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Effects of Subject Specific Integrated Multisensory Stimulation on Arousal in Traumatic Brain Injury-A Randomized Controlled Trial

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Abstract

Context: Enriched environment aims to improve arousal in subjects with disorders of consciousness. Adding a functional task-based arousal program with added personal salience could possibly enhance the recovery. However, the effect of one such program- "Subject specific integrated multisensory stimulation" on arousal for subjects with acute severe traumatic brain injury is lesser known.

Aim: The objective is to assess the effect of subject specific integrated multisensory stimulation program on arousal following traumatic brain injury.

Setting and design: Parallel arm randomized controlled trial in acute setup (Neuro intensive care unit and neuro wards)

Methods and materials:100 participants with Glasgow's coma scale score of less than 8 (severe) after traumatic brain injury were allocated under two groups. Control group was administered with Multimodal sensory stimulation program and experimental group with subject specific integrated multisensory stimulation program by a session of 45 minutes thrice a day for 14 days. Coma recovery scale -revised was used to assess arousal. Participants were re-assessed on 7th day and on 14th day of intervention by a blinded outcome assessor.

Statistical analysis used: Analysis of variance test for within group analysis and t-test for between group analysis with level of significance fixed at $P<0.05$ were used. Sub-group analysis of coma recovery scale revised was also done using same.

Results: Both the groups improved from baseline. However, the improvement by wilks lambda value in the subject specific integrated multisensory stimulation group (0.193) was better compared to that of control group (0.235). Subscale analysis of CRS-R showed better improvements on arousal in the experimental group (0.174) compared to control group (0.290).

Conclusion: Subject specific integrated multisensory stimulation program serves as a better way to facilitate arousal following acute severe traumatic brain injury.

Keywords: Consciousness, arousal program, Sensory Stimulation, Coma arousal, Multimodal Stimulation.

Clinical Trial Registry of India: CTRI/2021/02/031440

Introduction:

Learning is the essence of human existence. An enhanced environment accelerates the learning process. Hebb's experiment on mice brain shows a growth in nerve cells by exposing it to enriched environment. [1] Environmental enhancement if applied for human brain with disorders of consciousness, can it help to retrieve arousal?

Early neurorehabilitation and improved neurocritical care have raised the bar of number of individuals who survive a severe traumatic brain injury. Many patients significantly show an improvement in the cognitive and physical domains to reintegrate to society. Few patients however, fail to regain complete arousal and

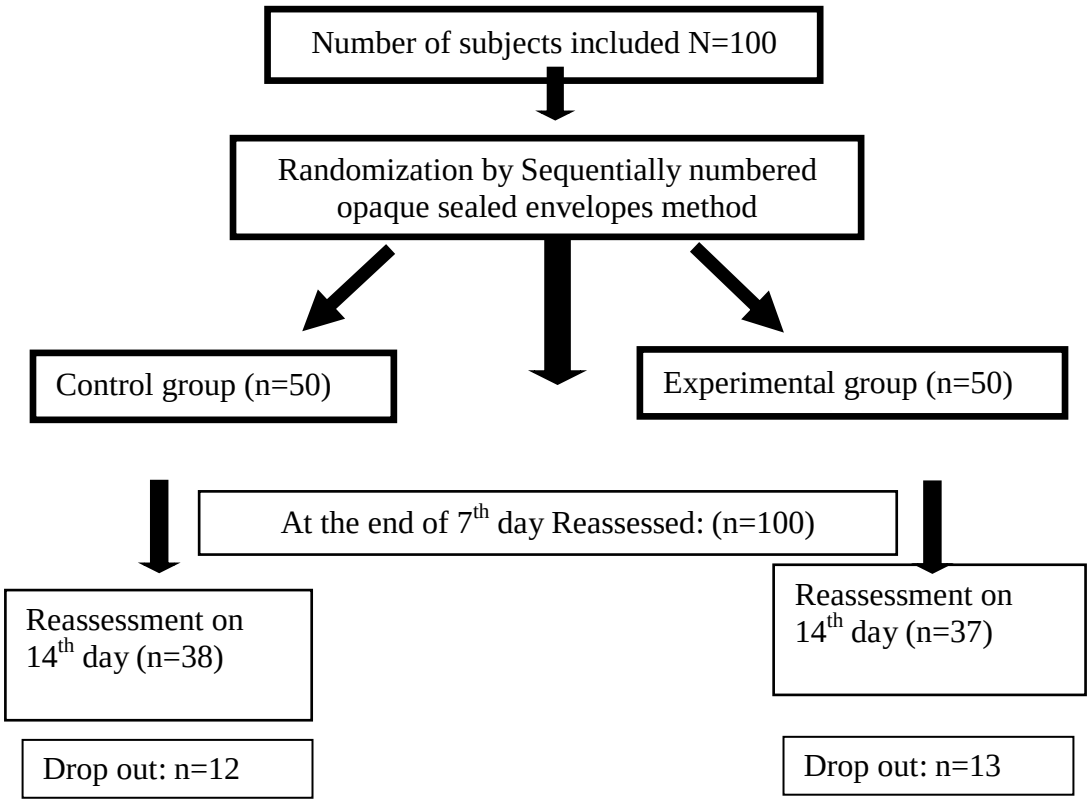
consciousness defined in the routine setup as the joint presence of awareness (e.g., to respond voluntarily) and arousal (i.e., periodic alternate cycles of eye-closure and opening) and slip into various disorders of consciousness (DOC) such as minimally conscious state (MCS), persistent vegetative state or coma.[2] Hence, it is important to target the arousal early in the acute setup by integrating personally salient functional task-based interventions with added environmental enhancement to optimize the recovery. One such coma arousal program is -Subject specific integrated multisensory stimulation (SSIMS0.[3] However, the effect of SSIMS on arousal in traumatic brain injury participants in acute setup needs to investigate.

