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Original article

Effectiveness of voice stimulus on the level of consciousness, physiological parameters and behavioural responses in comatose patients – A feasibility study

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ABSTRACT

Purpose: This research aimed to determine the effectiveness of voice stimulus on the level of consciousness, physiological parameters and behavioural response of comatose patients in a tertiary care hospital of Udupi district, Karnataka, India.

Methods: A randomised control trial was undertaken with 20 comatose patients, 10 in each group. The participants in the intervention group were provided with the voice stimulus of their close relative for 3 times a day for 5 consecutive days and were assessed for any change in the level of consciousness, physiological parameters and behavioural responses. RMANOVA was computed to evaluate the effectiveness of voice stimulus.

Results: The results showed a significant improvement in the level of consciousness in the interventional group compared to the control group ((F = 11.756, p = 0.003). The behavioural responses before and during the intervention on day1 (p 0.001), day 2 (p 0.000), day 3 (p 0.002), day 4 (p 0.002) and day 5 (p 0.004) and also before and after the intervention on day 1 (p 0.023), day 4 (p 0.031) and on day 5 (p 0.030) were significant among the intervention group. However physiological parameters did not show significant variation with the voice stimulus among the comatose patients SBP (p 0.213), DBP (p 0.155), and SpO_2 (p 0.601).

Conclusions: The results of the research showed that the voice stimulus with familiar voice showed a positive response among comatose patients on their level of consciousness and behavioural responses.

1. Introduction

Coma is a condition in which the patient's eyes remain continuously closed and cannot be aroused to a wakeful state.[1] Every year in India, approximately 1.5–1.7 million individuals are neurologically disabled due to Traumatic Brain Injury. Every year 0.45–0.6 million people have disability caused by stroke.[2] Despite many medical and surgical interventions, the morbidity and mortality among comatose patients are still high. If not managed appropriately, patients may develop long term disability, and this would result in economic burden and poor quality of life among the individuals, families, and communities. Comatose patients are at high risk of sensory deprivation.[3] With intense and repeated auditory stimulation, a patient could be recovered from coma to an improved level of functioning.[4] In a prospective quasi experimental study conducted at Bangkok, sensory stimulation program (SSP) with five sensory modalities such as visual, auditory, olfactory, tactile and gustatory was provided for 40 unconscious patients after brain injury for the age group greater than 18 years. The results showed that the SSP promotes brain recovery in traumatic brain-injury patients.[5] In a double-blind randomized placebo-controlled trial conducted on 15 participants with disorders of consciousness to study the neurobehavioral and neurophysiological effects related to sensory stimulation, the author found that the patients in the coma state responded better to their family members than to strangers. In this trial the patient was provided with customized recordings of stories told by people well known to the patient at least 1 year prior to injury.[6] A single blinded randomized controlled clinical trial with 30 patients with disorders of consciousness done in Brazil (Sao Paulo) on the usage of music and voice stimulus revealed that the voice message of the family members with volume 60–70 dB is effectual than the music.[7] The findings of the research conducted in Chiba, Japan revealed that the familiar voices of the participants activated the cerebral functioning better than the

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unfamiliar voices.[8] In Iran, a research revealed that auditory stimulation with the familiar voices of patients' family members can improve level of consciousness among patients with head trauma.[9]

Keeping these patients in emphatic environments leads to decreasing sensory inputs and abnormal level of brain activity. Auditory stimuli can be used as a beneficial neurorehabilitation method among these patients.[10] Auditory stimulation is essential as hearing is the last sense lost in comatose patients. It is the simplest method used through making verbal communications with the patient by nurses and health care workers during their routine health care activities. Healthcare providers should ensure that appropriate environmental stimuli are provided for the recovery of comatose patients. Auditory stimulation can be

