Research Proposal

Project: Development of an Assistive Care BCI for Locked-In Pediatric Patient

Principal Investigator: Dr. Joshua Pranjeevan Kulasingham, Senior Lecturer, University of Moratuwa

Co-Investigators:

- Dr. Chamira U. S. Edussooriya (Senior Lecturer, University of Moratuwa)
- Dr. Peshala Jayasekara (Senior Lecturer, University of Moratuwa)
- Prof. Jithangi Wanigasinghe (Consultant Paediatric Neurologist, Patient's Attending Doctor)
- Kithmin Wickremasinghe (Graduate Research Assistant, University of British Columbia)
- Chathura Nirmal Weerasinghe (Undergraduate, University of Moratuwa)
- Risini Kumarasinghe (Undergraduate, University of Moratuwa)
- Jayamadu Gammune (Undergraduate, University of Moratuwa)
- Dinujaya Wijewickrama (Undergraduate, University of Moratuwa)

1. Introduction

Locked-in syndrome (LIS) is a rare but devastating neurological condition [1, 2] in which individuals lose almost all voluntary muscle control while retaining full consciousness. For children, the condition is particularly tragic, as it halts natural development and severely restricts interaction with their environment.

Our identified patient is a 6-year-old boy who developed LIS following a spinal cord infection. He has been dependent on a ventilator for two years and has lost most motor functions below the neck, although he retains some control over eye movements and facial muscles. His parents provide constant care at home, but his opportunities for play, learning, and communication are extremely limited.

Brain-Computer Interface (BCI) systems offer a non-invasive means of restoring interaction for patients with severe paralysis. By recording brain activity, typically via electroencephalography (EEG) [4, 5] BCI systems can decode neural signals into actionable commands. Such technology has been applied in adult patients with amyotrophic lateral sclerosis (ALS), stroke, or LIS, but pediatric applications remain relatively unexplored [3, 4]].

Children with LIS require not only assistive communication but also engaging, developmentally appropriate interaction. A game controlled by brain signals provides a safe, motivating, and psychologically beneficial avenue [4] for the patient to interact actively with

the environment. It can reduce isolation, support cognitive stimulation, and improve quality of life.

This project proposes to design and implement a **low-cost EEG-based BCI interface** tailored for the child. We will explore three common paradigms: Steady-State Visual Evoked Potentials (SSVEP), P300 event-related potentials, and Motor Imagery (MI). Initially, the focus will be on simple two-class control to play a balloon-popping game, with the potential to scale to more advanced multi-class control if the patient shows adaptability.

2. Objectives

- The overall objective of this project is to design and implement a non-invasive brain-computer interface (BCI) system tailored to a six-year-old boy with locked-in syndrome (LIS). The system will provide him with a means of communication and engagement using brain activity, compensating for his severe motor impairments. The objectives are divided into primary and secondary goals, reflecting both the immediate deliverables required to benefit the identified patient and the broader contributions to research and future applications.

● 3.1 Primary Objectives

- The foremost objective of this project is to develop an EEG-based brain-computer interface capable of task-based interaction. Electroencephalography (EEG) is chosen for its non-invasive nature [10, 11, 12], safety profile, and widespread use in pediatric neurotechnology. By capturing and decoding EEG signals, the system will enable the patient to control simple game elements, thereby providing a channel of interaction despite his physical limitations.

- A second primary objective is identifying the most suitable BCI paradigm for a young child with LIS. Several paradigms are available in EEG-based BCI research [5, 6, 7], including steady-state visual evoked potentials (SSVEP), event-related potentials such as P300, and motor imagery (MI). Each has distinct strengths and challenges. SSVEP and P300 paradigms are easier to implement and require less training, making them more appropriate [6] as entry points. Motor imagery, although more cognitively demanding, may offer richer long-term possibilities [7, 9]. This project will explore these paradigms in stages, beginning with visual evoked potentials and gradually moving to motor imagery if feasible for the child.

- The third key objective is to develop a functional task interface that supports two-class control. This initial stage focuses on simple binary choices, such as selecting between two objects or triggering a single action (e.g., popping a balloon). Such a setup reduces complexity while still offering meaningful interaction, allowing the child to begin engaging with the system early in the project.

- ### 3.2 Secondary Objectives

- Beyond these initial goals, the project also aims to expand the system to multi-class control [7, 9] if the patient demonstrates the ability to engage with more complex paradigms. Multi-class control (five to six distinct commands) will primarily rely on motor imagery techniques, potentially enabling the patient to perform more sophisticated actions through multiple-choice tasks. While ambitious, this goal represents the long-term vision of creating a flexible, scalable system.