Objective:
To assess the effect of subject specific integrated multisensory stimulation program on arousal following severe traumatic brain injury (TBI) in acute setup

Material and methods:
Design: Parallel group randomized controlled trial

Participants: 234 participants with Glasgow's coma scale score of ≤ 8 were screened out of which 100 participants with TBI admitted in a tertiary care hospital between June 2021 to May 2022 were recruited. Either gender with age from 18 to 65 years, having stable vitals, with minimum of 48 hours after surgical or medical intervention were considered for inclusion. Participants with past conditions of brain damage**,** preexisting vision or hearing deficit, active otorrhea or rhinorrhea and associated unstable orthopedic fracture injuries were excluded from the study.

Procedure: Flow of participants is shown in figure 1.
Figure 1: Consort Flow diagram



The study was approved by institutional ethics committee RKU/SPT/2020/07/04.

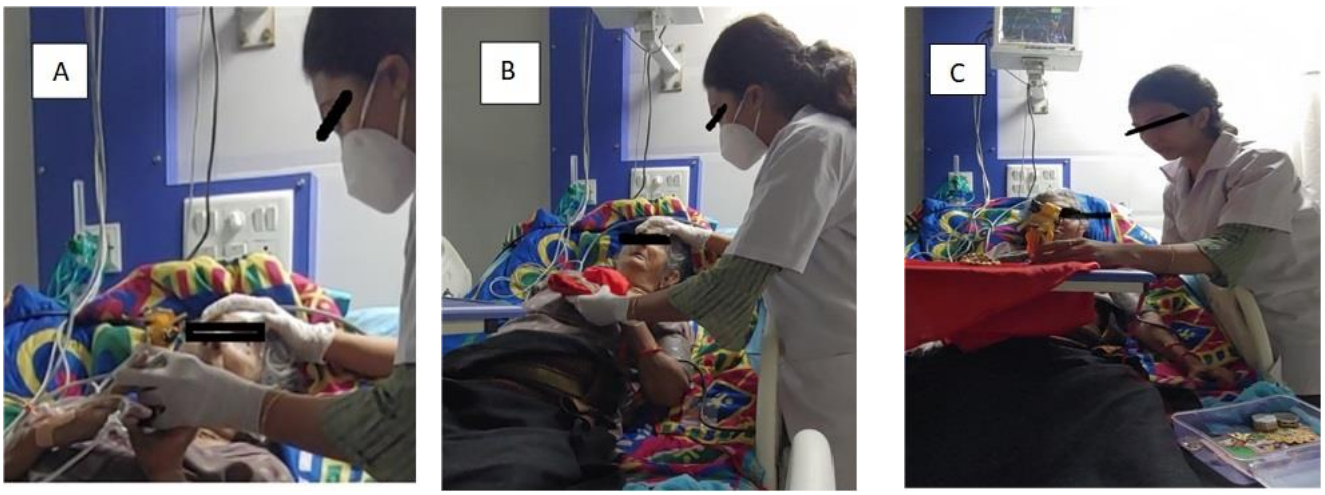
The legally accepted representative of the recruited participants (as the subjects were comatose) were explained about the study and informed consent to participate was taken**.** SNOSE method (sequentially numbered, opaque sealed envelopes) was used for allocation of participants.
50 subjects in control group were delivered multimodal sensory stimulation. It included a unimodal sensory stimulus or a combined stimulus like favorite tune for auditory domain, personally relevant photos for visual stimulation, a gentle touch from friends/relatives/family for tactile stimulation, non-noxious relevant smell of perfume or food as olfactory stimulation. Each stimulus was repeated every two to five minutes.
SSIMS was delivered to 50 participants in the experimental group. [3] A detailed history about occupation, personal preference, dislikes, and routine tasks of the subject was documented based upon the history given by primary caregiver. Recreational, professional, and personal tasks were designed for each participant. The task was administered as per the history from the primary caregiver about the routine time schedule of the participant prior to injury. Each structured task was repeated multiple times in a single session.

