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 sensory stimulation on the arousal level of persons in coma or persistent vegetative state after traumatic brain injury (TBI)?

Davis, A. E., & Gimenez, A. (2003). Cognitive-behavioral recovery in comatose patients following auditory sensory stimulation. *Journal of Neuroscience Nursing, 35,* 202–209, 214.

PROBLEM STATEMENT(JUSTIFICATION OF THE NEED FOR THE STUDY)

- Arousal is maintained by the reticular activating system (RAS). Arousal is prerequisite for selective attention necessary for recognizing and processing information.
- Without arousal, more complex cognitive processes, such as sustained attention or concentration necessary for learning, cannot occur.
- Evidence of plasticity has been noted throughout the nervous system.
- Enhancement of plasticity is known to occur through both endogenous factors, such as the release of nerve growth factor, and exogenous factors, such as environmental stimulation.
- There is substantial but indirect evidence that environmental stimulation can be used in an intervention to improve cognitive function and produce behavioral change in humans.
- Although reported improvements in arousal following the implementation of a sensory stimulation program are promising, the scientific methods and procedures have differed so significantly from study to study that interpretation and generalization of results are difficult.

State the problem the authors are investigating in this study.

- Will there be a [significant] increase in arousal between initial assessment (baseline) and discharge assessment scores as measured by the Glasgow Coma Scale (GCS), Sensory Stimulation Assessment Measure (SSAM), Rancho Los Amigos Level of Cognitive Functioning Scale (RLA), and Disability Rating Scale (DRS) in patients who receive an auditory sensory stimulation program?
- What is the effect of an auditory sensory stimulation program on cerebral hemodynamic status (intracranial pressure [ICP]) and cardiopulmonary status (heart rate [HR], respiratory rate [RR], and mean arterial pressure [MAP])?

RESEARCH OBJECTIVE(S)

List study objectives.

- The aim of this study was to measure increase in arousal, as measured by behavioral assessments, due to an auditory sensory stimulation program, in patients with traumatic brain injury (TBI) who were in coma with intact auditory pathways as determined by brain stem auditory-evoked responses.
- The secondary aim was to determine whether the auditory sensory stimulation program had a detrimental physiologic effect on the patients.

Describe how the research objectives address the focused question.

The research objectives directly relate to the focused question.

DESIGN TYPE:

Two-group, repeated measures pretest–posttest design

Level of Evidence:

II

Limitations (appropriateness of study design):

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

Yes

No ✓ The researchers should have used random assignment to group and balanced the sample size between groups.

SAMPLE SELECTION

How were subjects selected to participate? Please describe.

Purposive sampling technique: The participants were selected on the basis of criteria (male; age 17–55 years of age). Participants were purposively assigned to group; the first nine participants were assigned to intervention and then three more participants were recruited for control. The authors stated the reason for this was to control for perceived difference in care between groups by family members.

Inclusion Criteria

- Male
- 17–55 years old
- 3 or more days postinjury with a Glasgow Coma Scale score ≤8
- Stable ICP (≤ 20 mm Hg. for 24 hours prior to entry into the study)
- RLA score between Level I and Level III (unresponsive to sensory stimuli or responsive at a low or inconsistent level to sensory stimulation)
- Intact auditory pathways

Exclusion Criteria

NR

NR = Not reported.

Sample Selection Biases: *If yes*, e*xplain.*

Volunteers/Referrals

Yes

No ✓

Attention

Yes

No ✓

Others (list and explain):

SAMPLE CHARACTERISTICS

N = 12 (9 intervention; 3 control)

% Dropouts NR

#/ (%) Male 100% #/ (%) Female 0%

Ethnicity NR

Disease/disability diagnosis Coma secondary to TBI

Check appropriate group:

<20/study group ✓	20–50/study group	51–100/study group	101–149/study group	150–200/study group

Sample Characteristics Bias: *If no*, e*xplain.*

They recruited the intervention group first then later added a few control subjects.

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

Yes ✓ Partially. The control group entered the study 3.4 post-injury days later than the intervention group, but on age, mean GCS, and ISS (overall magnitude of traumatic injury), they were similar.

No

Were the reasons for the dropouts reported?