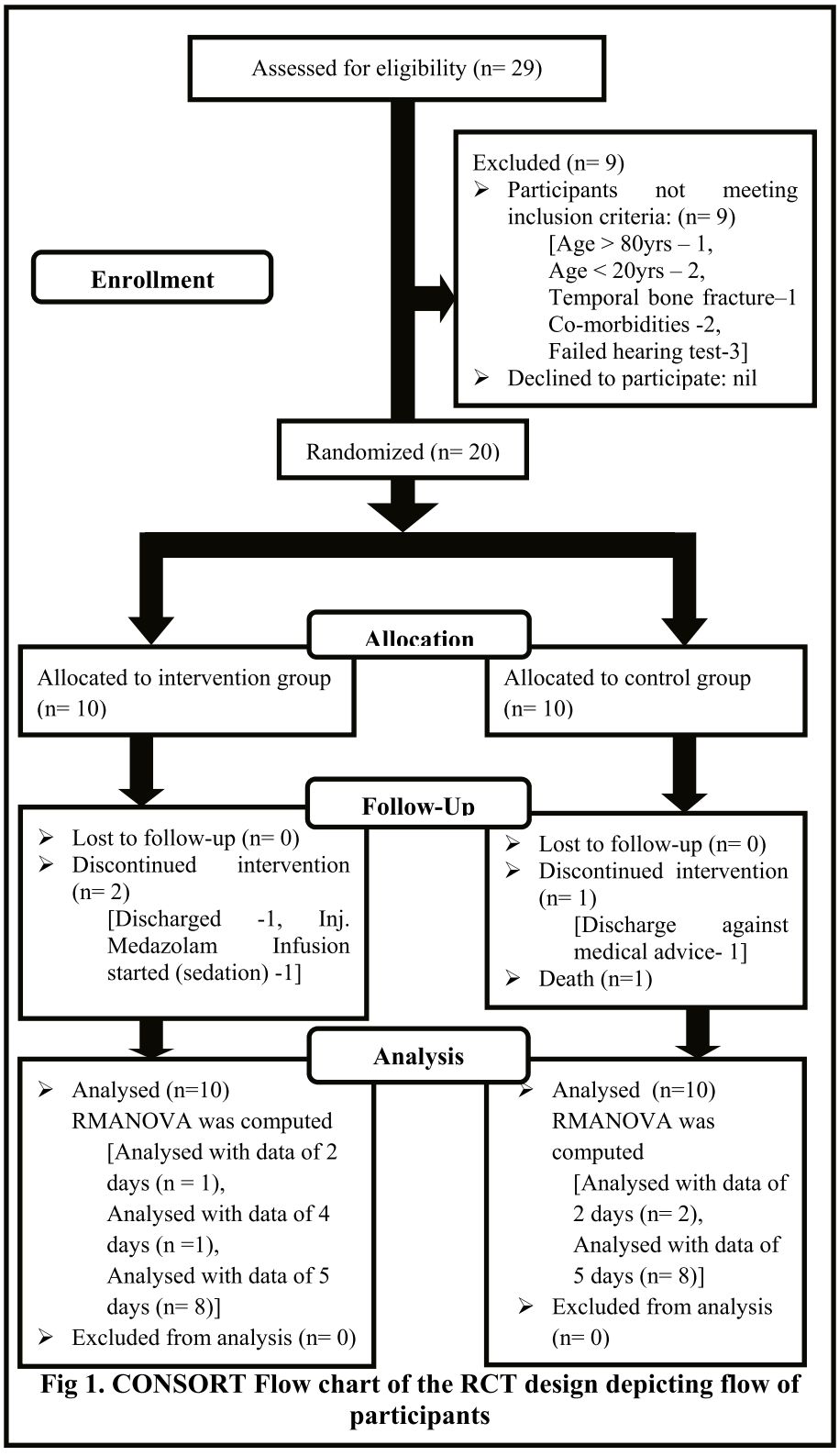

Fig 1. CONSORT Flow chart of the RCT design depicting flow of participants

Fig. 1. CONSORT Flow chart of the RCT design depicting flow of participants.

performed using different voices with different effects like familiar voice which can be more quickly recalled by the patient.[11]

2. Material & methods

This feasibility study adopted a Randomised Control Trial, with 20 comatose patients with Glasgow Coma Scale between 3 and 8. Block randomization (2 blocks of 10 samples) were used to allocate the participants into intervention[10] and control group.[10] Participants with the age group of 20–80 years after screening with Auditory Brain Stem Response test were included in the research. Patients who are right handed with left temporal hemorrhage, with temporal bone fracture and ear bleed {trauma to temporal bone is usually the result of blunt head injury and can result in damage to the middle and internal ear and can result in hearing loss[12]}, who received any sedative drugs (eg. Inj. Medazolam), with hearing impairement reported by family members and with any other co-morbidities were excluded from the research. The institutional ethical committee clearence was obtained from Kasturba Hospital Manipal (IEC No: IEC 649/2014)

Research design: The researcher used the Consolidated Standards of Reporting Clinical Trials (CONSORT) statement updated guidelines for randomized trials as shown in Fig. 1. The trial registration number is CTRI/2016/10/007368.