The intervention was administered thrice a day, each session lasting for 45 minutes for two weeks for both the groups. Coma Recovery Scale Revised (CRS-R) was administered at baseline, on 7th day and on 14th day of intervention by a blinded outcome assessor to assess its effects on arousal.

Figure 2: Example of items used for participant in Control group (Multimodal coma stimulation program)

A: Favourite saree used for tactile stimulation
B: Past photographs with fond memories used for visual stimulation
C: A cotton bud dipped in a cup of tea for gustatory stimulation
D: Incense cones for olfactory stimulation
E: Bell for auditory stimulation

Figure 3A,3B,3C: Example of items used for a participant in Experimental group (SSIMS)



Example: Personal task for 58-year-old female patient: The task of worshipping the idol of Lord Krishna.

The patient was made to look at the idol (A) for visual stimulation, was made to feel the texture of the idol and its clothes for tactile stimulation (B), made to perform the process of idol worshipping in a functional position (C) for kinesthetic and proprioceptive stimulation. Simultaneously the caregivers chanted the tune and sacred mantras as a part of auditory stimulation. The subject was made to smell the holy food for olfactory stimulation and the lower lip was stroked with a cotton bud dipped in the home cooked holy food (prashadam) for gustatory stimulation.

Data analysis

SPSS version 20 was used for data analysis. The demographic variables were explained by descriptive statistics. Analysis of variance test was used for within group analysis of CRS-R and t -test was used for between group analysis. Level of significance was fixed at $P<0.05$.

Results:

Table 1: Baseline characteristics of participants

Characteristics	Control Group (n=50)	Experimental group (n=50)
Age in years (Mean ± SD)	40.40 ±1.823	39.74 ±1.909
Gender Male: Female (ratio)	40:10	38:12
Type of injury (Frequency) Diffuse axonal injury Extra Dural hemorrhage Sub Dural hemorrhage Combination	 20 10 11 9	 12 5 14 19
Rx-Medical: Surgical	20:30	28:22
Handedness Right: Left (ratio)	43:7	45:5

Table 1 shows that both the group were found to be homogeneous at baseline. However, considering the etiology of traumatic brain injury, diffuse axonal injury cases were found to be more in the control group compared to the experimental group (20:12). More patients in the experimental group required surgical management. Spouses as primary caregivers were found to be more in the control group.

Figure 4: Within group analysis of coma recovery scale -revised scores across various time points for Control group (MMSS)

