ARTICLE

A COMPARATIVE STUDY ABOUT THE IMPACT OF SENSORY STIMULATION PERFORMED BY FAMILY MEMBERS AND NURSES ON VITAL SIGNS OF PATIENTS AT ICU: A RANDOMIZED CLINICAL TRIAL

Tahereh Toulabi[1], Mohammad Adineh[2,*], Mohammad Gholami[1], Reza Heidari Soureshjani[3]

[1]*Social Determinants of Health Research Center, Department of Nursing, School of Nursing & Midwifery, Lorestan University of Medical Sciences, Khorramabad, IRAN*

[2]*Nursing Care Research Center in Chronic Diseases, Department of Nursing, School of Nursing & Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, IRAN*

[3]*Students Research Committee, Shahrekord University of Medical Sciences, Shahrekord, IRAN*

ABSTRACT

Some studies have shown the effects of sensory stimulation on vital signs of patients at intensive care unit (ICU). However, little knowledge is available about family role compared to the role of nursing staff in this issue and current results are controversial.. The aim of this study is to compare the impact of sensory stimulation performed by family members and nurses on vital signs of patients at ICU. In this study, 6969 patients were categorized into two intervention groups and one control group by stratified block randomization method. Dyang sensory stimulation was provided by family members and nursing staff. No intervention was performed for control group. Sensory stimulation was performed 2 hours a day for 6 consecutive days. The vital signs were assessed 5 minutes before and 30 minutes after intervention.Data analysis was performed by ANCOVA, ANOVA and repeated measures. The results showed that there was significant difference between the experimental groups in terms of vital signs before and after the intervention ($p<0.001$). Of this aspect, family group was the best, nursing group was the second and control group was the last group in classification. The effect of sensory stimulation on vital signs of comatose patients was greater when provided by family members.

KEY WORDS
Family member, Nurse, Intensive care unit, Sensory stimulation, Vital signs

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***Corresponding Author**
Email:
mohadineh@gmail.com

INTRODUCTION

Admission in the intensive care unit (ICU) provides great physical and psychological tension to the patient [1, 2]. Being away from family members during admission period at ICU and also short duration of visiting time are considered as risk factors of psychological tension for patients [3, 4]. In most hospitals around the Europe and also Iran, some limitations have been defined for visiting the patients in the ICU [5]. Despite scientific advancements and progresses in the medicine and nursing profession, visiting the patient by family members is one of the most important issues in the hospitals that inappropriately have been neglected. Approximately, it is near to 40 years that visiting regulations have not been revised in Iran [6]. The results of studies since 1970 to 1980 showed that visitors may cause the blood pressure and heart rate of the patients to be increased; but recent studies indicate that no significant changes occur in cardiovascular state of patients during visiting by family members [7]. Besides, the effects of visiting by family members on heart rate, blood pressure or other ventricular events have not yet established well [8]. Mitchell et al showed that hemodynamic indices of patients with cerebrovascular accident who were admitted in ICU had not significantly changed before, during and after visiting time [9]. Loyalty et al reported a statistically significant difference in systolic blood pressure and heart rate of patients admitted in ICU before, during and after visiting time [10]. In addition, Fumagali et al in a 2-year follow-up study on 226 patients concluded that visiting not only does not impair the cardiovascular status, but also the elongation of visiting time will reduce cardiovascular events and alleviate patients' anxiety [11]. Currently, little papers are available focusing on the impact of presence of visitors at ICU on patients' medical condition [4]. Moreover, researchers believe that depriving the human from receiving stimulus and also over stimulation as well, may impair the physical and emotional balance [12, 13]. In the United States, 66% of patients who had been admitted in ICU for at least 10 days have experienced the consequences of stimulus deprivation during hospitalization and also after discharge. Stimulus deprivation can impact vital signs throughout changing physiological rhythms of the body [14].

The majority of the patients in the ICU in Teaching hospital affiliated with the Lorestan University of Medical Sciences come from the surrounding villages and tribes, and there are deeper emotional communications between these patients and their families. From religious and humanistic perspectives, visiting a patient is considered as a humanistic duty with spiritual rewards. The results of different studies are in favor of the effects of sensory stimulations on vital signs of patients at ICU, but the role of family members versus nursing staff and also stimulating more than one day have been less evaluated.