- Another secondary objective is to optimize the hardware design for use in a pediatric home environment. This involves ensuring that the EEG headset is comfortable, stable, and safe for repeated use. Special attention will be paid to electrode placement, headcap materials, and wireless transmission, with the aim of minimizing discomfort and maximizing usability. Since the trials will be conducted in the patient's home, the system must also be robust, portable, and easy for non-specialist caregivers (parents) to manage with minimal assistance.

- A further secondary goal is to evaluate patient engagement, usability, and performance metrics. In addition to measuring technical outcomes such as classification accuracy, latency, and false detection rates, the study will incorporate subjective measures such as the child's willingness to participate, observed enjoyment, and parental feedback on practicality. These human-centered metrics are crucial for determining whether the system is not only functional but also meaningful and beneficial in the patient's daily life.

- Finally, the project aims to document the development process and findings for academic dissemination. This includes producing a comprehensive report that details the design, methodology, challenges, and outcomes of the project. Where possible, results will be prepared for publication in academic venues to contribute to the growing body of knowledge on pediatric BCI applications. In doing so, the project will not only help a single identified patient but also pave the way for further research and development of assistive neurotechnologies for children with severe disabilities.

4. Methodology

The aim of this project is to design, develop, and test a brain-computer interface (BCI) system specifically tailored for a single pediatric patient diagnosed with locked-in syndrome (LIS). The study employs a mixed experimental approach: first validating the hardware and software with healthy adult volunteers, followed by a carefully supervised pilot trial with the patient in his home environment. The methodology encompasses participant details, study setting, recruitment, experimental procedure, and data analysis, all structured to ensure safety and reliability.

4.1 Participant Details

The primary participant of this study is a six-year-old boy diagnosed with locked-in syndrome following a severe spinal cord infection. The condition has left him paralyzed and

ventilator-dependent for over two years. Despite these physical limitations, he retains voluntary control over eye movements and some facial muscles. These preserved functions make him a suitable candidate for exploring alternative communication and interaction strategies using EEG-based BCIs.

The rationale for working with a single participant is the highly individualized nature of the project. Unlike larger studies that test a device on multiple participants, this project aims to design and optimize a system tailored to one identified child, ensuring that comfort, usability, and gameplay design are matched to his unique needs. Before the device is introduced to the patient, pilot testing will be conducted with healthy adult volunteers. This step will validate the safety of the hardware, electrode placement, and signal quality, while also providing initial benchmarks for EEG responses such as steady-state visual evoked potentials (SSVEP), event-related potentials (P300), and motor imagery signals. Only after confirming reliability and safety in this preliminary stage will trials with the patient be undertaken.

4.2 Study Location and Setting

The development and initial testing phases of the project will take place at the University of Moratuwa laboratories. This controlled environment allows for systematic debugging of the hardware, calibration of the amplifier, electrode fitting, and software testing under the guidance of the supervisors.

Final patient trials will be conducted in the child's home, which is already equipped with a ventilator and other necessary medical support devices. Carrying out the study in this familiar environment reduces the psychological burden on the child while ensuring immediate access to parental care. All trials will be performed with both parents present to monitor comfort and intervene if required. This approach balances technical rigor with the need for a safe and reassuring setting for the patient.

4.3 Recruitment Procedure

Unlike traditional clinical studies, no general recruitment procedure is necessary since the project is customized for a single, identified patient. The participant has been chosen based on the attending physician's referral, taking into account his condition, preserved cognitive functions, and potential to benefit from the intervention.

Prior to participation, written informed consent will be obtained from the patient's parents or legal guardians. The consent process will involve a comprehensive explanation of the study's aims, procedures, and potential risks, provided both orally and in writing. Parents will be encouraged to ask questions and will be assured that participation is voluntary and that they can withdraw their child from the study at any stage without consequence to his medical care.

4.4 Experimental Procedure

The experimental procedure consists of several stages, beginning with hardware validation and culminating in structured patient trials.

The first stage involves hardware validation with healthy adult volunteers. During this stage, the EEG headset will be tested for electrode skin contact quality, safety, comfort, and stability. Volunteers will provide feedback on the ease of wearing the device and any discomfort experienced. Simultaneously, EEG data will be recorded to verify that the system can capture stable alpha rhythms and SSVEP responses.