2.1. Procedure of data collection

Enrollment of the participants: The patients were assessed for their eligibility to participate after their admission. Those who met the sampling criteria were included in the study.

Screening of the hearing function: Every patient was screened for hearing function using Auditory brain stem response machine (Biologic, Navigator Pro 2) by an Audiologist. The time required for screening was approximately 15–30 min per participant. The screening was done without interfering the standard care provided to the participant in the hospital. The artefacts in the readings due to electrical interference in the setting was also taken care of during the assessment. The patients with failed hearing test were excluded as the voice stimulus provided cannot be heard by the patients. And patients who passed the hearing test were included in the study.

Obtaining informed consent: After the selection of the participants, the patient relatives were told about the details of the study and their partcipation role as either in the intervention or control group. Informed consent was obtained from their relatives. In the intervention group, the Kin (close relative), of the participant was identified by the researcher as per the information obtained by the patient relatives and informed consent for the recording of the voice message was obtained from the next of kin after the allocation of participants.

Allocation of participants: In this research, the researcher used block randomization. Two blocks of 10 samples were used to allocate the participants into intervention group (n = 10) and control group (n = 10). Allocation concealment was done using sequentially numbered opaque sealed envelopes (SNOSE) containing the allocation details. As the population included comatose patients, they were all blinded to the intervention and thus the research was a single blinded study. However the outcome assesser could not be blinded.

Process of recording voice message: The Kin of the participant's relative was asked to write the voice message in his/her own language in a paper provided as per the criteria of the script of the voice message in prior to the voice recording in the recording room. The accuracy and adequacy of the written message was confirmed by the researcher before the original recording of the voice message. The recording of the voice message was strictly based on the script and was done in a separate sound free environment providing all required confidentiality and comfort to the patient's close relative. The voice message was recorded for a duration of maximum 10 min with the computer software - Adobe audition 3.0 and a headset with microphone. Recording was done in a normal conversational voice with the microphone held at 4–5 inch distance. The recorded voice message was then edited and normalized for intensity by the researcher after thorough evaluation based on the script of the voice message. Only messages with normal prosody and appropriate content as judged by the researcher were included. The 10 min voice message was then duplicated to 20 min and was saved in MP3 format in Philips MP3 player as the intervention was provided for 20 min. The total time taken for writing, recording and editing of the voice message was approximately 1 to 1 ½ hour per participant.

Guidelines for the script of the voice message:

1. Should be in a language understood by the patient;
2. Should have a duration of 10 min maximum;
3. Should tell who is talking at the beginning and should repeat it at the end of the message;
4. Patient's name should be specified[4] at least 3 times during the message. If there is any cultural barrier, the relative can call the patient by the name which they have been using to address the patient;
5. Should tell regarding any event or any moment that they have spent together.
6. Patients should be informed where they are and what is happening to them and;
7. Should tell them a message of affection with an optimistic perspective, saying something about their family life.

Intervention session: Before the delivery of the intervention, it was made sure that the participants lie in a position which is appropriate for the researcher to monitor and measure the findings. The Physiological Monitoring system was also connected to the participants before the delivery of intervention. No purposeful stimulation was provided during this pre-intervention period. The researcher assessed the patients' level of consciousness and physiological parameters such as systolic blood pressure, diastolic blood pressure, heart rate and oxygen saturation with the standardised GCS and Philips VM4 cardiac monitor respectively before starting the intervention. Behavioural responses were observed for a duration of 5 min before every intervention using a structured observational checklist. Behavioural responses such as movement of the head, movement of the mouth, movement of the lips, facial tension and relaxation, eye ball movement visible under closed eyelids, eye opening and closing, eye brow movements, fluttering of the eyelid, tears, perspiration, non-comprehended words, movement of the upper limbs and movement of the lower limbs were observed. If the movement was present a score of '1' and '0' for absence was given. The measurements were obtained by the preset alarm of required timings as set by the researcher prior to the start of the intervention.