The present study was conducted to compare the effect of sensory stimulation by family members compared to nursing staff on vital signs of patients at ICU

MATERIALS AND METHODS

This clinical trial study was conducted on 69 patients hospitalized in the ICU in Teaching hospital affiliated with the Lorestan University of Medical Sciences in April to November 2014. A total number of 69 patients were recruited and 23 patients were allocated to each group. After evaluation of patient's records and calculation of Glasgow Coma Scale (6-12), patient information sheet was filled and family members were interviewed. After receiving written informed consent and assuring them about safety of sensory stimulations, the eligible patients were selected and were categorized into two test groups (nurse group & family group) and one control group by stratified block randomization method based on their age. The inclusion criteria were hospital admission for less than 3 days; providing informed consent by family members for participation in the study; the visitor to be first degree relative (father, mother, brother, sister, spouse or child) and > 18 years old; head trauma patients (all types of cerebral hematomas and other cerebral traumas except for diffuse axonal injury) who have pupil reflex at the time of entrance into the ICU; GCS between 6-12; age between 16-65 years and no history of delirium, dementia and hospitalization at psychiatry hospital. The exclusion criteria were withdrawal from the study for any reason, death, being transported to other medical centres and getting psychosis during hospitalization.

Dyang sensory stimulation program for test groups was performed 2 hours a day with 3 hours interval (started at 4:00 to 5:00 pm and repeated 8:00 to 9:00 pm) for 6 consecutive days. The family member who was selected for doing the intervention was the same one along with the 6 days. He/she was told to perform just sensory stimulations for 1 hour as educated by the researcher; and was being supervised from this aspect. It should be noted that the intervention was done while the half-life of analgesic medications had been passed. Dyang sensory stimulation program (1987) was educated to family members by researcher (nurse). For family group, the sensory stimulation was performed by a family member and for nurse group, it was done by the researcher, No intervention was performed for control group.

Dyang sensory stimulation program includes olfactory, hearing, visual, motor and tactile stimulations. Olfactory stimulation is implemented by holding an alcohol-soaked cotton in front of patient's nostrils for 5 seconds; visual stimulation by turning on and off a flashlight in front of patient's eyes for 2 seconds, hearing stimulation by telling patient's name, time, location and date near to patients ears for 3 times, tactile stimulation by hand pressure, massage and rubbing cotton and gauze against skin (one side of the body and then another side) and motor stimulation by moving the joints in the hand, foot, wrist, hip, and shoulder by flexion and extension and moving them upward and downward alternatively for 15 times. Each of the stimulations was done one time during one hour [13, 14].

The vital signs (pulse rate, respiratory rate, systolic and diastolic blood pressure and body temperature) were measured by research assistant (someone other than the stimulator), using cardiopulmonary monitoring device and auxiliary thermometer. The measurements were done for all subjects in three groups in 2 stages; 5 minutes before intervention and 30 minutes after the end of intervention (total of 12 interventions for each patient). Calibration of applied devices was being checked by medical device engineer of hospital on weekly basis.

Data were analysed using SPSS software (SPSS Inc, Chicago, Illinois, USA). Descriptive and analytical statistics were used to analyse the data. Mean and standard deviation were calculated for quantitative variables. Repeated measurement test was used to compare mean vital signs of the patients in each group before and after intervention, and one-way ANOVA was used to compare mean vital signs in 3 groups of patients. The Chi-squared test was used for some variables such as sex, level of education and diagnosis. This study was approved by the Ethics Committee of Lorestan University of Medical Sciences (N.20066375), and registered in the Iranian Clinical Trial Website with the IRCT201204149469N1 code. The objectives of the study were explained to all participants and all of them signed a written informed consent and were assured of the confidentiality of their individual information as well as the voluntary nature of participating in the study. In all stages the researchers were committed to observe the ethical issues in accordance to the Helsinki ethical declaration.

