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STUDY PROTOCOL

Psychomotor Rehabilitation for Pediatric Delirium: A Study Protocol for a Randomized Controlled Trial Investigating Efficacy and Brain Electrophysiological Mechanisms

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Purpose: Pediatric delirium is a serious complication in critically ill children with limited effective treatments. This study aims to evaluate the efficacy and safety of Psychomotor Therapy (PMT)—a comprehensive rehabilitation system integrating motor, cognitive, emotional, and psychological domains—in treating pediatric delirium, and to characterize its underlying mechanisms through electroencephalographic (EEG) and brain network analyses.

Patients and Methods: This is a single-center, assessor-blinded, randomized controlled trial. A total of 34 participants (22 children with delirium aged 2 months to 14 years, meeting Richmond Agitation-Sedation Scale [RASS] and Cornell Assessment of Pediatric Delirium [CAPD] criteria, plus 6 children without any neurological disorders, managed within the same clinical environment) will be enrolled. Participants will be randomized to receive either PMT plus routine care or routine care alone. The PMT intervention will be administered once daily for 3 days. Primary outcome is the change in CAPD score. Secondary outcomes include delirium duration, EEG parameters, length of PICU stay, and safety. Assessments will be conducted at multiple time points before and after intervention.

Results: This is a study protocol; as data collection is currently ongoing (January 2023–July 2026), final results are not yet available for analysis or reporting.

Conclusion: The study has been approved by the ethics boards of Shanghai Yangzhi Rehabilitation Hospital and Shanghai Children's Hospital and will adhere to the Declaration of Helsinki. Findings will be disseminated via scientific conferences and publications. Key strengths include the first investigation of brain functional networks in pediatric delirium, incorporation of an environmental control group to mitigate confounding, and pioneering application of PMT. Limitations include single-center design and geographical restriction to Shanghai, necessitating future multi-center studies with larger samples.

Keywords: randomized controlled trial, PICU, electroencephalography, brain networks, neurophysiological mechanisms, non-pharmacological intervention

Introduction

Delirium, a clinical syndrome of acute neurological dysfunction characterized by inattention, altered levels of consciousness, and fluctuating cognitive changes, represents a common and serious complication in critically ill children. Compared to adults, pediatric patients demonstrate heightened susceptibility, with delirium predominantly manifesting in those who are critically

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ill. Epidemiological studies report a varying incidence of delirium in pediatric intensive care units (PICU) ranging from 4.5% to 44%,[1,2] with notably higher rates—between 30% and 56%—observed in children under two years of age.[3]

The implications of pediatric delirium extend far beyond the acute phase. It is associated with an increased risk of adverse events, including unplanned extubation and falls,[4] and significantly impedes recovery from the primary illness. Delirium destabilizes the autonomic and endocrine systems, prolongs hospital stays, elevates healthcare costs, increases mortality, and can lead to long-term cognitive impairment, thereby profoundly affecting the quality of life of pediatric patients.[5–8] Consequently, the early identification and effective management of delirium are of paramount importance.

Current treatment strategies for pediatric delirium are predominantly informed by expert consensus, observational studies, and a limited number of clinical trials. While antipsychotic medications have been cited in retrospective literature as potentially alleviating symptoms in some cases, however, they are not approved for this indication in children and carry risks such as QTc interval prolongation and extrapyramidal symptoms. Other pharmacological agents, including dexmedetomidine, melatonin, and ondansetron, have been noted for potential efficacy;[7,9,10] however, evidence from studies does not support the use of medications for delirium prevention in high-risk settings,[11] and these drugs likewise lack approval for treating delirium in children. Crucially, robust evidence demonstrating that any pharmacological regimen can reduce the incidence or shorten the duration of delirium remains scarce. This therapeutic gap has intensified the focus on non-pharmacological interventions. Recent bundled management strategies underscore the critical roles of environmental optimization, early mobilization, pain management, sleep regulation, and compassionate care.[12,13]

Psychomotor Therapy (PMT) emerges as a promising non-pharmacological approach. It is a comprehensive rehabilitation system that integrates motor, cognitive, emotional, and psychological domains, treating the individual holistically. Through modalities such as body perception therapy, psychophysical training, music therapy, and relaxation techniques, PMT enhances body awareness, alleviates stress, and improves mental state.[14] Psychomotor Therapy (PMT) takes full advantage of children's natural tendency to explore the world and express themselves through physical activity and sensory experiences, enabling it to simultaneously address both the physical and psychological challenges that children may encounter during development. Given its strong theoretical alignment with the characteristics of child development, PMT has been widely applied in pediatric settings. The most common applications are found in autism spectrum disorder (ASD)[15] and developmental coordination disorder (DCD).[16] Furthermore, literature has also reported the use of PMT in childhood anxiety disorders,[17] highlighting its potential value in the treatment of pediatric mental disorders. Evidence suggests that PMT can enhance neural plasticity and functional connectivity in conditions like schizophrenia and mood disorders,[18,19] which share pathophysiological features with delirium, such as disruptions in brain network connectivity.

