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Music Therapy for Comatose Brain Injured Patients

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Study Purpose/Aim

The aim of the proposed investigation is to determine whether alpha music therapy, initiated early in the recovery period, can improve cognitive function for severe traumatic brain injury patients when compared to historic controls. The investigators will compare cognitive function between groups at three time points: ICU discharge, hospital discharge, and three months after injury.

Study Procedures

Setting, Population, and Length of Study

Trauma patients with severe traumatic brain injury admitted to St. Elizabeth Youngstown Hospital Surgical Intensive Care Unit. Individual participation will last for 7 days (14 sessions) or until ICU discharge, whichever occurs first. The investigation is expected to last approximately 2 years (2026-2028) to accrue roughly 20 participants.

Inclusion Criteria

- blunt trauma
- CT confirmed intracranial hemorrhage
- Glasgow Coma Scale (GCS) 3–8 for 48+ hours postinjury
- mechanical ventilation
- age ≥18 years
- expected intensive care unit (ICU) stay ≥72 hours
- approach family on hospital day 3 for consent; start study on hospital day 3 or 4 if consent given

Exclusion Criteria

- GCS >8 when considering candidacy
- imminent extubation without tracheostomy
- pregnancy or recent birth
- hospice care
- penetrating trauma
- bilateral fixed pupils
- cancer, advanced liver disease, end-stage renal disease, autoimmune disorder, prior brain disorder
- non-survivable injury
- other reasons in the opinion of the investigator or attending trauma physician

Informed Consent

Eligible patients will not have the cognitive capacity to provide consent to participate. Therefore, the patient's legally authorized representative (LAR), as indicated in the medical record, will be approached to provide written informed consent and HIPAA authorization to participate. The LAR will be approached on hospital day 3 or 4 for consent, after initial resuscitation and treatment. If the patient regains the ability to consent prior to the end of AMT course, he/she will be asked for consent.

The investigators will allow approximately 3-4 days for the family to adequately understand the gravity of their loved one's condition prior to approaching for consent. Informed consent will only be obtained by the listed qualified investigators. The treating trauma/critical care physician on duty will be available to answer any medical questions.

Alpha-Music Therapy Sessions

Alpha-music therapy (AMT) is to be played via headphones for 30 minutes twice each day for 7 study days (14 sessions) unless discharged from the ICU earlier. The chosen AMT will be "Deep Alpha (440 Hz) vol. 1," by Steven Halpern. AMT can be described as soothing and mildly stimulating and without lyrics. Although the AMT track is approximately 75 minutes, the track will be played from the beginning for 30 minutes at each AMT session. The volume will be maintained at a comfortable level, approximately 60 decibels. Each participant will be supplied with soft, over the ear headphones. A new set of headphones will be issued to each participant and will not be reused... The television will be turned off and other music will not be playing during the AMT session. The patient room will be darkened and as quiet as possible.

Sessions will be coordinated with the bedside nurse to minimize interference with patient care. Patient monitoring before, during, and after AMT sessions include the following routine procedures: heart rate (HR), systolic blood pressure (BP), respiratory rate (RR), bilateral pupil size and reaction, Richmond Agitation-Sedate Scale score (RASS), GCS and when an intracranial pressure (ICP) monitor is in-place, ICP and cerebral perfusion pressure (CPP).

For patient safety, AMT is initiated only when the following are present, indicating patient stability: HR 55–110, BP >90 and ≤170, pupils are reactive, RASS ≤+2, RR ≤24, and if an ICP is in-place, a CPP ≥60.

BIS Monitoring

BIS values are documented on each study day. BIS values are documented immediately before and after the first and second sessions. Even though comatose patients may exhibit no physical bodily response to sensory stimulation, EEG tracings have been demonstrated to show a brain electrical response.

AMT session discontinuation

Reasons for discontinuing AMT sessions will be captured. To minimize patient harm, AMT will be discontinued before 30 minutes when HR >110, systolic BP >170, a pupil diameter doubles, RASS >+2, RR >24, ICP >25, or CPP <60. AMT sessions may be discontinued by the bedside nurse, attending trauma/critical care physician, or investigator for other reasons if he/she feels it is causing patient distress. Participants/LAR have the right to stop participating at any time. The principal investigator can end the investigation early if deemed appropriate.

