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Official Title

Wearable and Deep Learning-Based Recognition of Real-World Movement Behavior of Adolescents With Cerebral Palsy: Feasibility and Discriminant Validity Study

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Statistical Analysis Plan (SAP)

Document

<u>Feasibility</u>: For the movement behavior monitoring to be considered technically feasible, all 72-hour recordings must have continuous data. The trustworthiness of data output will be evaluated by visually reviewing data according to the following criteria: The posture labels and walking labels are mutually exclusive. Hence, only one posture or walking can be classified at a given time. All four extremity movements can co-occur. During lying-, sitting-, and standing time, extremity movements may either be present or absent. In walking time, at least both lower extremity labels must be present.

For user acceptance, the sensors must be worn throughout the 72-hour wear time and without adverse events.

<u>Discriminant validity</u>: The network's ability to detect variations in movement behavior between groups will be based on the 72-hour recordings. The independent variables (Groups) include controls and GMFCS-E&R levels I, II, III, IV, and V; types of CP, Spastic, Dyskinetic, Ataxic, and Mixed; Affected body parts, unilateral, bilateral, diplegia, and quadriplegia; and sleep problem score using Jenkins Sleep Evaluation Questionnaire (JSEQ). The entire cohort will be stratified based on their sleep disturbance frequency, with a score of 12 or higher indicating frequent disturbance and a score below 12 indicating little to no disturbance.

The dependent variables include network data output, e.g., time spent walking, standing, sitting, and lying; time spent moving right arm, left arm, right leg, and left leg; number of transitions to and from lying, sitting, standing, and walking; and relative extremity movement.

To calculate the total time spent in bed (TIB), the difference between the noted times in the sleep diary will be used. This will define the start and end of the sleep analysis period. TIB also includes the time spent out of bed during nocturnal awakenings, which are a manifestation of sleep discontinuity. To calculate sleep onset latency (SOL), the time from lights out to the first epoch of > 2 minutes without any registered movement will be used. Any movement after that will be defined as wakefulness after sleep onset (WASO). All epochs without movement will be considered total sleep time (TST), and these outcomes will be reported in average daily hours. The ratio of TST to TIB (as a percentage) will be used to calculate sleep efficiency.

The discriminant validity analysis will be carried out using Kruskal-Wallis tests, and the results will be presented through Box and Whisker plots. If Kruskal Wallis shows a significant group effect, post-hoc testing will be performed to analyze differences between groups. To determine any association between movement behavior and groups, Spearmann rho correlations will be calculated. The correlation results will be interpreted as follows: .00-.19 "very weak"; .20-.39 "weak"; .40-.59 "moderate"; .60-.79 "strong"; .80-1.0 "very strong".

The significance level for both between group differences and correlations is set at p < 0.05. We hypothesize that control and GMFCS-E&R levels are significantly associated with time spent walking, standing, sitting, and lying, as well as number of transitions from either lying, sitting, standing, or walking.

Control and types of CP are associated with time spent moving extremities, and affected body parts are associated with relative extremity usage.

We do not expect any association between sleep disturbance and nighttime network output for individuals with GMFCS levels IV and V, as their disabilities limit their mobility even if they experience sleep disturbances.