Yes	
No	✓ No dropouts reported

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

Add groups if necessary

Group 1 Auditory sensory stimulation (Intervention)

Brief Description	Routine nursing care; routine rehabilitation services; and unimodal (auditory) sensory stimulation intervention using a wide range of tone frequencies (claps, bells, music), familiar and unfamiliar voice patterns, spoken messages requiring simple to complex interpretive processes. The sequence of delivery varied at each intervention.
Setting	NR
Who Delivered?	NR
Frequency?	Varied from 5 to 8 times per day between the hours of 8 a.m. and 5 p.m., based on schedules and visitations. There was a minimum of 1 hour between each intervention.
Duration?	Each session lasted 5–15 minutes; program lasted up to 7 days. Patient was discharged if he began to follow commands or demonstrate cognitive changes beyond Level III of the RLA.

Group 2 Control

Brief Description	Routine nursing care; routine rehabilitation services; and hourly GCS and RLA assessment
Setting	
Who Delivered?	
Frequency?	
Duration?	

Intervention Biases: *Explain, if needed.*

Contamination

Yes	
No	✓

Co-intervention

Yes	
No	✓

Timing

Yes	
No	✓

Site

Yes	
No	✓ Unknown; presumably site was held constant

Use of different therapists to provide intervention

Yes	
No	✓ Unknown; presumably therapist was held constant

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

Changes in arousal as measured by the following 4 assessments:

Name of measure:

Glasgow Coma Scale

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

Level of coma

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?

For intervention group, before and after each intervention. For the control group, every hour of an 8-hour period.

Name of measure:

Sensory Stimulation Assessment Measure

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

Response to sensory stimulation

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?

Intervention group: Up to 8 times a day at each stimulation session.
Control group: Not at all.

Name of measure:

Rancho Los Amigos Cognitive Functioning Scale

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

Cognition

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?

For intervention group, before and after each intervention. For the control group, every hour of an 8-hour period.

Name of measure:

Disability Rating Scale

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

Functional ability

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?

- At baseline and at discharge for both groups
- For safety, clinical parameters were measured before and after each intervention: MAP, HR, ICP, and cerebral perfusion pressure.

Measurement Biases

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

Yes	
No	✓ Unknown

Recall or memory bias *If yes, explain.*

Yes	
No	✓ Unknown; unlikely due to the nature of the diagnosis and the measures were observation of behavior, not requiring a directed response by the patient

Others (list and explain):

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

Did the measures adequately measure the outcome(s)?

Yes	✓ The measures lacked sensitivity to detect subtle changes, but did measure clinically significant changes.
No	

RESULTS

List results of outcomes relevant to answering the focused question

The intervention group improved more than the control group on all 4 measures, but only significantly more on the DRS (p = .0005; effect size, r = .95) and SSAM (p = .015; r = .63). The difference in mean change scores of the GCS was not significant (p = .14; r = .31) and RLA was ns (p = .278; r = .17), although the effects were moderate and small respectively.

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

There were no statistically or clinically significant changes in the physiologic measures.

Include effect size if reported

[I calculated the effect sizes from the p's, using a Z transformation and the formula: $Z/\sqrt{N}$]

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

Yes	
No	✓ There were too few subjects to show a statistically significant change on two of the outcome measures, even though the effect sizes showed that there was an effect of the independent variable on these measures. The failure to find a statistically significant difference may have been due to a Type II error.

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

Yes	✓ However, it would probably have been better to use nonparametric statistics because the assumption of normality of the parent distribution (all TBI patients in coma) could not be met.
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.

In this study, an auditory sensory stimulation program (SSP) was safely administered to a critically ill group of participants, and a positive trajectory of improvement was demonstrated in those participants who received SSP. The small sample size does not provide the power necessary to suggest an effect that was greater than normal recovery from brain injury. It can only be inferred that those who received the SSP had an upward trend in arousal.

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

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

Although the implementation of the design of this study was weak, the results suggest that a program of controlled auditory stimulation may be effective in improving functional level and response to sensory stimulation in acute, comatose patients following TBI. The study was not powerful enough to determine whether this program was effective in improving level of coma or cognition; however, it did determine that the auditory sensory stimulation program was not detrimental, in terms of vital functions, to the participants. Therefore, these findings suggest that using such a program in occupational therapy may be warranted for similarly affected patients. Observation of effectiveness for each patient must be carefully attended to and the program discontinued if it is not effective after a week of application.

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.