



# The effects of family-centered affective stimulation on brain-injured comatose patients' level of consciousness: A randomized controlled trial



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## ABSTRACT

**Background:** Despite the well-defined effects of sensory stimulation, the knowledge of the pure effects of affective stimulation is scarce.

**Objective:** To evaluate the effects of family-centered affective stimulation on the level of consciousness among comatose patients with brain injuries.

**Design:** This study was designed as a three-group double-blinded Randomized Controlled Trial.

**Methods:** Ninety consecutive patients with traumatic brain injuries and a Glasgow Coma Scale score of 5–8 were selected. Patients were randomly allocated to an experimental, a placebo, and a control group using permuted block randomization. Affective stimulation intervention was provided to patients in the experimental group by their family members twice a day during the first seven days of their hospitalization. In the placebo group, a sensory stimulation program was implemented by a fixed trained person who was not familiar with the patients. Patients in the control group solely received sensory stimulation which was routinely provided to all patients. The level of consciousness among the patients using the Glasgow Coma Scale and Coma Recovery Scale-Revised were measured both before and after a family visit. The SPSS software (version 17.0) was used to analyze the data through running the one-way and the repeated measure analyses of variance.

**Results:** Despite an insignificant difference among the groups regarding baseline level of consciousness, the results of the one-way analysis of variance revealed at the seventh day of this study, however, the level of consciousness in the experimental group was significantly higher ( $9.1 \pm 2.1$ ) than the placebo ( $7.2 \pm 1.1$ ), the control groups ( $6.6 \pm 1.7$ ) ( $P < 0.001$ ), subsequently. Moreover, at the seventh day of the study, the Coma Recovery Scale score in the experimental group ( $11.9 \pm 3.7$ ) was significantly greater than the placebo ( $9.0 \pm 2.0$ ) and the control ( $6.6 \pm 1.6$ ) groups ( $P < 0.001$ ). Recovery rate and effect size values also confirmed the greater effectiveness of affective stimulation compared with pure sensory stimulation.

**Conclusion:** Our findings in this study indicate that early family-centered affective stimulation is more effective than sensory stimulation in improving the level of consciousness among comatose patients with brain injuries. Family-centered affective stimulation is recommended to be integrated into the nursing curricula and routine care plans for comatose trauma patients in intensive care units.

## What is already known about the topic?

- Sensory stimulation is effective for improving the level of consciousness among comatose patients.
- Although family involvement in care delivery is an accepted practice in general hospital wards, it cannot be freely practiced in intensive care units due to the critical conditions of patients and the specialized care services provided in these units.
- Little is known about the effects of affective stimulation.

## What this paper adds

- Family-centered affective stimulation is more effective than sensory stimulation in improving the level of consciousness among comatose patients.
- Family-centered affective stimulation is distinct and beyond conventional sensory stimulation and can be integrated into routine care plans for comatose trauma patients in intensive care units.

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## 1. Introduction

Traumatic brain injuries are among the most common causes of disability, mortality, and hospitalization in intensive care units (ICU) around the world (Grafman and Salazar, 2015). Most patients with traumatic brain injuries experience alterations in the level of consciousness (LOC) for different periods (Doan et al., 2016).

Altered LOC is associated with i) adverse effects on normal functioning the longer the length of altered consciousness, ii) the sever the functional dysfunction, iii) the slower the recovery, and vi) the poorer the prognosis (Carlson and Louis, 2009).

One of the most serious problems among comatose patients is sensory deprivation. It can cause different mental and perceptual problems and life-threatening conditions for patients hospitalized in ICUs (Gaugler, 2005). Peripheral sensory stimulation can hasten the process of post-traumatic brain injury brain plasticity, promote brain regeneration, improve neurologic function (Davis and Gimenez, 2003), shorten the length of ICU stay, and alleviate anxiety (Hetland et al., 2015). Currently, sensory stimulation is considered as a safe and effective therapeutic, rehabilitative, caring measure and is widely used in different care settings (Abbate et al., 2014; Kavosipour et al., 2008).

Although giving sensory stimulation (including auditory, visual, and tactile) to comatose patients is currently among the main components of critical care (Hasanzadeh et al., 2012), affective stimulation has not been yet considered and evaluated as a distinct care measure. Sensory stimulation and interactions necessitate family involvement in the process of care delivery. Though family involvement in care delivery is an accepted practice in general hospital wards (Davidson, 2009), it cannot be freely practiced in ICUs due to the critical conditions of patients and the specialized care services provided in these units (Mitchell et al., 2009).