Other Data Collection

In addition to the data generated during AMT sessions, the following information will be collected from the pre-existing medical records: age, sex, Glasgow Coma Score (GCS) on admission, ICU length of stay, ventilator days, total hospital length of stay, comorbid conditions, hospital mortality, Injury Severity Score (ISS), Abbreviated Injury Score (AIS), extracranial ISS (EC-ISS), GCS at discharge, GCS at 3 months.

Study Training

Investigators will provide study education and training to attending trauma physicians, surgical residents, and bedside nurses in the surgical intensive care unit. The investigators will be available for oversight, monitoring, and clarifications.

Cost

The following items utilized for this study are not considered standard of care: 1) BIS sensors for BIS monitoring, 2) headphones, and 3) AMT soundtrack. Those items will be prospectively paid for by the principal investigator. Participants will not be charged for any items used for research purposes only. Participants will not be compensated for their participation.

AMT Session Data Form

Study ID #_____ Study Day #_____ AMT Session #_____

If receiving neuromuscular blocker: RR, GCS and RASS are marked with an "X"

	Before AMT		**End of AMT**	
Date and Time				
GCS				
BIS				
Heart rate				
Systolic BP				
Respiratory rate				
Right pupil size				
Right pupil reactive	Yes	No	Yes	No
Left pupil size				
Left pupil reactive	Yes	No	Yes	No
RASS				
ICP				
CPP				

Session Discontinued <30 minutes: yes / no

If yes, provide reason for early session discontinuation: _____

Statistical Analyses

The AMT patients will be matched to a historical cohort of 1,545 patients with ICH and blunt trauma (Bon Secours Mercy Health, IRB number 2025-TRAUMA-Dunham). Outcome comparisons between AMT and historical control non-AMT patients will be used to assess efficacy. The AMT cohort will have sequential GCS and BIS values to assess efficacy of each AMT session. HR, BP, RR, pupils, RASS, ICP, and CPP will be used to assess risk or safety of each AMT session. Matching the historical control group to the intervention group will minimize intergroup bias. All historical control patients will have had an admission-GCS 3–8, received mechanical ventilation, had blunt trauma and CT intracranial hemorrhage, and an ICU stay ≥7 days.

Each customized historical control patient will be matched to a single intervention patient according to age ± 5 years, admission GCS of 3–5 or 6–8, intracranial hemorrhage Abbreviated Injury Scale score of 2–3 or 4–5, and an extracranial-Injury Severity Score of <6 or ≥6.

Historical control patients will be compared to intervention patients according to ventilator days, ICU days, and hospital days and using a t-test or a non-paired Wilcoxon test depending on the distribution. Historical control patients will be compared to intervention patients according to hospital mortality, no hospital discharge commands, and no 3-month commands using a Fisher exact or Chi-square test depending on the 2X2 expected observation results.

A sequential GCS over a seven-day period will be determined for the historical control group. The first day for the historical group will be according to the hospital day for study day-1 in the matching intervention group. A mean pre-session GCS will be computed for each of the seven days in the intervention group. The GCS values for the intervention and control groups for each day will be assessed using a non-paired Wilcoxon test. A GCS comparison of the intervention and control groups considering all values for the seven days will be performed using a non-parametric analysis of variance test (Kruskal-Wallis).

BIS values for the intervention group will be assessed comparing all pre-session and post-session values using a paired Wilcoxon test. A mean pre-session and post-session BIS value will be computed for each of the three BIS days in the intervention group. A comparison of the mean pre-session BIS values will be assessed over the three days using a non-parametric analysis of variance test (Kruskal-Wallis) to determine whether BIS values are increasing over time. A comparison of the mean post-session BIS values will be assessed over the three days using a non-parametric analysis of variance test (Kruskal-Wallis) to determine whether BIS values are increasing over time.

Confidentiality

Patient anonymity will be maintained in all presentations and publications. Each participant will be assigned a study ID number. The identity will be known by the investigators only. The study data will be maintained in a secure excel file, only accessible by the investigators. All paper documentation will be stored in a locked cabinet in a badge-controlled office. Protected Health Information (PHI) will not be reused or disclosed except as required by law, for authorized oversight of the research. The data will be maintained for the length required by institutional policy and destroyed at the earliest opportunity after publication.