The intervention was provided via Audio-technica ATH-M40x Professional Monitor Headphones which prevents the patient from hearing any other background noise in the ICU other than the voice stimulus provided and Philips MP3 Player for a duration of 1 h each day in 3 divided sessions of 20 min with equal intervals in between for 5 consecutive days, during the day time.

The participants in the control group were not provided with the intervention, but headphones were placed over the external pinnae of the comatose patients after covering it with the disposable and stretchable paper cloth headphone covers as a placebo. The headphones were kept for a duration of 1 h each day in 3 divided sessions of 20 min with equal intervals in between,for 5 consecutive days, during the day time as similar to the intervention group without interfering the standard care provided to the participants.

The headphones were of driver – 40 mm, frequency response – 15 to 24,000 Hz, maximum input power - 1600 mW at 1 kHz, sensitivity – 98 dB and impedence – 35 Ω. The recorded voice message was administered to the intervention group only after confirmation of the volume of the message by the researcher to a comfortable listening level (55–80 dB), preset by the Audiologist.

Intervention was not provided to the participants while undergoing any of the standard care of the hospital. The ear cushions of the headphones were covered with specially made disposable and stretchable paper cloth headphone covers without interfering the quality of the voice message deliverd, in prior to the placement of headphones to the external pinnae of the comatose patients. These covers were removed and replaced with the fresh ones in every sessions before providing the intervention to prevent transmission of infection. The researcher was cautious enough not to cause any harm to the patients while placing the headphones (especially if any surgical intervention was done). The headphones were also wiped with an alcohol swab after providing the intervention.

Data measurements and follow-up: The demographic data was collected by the researcher from the relatives and from the case record.

The physiological parameters and behavioural response were assessed every 1 min, 5 mins, 10 mins, 15 mins, 20 mins and 25 mins of starting the voice stimulus in each session. The readings after 1min of starting the intervention was assessed to observe the immediate response. The readings during the intervention included the readings obtained at every 1 min, 5 mins, 10 mins, 15 mins, 20 mins of starting the intervention. The readings taken at 20 min indicates the observations at the stoppage of intervention and readings at 25 min indicate the responses after 5 min of stopping the intervention. The level of consciousness was assessed using the Glasgow coma scale before and after the intervention for 3 times a day for 5 consecutive days.

2.2. Statistical analysis

The following assumptions were made for sample size calculation. The formula used for sample size calculation was $N = 2\,\sigma^2\,(Z_{1-\alpha/2} + Z_{1-\beta})^2/d^2$. A standard deviation of 10, alpha error 0.05%, power 80% and approximate dropout of 20% which added up to a sample size of 20 in each group.[13] The sample size of 10 was taken in each group making a total sample of 20. RMANOVA was computed to determine the effectiveness of voice stimulus among the comatose patients.

3. Results

The sample characteristics of both intervention and control group and homogeneity comparison of the baseline characteristics were performed to ensure whether the groups were homogenous at inclusion. To determine whether the groups differed significantly at the baseline characteristics, chi-square tests were computed. The *p* values for all the variables were greater than 0.05 which indicated that the intervention and control group did not differ significantly regarding these variables at baseline as shown in Table 1.

The baseline values for all outcome measures such as GCS score, SBP, DBP, HR, SPO_2 and behavioural responses were statistically tested between the intervention and control group before providing the voice stimulus or placebo to know whether the groups differed significantly with respect to outcomes. Since the data was following the normality, an Independent sample *t*-test was done to compare the differences between the groups. There were no statistically significant difference in the outcome measures between the intervention and control group at the baseline as shown in Table 2.

The GCS scores of 3 sessions in a day were added together and the cumulative mean GCS score and standard deviation (SD) of the readings of before and after the intervention of 3 sessions in a day was computed separately. There was an increase in the cumulative mean GCS score of the intervention group from day 1, before the intervention (6.6) to day 5 (8.6) after the intervention. Whereas in the control group the cumulative mean GCS score before the intervention decreased from the day 1 (5.6) to day 5 (5.0). There was also an increase in the GCS scores after the intervention in the intervention group except on day 3 and day 4, whereas the GCS remained the same in the control group before and after the intervention from day 1 to day 5 as shown in Table 3.

Table 1
Sample characteristics and homogeneity comparison of comatose patients in intervention and control group.

