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# Implementing a Wearable BCI with Patients with Disorders of Consciousness: An Inter-professional Approach

**K. Hill[1]*, A.K. Wagner[2], A.M. Lieto[1], S. Baker[1], E. Mariperisena-Meinert[1], A. Bauer[2], G. Galang[2], K. Franzese[2], S. Koo[2], A. Yan[2], V.P. Reddy[2], N. Enam[3]**

[1] *University of Pittsburgh, Pittsburgh, PA USA, [2]University of Pittsburgh Medical Center (UPMC), Pittsburgh, PA, USA; [2]; [3]University of Pennsylvania, Philadelphia, PA, USA*

5023 Forbes Tower, University of Pittsburgh, 55106. Email: khill@pitt.edu

*Introduction:* Patients diagnosed with disorders of consciousness (DoC) face incomparable challenges in communicating awareness. DoC encompasses a spectrum of impaired consciousness, ranging from coma to minimally conscious states, where limited or intermittent interaction with the environment may P300 occur. Research using functional magnetic resonance imaging suggests that approximately 1 in 5 individuals with DoC exhibit what is known as cognitive motor dissociation (also known as covert consciousness)- a state in which they are aware of their surroundings and can understand language but are unable to communicate. Wearable brain-computer interfaces (BCIs) offer a potential solution for providing prognostic insights and developing strategies to evaluate comprehension and communication abilities.

*Material and Methods:* Our feasibility trial was designed 1) to evaluate the technical and clinical challenges of successfully collecting physiological data derived from g.tec's mindBEAGLE P300 and motor imagery assessment paradigms among research participants with DoC 2) to establish data reproducibility and interpretability across multiple paradigms required for assessing and utilizing functional cognition and communication for the DoC population treated within the UPMC Rehabilitation Institute, 3) to characterize participant tolerance of training and communication within each paradigm. Our study focused on the Institutional Review Board (IRB) and data collection protocol development and refinements, as well as reporting individual case report results and preliminary inter-professional feedback regarding the acceptability of the protocol. Initial clinician training occurred over 5 days using a competency-based approach. Results indicated that a minimum of 35 hours of didactic and hands-on training was required for trainees to achieve competencies such as equipment set-up, cap fitting, electrode testing, executing paradigm assessments and recording data results. This training included multiple opportunities to perform the mindBEAGLE assessment and treatment protocols by troubleshooting common scenarios, identifying the key variables for clinical assessment and interpretation, and becoming familiar with the software and associated data management. Training considered how DoC participants might vary in terms of feasibility and implementation, data reproducibility and interpretation, and patient tolerance and conditioning over time for participation and considerations for measuring physiological changes and neurological improvement within and between sessions.

The initial protocol design approved by the University of Pittsburgh's IRB was revised early in the study to address identified challenges with inclusion/exclusion criteria, recruitment strategy (inpatient/outpatient), participant age range and diagnosis, participant availability, and the clinical environment. Protocol changes were made in collaboration with g.tec on how to manage artifacts due to participant movement, electrode placement, and software data capture and utilization. In addition, database development using REDCap provided for systematic data collection that required refinement in data structure an expanded menu of data elements.

*Results and Conclusion*: Our inter-professional approach allowed for ongoing protocol refinement and identification of implementation strategies and techniques to begin to advance feasibility and person-centered implementation goals needed for clinical sustainability. Exemplars demonstrating our progress with both inpatient and outpatient participants are provided across the various technical and implementation themes introduced. Multiple DoC participants were able to reproducibly communicate with yes/no responses using at least one mindBEAGLE paradigm. Our inter-professional approach will continue to advance this work into a T2-Translation to Patients Clinical trial.

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