment effects on nine tests. Group means were not presented, preventing an assessment of the magnitude of improvement. As with the RCTs for this category, equal amounts of stimulation were provided to both the treatment and control groups. Improvements from posttreatment to follow-up suggest the presence of spontaneous recovery. These small, Class II(b) studies provide limited evidence that CACR improves performance on laboratory tests of cognition for persons with TBI. How the improved performance translates into daily life is not established.

In Table 1, column (a) shows the number of RCTs in which cognitive rehabilitation had a statistically significant effect on the test listed for that row; column (b) presents the same information for comparative studies. Column (c) gives the number of correlational studies in which there was a significant association between the test and a health outcome or employment. Columns (d), (e), and (f) list numbers of studies for each test for which there was no effect or association. The last two columns are

- 1. the proportion of times that the test was used in controlled studies (RCTs and other comparative studies) in which the intervention produced an effect on the test and
- 2. the proportion of times the test was used in correlation studies in which there was a positive correlation between the test and a health outcome or employment.

For RCTs, there was an effect of treatment 14 of 51 times (27%). Other comparative studies produced a treatment effect 12 of 45 times (27%). For correlation studies, there was a significant association between intermediate tests and health outcomes or employment 33 of 64 times (52%). Thus, as the strength of evidence decreased, the effect increased. In addition, as the strength of research design decreased, the number of studies increased.

Although limited, there is some evidence that certain cognitive rehabilitation methods improve performance on neuropsychological tests and other laboratory-based methods of evaluating cognitive function. The next question addresses the second link in the indirect path from intervention to relevant outcome.

# Do intermediate measures of cognitive function associate with bealth outcomes (Arc 4) or employment (Arc 5)?

No studies meeting the criteria for this review reported an association between laboratory-based measures of cognitive function and health outcomes such as functional independence, ADLs, or measures of everyday memory.

Table 6 presents eight studies that measured the cognitive function of persons with TBI, using a variety of neuropsychological tests. It also measures postinjury employment status or productivity and activity level.28-35 Each used a correlation-based method to analyze the relationship between the laboratory tests and employment status. Although specific research methods varied, in general, these studies retrospectively gathered hospital and inpatient rehabilitation chart data to establish test scores, then interviewed clients and/or relatives to establish employment status. Sample sizes ranged from 20 to 152 participants; 724 people were observed. Chronicity and severity varied within and across samples.

One hundred twenty-three tests of cognition were administered. Two studies<sup>30,33</sup> used numeric scales to measure productivity from 1 (worst) to 10 and 6, respectively. Four studies<sup>28,29,32,34</sup> used dichotomous measures of return to work or former level of productive activity. Two<sup>31,35</sup> placed clients into five and four categories of employment, respectively. Methods of analysis included regression, ttests, chi-square, Wilcoxon rank sum, discriminant analysis, and factor analysis.

Approximately half of the time, clients with higher intermediate test scores had returned to work or productivity, full or part time, but not necessarily to the pretrauma level. In one study that used a regression analysis,<sup>33</sup> 9 of 28 test scores, combined with 3 demographic characteristics, accounted for 30 % of the variance in outcome; 19 of the tests did not help explain the difference in employment outcomes. In another study,<sup>31</sup> intermediate test scores were used in a discriminant analysis to derive a formula for predicting employment status. With this method, high scores on tests accurately predicted fulltime employment 62% of the time, and low scores on tests accurately predicted unemployment 67% of the time. These proportions indicate that, whereas there appears to be some relationship between intermediate measures of cognition and employment, the association is not strong.

#### **OBSERVATIONAL RESEARCH**

Although research designs without control groups have limitations, they can be a source of hypotheses that can be tested in controlled trial settings. This section highlights insights from studies with uncontrolled research designs identified in our literature search.

Nine observational studies of clients before and after cognitive rehabilitation fulfilled the criteria for inclusion in this review.<sup>36–44</sup> One used a measure of a relevant health outcome, EMFs, and an A-B-A design (baseline-treatment-return to baseline) to evaluate treatment effect (Table 7).<sup>44</sup>

The other eight studies either compared clients' performance from baseline phase with treatment phase (without a return to baseline), provided the same or similar treatments to different matched groups, or combined group and individual methods of measurement. In general, results indicate that, for the selected clients treated in these clinical studies, one-on-one interaction with therapists in a rehabilitation environment is likely to improve individual performance on targeted laboratory tasks. Based on the criteria for evidence used in this review, the studies do not contribute to the body of evidence about the intervention being provided. However, the fact that clients do, in fact, improve gives rise to innovations in rehabilitation technology that may be useful to persons with TBI and that warrant further evaluation.

For example, in the study presented in Table 7,<sup>44</sup> 15 clients were provided with an electronic device programmed to assist them in remembering to do routine daily tasks. Prior to the intervention, they were inter-

viewed to identify targets for memory remediation unique and important to them. Thus, the intervention was individually adapted. The score for EMFs was the number of times that a target was forgotten. Everyday Memory Functions were measured for 2—6 weeks during baseline. During the treatment phase, which lasted 12 weeks, each person in the study wore and used the device. The return-to-baseline phase was 3 weeks.

All participants had significant decreases in EMFs during treatment. During the return-tobaseline phase, EMFs increased for 11 of the 15 participants; 5 increases were statistically significant. The results of this study suggest that the use of an electronic cueing device decreases EMFs for some people with TBI, contributing to the link represented by Arc 1 of the Causal Pathway. The observational design of this study weakens its value as evidence of effectiveness. However, in considering that the nature of most of the interventions reviewed here is not individually adapted and, on face value, does not appear to be as pragmatic as an effective reminder device, this study is useful, in that it generates a hypothesis about an intervention that may have potential to prosthetically improve memory for persons with TBI.

