



AOTA Critically Appraised Topics and Papers Series
Traumatic Brain Injury

**A product of the American Occupational Therapy Association's
Evidence-Based Literature Review Project*

CRITICALLY APPRAISED PAPER (CAP)

Focused Question

What is the evidence for the effect of interventions to address cognitive/perceptual functions (attention, memory, executive functions) on the occupational performance for persons with traumatic brain injury (TBI)?

Salazar, A. M., Warden, D. L., Schwab, K., Spector, J., Braverman, S., Waler, J., et al., for the Defense and Veterans Head Injury Program (DVHIP) Study Group. (2000). Cognitive rehabilitation for traumatic brain injury: A randomized trial. *Journal of the American Medical Association [JAMA]*, 283, 3075–3081.

PROBLEM STATEMENT (JUSTIFICATION OF THE NEED FOR THE STUDY)

State the problem the authors are investigating in this study.

Traumatic brain injury (TBI) is a principal cause of death and disability in young adults. The cost of TBI in the United States is estimated at >\$37 billion per year. Most rehabilitation strategies have not been subjected to the degree of scientific scrutiny for the effectiveness and cost efficiency that is expected of other medical therapies. Thus, the question remains whether interdisciplinary cognitive TBI rehabilitation as currently practiced (2000) is an effective and cost-efficient method of returning patients with TBI to their maximum potential.

RESEARCH OBJECTIVE(S)

List study objectives.

Evaluate the efficacy of inpatient cognitive rehabilitation for patients with moderate to severe TBI. Hypothesis: An in-hospital rehabilitation program would yield greater return to work and fitness for duty rates than a limited home program at 1-year follow-up.

Describe how the research objectives address the focused question.

Exactly addresses the question, as this study examines the effectiveness of therapy (comprehensive program, including occupational therapy) to restore persons with TBI to their occupational role of work.

DESIGN TYPE:

Single center, parallel group, randomized trial

Level of Evidence:

I

Limitations (appropriateness of study design):

Was the study design type appropriate for the knowledge level about this topic? *If no, explain.*

Yes

No

SAMPLE SELECTION

How were subjects selected to participate? Please describe.

273 consecutively hospitalized patients with TBI referred to Walter Reed Army Medical Center during the 5 years of data collection. 167 met inclusion criteria.

Inclusion Criteria

- a) Moderate to severe closed head injury manifested by Glasgow Coma Scale of 13 or less or posttraumatic amnesia of 24 hours or more or focal cerebral damage by CT scan or MRI
- b) Randomization within 3 months of head injury
- c) Rancho Los Amigos cognitive level of VII (oriented; appropriate)
- d) Active duty military member, not pending medical separation
- e) Accompanied home setting with at least 1 responsible adult available
- f) Independent in ambulation
- g) No prior severe TBI or other severe disability that would preclude return to active duty after study treatment

Exclusion Criteria

Mild TBI

Sample Selection Biases: *If yes, explain.*

Volunteers/Referrals

Yes 273 consecutive hospitalized TBI patients were referred to Walter Reed Army Medical Center from January 1992 to February 1997. 167 met eligibility criteria. 47 refused to participate; 120 chose to participate.

No

Attention

Yes

No

Others (list and explain):

SAMPLE CHARACTERISTICS

N = 167; 120 active duty military personnel, 107 completed. Mean age = 25.5 years; 42.5% some college; 29% ranked at sergeant or higher; 37% prior substance abuse; 22% prior psychiatric diagnosis; 38.5 days time postinjury. Randomly assigned to group

% Dropouts

(%) Male

(%) Female

Ethnicity

Disease/disability diagnosis

Check appropriate group:

<20/study group	20–50/study group	51–100/study group <input checked="" type="checkbox"/>	101–149/study group	150–200/study group
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Sample Characteristics Bias: *If no, explain.*

If there is more than one study group, was there a similarity between the groups?

Yes There were some significant differences: significantly more of the in-hospital group were TBI secondary to assault; significantly more of the at-home group were injured in a motor vehicle accident; significantly more of the at-home group had 1 hour or more (not more than 24 hours) of unconsciousness. No significant differences between groups on ~18 other important variables.

No

Were the reasons for the dropouts reported?

Yes refused; not different from those who participated; independent variable (IV) contaminated by adjunctive therapy.

No

INTERVENTION(S)—Included are only those interventions relevant to answering the evidence-based question.

Add groups if necessary

Group 1: Intensive, standardized in-hospital cognitive rehabilitation program; $N = 67$

Brief Description	Both group and individual therapies using a milieu-oriented approach that was modified to fit into a military framework. Free time in late afternoons and evenings. Standard protocol defined structured daily routine, including morning physical fitness training and group and individual cognitive, speech, occupational, and coping skills therapies. Group therapies were planning and organization, cognitive skills, pragmatic speech, milieu, psychotherapy, and community reentry. Afternoon structured job placement, which placed patients in settings similar to previous military specialty, coordinated by the occupational therapist.
Setting	United States military referral center (Walter Reed Army Hospital)
Who Delivered?	Board certified psychiatrist in charge; carried out by certified neuropsychologist, certified occupational therapist, speech pathologist, and two rehabilitation assistants. Physical therapy and psychiatry consultations as needed.
Frequency?	Daily, all day until late afternoon.
Duration?	8 weeks

Group 2: Limited, standardized home rehabilitation program with weekly telephone support from a psychiatric nurse; $N = 53$.