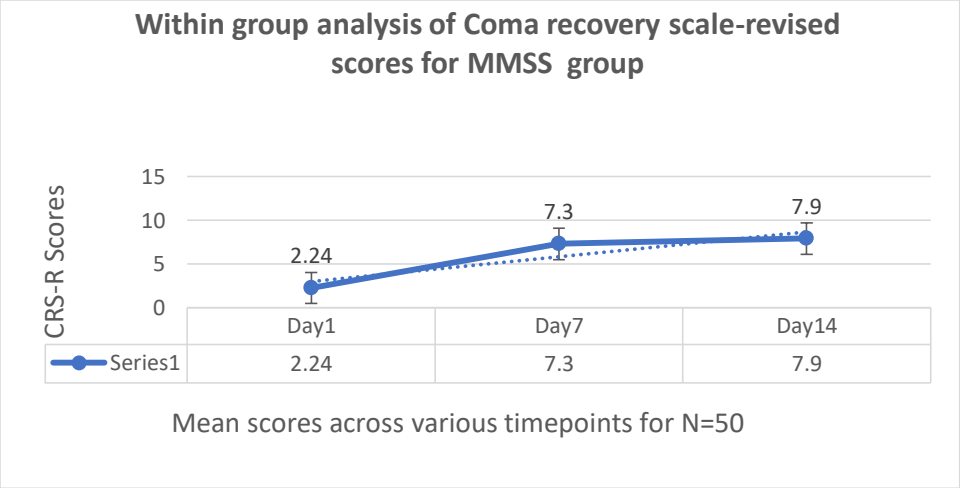


Figure 5: Within group analysis of coma recovery scale -revised scores across various time points for Experimental group (SSIMS)

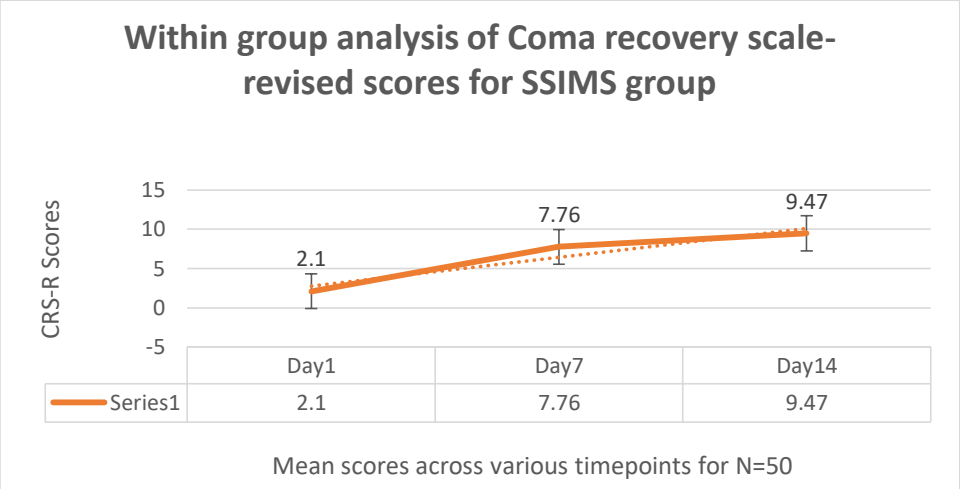


Figure 4 shows within group analysis of coma recovery scale -revised scores across various time points for control group (MMSS)N=50 subjects by analysis of variance test. There was significant improvement from baseline to day 7. However, the scores nearly plateaued from day 7 to day 14. Whereas, for experimental group (SSIMS group N=50) there was significant improvement from baseline to day 7 and the improvement continued from day 7 to day 14 as well by mean scores of 9.47 on 14th day with a p value of ≤0. 05 shown in figure 5. Overall, there was a statistically significant improvement from baseline to 14th day of intervention for both the groups.

Table 2: Between group analysis of Coma recovery scale revised scores across control (MMSS) and experimental (SSIMS) groups.

Analysis parameters	**MMSS**	**SSIMS**
Wilks lambda scores	0.235	0.193
T test values from Day 1-7	0	0
T test values from Day 7-14	1	0.283

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Table 2 shows between group analysis of Coma recovery scale revised scores. Wilks lambda values for experimental group was 0.193 compared to control group 0.235 which showed significant improvement from baseline till 14th day in both the groups. However, the improvement was more in the SSIMS group. Between group analysis was done using t -test. The t-value from day 0 to 7 for control group was significant but turned insignificant from day 7 to 14 whereas for experimental group it was found to be significant throughout with a t-value of 0.0 for day 0 to 7 and 0. 283 for day 7 to 14 respectively.