RESULTS

The results of this study showed that the subjects in all groups had no significant difference in terms of age and basic vital signs. In addition, there was no significant difference in terms of sex, level of education, occupation, cause of coma, diagnosis at time of admission and location. Most of the studied subjects (89.9%) in 3 groups were male. There were statistically significant difference between mean systolic blood pressure in three groups before 10^{th} and 11^{th} intervention; body temperature before and after 9^{th} intervention; mean respiratory rate of patients after 9^{th} intervention and mean pulse rate of the patients before 6^{th} and after 12^{th} intervention. But, regarding the diastolic blood pressure and other interventions related to other variables, no significant difference was noted between variables before or after intervention in 3 groups [Table 1].

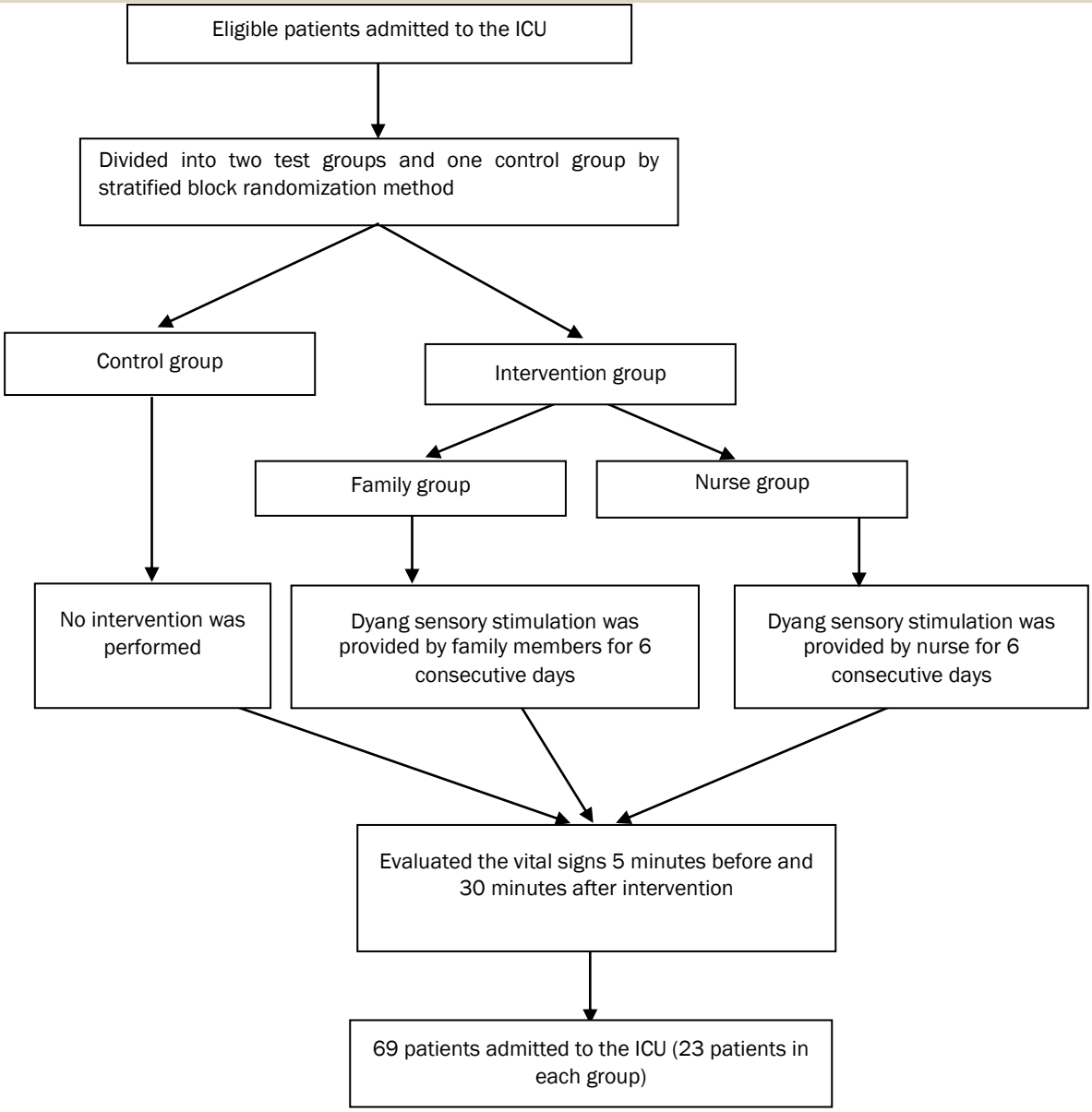

Diagram 1: The flowchart of study groups

Table 1: Comparison of the three groups in terms of variable means before and after each intervention

