

The Effect of Family-Centered Affective Stimulation on Brain-Injured Comatose Patient's Level of Consciousness Randomized Controlled Trial: A Literature Review

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ABSTRACT

Introduction: Traumatic brain injury is one of the most common causes of disability, death and intensive care unit (ICU) hospitalization worldwide. Each year an estimated ten million people experience brain injuries. All kinds of stimulation can effectively affect the brain, especially the reticular activation system. The aims to determine the effect of family-centered sensory stimulation by comparing the experimental, placebo and control groups.

Method: This study used a randomized controlled trial involving comatose patients with brain injury. The investigators concluded that 30 patients were needed for each study group. Initially, an allocation protocol was developed using the permutation block randomization technique.

Result: The one-way ANOVA results illustrated that the differences between groups regarding GCS scores on the first day and the second day of the intervention were not statistically significant, whereas on days 3-7, the differences were statistically significant. The results of this study indicate that early family-centered stimulation is more effective than sensory stimulation in correcting LOC among comatose patients with traumatic brain injury.

Conclusion: Family-centered stimulation was effective in improving levels of consciousness among comatose patients from day three to day seven.

Keywords: *Family Centered Stimulation; Brain Injured; Consciousness*

Introduction

Traumatic brain injury is one of the most common causes of disability, death and intensive care unit (ICU) hospitalization worldwide. Each year an estimated ten million people experience brain injuries (Oyesanya, Brown and Turkstra, 2017). Based on data in Korea, 935 brain injury patients between September 2009-December 2013 (Hong et al., 2017). Most patients with traumatic brain injury experience a change in their level of consciousness (Salmani et al., 2017).

All kinds of stimulation can effectively affect the brain, especially the reticular activation system. Activation of this system increases sympathetic activity throughout the body which in turn increases norepinephrine levels at the nerve terminals and causes arousal and awareness of the patient (Salmani et al., 2017).

Family-centered care is a way of caring for their family in health services that ensures that care is planned throughout the family, not just individuals, and where all family members are recognized as recipients of care (Coyne et al., 2013). Family-centered care is an effective stimulation based on three aspects, namely psychological, cognitive, and motivational (Salmani et al., 2017).

Therefore, this study aimed to evaluate family-centered factors for effective stimulation of the level of consciousness among comatose patients with brain injury. The study was conducted at a trauma care unit at a teaching hospital located in Isfahan, Iran. Routine visit protocol in this setting three times a week (Monday, Wednesday and Friday).

In this journal, it is clear that the research problem is focused, namely the introduction and conclusion. The problem of this study focuses on evaluating the effect of local family-centered stimulation on the level of consciousness of comatose patients with traumatic brain injury. This is the novelty of this examination.

Method

The author uses the tools as a guide for this critical appraisal, namely the Critical Appraisal Skills Program (CASP). The CASP has eight critical assessment tools designed for research reading including Randomized Controlled Trials (RCTs). RCT is a type of intervention or experimental study design. Participants are randomly allocated

to receive new interventions that are being tested or control care (usually standard treatment or placebo) (Cossio et al., 2012).

The focus of the study can be considered from the PICO analysis with the explanation in which the population (P) is patients with GCS 5-8 brain injury aged 18-65 years, intervention (I) is that eligible patients are randomly recruited and allocated to the experimental group, the placebo group, and the control group. Outcome (O) is that there is a difference that early family-centered stimulation is more effective than sensory stimulation in improving the level of consciousness among comatose patients with brain injury.

This research belongs to experimental research (Newhouse et al., 2007) which aims to determine the effect of family-centered sensory stimulation by comparing the experimental, placebo and control groups. Based on the research objectives, the selection of the study design in this study was appropriate using a randomized controlled trial.

This study used a randomized controlled trial involving comatose patients with brain injury. Family members of all participants were informed about the aims of the study. All patients are free to participate or withdraw from attendance. In addition, all relevant data regarding patients is still confidential. This was explained in the approval of the research ethics committee.

The investigators concluded that 30 patients were needed for each study group. Initially, an allocation protocol was developed using the permutation block randomization technique. Then, consecutively eligible patients were recruited and randomly allocated to the experimental, placebo, or control groups based on the block randomisation protocol. The sampling process took place from March 2015 to June 2016.