Table 3: Sub-scale analysis of Coma recovery scale scores across various time points for both the groups

Sub-scales of CRS-R	Control group MMSS		Experimental group SSIMS	
	Mean scores day wise	Values T-Test	Mean scores day wise (D)	Values T-Test

	1	7	14	Wilk sΛ	Day 1-7	Day 7-14	1	7	14	Wilks Λ	Day 1-7	Day 7-14
Auditory	0.60	1.24	1.40	0.556	0.00	0.943	0.20	1.26	1.68	0.265	0.00	0.890
Visual	0.46	1.36	1.58	0.415	0.00	0.916	0.68	2.04	2.02	0.261	0.00	1.000
Motor	0.40	1.20	1.62	0.505	0.00	0.295	0.78	1.80	2.22	0.454	0.00	0.621
Oro-motor	0.30	1.24	0.86	0.480	0.00	0.008	0.24	1.04	1.00	0.352	0.00	1.000
Communication	0.00	0.54	0.90	0.423	0.00	0.001	0.0	0.24	0.74	0.483	0.02	0.010
Arousal	0.48	1.72	1.64	0.290	0.00	1.000	0.22	1.74	1.68	0.174	0.00	0.422

Table 3 shows the sub-scale analysis of Coma recovery scale scores across various time points for both the groups. Wilks lambda was found to be significant for the experimental group for all the domains viz. auditory, visual, motor, oro-motor and arousal except for communication domain which was found to be better in the control group. However, both the groups showed statistically significant improvements in all the domains from baseline to 14th day.

Discussion

The intend of the trial was to test the efficacy of SSIMS program on arousal for patients with coma following traumatic brain injury. The improvement seen in both the groups could be attributed to the emotionally salient stimuli used as a part of intervention. The arousal program used in the control group i.e., multimodal sensory stimulation although said to be multimodal delivers a sequence of unimodal stimuli, one after another in a session of 45 minutes. Two consecutive stimuli do not have an associated connection based upon function to it. Since the content of the MMSS program for each participant was based upon personally salient stimuli, it could have resulted in the improvement of arousal from baseline.

There was better improvement in the overall CRS-R scores in SSIMS group compared to MMSS group from baseline to 7th day and 14th day. This could have been attributed to the nature of the program administered to each participant in the experimental group. The content of the SSIMS program was structured after a thorough history about likes and dislikes of the participant to curate a personally salient task. The delivery of personal, professional, and recreational tasks was also opted as per the routine time schedule of the participants prior to injury. Each unimodal stimuli was integrated in a functional task, administered in a functional position, and delivered as a simultaneous real time job/chores. Moreover, the items used for the SSIMS program were the actual items used by the participant at home or workplace prior to injury and was brought by the relatives. This could have contributed to enhancing the overall environmental experience of the participant in the acute setup.

Sub scale analysis of CRS-R showed better improvements in the auditory, visual, motor, oro-motor, and arousal components from baseline to 7th day and kept improving till 14th day which was found to have plateau in the control group. The potential reason behind this improvement could have been because of the home cooked personally favorite food being used for olfactory and gustatory stimulation. Grunting of mouth, increased salivation, rowing of eyes and tongue movements were the common responses noted during gustatory stimulation in SSIMS group. All the stimuli were linked to each other and delivered simultaneously. The communication domain was found to be better in the control group. This could be justified by the content of the auditory stimulation delivered by single caregiver as a form of conversation with the participant. Clear short sentences were used repeatedly without any voice modulation in the control group which could have been easy to comprehend for the patient compared to the complex task-based conversations from multiple people in the experimental group.

Furthermore, the improvement in both the group could be ascribed to the mechanism of spontaneous recovery which follows immediately after traumatic brain injury.[4] Considering the etiology of diffuse axonal injury which was slightly higher in the MMSS group compared to SSIMS group could have contributed to the relatively poor outcome in control group.[5]

Environmental enhancement in the intensive care unit was done by the items used in the functional tasks for SSIMS group. This could have favored the emotional experience of the participant by retrieving the preserved areas in the cortex through representation of thoughts and actions.[6] Enriched environment furthermore accelerates the mechanisms of neuroplasticity and functional reorganization.[7] The initiation of arousal program by early stimulation also plays a key role in avoiding the sensory deprivation and by promoting environmental enrichment which could have been the potential reason behind arousal.[8] These all-possible mechanisms could have collectively led to improvements of arousal in both the groups**.**

Conclusion

Early stimulation of consciousness by subject specific integrated multisensory stimulation program (SSIMS) is effective in facilitating arousal in participants with coma after traumatic brain injury. This program can be used as an adjuvant to be existing multimodal sensory stimulation program to promote better recovery from disorders of consciousness in acute setup.

Running title: Novel coma arousal program

Financial support and sponsorship: Nil

Conflict of interest: The author declares that there is no conflict of interest.

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