Type of variable	Number of intervention	Before or after the intervention	Family group N (Mean ± SD)	Nursing group N (Mean ± SD)	Control group N (Mean ± SD)	Number N (Mean ± SD)	P-Value
Systolic blood pressure	Tenth	Before	23 (120.47 ± 10.89)	23 (125.78 ±7.71)	23 (129.91 ± 17.53)	69 (125.39 ± 13.12)	0.048
	Eleventh	Before	23 (116.48 ± 10.31)	23 (122.95 ± 12.00)	23 (127.43 ± 14.35)	69 (122.27 ± 12.97)	0.013
Temperature	Ninth	Before	23 (37.14 ± 0.44)	23 (37.47 ± 0.38)	23 (37.13 ± 0.57)	69 (37.22 ± 0.49)	0.027
	Ninth	After	23 (37.15 ± 0.41)	23 (37.49 ± 0.40)	23 (37.19 ± 0.50)	69 (37.27 ± 0.46)	0.024
Respiratory Rate	Ninth	After	23 (21.21 ±4.33)	23 (21.30 ±3.16)	23 (18.52 ± 2.50)	69 (20.34 ± 3.34)	0.010
Pulse Rate	Sixth	Before	23 (79.60 ±14.75)	23 (92.04 ± 20.61)	23 (89.73 ± 13.76)	69 (87.131 ± 7.28)	0.032
	Twelfth	After	23 (89.82 ± 19.53)	23 (90.47 ±16.24)	23 (78.60 ± 17.27)	69 (86.30 ± 18.31)	0.045

In addition, the ANCOVA results showed that there were statistically significant difference between mean systolic blood pressure of patients before and after 3rd, 7th to 12th interventions; mean diastolic blood pressure before and after 9th and 11th interventions; body temperature before and after first intervention; respiratory rate before and after 2nd, 5th, 8th and 12th interventions and pulse rate before and after first, 5th to 7th, 9th and 12th interventions; but the difference was not significant in other items [Table 2].

Based on the results of repeated measurement test, there was no significant difference between mean vital signs except for respiratory rate of patients before and after intervention in different days. In other words, in general, the impact of intervention in different days was the same on vital signs, except for respiratory rate. Besides, considering the results of this test, there was no interactive effects between mean vital signs before and after intervention and between the test groups. In other words, the impact of intervention was the same on different days in 3 groups [Table 3].

But according to ANCOVA results, there was statistically significant difference between test groups in terms of mean vital signs of patients before and after intervention except for body temperature (p<0.001). The Tukey paired test showed that there is significant difference between test groups in terms of mean vital signs before and after intervention except for body temperature. In other words, in all subjects, family group was the best test group and nursing group was the second and control group was the last group in classification [Table 4].

Table 2: Comparison of three groups in terms of mean vital signs before and after intervention