In patients with delirium, cerebral neurotransmitters exhibit a state of systemic imbalance, primarily characterized by cholinergic deficiency, dopaminergic hyperactivity, and glutamatergic hyperactivity. Electroencephalographic (EEG) measures are closely correlated with the cerebral levels of these neurotransmitters. As an explicit indicator of neuroelectrophysiological activity, EEG can reflect patients' cognitive function[20] and also serve as a tool for real-time monitoring of neurological status. Therefore, EEG assessment holds promise for investigating the onset and progression of delirium. Quantitative EEG (qEEG) allows for the identification of characteristic patterns in delirium. For instance, spectral analysis in adult populations has demonstrated that compared to non-delirious ICU patients (with EEG power spectra of approximately 55.6% for θ waves, 29.5% for α waves, 14.9% for β waves), delirious patients exhibit a marked increase in θ power (69.0%) alongside decreases in α (21.0%) and β (10.0%) power.[21,] Furthermore, studies in elderly patients with delirium have reported predominantly θ or δ wave backgrounds, often with moderate-to-severe abnormalities. Moreover, advanced analytical techniques can quantify brain network parameters, such as functional connectivity strength and integration. In adults, delirium is consistently associated with disruptions in these functional network, including lower EEG connectivity strength.[22,] Electrophysiological studies indicate that the functional connections between brain regions, which are present in normal consciousness, disappear during unconsciousness and reappear as consciousness is restored, highlighting the potential of network parameters as biomarkers. Investigating these parameters in children could provide deeper insights into the neurophysiological mechanisms underlying delirium.

Given the limitations of current pharmacotherapy and the potential of PMT to address core symptoms and neural mechanisms, and the opportunity to leverage objective EEG biomarkers, this study aims to: 1) characterize the qEEG and

brain network parameters in pediatric delirium; 2) validate the efficacy and safety of PMT in treating children with delirium; and 3) elucidate the impact of PMT on brain network connectivity in this population.

Methods and Analysis

Study Design

This is a 4-year, single-center, Chinese study. This study adopts a single-center, assessor-blinded, two-arm, randomized controlled trial design, incorporating an independent environmental control cohort, aiming to explore the effectiveness of PMT and the associated changes in electrophysiological and brain network parameters following treatment for delirium. It seeks to investigate the mechanisms of its onset and alleviation in depth. Accounting for an estimated dropout rate of 20%, a total of 34 pediatric patients were planned to be enrolled. Participants will be 22 individuals meeting criteria for Richmond Agitation-Sedation Scale (RASS) and The Cornell Assessment of Pediatric Delirium (CAPD) and 6 children without any neurological disorders, managed within the same clinical environment.

To control for the potential confounding effect of the PICU environment itself on study outcomes, an environmental control group was included in this study. Children in this group receive no study intervention and are only exposed to the routine PICU environment. The primary purposes of this group are: (1) to quantify the effect of the PICU environment on EEG metrics and delirium outcomes; and (2) to provide a reference benchmark for distinguishing specific PMT effects from non-specific environmental effects.

The participants aged between 2 months and 14 years. While broad, this age range was selected to ensure the feasibility of participant recruitment. The CAPD will be used as the primary outcome measure, while delirium subtypes, frequency and duration of episodes, qEEG parameters, length of pediatric patients in the intensive care unit (PICU) stay, and total hospital stay will be explored as secondary outcomes. In the experimental group, children will complete the evaluation of primary and secondary outcomes before and after each PMT treatment. The control group will be assessed upon enrollment and three days later, while the environmental control group will only undergo EEG collection. Both the experimental group and the negative control group may receive pharmacological treatment for delirium.

Participants and Recruitment

Participants

The use and discontinuation of sedative medications can easily trigger the onset of delirium, especially in pediatric patients receiving mechanical ventilation who require prolonged sedation, approximately 29% of these patients develop delirium.[3] The current study is recruiting children who have experienced delirium after mechanical ventilation. The target population for this study comprises children who have experienced delirium after mechanical ventilation at Shanghai Children's Hospital beginning 1 Jan 2023 and until the study enrolment goal of 34 assessed patients is reached. Patients or their legal guardian may choose to refuse participation in this study at any time point.