Variables	Intervention group		Control group		Homogeneity comparison		
F	*%*	*F*	*%*	χ^2 value	*p* value	*Df*	
Age in years							
20–50	3	30	4	40	1.27	0.33	1
51–80	7	70	6	60	–	–	–
Gender							
Male	6	60	6	60	4.44	0.07	1
Female	4	40	4	40	–	–	–
Religion							
Hindu	10	100	8	80	0	0	0
Muslim	0	0	2	20	–	–	–
Christian	0	0	0	0	–	–	–
Marital status							
Single	2	20	0	0	0	0	0
Married	8	80	10	100	–	–	–
Type of family							
Nuclear	10	100	9	90	0	0	0
Joint	0	0	1	10	–	–	–
Educational status							
Primary and secondary	4	40	3	30	3.58	0.46	2
Higher secondary	1	10	1	10	–	–	–
Illiterate	5	50	6	60	–	–	–
Occupation							
Skilled worker	2	20	2	20	4.76	0.31	1
Unskilled worker	5	50	5	50	–	–	–
House hold work	3	30	3	30	–	–	–
Informant							
Parent	1	10	1	10	10.0	0.12	2
Children	8	80	6	60	–	–	–
Sibling	1	10	1	10	–	–	–
Spouse	0	0	2	20	–	–	–
Medical diagnosis							
Cerebrovascular disorders	6	60	7	70	2.85	0.24	2
Crainiocerebral injuries	3	30	3	30	–	–	–
Neuroinfections	1	10	0	0	–	–	–
Duration of hospitalisation in days							
<10	6	60	9	90	0.74	0.38	1
≥10	4	40	1	10	–	–	–
GCS score on admission							
3–5	2	20	4	40	0.10	0.74	1
6–8	8	80	6	60	–	–	–
Surgical intervention							
Hematoma evacuation	4	40	4	40	3.54	0.73	1
Aneurysm clipping	0	0	2	20	–	–	–
Extra ventricular drainage	3	30	2	20	–	–	–
No surgical intervention	3	30	2	20	–	–	–

Tests of significance - # - chi-square.

RMANOVA was computed between baseline GCS score of first session of the day one and after intervention GCS scores of last session of day five. There was a significant difference in the GCS scores between the intervention and control group (F value = 11.756, $p = 0.003$).

There was no significant difference in the physiological parameters such as SBP (F value - 1.665, *p* 0.213), DBP (F value - 2.203, *p* 0.155), and SpO_2 (F value - 0.283, *p* 0.601), among the intervention and control group as the *p* value was found to be > 0.05. There was a significant

Table 2
Homogenity comarison of outcome measures.

Variable	Group	Mean	SD	t value	p value
GCS score	Intervention	6.1	±1.197	0.738	0.470
	Control	5.6	±1.776	–	–
SBP	Intervention	1.39	±25.21	−0.021	0.984
	Control	1.39	±38.59	–	–
DBP	Intervention	89.9	±18.29	0.828	0.419
	Control	80.8	±29.56	–	–
HR	Intervention	1.01	±17.05	0.696	0.496
	Control	95.2	±20.10	–	–
SPO_2	Intervention	99.2	±1.68	0.000	1.000
	Control	99.2	±1.31	–	–
Behavioural responses	Intervention	2.8	±2.44	0.081	0.936
	Control	2.7	±3.02	–	–

difference in the heart rate and voice stimulus of comatose patients (F value - 7.081, p 0.016), which was not clinically significant. As the difference in heart rate was less than 10 after the intervention, it was reported as clinically not significant.

As the intervention was provided in 3 sessions, all the scores obtained from behavioural responses in 3 sessions in a day for each participant was added. Thus the maximum possible score for the scale in a day was 39 and minimum was 0. To obtain the scores of the intervention, readings obtained at 1 min, 5 min, 10 min, 15 min, and 20 min were added, and cumulative mean was computed. Also the same was computed in the control group. The maximum scores obtained in the intervention group during the voice stimulus from day 1 to day 5 is higher than the control group. The behavioural responses in the control group is negligible when compared to the intervention group as shown in Table 4.

RMANOVA was computed to find the effectiveness of voice stimulus on behavioural response among comatose patients before, during and after in the intervention group when compared with the control group. It was found that there exists a significant difference in the behavioural responses before and during the intervention on day1, day 2, day 3, day 4 and day 5 with the p values 0.001, 0.000, 0.002, 0.002 and 0.004 respectively. There was a significant difference in the behavioural responses before and after the intervention on day 1, day 4 and on day 5 with the p values 0.023, 0.031 and 0.030 respectively. Whereas the behavioural responses between before and after the intervention did not differ significantly on day 2 and day 3 with the p values 1.000 and 0.059 respectively as shown in Table 5.