In the second stage, signal acquisition will be refined. EEG electrodes will be positioned over the occipital and parietal regions to capture SSVEP and P300 responses, while electrodes over the motor cortex will be used for motor imagery tasks. The signals will be continuously monitored to ensure low noise levels and high signal-to-noise ratio.

Parallel to these steps, task development will proceed. The first prototype will be a Unity-based balloon-popping game [15] controlled by two-class BCI paradigms such as SSVEP or P300. This simple design reduces the learning curve for the patient and provides a fun, motivating environment for interaction. As the system matures, the game will be expanded to multi-choice tasks, allowing for more complex interaction patterns.

The final stage consists of patient trials. To prevent fatigue, sessions will initially be very short, lasting only 5–10 minutes, and will be gradually extended based on the child's tolerance. The trials will begin with visual paradigms (SSVEP and P300), which are relatively easy to implement and train. Once familiarity is established, motor imagery (MI) tasks will be introduced, allowing the child to attempt control through imagined movements. Throughout all trials, EEG signals, classification performance, and game outcomes will be recorded. Additionally, parental observations and patient responses (e.g., signs of fatigue, frustration, or enjoyment) will be documented.

4.5 Data Analysis

The data analysis process will focus on evaluating both the technical performance of the system and the subjective experience of the patient. EEG signals will be pre-processed using digital filters (0.5–40 Hz band-pass) to remove baseline drifts, muscle artifacts, and environmental noise. Artifact removal techniques will be applied to address common issues such as eye blinks or ventilator-induced artifacts.

For feature extraction, different methods will be employed depending on the paradigm: Fast Fourier Transform (FFT) will be used to isolate frequency-domain features in SSVEP; time-domain averaging will enhance P300 signals; and Common Spatial Patterns (CSP) will be used for motor imagery feature extraction [5, 7].

For classification, several machine learning methods will be explored, including Support Vector Machines (SVM), Linear Discriminant Analysis (LDA), and deep learning models such as convolutional neural networks (CNNs), depending on which achieves the best trade-off between accuracy and computational efficiency.

Finally, evaluation metrics will include classification accuracy, latency (response time), false detection rate, and patient comfort scores based on parental feedback. The combined analysis of these measures will help determine the effectiveness of the system both as a technical prototype and as a usable assistive technology for the patient.

5. Ethical Considerations

5.1 Risks and Mitigation

The most immediate risk associated with EEG based BCI systems is electrical safety. To mitigate this, the device will be entirely battery-powered, thus eliminating any danger of mains related hazards. The amplifier, built around the ADS1299 integrated circuit [10], is widely recognized in research as safe for human use [10], and it will be supplemented with high-impedance input buffers and current-limiting resistors [10]. These protective features ensure that even in the unlikely event of a system fault, the currents experienced by the patient remain far below medical safety thresholds. Each session will begin with a safety check of the equipment, which is similar to that used by the previous group already granted the Ethics Declaration (Ethics Declaration Number: ERN/2025/001), to confirm compliance.

Comfort is another major concern, particularly since the patient is a young child. EEG headsets can cause itching, pressure marks, or redness when worn for extended periods. To minimize this, the design will use lightweight materials with adjustable straps, ensuring that no undue pressure is applied to the scalp. Dry silver/silver-chloride electrodes [14] will be used to avoid the irritation and mess of conductive gels. Moreover, session times will be limited to short intervals of about 20–30 minutes, with frequent breaks, so that the child never experiences fatigue or discomfort that outweighs the benefits of participation.

Skin sensitivity and allergic reactions also pose possible risks. Although the electrodes and polyester fabric used in the cap are standard in EEG research, the parents will be questioned in advance regarding any known allergies. If the child shows even the slightest sign of irritation during use, the experiment will be stopped immediately, and medical attention will be sought if necessary.

Since the patient is ventilator-dependent, all trials will be carried out in the child’s home environment, with medical equipment such as the ventilator fully operational during sessions.

Finally, psychological fatigue [8] and cognitive stress must be addressed. BCI tasks require sustained attention, which can be challenging for young children. To prevent mental overload, the game environment will be designed with child-friendly visuals such as balloons, animals, or colorful interactive objects, avoiding harsh or overstimulating graphics. Sessions will be structured to include frequent pauses, and the child will always be free to stop without pressure. In this way, the project aims to safeguard not only the physical health but also the emotional well-being of the participant.

5.2 Benefits

The benefits of this project are both immediate and long-term. For the child, the most direct benefit is psychological well-being. By enabling him to interact with his environment through

a task controlled by his brain activity, the project provides a sense of agency and engagement that his current physical limitations deny. This interaction may reduce feelings of isolation and boredom, offering meaningful entertainment in his daily life.