Eligibility Criteria

Inclusion Criteria

- Children aged 2 months to 14 years in the PICU
- Diagnosed with delirium using the RASS and the CAPD criteria
- Children after mechanical ventilation

Exclusion Criteria

- Hemodynamic instability: a) Vasoactive-Inotropic Score (VIS) >20 (within 1 hour before assessment); b) Receiving extracorporeal membrane oxygenation (ECMO) or undergoing continuous cardiopulmonary resuscitation; c) Presence of uncorrected hypovolemic shock.
- Neurological conditions: a) Severe developmental delay; b) Severe hearing or visual impairment; c) New-onset moderate-to-severe traumatic brain injury, intracranial hemorrhage, or ischemic stroke after PICU admission; d) Active central nervous system infection; e) Status epilepticus occurring within 24 hours before enrollment; f) Neurodevelopmental disorders such as neurodegenerative diseases or autism spectrum disorder.

- Contraindications to movement
- Participation in other trials

The inclusion criteria for the environmental control group are identical to those for the intervention and control groups, with the additional requirement that participants do not engage in any study-related intervention activities during the data collection period.

Recruitment Process

Recruitment for this study is currently underway. Recruitment will continue until May 2026. PICU nurses or physicians will screen potential patients for eligibility and engage with the children's guardians in person. The informed consent form will be signed by the guardian.

Study Procedure

Children meeting the inclusion and exclusion criteria will be screened by trained PICU nurses and doctors. Eligible participants will be randomly assigned to either the intervention group or the control group.

The intervention group will receive PMT in addition to routine care, once daily for three days, according to the following schedule:

Initial assessment within 24 hours (T0);

First PMT treatment and assessment within 48 hours (T1);

Second PMT treatment and assessment within 72 hours (T2);

Final PMT treatment and assessment within 96 hours (T3);

The PMT intervention in this study is set for 3 consecutive days. This duration was chosen based on the following considerations: (1) Clinical feasibility: In the target PICU, children are typically transferred to the general ward within 3–4 days after extubation; thus, 3 days represents the maximum feasible intervention window in this setting. (2) Literature support: A previous study on childhood ADHD suggests that short-term interventions may capture neurophysiological changes.[23] (3) Acute nature of delirium: Delirium-related neurophysiological alterations typically occur within hours to days, making a 3-day intervention period appropriate for capturing such changes.

The control group will receive routine care only, with assessments at enrollment and at 96 hours. The environmental control group will undergo only EEG data collection.

Intervention

The intervention will be administered by a psychomotor rehabilitation therapist who is not involved in the randomization process or patient assessment. In intervention group, the intervention strategies are categorized into four distinct treatment protocols based on the patient's age, interactive responses, and delirium subtype. Each protocol maintains a consistent duration of 40 minutes, with the primary variation lying in the sequential arrangement of therapeutic components (Table 1). Patients in the control group will receive standard PICU treatment and nursing care for their underlying medical condition, without receiving rehabilitation therapy.

Assessments

Delirium Assessment

The primary tool for delirium assessment is the Cornell Assessment of Pediatric Delirium (CAPD). Developed based on the Pediatric Anesthesia Emergence Delirium scale (PAED), the CAPD evaluates delirium through observation of behavioral states and is suitable for children of all ages and developmental stages, demonstrating an ability to detect subtle signs of hypoactive delirium.[24,] It is recommended by the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) for assessing critically ill infants and children (Grade A recommendation).[25,] The Chinese version, translated by the Children's Hospital of Chongqing Medical University, has shown good reliability and validity.[26,] This scale enables rapid, real-time delirium screening in the PICU, with high compliance among bedside nurses and caregivers, making it relatively easy to promote in clinical settings.

