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Subject Specific Integrated Multisensory Stimulation Program A Ray of Hope to Facilitate Arousal Following Traumatic Brain Injury

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Abstract

Objective: The objective of the study was to test a newly developed subject specific integrated multisensory stimulation program (SSIMS) on arousal of patients in coma following traumatic brain injury (TBI). **Design:** Parallel group pilot randomized controlled trial. **Patients:** Twenty patients in coma following TBI from a tertiary care hospital with Glasgow coma scale score ≤8 and hemodynamically stable participated in the study. **Interventions:** Conventional coma stimulation was administered to control group and SSIMS to the experimental group participants. **Measurement and Main Results:** Baseline assessment was done using Coma Recovery Scale Revised (CRS-R) and Sensory Stimulation Assessment Measure by a blinded outcome assessor. Reassessment was done on 7th day and 14th day post initiation of treatment in both groups. Patients in the experimental group showed better improvement on 7th day ($P = 0.04$) and on 14th day ($P = 0.009$) of intervention on arousal measured by CRS-R scores. **Conclusion:** SSIMS is a safe and feasible protocol to improve arousal in comatose patients post TBI, which could be a better choice for coma stimulation in routine clinical setups.

Keywords: Coma stimulation, Minimal conscious state, Multimodal stimulation, Arousal, Rehabilitation, Sensory stimulation

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Introduction

Traumatic brain injury (TBI) is a leading cause of morbidity, mortality, disability, and socioeconomic losses worldwide. According to National institute of mental health and Neurosciences in India nearly 200,000 people die of head injury every year out of which 1 million require rehab services. Prolonged coma and vegetative state follow severe TBI in about one of eight patients. These patients usually pass through various phases of recovery which can stop at any stage. Environmental (i.e., sensory) deprivation can slow down the recovery and development of central nervous function, further depressing the threshold of activation of the reticular activating system.[1] Thus, optimizing the recovery from coma is a priority to improve patient's functional outcomes.

Interventions used so far to improve arousal in TBI patients have controversial results. Some of the existing coma stimulation techniques uses individual stimulus instead of multiple stimuli with less emphasis on personal salience while others suggest a multimodal stimulation program. It is hypothesized that multimodal sensory stimulation technique which involves the stimulation of many different sensory modalities (e.g., visual, auditory, and tactile) reduces coma duration by avoiding sensory deprivation.[2] However, this multimodal sensory program though said to be multimodal, provides individual stimuli instead of combined stimuli.[3] Sensory stimuli combined together in a task provides meaningfulness to the stimuli. Such meaningful tasks could have better personal salience and promote recovery.[3] Hence, a structured meaningful stimulation protocol delivered through multiple sensory channels in an integrated way can pay way for better outcome. However; no such established protocols are available till date. Hence, we decided to develop a subject specific integrated multisensory stimulation program (SSIMS) program operationally defined as "*A structured stimulation program comprising the activities of daily living delivered through multiple sensory channels in an integrated manner by incorporating personal, professional and recreational functional task to target arousal from impaired consciousness*." This protocol before applying in clinical trials, need to be pilot tested for its feasibility and influence on arousal.

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Methods

Design

Parallel group pilot randomized controlled trial.

Participants

Patients who sustained TBI and admitted in a tertiary care hospital between February 2021 and June 2021 were screened for the study. Patients in the age range of 18–65 years, either gender, with Glasgow coma scale scores ≤8 and hemo-dynamically stable after 48 h of medical or surgical intervention were included in the study. Patients with the previous history of brain damage**,** known case of impaired vision and hearing, autonomic dysfunction, active cerebrospinal fluid leak, unstable long bone fracture, and associated injuries were excluded from the study.

Procedure

Study approval was obtained from Institutional Ethics Committee RKU/SPT/2020/07/04 and protocol was registered under Clinical Trial Registry of India CTRI/2021/02/031440 before commencement of study. Participants were selected based on the screening criteria and informed consent to participate in the study was taken from the legally accepted representative as the participant was comatose. Provision for re-consent was made once the participant was cognitively capable. Participants were assessed by Coma Recovery Scale Revised (CRS-R) and Sensory Stimulation Assessment Measure (SSAM) by a blinded outcome assessor. Allocation concealment was done using sequentially numbered, opaque sealed envelopes. Randomization of patients to control and experimental group was done using five blocks with four envelops each. Control group was administered with the conventional coma arousal technique according to coma stimulation guidelines. It included sensory stimulation with single stimulus or a combination of them viz. music for auditory stimulation, photos for visual stimulation, touch for tactile stimulation, non-noxious smell as olfactory stimulation, and food for gustatory stimulation. Duration of each stimulus was 5–15 min depending on participant's response in 45 min of total program duration of 2 weeks.