The project also benefits the parents by opening a new channel of interaction with their child. At present, communication is severely restricted due to the child's locked-in state. A game-based BCI interface creates an alternative, playful mode of connection, potentially strengthening parent–child bonding.

Beyond this specific case, the project establishes a foundation for future assistive technologies. A successful prototype could inspire the development of more advanced systems, particularly low-cost EEG-based interfaces for children with neurological disabilities. Such research contributes to the growing field of pediatric neurorehabilitation and may eventually improve quality of life for many patients worldwide.

5.3 Consent

Since the participant is a minor, informed consent will be obtained in writing from his parents or legal guardians. The consent process will involve a detailed oral and written explanation of the study, including its purpose, procedures, potential risks, and anticipated benefits. Parents will be explicitly informed that their child's participation is voluntary and that they have the right to withdraw him from the study at any time without affecting his ongoing care. The information will be presented in simple, non-technical language to ensure clarity.

5.4 Confidentiality and Data Security

All data collected during this study will be handled with the strictest confidentiality. EEG recordings and questionnaire responses will be anonymized, with all personally identifiable details such as names, addresses, and medical record numbers removed before analysis or publication. Digital data will be stored on encrypted, password-protected drives accessible only to the research team, while hard copies of consent forms and questionnaires will be locked securely in the university's storage facilities. Only supervisors and designated student researchers will have access to these materials. At no stage will identifying information be included in academic reports, publications, or presentations.

6. Annex A – The EEG Recording System

6.1 General Overview

The EEG recording system developed for this project consists of three integrated subsystems. The first is the headset, a lightweight, custom-designed cap fitted with dry Ag/AgCl electrodes [14]. These electrodes are positioned according to the International 10–20 system [12] to ensure the accurate acquisition of signals associated with visual evoked potentials and motor imagery. The second component is the wireless module, which houses the amplifier (based on the ADS1299 IC) and an ESP32 microcontroller [11] responsible for digitizing the signals and transmitting them wirelessly. The third subsystem is the computer interface, which receives the EEG data in real time, processes the signals, and

renders the corresponding game feedback for the child. Together, these components form a closed loop of brain-signal acquisition, wireless data transfer, and interactive game control. This system is based on the design developed by the prior group, which has already been granted ethical clearance(Ethics Declaration Number: ERN/2025/001), ensuring compliance.

6.2 Electrical Safety

The entire system is powered by a rechargeable lithium-ion battery rather than mains electricity, ensuring there is no risk of harmful current reaching the child. Additional safety layers include input buffers with extremely high impedance and series safety resistors that limit any possible current flow to negligible levels. The ADS1299 amplifier, chosen for its low-noise and high-safety characteristics, has been used in numerous BCI applications with no reported safety incidents. Routine inspections of the headset and amplifier will be performed before every session to confirm safe operation.

6.3 EMF Safety

The system relies on wireless transmission [13] to send EEG signals from the headset to the computer. The ESP32 module, which supports both Wi-Fi and Bluetooth, operates at power levels well below regulatory thresholds for electromagnetic exposure. To further minimize exposure, the transmitter will be positioned at least 20–30 cm away from the child's head. Previous research and commercially available EEG headsets using similar wireless methods have received FDA and FCC approval, reinforcing the safety of this approach.

6.4 Materials Safety

The headset materials were selected for both functionality and biocompatibility. The electrodes are silver/silver-chloride (Ag/AgCl), a standard in clinical EEG recording with minimal side effects. The cap itself is made from soft polyester or lightweight plastic, ensuring durability and comfort during wear. Previous research has demonstrated that any temporary effects, such as mild redness or skin indentation, typically disappear within minutes of removal. Prior to testing, parents will be fully informed about the materials, and any signs of skin irritation during sessions will result in immediate termination of the experiment.

6.5 Benchmarking Procedure

To validate the system's reliability and comfort before involving the child participant, preliminary benchmarking will be conducted with adult volunteers. These tests will measure the ability of the system to capture common EEG responses such as alpha rhythms (eyes closed) and steady-state visual evoked potentials (SSVEP) in response to flickering stimuli. Volunteers will also provide feedback on headset comfort, electrode stability, and any perceived discomfort. Only after these trials confirm that the device is safe and functional will

it be introduced for pediatric testing. This staged approach ensures that both technical performance and user comfort are verified before involving the vulnerable child participant.

7. References

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