Table 1 Intervention Strategies for Psychomotor Therapy (PMT) Based on Delirium Subtype and Patient Responsiveness. Hyperactive Delirium: <3 years or Unable to Respond → Method 1; ≥3 years and Able to Respond → Method 2. Hypoactive Delirium: <3 years or Unable to Respond → Method 3; ≥3 years and Able to Respond → Method 4

	Age<3 Years or Lack of Interactive Responses	**Age≥3 Years and with Interactive Responses**
Hyperactive Delirium	**Intervention Method 1**	**Intervention Method 2**
	• Establishing Therapeutic Rapport (2–5min) • Therapeutic Positioning (2min) • Sensory Relaxation Techniques (15min) • Movement-Based Relaxation Techniques (15min) • Positioning and Postural Organization (5min)	• Establishing Therapeutic Rapport (2–5min) • Therapeutic Positioning (2min) • Expressive Movement Activities • (15min) • Sensory Relaxation Techniques (15min) • Positioning and Postural Organization (5min)
Hypoactive Delirium	**Intervention Method 3**	**Intervention Method 4**
	• Establishing Therapeutic Rapport (2–5min) • Therapeutic Positioning (2min) • Movement-Based Relaxation Techniques (15min) • Sensory Relaxation Techniques (15min) • Positioning and Postural Organization (5min)	• Establishing Therapeutic Rapport (2–5min) • Therapeutic Positioning (2min) • Movement-Based Relaxation Techniques (15min) • Expressive Movement Activities • (15min) • Positioning and Postural Organization (5min)

Prior to CAPD assessment, the patient's level of consciousness must be evaluated using the RASS. Children with a RASS score ≥ -3 should proceed to CAPD evaluation.[21] The CAPD consists of 8 items, each rated from 0 to 4. A total score of 7–9 suggests potential delirium requiring re-assessment, while a score of ≥10 confirms delirium. For children under 2 years of age, a revised version [CAPD(R)] is used to account for developmental characteristics.[27,] Additional observational indicators include delirium subtypes, duration, and frequency of episodes, which help characterize the fluctuating nature of the condition.

Pain Assessment

Given that pain is a key triggers for delirium, especially in the PICU, effective pain assessment is integral to delirium management. The choice of tool is age-dependent:

- For children aged 2 months to 3 years, the Faces, Legs, Activity, Cry, Consolability (FLACC) Scale is used. It assesses pain through behavioral observation across five components, with a total score ranging from 0 to 10.
- For children older than 3 years, the Wong-Baker FACES Pain Rating Scale (WBS) is employed. This tool uses facial expression illustrations to help children self-report pain levels.

Healthcare Cost Indicators

- To evaluate economic outcomes, the following indicators are recorded:
- Duration of mechanical ventilation (MVD).
- Length of stay in the PICU (PICU LOS).
- Total hospital length of stay (HLOS).

EEG Acquisition

EEG data are acquired at the bedside using NicVue Connect HL7 Software (v.3.0, Natus Neurology, USA) and a Nicolet v32 Amplifier. A 32-channel electrode cap positioned according to the 10–10 system is used for an 80-minute recording session at a sampling rate of 500 Hz. To ensure signal quality, electrode-scalp impedance is maintained below 10 kΩ. Data for quantitative EEG (qEEG) analysis are simultaneously collected. Patients are monitored for 20 minutes before and PMT, during the 40-minute PMT session, and for 20 minutes after PMT.

Outcomes

Data collection and study timings are presented (Table 2). Participants are assessed prior to PMT (T0, T2, T4), and immediately after PMT (T1, T3, T5). The environmental control subjects just collect qEEG after written informed consent. All these data will be collected by Critical care physicians who will not participate in treatment and do not know the randomized allocation.

Table 2 Participant Timeline: Schedule of Enrollment, Interventions, and Assessments

	TRIAL PERIOD					
	Enrollment		**Post-Randomization**			**Close-Out**
TIMEPOINT	***−24h~0***	**0**	***24h***	***48h***	***72h***	***Discharge***
ENROLLMENT:						
Eligibility screen	X	X				
Informed consent	X					
Randomization		X				
Demographics		X				
Medical history		X				
Withdrawal criteria			X	X	X	
INTERVENTION/COMPARATOR:						
PMT			X	X	X	
Conventional Therapy			X	X	X	
ASSESSMENTS:						
RASS	X		X	X	X	
CAPD	X		X	X	X	
Duration of Delirium			X			X
Frequency of delirium			X			X
Subtype of delirium			X	X	X	
FLACC/WBS			X	X	X	
qEEG			X	X	X	
MVD		X				X
PICU LOS		X				X
HLOS		X				X
Adverse Event			X	X	X	

Notes: X indicates items to be completed at that time point.

Abbreviations: CAPD, Cornell Assessment of Pediatric Delirium; FLACC/WBS, two pain assessment scales. Face, Legs, Activity, Cry, Consolability Scale, FLACC: 2 months to 7 years; Wong-Baker FACES Pain Rating Scale, WBS: 3 to 18 years. FLACC was also used as an alternative for children over 7 years unable to self-report. HLOS, hospital length of stay; MVD, mechanical ventilation duration; PICU LOS, pediatric intensive care unit length of stay; PMT, psychomotor therapy; qEEG, quantitative electroencephalography; RASS, Richmond Agitation-Sedation Scale.