Type of variable	Number of intervention	Family group N (Mean ± SD)	Nursing group N (Mean ± SD)	Control group N (Mean ± SD)	Total N (Mean ± SD)	P-Value
Systolic blood pressure	Third	23 (3.56 ± 6.08)	23 (2.27 ± 5.97)	23 (2.04 ± 7.91)	69 (1.24 ± 7.04)	0.017
	Seventh	23 (7.43 ±6.94)	23 (0.13 ± 9.85)	23 (0.13 ± 5.97)	69 (2.39 ± 8.45)	0.001
	Eight	23 (4.39 ± 4.87)	23 (0.82 ± 6.25)	23 (1.04 ± 6.29)	69 (1.53 ± 6.15)	0.012
	Ninth	23 (5.95 ± 5.76)	23 (1.13 ± 6.48)	23 (0.82 ± 6.69)	69 (1.33 ± 7.04)	0.000
	Tenth	23 (4.47 ± 5.46)	23 (0.00 ± 5.72)	23 (1.26 ± 4.96)	69 (1.07 ± 5.86)	0.002
	Eleventh	23 (5.69 ± 7.44)	23 (2.04 ± 9.09)	23 (2.39 ± 4.27)	69 (1.11 ± 7.88)	0.001
	Twelfth	23 (5.30 ± 6.75)	23 (3.39 ± 7.79)	23 (0.65 ± 5.82)	69 (2.42 ±7.66)	0.000
Diastolic blood pressure	Ninth	23 (4.82 ± 8.47)	23 (1.65 ± 5.74)	23 (1.39 ± 7.56)	69 (1.69 ± 7.68)	0.021
	Eleventh	23 (2.47 ± 6.02)	23 (1.60 ± 5.33)	23 (0.60 ± 5.50)	69 (0.08 ± 5.81)	0.043
Temperature	First	23 (0.07 ± 0.10)	23 (0.03 ± 0.11)	23 (0.02 ± 0.17)	69 (0.02 ± 0.14)	0.022
Respiratory rate	Second	23 (2.65 ± 2.40)	23 (0.47 ± 2.76)	23 (0.60 ± 2.82)	69 (0.84 ± 2.96)	0.000
	Fifth	23 (1.26 ± 2.71)	23 (0.65 ± 2.70)	23 (0.65 ± 2.46)	69 (0.42 ± 2.71)	0.048
	Eight	23 (2.00 ± 2.79)	23 (0.00 ± 2.95)	23 (1.52 ± 2.52)	69 (1.17 ± 2.85)	0.044
	Twelfth	23 (1.86 ± 2.11)	23 (0.56 ± 3.02)	23 (0.39 ±2.88)	69 (0.68 ± 2.82)	0.022
Pulse rate	First	23 (4.60 ± 4.47)	23 (1.08 ±11.26)	23 (3.56 ± 7.45)	69 (0.71 ± 8.76)	0.05
	Fifth	23 (5.39 ± 5.77)	23 (2.26 ±11.06)	23 (0.52 ± 4.75)	69 (2.37 ± 7.97)	0.040
	Sixth	23 (5.43 ± 11.43)	23 (2.30 ±14.71)	23 (2.21 ± 5.76)	69 (0.30 ± 11.68)	0.033
	Seventh	23 (5.60 ± 5.49)	23 (4.39±21.02)	23 (3.52 ± 5.13)	69 (1.57 ± 13.42)	0.026
	Ninth	23 (5.47 ±7.91)	23 (0.47± 9.07)	23 (1.65 ± 8.46)	69 (1.11 ± 8.94)	0.013
	Twelfth	23 (8.95 ± 23.99)	23 (0.82 ± 5.53)	23 (4.34 ± 16.12)	69 (1.81 ± 17.62)	0.033

Table 3: Analysis of variance for mean vital signs before and after after intervention in different days

Vital signs	The variable name	Degrees of freedom	F	P-Value
Systolic blood pressure	Overall effect of the intervention	11	1.095	0.362
	Interaction between the intervention and control group	22	0.847	0.667
	Interaction between the intervention and control group	11	0.951	0.490
Diastolic blood pressure	Overall effect of the intervention	11	0.257	0.993
	Interaction between the intervention and control group	22	0.540	0.958
	Interaction between the intervention and control group	11	0.321	0.981
Temperature	Overall effect of the intervention	11	0.189	0.998
	Interaction between the intervention and control group	22	0.852	0.660
	Interaction between the intervention and control group	11	0.619	0.813
Respiratory rate	Overall effect of the intervention	11	1.289	0.226
	Interaction between the intervention and control group	22	1.099	0.342
	Interaction between the intervention and control group	11	1.511	0.122
Pulse rate	Overall effect of the intervention	11	0.272	0.991
	Interaction between the intervention and control group	22	1.176	0.262
	Interaction between the intervention and control group	11	0.317	0.982

Table 4: Analysis of variance between the mean vital signs before and after Intervention

Type of variable	The variable name	Degrees of freedom	F	P-Value
Systolic blood pressure	The overall effect of the test group	2	38.677	<0.001
	The overall effect of age	1	10.282	0.673
Diastolic blood pressure	The overall effect of the test group	2	14.424	<0.001
	The overall effect of age	1	1.069	0.305
Temperature	The overall effect of the test group	2	0.930	0.404
	The overall effect of age	1	0.243	0.624
Respiratory rate	The overall effect of the test group	2	6.691	0.02
	The overall effect of age	1	0.118	0.732
Pulse rate	The overall effect of the test group	2	2.656	<0.001
	The overall effect of age	1	4.937	0.030