Experimental group was administered with the newly developed SSIMS program. A detailed history about likes and dislikes of the patients, the phase and time of the day when the task was performed was taken from the family member. Based on the likings and history personal, professional and recreational tasks were created. The task included visual, auditory, tactile, proprioceptive, gustatory and vestibular stimuli implemented in a functional position. The entire functional program was delivered multiple times in a single session. Duration of treatment was 45 min thrice a day for 2 weeks.

CRS-R and SSAM were administered for all participants on 7th and 14th days after starting the treatment.

Analysis

SPSS version 21 was used for data analysis. Descriptive statistics was used to describe demographic variables of participants. Friedman's ANOVA and Kruskal-Wallis H Test were used to compare CRS-R and SSAM scores within and between groups, respectively. Level of significance was fixed at $P < 0.05$ for analysis.

Results

Flow of participants is shown in Figure 1.

There was no difference between participants in control and experimental group on baseline characteristics [Table 1].

There was no statistical difference found between baseline scores of CRS-R and SSAM scores of both group participants. On 7th day of intervention, control group showed improvement by a median score of 2.5 (2.5, 5.5) from baseline on CRS-R scores and 2.5 (2, 2.25) on SSAM scores. Difference in scores of experimental group on 7th day from baseline scores on CRS-R was 7 (6, 10.25) and on SSAM was 10.5 (6, 25). On 14th day 6/10 participants were analyzed in control group and 8/10 in experimental group. Difference in the median CRS-R scores on 14th day for control group was 1 (0, 0.25) and experimental group was 5 (2.5, 7.25) while SSAM scores showed improvements by −0.5 (−0.25, −2.25) for control and 10.54 (3.5, 33.25) for experimental group. The results are shown in Figure 2.

Discussion

The purpose of the study was to test the effect of SSIMS program on patients with coma following TBI. Results showed both the groups improved from baseline, which could be attributed to the multimodal stimuli delivered to both the groups as well as to spontaneous recovery, which is common immediately following TBI.[4] SSIMS showed better recovery than conventional coma stimulation which could be attributed to the nature of SSIMS program that is task based, multimodal in nature and delivered in functional position. This is supported by results from earlier study which showed significant improvement following meaningful auditory stimulation.[3,5]

Further analysis showed that improvement was significant between 7th and 14th days in the experimental group but not in the control group where the scores plateaued. This could be explained by more drop outs (4/10) and severity of condition in the control group participants. Four out of six participants had diffuse axonal injury (DAI) whereas experimental group participants had only two patients with DAI. Hence, DAI can be one of the factors leading to poor outcome in control group.[5]

In our study, the difference in CRS-R change of scores between two groups was 4 at 7th day and 9 on 14th day in favor of experimental group, compared to the previous study that had a CRS change score of 1.9 and 4.9, respectively, for the control group that used multimodal sensory stimulation program.[4] The increase in quantum of recovery in our study could be attributed to the characteristics of SSIMS program which was constructed on basis of what is respectful and compatible with persons past experiences. Moreover, the content of auditory stimulation was self-referential and provided by people with familiar voice with whom the patient had a preexisting emotional bond. Emotional experience given to the patients along with the tasks performed may influence high level representations as thoughts and actions which could have facilitated islands of preserved high-order cognitive functioning[1,6] Better improvements in the SSIMS group could also be justified by the reason that the stimuli in conventional coma stimulation technique provided a serial implementation of different unimodal stimulations. Whereas, SSIMS protocol had combination of various stimuli used in a functional task creating a favorable environment for the patients. Possible mechanism for the same could be functional reorganization and neuroplasticity.[2] This is in accordance with the previous studies which emphasizes to avoid sensory deprivation by creating an enriched environment.[2,6-8] Our results are even supported by a systematic review that implies the importance of early multisensory stimulation for coma arousal.[9] We noted hyperventilation, sweating, and reflex oral movements during administering the protocol which lasted for few minutes after termination of treatment. These variations were seen in both the groups and it returned to baseline after the cessation of stimulus.