Primary Outcome Measures

The primary outcome of current study is Cornell Assessment of Pediatric Delirium (CAPD). CAPD will be collected prior to PMT (T0, T2, T4), and immediately after PMT (T1, T3, T5) in both experimental group and control group. Critical care physicians will take these data. While it will not be collected in environmental control group.

Secondary Outcome Measures

Secondary outcomes encompass a range of clinical therapeutic effect evaluation, cerebral electrophysiological parameters, as well as safety and economic evaluation.

Clinical therapeutic effect evaluation include: The Richmond Agitation Sedation Scale (RASS), Duration of delirium, Frequency of delirium, Subtype of delirium and FLACC/WBS. FLACC is assessed for age from 2 months to 3 years old. WBS is assessed for children more than 3 years old.

Cerebral electrophysiological parameters include: electroencephalographic background, Amplitude-integrated EEG (aEEG), relative band power, relative α variability and spectral entropy.

Healthcare cost indicators include: Duration of mechanical ventilation (MVD), Length of stay in PICU (PICU LOS) and Length of stay in hospital (HLOS). These outcomes will be collected after patients discharge.

Sample Size

Based on the results of the preliminary experiment, psychomotor therapy can improve delirium with a CAPD score of 2.6, SD of 1, a Type I error of 5%, a statistical power of 80%, and a significance level of 0.05. The clinical superiority threshold is set at 1. Using the sample size calculation formula, a total sample size of 22 participants is required, with 11 in both the experimental and control groups, and 6 in the blank control group. Assuming a dropout rate of 20% for participants due to various reasons during treatment, approximately 34 participants will meet the statistical analysis requirements. Therefore, this study plans to recruit 34 participants to achieve the expected results.

Randomisation

The random allocation sequence was generated by an independent statistical analyst who was not involved in participant recruitment or assessment, using the SAS software (PROC PLAN procedure). Block randomization was employed with a block size of 4 to allocate participants in a 1:1 ratio between the experimental and control groups. This sequence was uploaded into a central randomization system by study nurses. A web-based central randomization system will be used to assign participants to groups in real time, ensuring allocation concealment. After an eligible child completed the enrollment procedures, the study nurse obtained the irrevocable group assignment via this system. A blinded researcher will confirm the group assignment in the system and notify the therapist only when the participant is allocated to the intervention group.

Blinding

This study employs an assessor-blinded design. The children with delirium assigned to the experimental group will be treated with PMT by therapist. So the therapist will therefore not be blinded, but this individual will not conduct any of the assessment or be involved in the statistical analyses. The children were in a state of impaired consciousness, precluding the possibility of blinding them. This is a assessor-blinded study, accordingly, the testing researchers and statisticians will be blinded to intervention condition. To ensure objective outcome assessment, a robust blinded assessment chain was implemented: all primary efficacy measures were video-recorded following a standardized protocol. Subsequently, these blinded video records were independently rated by at least two assessors who were entirely unaware of group allocation. Assessments results will be reviewed and entered into the study database by a second researcher to ensure accuracy in the delirium assessment. Data processing and statistical analysis were also performed under blinded conditions until the completion of the primary analysis. Unblinding may occur in the event of an adverse event.

At the conclusion of the final assessment (T5), participants will be unblinded as to their intervention condition by a member of the research team who is not blinded. Those who were allocated to the control group intervention will be offered the opportunity to undergo the PMT intervention if they remain in a state of delirium. While this will occur after all assessments have been administered, scored and entered into database.

Data Processing and Analysis

Processing of Delirium Outcome

Enrolled patients will be assessed using the RASS score and CAPD/CAPD (R) score before and after each intervention. CAPD evaluates delirium by assessing the child's behavioral state and is applicable to children of all ages and developmental stages. It is also capable of detecting subtle manifestations of hypoactive delirium.[24] Prior to assessment and diagnosis, the RASS score must be used to evaluate the patient's level of consciousness and determine the degree of sedation. Children with a score≥-3 will proceed to CAPD evaluation.[25] The CAPD consists of eight observation items, each scored from 0 to 4. A total score of 7–9 indicates potential delirium requiring re-evaluation, while a score ≥10 confirms the presence of delirium. To detect cognitive changes during delirium diagnosis, the revised CAPD scale [CAPD(R)] is used for children under 2 years of age. This revised version assesses the ability to express needs and desires based on developmental characteristics and the specific PICU environment.