Table 3
Mean and standard deviation of GCS scores of the comatose patients before andd after the intervention from day 1 to day 5.

		Day 1		Day 2		Day 3		Day 4		Day 5	
		B	A	B	A	B	A	B	A	B	A
Intervention group	Mean	6.6	7.0	7.4	7.5	7.9	7.9	8.1	8.1	8.4	8.6
	SD	1.5	2.0	2.1	2.1	2.3	2.3	2.2	2.2	2.4	2.5
Control group	Mean	5.6	5.6	5.0	5.0	4.9	4.9	5.0	5.0	5.0	5.0
	SD	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9

B-before the intervention.
A-after the intervention.

Table 4
The minimum, maximum, mean and SD, scores before, during and after the intervention in the intervention and control group from day 1 to day 5.

	Groups	Measurements	Minimum	Maximum	Mean	SD
Day 1	Intervention Group	Before	0	7	2.80	±2.44
		During	5.8	23.2	1.16	±5.11
		After	1	16	8	±5.24
	Control group	Before	0	10	2.70	±3.02
		During	0.2	3.6	7.90	±5.21
		After	0	4	1.30	±1.56
Day 2	Intervention Group	Before	0	7	2.10	±2.33
		During	4.6	22	1.29	±4.60
		After	1	26	2.10	±2.72
	Control group	Before	0	4	1.0	±1.33
		During	0	3	7.10	±5.50
		After	0	3	0.90	±1.10
Day 3	Intervention Group	Before	0	8	2.10	±2.72
		During	0.2	15.4	9.42	±4.81
		After	0	12	5.90	±4.06
	Control group	Before	0	3	0.60	±0.96
		During	0	4.2	6.30	±6.94
		After	0	3	0.60	±0.96
Day 4	Intervention Group	Before	0	11	1.70	±3.40
		During	0	17.6	9.48	±6.35
		After	0	19	7.60	±6.76
	Control group	Before	0	8	1.60	±2.67
		During	0	3.8	8.40	±7.01
		After	0	1	0.60	±0.51
Day 5	Intervention Group	Before	0	11	3.0	±4.47
		During	0	29.2	10.66	±9.35
		After	0	22	7.90	±8.42
	Control group	Before	0	9	1.70	±2.86
		During	0	9	9.60	±13.49
		After	0	9	2.10	±2.80

Table 5
RMANOVA with in the group for before, during and after the intervention from day 1 to day 5.

Days	Measurements		Mean difference	p value	Confidence interval (95%)	
					Lower bound	Upper bound
Day 1	Before	During	−8.880	0.001[a]	−13.09	−4.6
		After	−5.200	0.023[a]	−9.48	−0.91
Day 2	Before	During	−10.800	0.000[a]	−14.28	−7.31
		After	0.000	1.000	−2.23	2.23
Day 3	Before	During	−7.320	0.002[a]	−11.27	−3.36
		After	−3.800	0.059	−7.78	0.18
Day 4	Before	During	−7.780	0.002[a]	−11.89	−3.66
		After	−5.900	0.031[a]	−11.10	−0.69
Day 5	Before	During	−7.660	0.004[a]	−12.11	−3.20
		After	−4.900	0.030[a]	−9.21	−0.58

[a] p value less than 0.05.

4. Discussion

Eventhough there are studies conducted on the effectiveness of auditory stimulation among comatose patients which includes music and other voice stimulus. There is a paucity of studies reported on the effectiveness of the recorded voice message of the close relative among comatose patients. The present research showed the voice stimulus had a positive effect on the level of consciousness of the comatose patients. The effectiveness of auditory stimulation investigated on the duration to reach GCS score of 15 among patients with traumatic coma revealed that the participants in the intervention group recovered early and reached a GCS score of 15 ($\chi 2 = 12/96$, $P < 0/001$) when provided with a familiar recorded MP3 sound along with the regular treatment in ICU when compared with the control group.[14] The present research is further supported by an experimental study conducted to find the effectiveness of coma arousal therapy among comatose patients with traumatic head injury which showed significant improvement in GCS between the intervention and control group.[15] The effectiveness of structured auditory sensory stimulation program (SSP) among patients diagnosed with traumatic brain injury also reported an increase in the mean daily GCS scores in the intervention group as compared to the control group. The mean daily GCS scores for the intervention was lower (6.1) and rose (6.8) over time compared to the mean daily GCS score of the control group, which began higher (7.4) and decreased over time (6.0).[16] Auditory stimulation improves GCS in comatose patients.[3,17]

