AOTA Evidence Briefs
Brain Injury

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

BI #10

A coma arousal program is no more effective than conventional treatment

Pierce, J. P., Lyle, D. M., Quine, S., Evans, N. J., Morris, J., & Fearnside, M. R. (1990). The effectiveness of coma arousal intervention. *Brain Injury, 4*, 191–197.

Level: IIA3c

Nonrandomized controlled trial, 2 groups, 20 or more participants per condition, low internal validity, low external validity

Why research this topic?

Despite wide variation in conventional care and few guidelines regarding therapy for patients with severe head injury who are in a coma, the literature reflects a belief that early intervention is beneficial. Typically, comprehensive rehabilitation occurs after patients have recovered from a coma. But some people have proposed a more far-reaching approach: beginning intervention while patients are still in a coma, using massive sensory inputs.

What did the researchers do?

The researchers, variously affiliated with the U.S. Centers for Disease Control and Prevention, the University of Sydney (Australia), and Westmead Hospital (Sydney), conducted a pilot study to test the effectiveness of **coma arousal** *(see Glossary)* in improving outcomes for patients. The study was intended to be preliminary to a controlled trial.

The researchers recruited 31 participants (21 men and 10 women) from all the patients in a coma from a head injury who arrived at Westmead Hospital over a 15-month period in 1984 and 1985. Those who were still in a coma or a persistent vegetative state at least 2 weeks after their injury were considered eligible for the study as long as they showed no evidence of another major medical condition. The patients ranged in age from 6 to 75 years, with an average age of 24 years.

The treatment consisted of vigorous multisensory stimulation for up to 8 hours a day, 7 days a week, until the participant was accepted for conventional rehabilitation therapy. The stimuli were applied to the auditory, **vestibular** *(see Glossary)*, visual, and **cutaneous** *(see Glossary)* systems. Close relatives of the patients delivered the stimuli, increasing their complexity and sophistication as the participants' level of consciousness improved.

The researchers did not use a control group. Instead, they compared the outcomes with those of the only large-scale study reported in the literature at the time for the same kind of patient. This reference group consisted of 135 participants (gender not reported) in a prolonged coma.

The researchers were interested in *the time from injury to recovery from coma* (defined as the participant's ability to obey a simple command on two consecutive occasions at least 24 hours apart) and *level of disability* 10 to 12 months after injury (as measured by the Glasgow Outcome Scale).

What did the researchers find?

On the time taken to recover from the coma, the participants in the pilot study did not differ **significantly** *(see Glossary)* from the participants in the reference study.

On the outcomes 10 to 12 months after injury, there was no significant difference between members of the pilot group and members of the reference group.

What do the findings mean?

- For *therapists and other providers*, the findings question the value of a coma arousal program for rehabilitation. The researchers found at least two differences between the pilot group and the reference group that may have influenced the outcomes. Most notably, there was a significant difference in the management of the patients while they were in intensive care. All members of the pilot group were **intubated** *(see Glossary)* and **ventilated** *(see Glossary)* during their stay, compared with just under half the members of the reference group. Also, the average age of the pilot group was slightly lower than that of the reference group: 24 years versus 29 years. Both differences should have favored the pilot group, however.
- Readers should compare the findings of this study with those of the study by Mitchell et al. (Mitchell, S., Bradley, V. A., Welch, J. L., & Britton, P. G. [1990]. Coma arousal procedures: A therapeutic intervention in the treatment of head injury. *Brain Injury*, *4*, 273–279), which support the short-term effects of a particular program of coma arousal (broader in scope but less intense than the one reported here).
- The findings suggest a direction for research: more intensive investigation of coma-arousal programs in a randomized controlled trial, with a sufficiently large sample, looking at short- and long-term outcomes.

What are the study's limitations?

The researchers' method of selecting their study participants was not systematic. That is, they selected patients on the basis of consecutive admittance to the facility. This flaw in the study's design lowers confidence that the results can be attributed to the intervention.

The study provides useful information. However, it has limited generalizability for the population of persons with traumatic brain injury in a variety of settings. Although the treatment represents current practice, the study participants did not represent all age ranges and all types of head injuries.

Glossary

coma arousal—attempting to arouse patients from a coma using sensory stimulation

cutaneous—relating to the skin

intubated—tube has been inserted into the larynx or trachea

significance (or significant)—A statistical term, this refers to the probability that the results obtained in the study are not due to chance, but to some other factor (such as the treatment of interest). A significant result is one that is likely to be generalizable to populations outside the study.

Significance should not be confused with clinical effect. A study can be statistically significant without having a very large clinical effect on the sample. For example, a study that examines the effect of a treatment on a client's ability to walk, may report that the participants in the treatment group were able to walk significantly longer distances than the control. However, if you read the study you may find that the treatment group was able to walk, on average, six feet, while the control group was able to walk, on average, five feet. While the outcome may be statistically significant, a clinician may not feel that a one foot increase will make his or her client functional.

ventilated—use of a respirator for breathing

vestibular—relating to balance

■ Terminology used in this document is based on two systems of classification current at the time the evidence-based literature reviews were completed: *Uniform Terminology for Occupational Therapy Practice—Third Edition* (AOTA, 1994) and *International Classification of Functioning, Disability and Health (ICIDH-2)* (World Health Organization [WHO], 1999). More recently, the *Uniform Terminology* document was replaced by *Occupational Therapy Practice Framework: Domain and Process* (AOTA, 2002), and modifications to *ICIDH-2* were finalized in the *International Classification of Functioning, Disability and Health* (WHO, 2001).

This work is based on the evidence-based literature review completed by Beatriz C. Abreu, PhD, OTR, FAOTA, and colleagues.

For more information about the Evidence-Based Literature Review Project, contact the Practice Department at the American Occupational Therapy Association, 301-652-6611, x 2040.