Numerous studies have been conducted to evaluate the effectiveness of sensory stimulation in improving comatose patients' LOC (Davis and Gimenez, 2003; Mahmoodi et al., 2013; Mandeep, 2012; Oh and Seo, 2003). Moreover, some contradictory reports evaluated the effectiveness of family involvement as a source of sensory stimulation (Hasanzadeh et al., 2012; Abbasi et al., 2009; Bassampoor et al., 2007; Gorji et al., 2014; Kalani et al., 2016; Karma and Rawat, 2006; Megha et al., 2013; Moattari et al., 2016; Tavangar et al., 2016). So far, none of these studies investigated the pure effects of affective stimulation on patient outcomes in ICUs (Davis and Gimenez, 2003; Mahmoodi et al., 2013; Bassampoor et al., 2007; Gorji et al., 2014; Kalani et al., 2016; Tavangar et al., 2016; Hoseini Azizi et al., 2016; Lombardi et al., 2002; Urbenjaphol et al., 2009).

Affective given stimulation by family members (henceforth referred to as family-centered affective stimulation) was first introduced by Abbasi et al. (2009) as a care measure which is distinct from and beyond sensory stimulation. They declared that the pure effects of family-centered affective stimulation on patient outcomes in ICUs had not been evaluated yet (Abbasi et al., 2009). Therefore, the present study was performed to examine the pure effects of family-centered affective stimulation on LOC among comatose patients with traumatic brain injuries.

### 1.1. Theoretical framework

Theoretically or physiologically; a distinction between sensory and family-centered affective stimulation is based on three aspects namely psychological, cognitive, and motivational. These aspects can accelerate cognitive processes, stimulate sympathetic nervous system, and later promote arousal (Harmon-Jones et al., 2013). Moreover, any type of affective stimulation can affect the brain, particularly the reticular activating system. Activation of this system increases sympathetic activity throughout the neither body which in turn increases the levels of norepinephrine at nerve terminals and causes arousal and consciousness (Olausson et al., 2016). A critical point is about the possibility of

any differences in the effects of stimulation provided by familiar and unfamiliar people. In other words, comatose patients may perceive a stimulation provided by a familiar person differently from a stimulation provided by an unfamiliar one (Eysenck and Flanagan, 2001; Kreibig et al., 2013). As such, Harmon-Jones et al. (2013) recommended that in order to produce more significant results, affective stimulation should be provided by the most familiar people to the clients, i.e. their family members (Urbenjaphol et al., 2009). On the other hand, continuous sensory stimulation provided by unfamiliar people can eventually lead to the inhabitation of the stimulation. Conclusively, the effects of sensory stimulation may decrease over the time and thus this stimulation may no longer be interpreted by the person (Eysenck and Flanagan, 2001).

Beside external factors, the needs, aims, and expectations of people affect their feelings and perceptions. One of the most important needs of patients hospitalized in ICUs is the emotional need to be with their family members. However, this need is often taken for granted (Kreibig et al., 2013).

Emotions are produced when signals reach the thalamus either directly from the sensory receptors or by descending cortical input. In other words, the character of the emotion is determined by the pattern of activation of the thalamus irrespective of the physiological response to the sensory input. the cortex is critically involved in the experience of emotion. Following damage to certain cortical areas, there are sometimes profound changes in emotional expression with little change in perception or intelligence (Paradiso et al., 2016). Fig. 1 shows the effects of external affective stimulation on the centers of emotional response in the cerebral cortex, thalamus and limbic system (it was developed by the authors based on the explanation of the theoretical framework).

Although affective stimulation has been known theoretically to have positive effects on patient outcomes, the strong empirical evidence is needed before it can be used as a care measure in clinical settings. Nonetheless, our literature review showed that there is neither experimental nor clinical evidence in this area. Thus, the present study was made to evaluate the effects of family-centered affective stimulation on LOC among comatose patients with traumatic brain injuries. This is the main novelty of this examination.

## 2. Methods

### 2.1. Design

This was a three-group double-blind randomized controlled trial. Nurses who measured patients' LOC were blind to the study aims and interventions. Participating patients were blind to the interventions. The study setting was the adult trauma care unit of a teaching hospital located in Isfahan, Iran. The routine visitation protocol in the setting was thrice a week (Monday, Wednesday, and Friday) through the ward windows and without any close physical or affective contact between patients and their family members.

### 2.2. Participants

The inclusion criteria were affliction by a traumatic brain injury, a Glasgow Coma Scale (GCS) score of 5–8, and an age of 18–65. Patients who discharged from the ICU, died, or needed an emergency operation during the study were excluded. The sample size was calculated using the results reported by Abbasi et al. (2009). They reported that the means of GCS score in their groups were  $6.8 \pm 1.4$  and  $7.8 \pm 0.70$  (Abbasi et al., 2009). So far, with a confidence level of 0.95 and a power of 0.90, we concluded that 30 patients were needed for each study group. Initially, an allocation protocol was developed using the permuted block randomization technique (Pocock, 2013). Then, eligible patients were consecutively recruited and randomly allocated to an experimental, a placebo, or a control group based on the permuted

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