#### DISCUSSION

Our goals for this review were to

- 1. present the findings of our search for evidence of the effectiveness of cognitive rehabilitation,
- 2. highlight controversies about methods for evaluating forms of the intervention and their outcomes, and
- 3. make recommendations for practice and future research.

# SUMMARY OF THE EVIDENCE

Very few controlled studies of cognitive rehabilitation have examined health outcomes or employment. One small randomized controlled trial (Level I) and one observational study (Level III) provide evidence of the direct effect of compensatory cognitive devices (notebooks, wristwatch alarms, programmed reminder devices) on the reduction of EMFs for persons with TBI. A second randomized controlled trial (Level II[a]) provides evidence that cognitive rehabilitation reduces anxiety and improves self-concept and interpersonal relationships for persons with TBI.

In the absence of strong and sufficient evidence for a direct effect of cognitive interventions on health and employment, we examined a causal pathway linking cognitive rehabilitation to intermediate measures of cognition and subsequent associations between those measures and health or employment. Three small randomized controlled trials (Level I) and two comparative studies (Level II[b]) provide evidence that practice and CACR improve performance on laboratory-based measures of immediate recall. However, no studies evaluated the link between cognitive tests and health outcomes, and associations between performance on cognitive tests and posttrauma employment and productivity were equivocal.

#### **Clinical protocols and TBI**

In a previous publication summarizing the five key questions addressed in the evidence report,<sup>12</sup> we illustrated a controversy in TBI rehabilitation that we characterized as standardization of care versus individualized treatment. The analog in research is the use of RCTs versus single-subject designs and other observational techniques to evaluate treatment effect. Some professionals assert that, by definition, application of a standard clinical protocol eliminates the best avenue available for a person with TBI to respond to treatment. Constrained by clinical procedure, the person cannot follow the best course to recovery-that of ongoing, individual, strategic modification.5,45 If so, lack of treatment effect from RCTs would be the expected outcome.

This is a cogent argument, and it seems to direct attention to the importance of process in the recovery from TBI instead of to static clinical regimens of testing and skill training. However, this argument must not become merely a non sequitur addressed to researchers who are seeking ways to establish methods for proving effectiveness. Clinicians who present this argument must work to specify and define their methods of treatment to a degree that allows their methods to be tested for efficacy. Failing to do so will expose their clients to the danger of withdrawal of benefits that support their treatment because it is increasingly the case that health plans will pay for only proven treatments. Clinicians and researchers must join forces to discover how best to demonstrate the success of effective methods.

In fact, the best clinicians are providing both a standard protocol and individualized treatment dictated by their clinical experience. We assert that this practice model can be transcribed into a research model, with variability arising from individual needs accounted for by multivariate analysis and innovative research designs.

# RECOMMENDATIONS

#### **Future research**

#### Independent variables

The work begins with the basic task of formulating operational definitions. What is the scope of cognitive rehabilitation overall? How is it best defined, in general? What are its subcomponents? To what extent can cognitive rehabilitation be divided into parts for the purpose of evaluating the relative effectiveness of its components within specified patient groups, before division into parts renders the evaluation meaningless?

#### Dependent variables

What outcomes are relevant to people with TBI and their families? What outcomes are rel-

evant to insurance companies? Among the studies we reviewed, perhaps the most pragmatic outcome measure was EMFs. It is possible that the absence of treatment effect in some studies is a function of the lack of relevance in the lives of the people being evaluated, represented in outcome measures and interventions that have little meaning to those people.

# Subject variables

In studies with large samples, variability arising from individual differences can be managed with multivariate analysis. However, the majority of studies has been too small for statistical control of variability. One solution is to limit the range of severity, age, chronicity, social factors, premorbid factors, and other sources of individual differences for each study to become very specific in describing the category of individual being evaluated.

#### Intermediate measures

Laboratory tests that are strongest and most reliable in their ability to measure cognitive function in relevant contexts must be identified and their use standardized across research projects and hospital and clinical settings.

#### **Confounding variables**

How should spontaneous recovery and the effect of stimulation be measured? In general, the studies in this review that did not produce a treatment effect compared one form of cognitive rehabilitation with another form— CACR to non-CACR practice and specific to unstructured rehabilitation methods. Treatment effects were not observed when one kind of remediation was compared with another, given equal levels of stimulation for both treatment and comparison groups. We must test the differential effects of general stimulation versus cognitive rehabilitation technology with a strong research design that accounts for both the unique and universal characteristics of the patient group, validate the findings, be willing to accept what is found, and use it to build reasonable practice standards.

#### Practice

Based on the evidence found in this review, we recommend the application of compensatory cognitive strategies, adapted to patient groups and to individuals, to improve the functional ability of persons with TBI. We acknowledge that, for optimal success, this set of interventions must be delivered within a broader program that accounts for individual needs and utilizes various cognitive remediation technologies traditionally labeled restorative and/or compensatory.

In the absence of strong evidence for the effectiveness of other cognitive rehabilitation methods and in light of the strong possibility that traditional distinctions for therapies (restorative versus compensatory) are simplistic and not clinically useful, we see no good reason why they should be abandoned. In effectively all of the studies in this review, patients improved. Although group differences were rarely observed, recovery across groups occurred. Until we have done the work necessary to be able to demonstrate what is operating to produce improvement, we are bound to provide the services and care at our disposal for this population of people.

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