DISCUSSION

Despite the homogeneity of the patients' vital signs in three groups on the first day before study initiation, the results showed the effectiveness of Dyang sensory stimulation on mean vital signs of comatose patients except for body temperature. However, the long-term impact of sensory stimulations on reducing or increasing mean vital signs was not obvious. Along with the current research, results of the study done by Rahmaniet al who evaluated the effect of planed meeting on the physiologic indicators of the patients who suffer from Acute Coronary Syndrome,showed that heart rate and systolic/diastolic blood pressure of study subjects were increased after the start of visiting compared to pre-visiting time and this increase was

continued throughout the visiting time. However, they found that these values were decreased at the end of visiting; as during half an hour after visiting, the heart rate, systolic/diastolic pressure are decreased to the level that is lower than the pre-visiting stage [15]. This indicates that overall effects of time on the impact of intervention on mean vital sign is not significant. Kamranifar et al also in a separate study found the same results [16]. Although higher difference of mean vital signs after intervention in this study compared with the studies of Rahmani and Kamranifar may be caused by scheduled Dyang sensory stimulations, presence of a constant and the closest family member on the bedside and continued intervention during different days. However, unlike the results of the current study, Mitchell et al found that there is no significant difference between mean arterial blood pressure before, during and after visiting time [9]. This fact may be caused by shorter duration of visiting time and shorter duration of intervention in their study, As well as, this study was conducted in NICU.

In this study, no significant difference was noted between body temperature of patients before, during and after intervention. So, it can be concluded that the intervention did not provide any impact on body temperature of subjects. This fact may indicate that the intervention has not increased the metabolic rate of the patients and so is beneficial for the patients because increased metabolic rate can increase the body temperature [17]. But, in the study of Kamranifar et al, there was significant difference in mean body temperature before, during and after visiting [16]. This difference may be caused by using Dyang sensory stimulation program; because no specific program had been utilized in Kamranifar study and family members had performed the sensory stimulations in any desired format and might over-stimulate or under-stimulate the patient. The results of this study showed that there is significant correlation between mean respiratory rates before, during and after intervention and respiratory rate has been increased after visiting and after sensory stimulation but has been decreased 30 minutes after visiting and intervention. The recently mentioned findings are in accordance with Rahmani and Kamranifar studies, but in this case, Hart et al showed that there is no significant difference between mean respiratory rate before, during and after visiting [18]. This fact may be caused by shorter duration of visiting time in this study and the above mentioned researches. In addition, our findings showed that regarding the impact of sensory stimulation on vital signs, the family group was the best, nursing group was the second and control group was the last group in classification. This result can be utilized on the best way for patients who are admitted in ICU. Tavangar et al showed that performing sensory stimulation by family members for 10 consecutive days could increase patients' GCS at the end of 10^{th} day compared with the first day ($p=0.0001$), but, no significant changing in GCS was noted in the control group (without receiving sensory stimulation) [19]. Besides, the presence of family members at the bedside can improve general health of the patients; because the family and family life is an essential part of every person's health. So, considering the importance of family and its impressive role for patients, it should be considered as a very important issue in nursing plans. Today, caring environment includes both patient and family and general care includes patient and family care together [20, 21]. Leon et al and Alvarez et al showed that the presence of family members at ICU and engaging them in the treatment process can reduce anxiety and help families cope with the current crisis [22, 23].

So it can be concluded that the vital signs are influenced by visiting and sensory stimulations; but these effects are transient and usually reset after the visiting time and are not clinically significant. If family members perform sensory stimulations, a greater impact on the vital signs will be observed at short time. Moreover, formal sensory stimulations by Dyang will provide less negative and more positive impact on physiological parameters of the patients.

CONCLUSION

The effect of sensory stimulation on vital signs of comatose patients was greater when provided by family members. It is suggested that in future studies, a closest member of patient's family to be trained to perform sensory stimulation on appropriate time for the patient at ICU.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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