Result

From a total of 90 respondents, respondents who were counted in the data analysis were 30 respondents from the family-centered intervention group, 30 respondents from the placebo group and 30 respondents from the control group. All respondents in this study were included in the data analysis. The results of this calculation support the conclusion.

In the experimental group, close family members who have the strongest emotional relationships with patients were selected based on the recommendations of other family members. Family members were selected near the patient's bed and provided routine family-centered stimulation twice daily (11:00 am and 3:00 pm) for seven consecutive days (fourteen-fold). The length of each session is 30-45 minutes. During the session, the nurse in charge of the target patient accompanies the family member to ensure accurate intervention is carried out.

Intervention in the placebo group: A trained person unfamiliar with all patients in the placebo arm provided sensory stimulation (auditory, tactile, and kinetic 30-45 minutes twice daily for seven consecutive days). Whereas in the control group: Patients did not receive sensory stimulation or stimulation above. Instead, they receive care and sensory stimulation services that are routinely provided to all patients. This stimulation includes normal ICU lighting, equipment sounds, medication administration, and physical care services such as back and body massage by nurses, physical therapists, and nursing assistants.

This study was a double-blind randomized controlled trial with three groups. The nurse measuring the patient's LOC and the patient himself were not aware of the aims of the study and the intervention. This is to minimize bias in subject and researcher (Newhouse et al., 2007). Researchers have determined inclusion and exclusion criteria. Patients who were discharged from the ICU, died, or required emergency surgery during the study were excluded. Families that provide stimulation are those who have good and close relationships with patients recommended by other family members. Effective family-centered stimulation through four steps, namely auditory stimulation, sensory stimulation, kinetic stimulation, and affective conversation.

All groups were given the same treatment in addition to the prescribed intervention. The intervention group was given effective family-centered stimulation, the placebo group was given effective stimulation by trained people, and the control group received routine nurse action in comatose patients.

Discussion

The one-way ANOVA results illustrated that the differences between groups regarding GCS scores on the first day and the second day of the intervention were not

statistically significant, whereas on days 3-7, the differences were statistically significant. On the other hand, the recovery rate was also calculated to provide information showing that the recovery rates in the experimental, placebo, and control groups were 71%, 39%, and 24%. These findings indicate that the recovery rate in the experimental group was higher than in the placebo and control groups.

The results of Tukey's post hoc test showed that the differences between the experimental group and the control group and between the experimental group and the placebo group that had GCS scores were statistically significant, while the differences between placebo and control groups were not statistically significant. In each study group was statistically significant at the seven time measurement points. The improvement in the level of consciousness in the experimental group (i.e. pure effective stimulation) was significantly greater than that in the control and placebo groups.

This study involved 90 respondents based on inclusion and exclusion criteria so that this research could be generalized and representative. This shows that the results of this study can contribute to the local area. All clinical results in this study have been considered, this can be seen in the collection of clinical data from patients through the GCS instrument, Coma Recovery Scale-Revised (CRS-R), and Acute Physiology and Chronic Health Evaluation (APACHE II). And include patient demographic data including gender, education, diagnosis, causes of brain injury, GCS score, and RCS score.

The benefit of research in this journal is that this study is designed to evaluate the stimulating factors that play a role in the level of awareness of comatose patients who have experienced traumatic brain injury and are admitted to the ICU. The findings indicated that family-centered stimulation was effective in improving levels of consciousness among comatose patients from day three to day seven. Weaknesses in this study although it can be concluded that patient awareness in the hospital is based on a good outcome measure, there may be limitations to the use of this protocol in different areas according to organizational protocols and emerging cultural factors. This point can be taken seriously in future research.

The results of this study indicate that early family-centered stimulation is more effective than sensory stimulation in correcting LOC among comatose patients with traumatic brain injury. In other words, the improvements in LOC in the experimental

group (i.e. pure effective stimulation) were significantly greater than the placebo and control groups. There is still a need for strong evidence regarding family stimulation.

Conclusion

RCT has strength and quality at level I in this type of study and is supported by a randomized double-blind trial that reduces false so that the quality of this article is quite good although there are still weaknesses regarding the generalizability of application in the region. This journal article has been critically reviewed so that it can be used as scientific evidence for advanced Evidence Based Nursing research.

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