The present research showed that there was no significant difference in the physiological parameters such as SBP, DBP and SpO_2 among the intervention and control group. In a review done to investigate the role of music among the patients admitted in ICU's revealed that the various stressors and sounds from telephones, alarms, monitors and nursing activities in the ICUs led to a rise in HR, RR, BP hence music can be used as one of the nursing intervention among patients to decrease stress and to facilitate relaxation responses.[18] A Cochrane review on effectiveness of music as an intervention in mechanically ventilated patients reported that the music showed a reduction in heart rate.[19] A quazi-experimental pilot study was done to evaluate the changes in BP, HR, RR, SpO_2 to different musical stimuli among patients with severe cerebral damage reported significant increase in the systolic BP, HR with the radio stimulus. SpO_2 showed a significant increase with classical relaxing music. There was decrease in systolic and diastolic BP, HR and an increase in SpO_2 due to the exposure to relaxing music with the sounds of nature. Significant statistical variations of the oxygen saturation were noted during the message playback among 30 patients with disorders of consciousness of GCS score 3 to 8.[7] Structured auditory sensory stimulation program conducted among comatose patients diagnosed with traumatic brain injury reported that five participants had significant changes in HR across time.[16] In contradiction to all the above mentioned studies, a previous research done to assess the effectiveness of taped messages by a family member on the physiological parameters among 10 comatose patients revealed no statistical significant differences before the playback of the taped messages on the mean of the measures of the heart rate, SBP, DBP, SPO_2. It also reported no statistical significance difference on the heart rate, SBP, DBP, SPO_2 during the playback of taped messages, and no statistical significance difference on the heart rate, SBP, DBP and SPO_2 after the playback of taped messages.[20]

In the present research, it was found that there exists a significant difference in the behavioural responses such as movement of the head, movement of the mouth, movement of the lips, facial tension and relaxation, eye ball movement visible under closed eyelids, eye opening and closing, eye brow movements, fluttering of the eyelid, tears, perspiration, non-comprehended words, movement of the upper limbs and movement of the lower limbs before and during the intervention on day 1–5. And there was a significant difference in the behavioural responses before and after the intervention on day 1, day 4 and on day 5. The changes in facial expressions to different musical stimuli among patients with severe cerebral damage reported that patients showed muscular facial relaxation, eye opening, mouth movements, head movements, smiling and eyebrow movements when presented with classical relaxing music. Patients showed muscular facial relaxation, eye opening, smiling, mouth movements, head movements, yawning, eyebrow movements, and an emission of sound and presence of tears to relaxing music with the sounds of nature. In a single blinded RCT done among 30 patients with disorders of consciousness to analyze the influence of voice message and music on facial expressions, voice message was found to be more effective than music.[7] Changes in responsiveness were reported among the patients with impaired consciousness among the survivors of acute brain injury when presented with synthetic, familiar and unfamiliar voice messages among patients with impaired state of consciousness.[21]

4.1. Limitations

The study has few limitations. The sample size is small and patients are selected from a single center. The intervention was provided only for 5 days which may be of short duration. We included patients between the agre group of 20–80 which may affect the outcome due to the wide range. The intervention and the researcher were not blinded and the extraneous variables were not controlled. the patients selected for the research as participants where not on the same day of inclusion and the relatives were not restricted from visiting the patient.

In conclusion the present research demonstrated the positive effect of voice message of the close relative among the comatose patients on their level of consciousness and behavioural responses. It can be used routinely as an intervention to improve the level of consciousness of comatose patients in hospitals as well as in home set up as it provides them an early recovery. It can be used as a supportive measure and can be incorporated in the daily nursing care interventions without interfering with the routine care given in the hospitals. Providing auditory stimulus is beneficial when relatives are not allowed in ICU due to infection risk and at homes as a rehabilitative measure especially when their loved ones are not near the comatose patients. This research was done in a small sample size and needs to be repeated with a larger sample size to make further generalizations.

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