The delirium subtype will also be documented based on RASS scores: a RASS score ranging from −3 to 0 indicates hypoactive delirium; a score between +1 and +4 indicates hyperactive delirium; and fluctuating RASS scores across positive and negative values indicate mixed-type delirium. The severity of delirium will be quantified using CAPD/CAPD (R), with higher CAPD scores (above 10) reflecting greater delirium severity. Additionally, the daily frequency of delirium episodes and the total duration of delirium will be recorded for each patient.

Interpretation of Quantitative Electroencephalography (qEEG)

The main observations of EEG were: a) aEEG background; b) upper boundary and lower boundary: the voltage value representing the highest and lowest amplitude, respectively, in the segment; c) Bandwidth: that is, the width between the upper and lower boundaries, representing the range of amplitude variation; d) Change trend, that is, the change process or specific patterns of aEEG parameters over time, which often represent specific brain functional states and can be used as diagnostic indicators of aEEG; e) Relative Band Power, RBP, refers to the proportion of the power in a specific frequency band; f) Relative α variability, RAV, refers to the fluctuation in the power of alpha brain waves relative to the total variability across all frequency bands.

The abnormal degree of aEEG background was determined as follows: 1. normal aEEG: continuous normal voltage and normal amplitude (boundary voltage value >10 μV, lower boundary voltage value >5 μV). 2. Mild abnormal aEEG: mild abnormal amplitude (boundary voltage >10 μV, lower boundary voltage <5 μV; Or upper boundary voltage value <10 μV, lower boundary voltage value >5 μV); Or normal amplitude but with epileptiform electrical activity. 3. Severe abnormal aEEG: severe abnormal amplitude (boundary voltage <10 μV, lower boundary voltage <5 μV), regardless of whether accompanied by epileptiform electrical activity, or mild abnormal amplitude but accompanied by epileptiform electrical activity.

In RBP, the proportion of α, β, θ and δ waves in different brain waves before and after treatment and during treatment were observed. The fluctuation of RAV was observed before, during and after treatment, and the grading of RAV was observed as follows: GradeI (4 points): the value exceeded the baseline every hour, or exceeded the baseline by more than 15%, indicating that the cerebral blood flow/cerebral oxygen metabolism was very good; GradeII (3 points): the values exceeded the baseline by 10% every 4 hours, indicating good cerebral blood flow/cerebral oxygen metabolism; 5 Grade III (2 points): rarely exceeded the baseline or exceeded the baseline by less than 10%, indicating normal cerebral blood flow/cerebral oxygen metabolism; Grade IV (1 point): less than 2% above baseline, indicating poor CBF/cerebral oxygen metabolism.

EEG Preprocessing

All electroencephalographic data underwent preprocessing using the EEGLAB toolbox within the MATLAB v2022b environment. The initial step involved format conversion and electrode spatial localization: raw data were uniformly converted to set format, and channel positions were registered according to the International 10–20 System coordinate template to ensure spatial accuracy for subsequent analyses. Subsequently, unused electrodes were removed, and band-pass filtering (0.5–25 Hz) was applied to eliminate high-frequency noise and low-frequency drift, followed by a notch filter (48–52 Hz) to suppress line-frequency interference. Data were down-sampled to 500 Hz to balance temporal resolution and computational load. Continuous data were segmented into standardized 2-s epochs (1000 samples per epoch) using a non-overlapping sliding-window approach. Bad channels were interpolated via spherical spline interpolation, and epochs containing prominent artifacts were manually identified and excluded. Subsequently, Independent Component Analysis (ICA) was performed, and components associated with ocular, cardiac, or muscular artifacts were visually identified and removed. Further artifact rejection was conducted through amplitude-based thresholding (±100 μV), automatically flagging and removing epochs with excessive amplitude excursions. Data were then re-referenced to the average of all scalp channels. Finally, a visual quality-control inspection was performed on the preprocessed datasets to ensure suitability for subsequent analytical procedures.

Analytical Approach

Key electrodes underwent Fourier transformation to compute the Power Spectral Density (PSD) across frequency bands (δ, θ, α, β), serving as indicators of EEG activity. For each 2-second segment, a Fast Fourier Transform (FFT) was performed, and the average PSD was calculated across epochs, ultimately yielding the spectral characteristics for each electrode.

Relative power was derived by calculating both absolute power and total power for each frequency band. The average PSD across all segments for the same electrode of each subject was computed, followed by integration to obtain absolute power values. The ratio of absolute power to total power was then calculated to determine relative power, reflecting the distribution of energy across different frequency bands.