This was an exploratory pilot randomized study so the sample size limits the generalizability, but it also demonstrates potential feasibility and benefits to patients with coma following TBI. Hence, a large sample RCT can be initiated which could help in establishing it as a routine treatment for patients in coma following TBI to improve arousal. Further research is required to determine the dosage and the impact of sensory stimulation

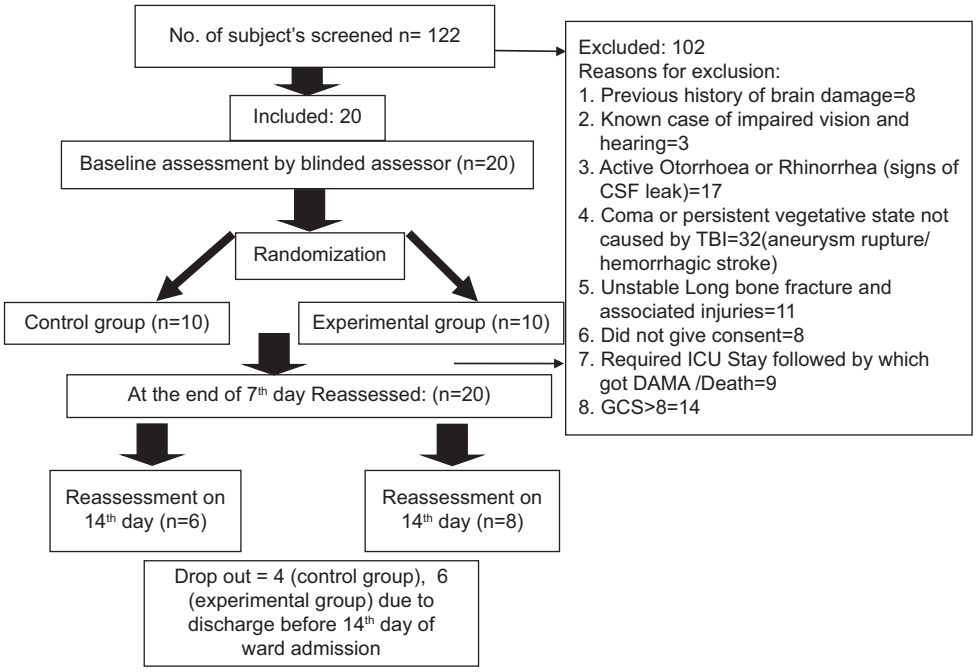

Figure 1: Consort flow diagram

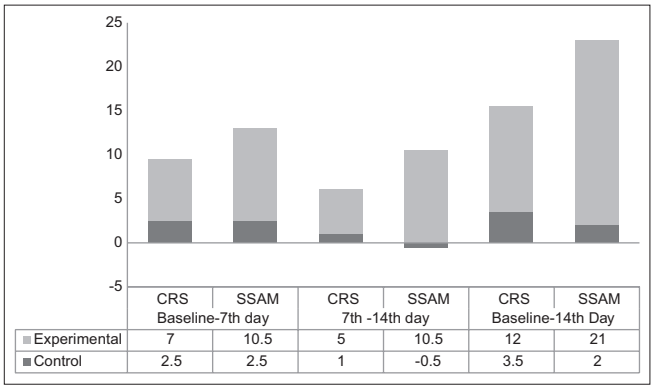

Figure 2: Comparison of CRS-R and SSAM scores between groups at baseline, 7th day and 14th day of intervention

Table 1: Baseline characteristics of participants

Characteristics	*Control (n=10)*	*Experimental (n=10)*
Age in years (Mean±SD)	41.10±14.571	42±13.952
Gender		
Male: female (ratio)	8:2	9:1
Type of injury (Frequency)		
DAI*	7	6
SAHŁ/ SDHŦ/ EDH§	3	4
Management (Frequency)		
Medical: Surgical	2:8	3:7
Days post-injury (Mean±SD)	9.40±3.921	11.90±13.952
Handedness		
Right: Left (ratio)	7:3	10:0
Caregiver: (Frequency)		
Spouse	3	6
Children	3	2
Siblings	2	0
Mother	2	2
Length of stay (Mean±SD)	11.30±3.335	11.90±3.035

* DAI: Diffuse axonal injury, Ł SAH: Sub Arachnoid hemorrhage, Ŧ SDH: Sub Dural hemorrhage, § EDH: Extra Dural hemorrhage

on long-term functional outcomes for patients in a coma or persistent vegetative state. It provides future direction towards testing its effect on arousal amongst patients with coma not caused due to TBI.

We conclude that the newly developed SSIMS program is safe and feasible for patients with coma following TBI. It may serve as a better choice to improve arousal in comatose patients post TBI and a large clinical trial is warranted to prove this hypothesis.

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