Brief Description	TBI education and individual counseling from a psychiatric nurse. Given educational materials and recommended strategies for enhancing cognitive and organizational skills. Training included card games, watching TV news, and reading magazines and books. Physical exercise at own pace. Some patients resumed vocational activities on their own.
Setting	Home
Who Delivered?	Psychiatric nurse
Frequency?	30 minutes per day practice on own; received 30-minute phone call per week
Duration?	8 weeks

Intervention Biases: *Explain, if needed.*

Contamination

Yes

No

Co-intervention

Yes

No patients who received concurrent adjunctive therapy (in at-home group) were included in the intention-to-treat from data analysis

Timing

Yes the research was conducted from January 1992 to February 1997 (5 years), during which practices could have changed. Partially controlled by continuing education to ensure uniformity of treatment over time

No

Site

Yes one in-hospital and one at home (the IV)

No

Use of different therapists to provide intervention

Yes

No

MEASURES AND OUTCOMES—Included are measures relevant to answering the focused question.

They were tested on 10 cognitive/psychological measures that are not the focus of this review.

Name of measure:

Return to gainful employment at 1 year posttreatment determined by interview, military records, or both.

Outcome(s) measured (what was measured?):

Full time work \geq 35 hr/wk; part time $<$ 35 hr/wk gainful or civilian employment

Is the measure reliable (as reported in article)?

Yes

No

NR

NR = Not reported

Is the measure valid (as reported in article)?

Yes

No

NR

How frequently was the measure used for each group in the study?

1-year follow up

Name of measure:

Fitness for military duty as defined by standard military regulations. With its unique requirements, this measure is more stringent than a measure of work capacity.

Outcome(s) measured (what was measured?):

Still on active military duty or had received a normal discharge from the service, but excluded those who had a medical discharge or whose discharge was pending.

Is the measure reliable (as reported in article)?

Yes

No

NR

Is the measure valid (as reported in article)?

Yes

No

NR

How frequently was the measure used for each group in the study?

1-year follow up

Measurement Biases

Were the evaluators blinded to treatment status? *If no, explain.*

Yes

No but specificity of military regulations and various levels of review helped protect against systematic bias in duty fitness determinations

Recall or memory bias *If yes, explain.*

Yes

No

Others (list and explain):

Limitations (appropriateness of outcomes and measures) *If no, explain.*

Did the measures adequately measure the outcome(s)?

Yes

No

RESULTS

List results of outcomes relevant to answering the focused question

Include statistical significance where appropriate ($p < 0.05$)

Fisher Exact Test; intention-to-treat analysis

Include effect size if reported

Effect size calculated from p values $r = z / \sqrt{N}$

At 1-year follow up, there was no significant difference between patients who had received the intensive in-hospital cognitive rehabilitation program versus the limited home rehabilitation program in return to employment (90% vs. 94%, respectively; $p = .51$, $r = 0$) or fitness for duty (73% vs. 66%, respectively, $p = .43$, $r = .01$). At 1 year, 91% of the hospital group and 93% of the at-home group were working full-time ($P > .99$). In a post-hoc subset analysis of patients who were unconscious for > 1 hour ($n = 75$) following TBI, the in-hospital group had a significantly greater return to duty rate (80% vs. 58%, $p = .05$, $r = .15$ [small effect]).

Was this study adequately powered (large enough to show a difference)? *If no, explain.*

Yes

No 200 participants had been determined in a power analysis to give an 80% power with alpha at .05 to detect differences in treatments; post-hoc power analysis indicated that more than 500 patients would be needed per group to reach statistical significance. This was too great a number so with statistical consultation, the trial was terminated with an N of 120.

Were appropriate analytic methods used? *If no, explain.*

Yes

No

Were statistics appropriately reported (in written or table format)? *If no, explain.*

Yes

No

CONCLUSIONS

State the authors' conclusions that are applicable to answering the evidence-based question.

The overall benefit of in-hospital cognitive rehabilitation for patients with moderate to severe TBI was similar to that of home rehabilitation. The outcomes at 1 year after treatment for patients who received in-hospital cognitive rehabilitation did not differ from those patients who received a limited home rehabilitation program with respect to return to work or fitness for military duty rates or in measures of social adaptation, cognition, mood, or behavior.

Cost estimated to be \$51,840/patient for in-hospital (~\$864/day) versus \$504/patient at home (~\$63/hour). Commentators made these observations: The cost to caregivers and family were not considered in the calculation of cost.

Were the conclusions appropriate for the study design (level of evidence)? *If no, explain.*

Yes

No

Were the conclusions appropriate for the statistical results? *If no, explain.*

Yes

No

Were the conclusions appropriate given the study limitation and biases? *If no, explain.*

Yes

No

IMPLICATIONS FOR OCCUPATIONAL THERAPY

The results of this study are not supportive of a major, comprehensive rehabilitation program that includes occupational therapy for restoration to work of patients with moderate to severe TBI. Unfortunately this study may be cited by third-party payers to deny in-hospital intensive therapy. Heaney¹, one of the commentators who responded to the article, made the important point that the cost to caregivers and family were not considered in the calculation of cost. Nevertheless, it is imperative that occupational therapists who treat patients with traumatic brain injuries conduct studies of the efficacy and cost-effectiveness of at-home occupational therapy programs to ensure ongoing coverage of services. Because this study reports such high percentages of return to work that is not common in the brain injury literature, it is imperative that the study be repeated in a nonmilitary, less-standardized (more ecological) setting to verify the finding.

This work is based on the evidence-based literature review completed by Catherine Trombly, ScD, OTR/L, FAOTA.

CAP Worksheet adapted from: Critical Review Form – Quantitative Studies ©Law, M., Stewart, D., Pollack, N., Letts, L., Bosch, J., & Westmorland, M., 1998, McMaster University. Used with permission.

For more information about the Evidence-Based Literature Review Project, contact the American Occupational Therapy Association, 301-652-6611, x 2052.



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¹ Heaney, D. (2000, October 11). Rehabilitation for traumatic brain injury [letter]. *Journal of the American Medical Association*, 284, 1783–1784.