To mitigate the effects of volume conduction, current source density transformations were applied to the EEG data prior to calculating functional connectivity metrics. The Phase Lag Index (PLI) and directed Phase Lag Index (dPLI) were employed to construct a brain functional connectivity network, elucidating connection strength and directionality. The PLI quantifies the asymmetry of instantaneous-phase differences between signals, while the dPLI addresses the lead-lag relationship between signals, thereby providing a comprehensive functional connectivity analysis.

Statistical Analyses

The primary endpoint (CAPD score) will be compared between groups using analysis of covariance (ANCOVA) adjusting for the baseline score. Delirium duration will be compared using *t*-test or Mann–Whitney *U*-test based on distribution; delirium frequency will be analyzed using negative binomial regression, reporting the incidence rate ratio (IRR). EEG features will be extracted and analyzed using baseline-adjusted ANCOVA.

To investigate delirium-related brain network features, all children with delirium at baseline will be compared with the environmental control group using two-sample *t*-tests, with False Discovery Rate (FDR) correction for multiple comparisons. Repeated measures ANOVA will be performed on EEG indices within the experimental group, followed by Bonferroni post-hoc tests if a significant time effect is found.

Within each developmental subgroup, descriptive statistics (means, standard deviations, frequencies, percentages) and effect sizes for primary and secondary outcomes will be calculated for both the PMT and control groups.

The primary outcome will be tested confirmatorily at $\alpha=0.05$. All secondary and exploratory findings are considered hypothesis-generating; p-values and effect sizes (with 95% CIs) will be fully reported. Given the exploratory nature and sample size, interpretation will emphasize the direction of effects as suggested by the point estimates.

Patient and Public Involvement

As a prospective randomized controlled trial, this study engaged patient representatives solely during the recruitment phase through the informed consent process. Patient perspectives did not inform the trial design or burden assessment. The principal investigator maintained structured communication with participants' families regarding trial progress.

Discussion

Delirium significantly impairs the prognosis of underlying diseases in pediatric patients, disrupts their growth and development processes, and imposes substantial healthcare costs. Non-pharmacological interventions for delirium are receiving increasing emphasis, with recent bundled management strategies highlighting the critical roles of environmental optimization, early mobilization, pain management, sleep regulation, and humanistic care in delirium management.[12,13] PMT is a comprehensive rehabilitation system that integrates motor, cognitive, emotional, and psychological dimensions. This study protocol describes a randomized controlled trial focusing on non-pharmacological interventions for pediatric delirium, while the adoption of tailored PMT strategies for distinct delirium subtypes represents an important early-stage exploration in the field of delirium rehabilitation therapy.

For a long time, the objective assessment and diagnosis of delirium has remained a clinical challenge, with pediatric delirium posing even greater difficulties. Current evaluations primarily rely on clinical rating scales, the results of which are susceptible to the assessor's experience and training level. Timely and accurate neurofunctional assessment is crucial for evaluating brain function status and the extent of cerebral injury in critically ill children. Continuous bedside neuromonitoring technology serves as an important tool for monitoring neurological function and determining disease prognosis.[28,] At present, there is limited research on electroencephalography and brain networks in pediatric delirium. This study aims to investigate quantitative electroencephalography and brain network characteristic parameters in delirium, further elucidate the neuroelectrophysiological mechanisms underlying pediatric delirium, and simultaneously observe the therapeutic efficacy of PMT in children with delirium and its impact on brain networks. Secondary outcome and EEG network findings should be interpreted as exploratory and hypothesis-generating, requiring replication in larger samples. Given the broad age range (2 months to 14 years), we plan to conduct descriptive age-stratified analyses, infancy (2 months to <2 years), preschool age (2 to <6 years), and school age/adolescence (6 to 14 years). Due to the small sample size within each subgroup, formal hypothesis testing is not feasible; thus, these analyses are exploratory and descriptive, intended to provide effect size estimates for future research.

The trends of change in primary and secondary outcomes across the three groups (PMT, usual care, and environmental control) will be interpreted with reference to EEG changes in the environmental control group, helping to assess the specificity of the intervention effect. If the environmental control group shows noticeable EEG changes, this will be addressed in the Discussion. It should be noted that the sample size of the environmental control group is small (n = 6); therefore, the relevant analyses are exploratory and descriptive in nature, intended to inform future research rather than to draw definitive conclusions.

