



**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 (published between 2000-2004) to enable persons with traumatic brain injury (TBI) to participate in areas of occupation (activities of daily living [ADL], instrumental activities of daily living [IADL], work, leisure, social participation, and education)?**

Zhu, X. L., Poon, W. S., Chan, C. H., & Chan, S. H. (2001). Does intensive rehabilitation improve the functional outcome of patients with traumatic brain injury? Interim result of a randomized controlled trial. *British Journal of Neurosurgery*, 15, 464-473.

**PROBLEM STATEMENT (JUSTIFICATION OF THE NEED FOR THE STUDY)**

- There is worldwide variation in the intensity level of rehabilitation provided to persons with traumatic brain injury (TBI).
- Rehabilitation training averages 1-2 hours per day, but it varies from 1 to 7 hours.
- There are only a few studies of the differences in effect for different levels of intensity and the results were inconsistent.
- It is yet to be established whether an intensive rehabilitation program involving physiotherapy, occupational therapy, and speech therapy throughout the day for several days a week can be justified in terms of its ultimate effectiveness.

State the problem the authors are investigating in this study.

Whether greater intensity of rehabilitation (occupational therapy, physical therapy, speech therapy) improves functional outcome for neurosurgical TBI patients better than a less intense rehabilitation.

**RESEARCH OBJECTIVE(S)**

List study objectives.

To evaluate the effects of intensive rehabilitation (including occupational therapy) on the functional outcome in patients with TBI (6-month interim report).

Describe how the research objectives address the focused question.

The research objectives address the focused question by examining the effects of different intensities of rehabilitation therapies on functional outcome (participation in occupational areas).

**DESIGN TYPE:**

Randomized controlled trial

**Level of Evidence:**

Level 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.

All head injured patients admitted to the neurosurgery unit were screened for eligibility. After baseline measurement, participants were randomized via double-sealed envelopes by a person not connected to the study.

**Inclusion Criteria**

- Moderate (9–12) or severe (<8/15) Glasgow Coma Scale score
- Aged 12–65 years

**Exclusion Criteria**

- Severe medical disease or associated injury which may compromise the rehabilitation program
- Preexisting disability.
- Problem of follow-up for a year
- Rapid and good recovery that did not require rehabilitation
- Persistent vegetative state

Sample Selection Biases: *If yes, explain.*

Volunteers/Referrals

Yes

No

Attention

Yes

No

Others (list and explain):

### SAMPLE CHARACTERISTICS

N= 82 → 36 (46 excluded primarily for death)

% Dropouts

#/ (%) Male

#/ (%) Female

Ethnicity

Disease/disability diagnosis

NR= Not reported.

Check appropriate group:

<20/study group	20–50/study group	51–100/study group	101–149/study group	150–200/study group
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Characteristics Bias: If no, explain.

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

Yes  No significant differences between groups on demographics, severity of TBI, number of days of not obeying commands, number of days requiring intracranial pressure (ICP) monitoring. All were in good health and productive before injury.

No

Were the reasons for the dropouts reported?

Yes  Failed to appear for follow-up evaluations because they were working.

No

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

*Add groups if necessary*

Group 1 Intensive therapy N = 15

Brief Description	Individual treatment including physical and sensorimotor training. Functional retraining (activities of daily living [ADL], instrumental activities of daily living [IADL]), psychosocial retraining (social skills, hearing, speech).
Setting	Academic neurosurgical inpatient unit
Who Delivered?	Team: Occupational therapist, physical therapist, speech therapist, neurosurgeon, physician, nurses, medical social worker
Frequency?	4 hours/day ( 2 2-hr. sessions; 1 hr. physical therapy, 1 hr. occupational therapy; 2 hr/week speech therapy); 5 days/week
Duration?	Up to 6 months

Group 2 Conventional therapy N = 21

Brief Description	Same therapy
Setting	Same setting
Who Delivered?	Same team
Frequency?	2 hours per day (1 hr. occupational therapy, 1 hr. physical therapy; 1 hr./week speech therapy), 5 days/week
Duration?	Same

Intervention Biases: *Explain, if needed.*

Contamination

Yes

No  Controls for this were reported

Co-intervention

Yes

No

Timing

Yes

No

Site

Yes

No

Use of different therapists to provide intervention

Yes

No  They controlled for the quality of rehabilitation and personnel involved.

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

Name of measure:

Glasgow Outcome Scale (GOS)

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

NR

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?

Monthly for the first 6 months, then bimonthly up to 1 year.

Name of measure:

Functional Independence Measure (FIM) multi-discipline assessment

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

Basic ADL. It does not measure complicated daily tasks, success at work, or community integration.

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?

Monthly for the first 6 months, then bimonthly up to 1 year.

Measurement Biases

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

Yes

No

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  Insofar as the FIM measures basic ADL, not IADL

No

## RESULTS

List results of outcomes relevant to answering the focused question

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

Include effect size if reported

There was a trend of more patients in the intensive group achieving full FIM scores and good GOS scores at 2 and 3 months, but the control group was catching up at 6 months.

GOS: The GOS scores of the intensive group were significantly better at 1 month ( $p = .037$ ); a significant percentage of patients in the intensive group achieved “good” status at 2 months (40% vs. 10%,  $p = .046$ ). Differences between groups diminished toward the 6<sup>th</sup> month as the conventional group appeared to catch up.

FIM: No significant differences between groups in motor or cognitive scale scores, but a greater percentage of persons in the intensive group achieved full independence at 3 months. The advantage diminished to nonsignificant levels at 4 months and following, which may be due to the ceiling effect of the FIM.

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

Yes

No

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 interim results of this “study showed that increasing the amount of rehabilitation therapy from the conventional 2 to 4 hours/ day improved the functional outcome of TBI patients as measured by GOS”. “The improvement was most significant in the early postinjury period at 2 to 3 months”. “...early intensive rehabilitation was effective in increasing the rate of functional improvement for patients with TBI in the early months postinjury”. (p.472). The effect of therapy is in potentiating the recovery, rather than changing the final outcome.

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  The study needed greater power

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

Yes

No

## IMPLICATIONS FOR OCCUPATIONAL THERAPY

This section provides guidance about clinical practice, program development, and other implications of the study findings as they relate to the focused question.

More intensive therapy soon after the injury facilitates the person's ability to engage in some occupational areas sooner. However, conventional dosage of therapy results in comparable outcome as spontaneous recovery slows (after 4 to 6 months). Managers need to consider whether doubling the expense of therapy early on is worth it. If hospitalization is to be brief, then intensive therapy is needed to prepare the patient for discharge. Whether the intensive therapy would result in higher levels of functional achievement as the months went on in a longer hospitalization is an interesting question needing study. This study did not determine that because the FIM and GOS do not measure higher levels of functional achievement.

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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