Strengths and Limitations

- This study represents the first investigation of brain functional networks in pediatric delirium. Our findings will provide a novel method of observation to advance diagnostic precision for delirium in children.
- This study pioneers the application of psychomotor rehabilitation in the treatment of pediatric delirium, which may reduce the use of sedative and analgesic medications.
- This study incorporated an independent environmental control group to distinguish between the confounding effects of the PICU setting and the specific neurophysiological impact of delirium on EEG patterns and functional brain networks.
- This study is limited geographically to Shanghai, China, and is limited by single-center study. Studies with larger sample sizes conducted across multiple centers are needed.

Conclusion

The non-pharmacological intervention (PMT) may help reduce the use of sedative and analgesic medications, shorten delirium duration, and promote patient recovery. This exploratory attempt holds promise for providing initial reference for refining and advancing the bundled management approach in the PICU, and for offering an exploratory practical example for understanding and implementing integrated care strategies. Furthermore, PMT may serve as an operational platform to strengthen interdisciplinary collaboration between rehabilitation and critical care teams, thereby fostering the development of pediatric critical care rehabilitation.

As an exploratory pilot study, the preliminary findings suggest that PMT may have potential effects on the neurophysiological status of children with delirium in the PICU, but these findings require validation in larger samples. More importantly, this study represents the first attempt to apply EEG network analysis in pediatric delirium research, providing a methodological reference for investigating the neural mechanisms of non-pharmacological interventions and offering effect size estimates for future EEG-based studies.

Data Management

All identifying information is kept on a secure database accessible only by authorized researchers through a username and password login. Information collected at recruitment is taken to secure storage in the laboratory immediately after. The data that support the findings of this study are available on request from the corresponding author, Lijuan Ao, upon reasonable request.

Dissemination Plans

Results from this study will be disseminated through presentations at scientific conferences, publications in peer-reviewed journals, and communications to the public via mass media.

Honoraria

Participants in this study will not receive gifts or compensation. Participation in this research project will not require any additional expenses from you; the treatment costs, examination fees, and other expenses incurred by this study will be covered by the research funding.

Setting

This study is ongoing and conducted in Shanghai Children's Hospital. Recruitment and delirium assessments are conducted at PICU. We collect data at the bedside.

Risks

This study presents minimal risk to participants. Intervention tools such as feathers, blankets, tactile balls used in psychomotor therapy, as well as the conductive gel applied for EEG acquisition, may potentially cause allergic reactions. A preliminary patch test should be conducted on the child's earlobe prior to use. Intervention must be discontinued immediately if any skin allergic reactions occur, with topical medication applied if necessary.

Ethical and Dissemination

The study protocol, including all procedures and informed consent documents, has been approved by the Ethics Committee of Shanghai Children's Hospital (2023R019-F02). The trial will be conducted in accordance with the principles of the Declaration of Helsinki. All participants' legal guardians will provide written informed consent prior to enrollment.

Any protocol modifications that may impact study conduct, participant safety, or data integrity will require a formal amendment, to the protocol. Protocol amendments which must be jointly decided by the principal investigator and approved by the Ethics committee and relevant regulatory authorities before implementation. All approved amendments will be updated in the trial registry (ChiCTR2400091968) within 30 days.

In the event of a research-related injury, necessary medical care will be provided immediately at no cost to the participant. All related expenses, medical compensation, and appropriate financial support will be covered by the study team will maintain transparent communication and report any such events to the Ethics Committee promptly.

Given the exploratory nature, small sample size, short duration, and minimal risk of this study, no independent Data Monitoring Committee (DMC) will be established, and no interim analysis is planned. Internal quality control will be managed by the study team.

Ethical Considerations for Participants

As the enrolled pediatric patients are in a state of impaired consciousness, the principal investigator (PI) will provide comprehensive information to their parents or legal guardians to ensure full understanding of the study protocol, thereby enhancing understanding. Data management personnel will conduct real-time surveillance to promptly identify and address any missing data.

Informed Consent

The principal investigator will conduct the informed consent discussion in person, explaining the study details and answering any questions from the parents. Since the participants are children in a delirious state and unable to provide consent themselves, informed consent will primarily be signed by their legal guardians. If the guardian is illiterate, a witness must be present. Verbal consent will be given by the patient or their legal guardian, and the witness will sign and date the consent form. An optional, separate clause will be included in the informed consent form, allowing participants to authorize the use of their de-identified data and specimens for future ethically approved medical research. Participants are reassured that participation is completely voluntary and that they can withdraw at any time, and that it will not affect the care provided to them while in hospital for their procedure.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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