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Validity, responsiveness, minimal detectable change, and minimal clinically important change of *Pediatric Balance Scale* in children with cerebral palsy

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ABSTRACT

This study examined criterion-related validity and clinimetric properties of the pediatric balance scale (*PBS*) in children with cerebral palsy (CP). Forty-five children with CP (age range: 19–77 months) and their parents participated in this study. At baseline and at follow up, Pearson correlation coefficients were used to determine criterion-related validity by analyzing the correlation between the *PBS*, including *PBS-static*, *PBS-dynamic*, and *PBS-total*, and criterion measures, including the *Gross Motor Function Measure-66* items (*GMFM-66*) and *Functional Independence Measures for Children* (*WeeFIM*). Responsiveness was examined by paired *t* test and by standardized response mean (SRM). The minimal detectable change (MDC) was analyzed at the 90% confidence level, and the minimal clinically important differences (MCID) was estimated by anchor-based and distribution-based approaches. The *PBS* with *GMFM-66* and *WeeFIM* showed fair-to-excellent concurrent validity at pretreatment and follow up and predictive validity. The SRM values of all PBS scales were 0.75. For the *PBS-static*, *PBS-dynamic*, and *PBS-total*, the MDC_{90} values were 0.79, 0.96, and 1.59, and the MCID ranges were 1.47–2.92, 2.23–2.92, and 3.66–5.83, respectively. Improvement of at least MDC values on the *PBS* can be considered a true change, not measurement error. A mean change must exceed the MCID range on *PBS* to be considered clinically important change. Therefore, all *PBS* scales were moderately responsive to change. Clinicians and researchers can use these clinimetric data for *PBS* to determine if a change score represents a true or clinically meaningful effect at posttreatment and follow up.

1. Introduction

Cerebral palsy (CP) describes a group of permanent disorders in movement and posture that limit activity and participation and are attributed to non-progressive disturbances in the developing fetal or infant brain (Rosenbaum et al., 2007).

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In CP, motor disorders are often accompanied by poor balance control (Katz-Leurer, Rotem, Keren, & Meyer, 2009; Woollacott & Shumway-Cook, 2005). Children with CP may have difficulties maintaining standing balance because of an inability to resolve intersensory conflicts (Cherng, Su, Chen, & Kuan, 1999). For example, a recent study showed that, compared to controls without CP, children with CP have lower platform velocity thresholds, greater percentages of loss in balance trials, and increased distances and increased frequency of directional changes in center-of-pressure trajectories (Cherng et al., 1999). The balance problems associated with CP further impaired motor functions, mobility, activities of daily living (ADL), and participation. Finally, the balance problems increased the incidence of falls in this group.

Balance, the ability to maintain a state of equilibrium, is a critical element of movement that facilitates performance of functional skills (Franjoine, Gunther, & Taylor, 2003). For example, balance control is essential for walking and most functional skills and for recovery from unexpected balance disturbances caused by slips, trips or instability (Woollacott & Shumway-Cook, 2005). Functional balance, which is an element of postural control, allows a child to perform everyday tasks activities of daily living (ADL), social activities, and recreational activities at home, in school, and in the community (Franjoine et al., 2003). Clinicians must measure functional balance control to determine whether the control safely meet the demands of daily activities for children with CP. Therefore, valid and reliable functional balance measures are essential for measuring balance improvement and justifying intervention effects in these children.

The *Pediatric Balance Scale* (*PBS*), a modification of the *Berg Balance Scale* (*BSS*) (Berg, Maki, Williams, Holliday, & Wood-Dauphinee, 1992), was developed as a balance measure for children (Franjoine et al., 2003). The *PBS* measure can be performed without specialized equipment and is quickly and easily administered. The *PBS* has been used to measure the balance functions for school-age children with mild-to-moderate motor impairments (Franjoine et al., 2003), and children with CP (Gan, Tung, Tang, & Wang, 2008). The tasks range from timed sitting balance to standing on one leg and. Therefore, the *PBS* provides clinicians with a standardized format for measuring performance of functional balance tasks. The clinimetric properties of *PBS* enable determination of whether changes at post-treatment or follow up are significant and important for patients. Change scores from pretreatment to post-treatment reflect the effect of treatment and undesired measurement error. The importance of a difference after treatment is typically measured in terms of responsiveness, minimal detectable change (MDC) and minimal clinically important difference (MCID) (de Vet et al., 2006). Responsiveness is a measure of longitudinal validity that describes the capability of an instrument to detect important changes in performance over time. That is, it indicates the capability of an instrument to detect the efficacy of a treatment (Stratford, Binkley, & Riddle, 1996). The MDC, which is a measure of the smallest change beyond measurement error, reflects a true difference and a statistically reliable change (de Vet et al., 2006). The MCID depicts the smallest change in scores that would be considered important to the client or clinician (de Vet et al., 2006). The MCID provides a new measure for determining the effectiveness of a treatment and for describing patient satisfaction with the treatment (Copay, Subach, Glassman, Polly, & Schuler, 2007). Therefore, the MDC and MCID provide clinicians with the information needed for effective clinical decision making when interpreting score changes at post-treatment or follow up.

Both distribution-based and anchor-based approaches are widely used to estimate MCID (Copay et al., 2007). A distribution-based approach expresses changes underlying a specific sampling distribution using statistical significance, sample variability, and measurement precision to estimate the MCID. Anchor-based approaches, however, determine clinical importance by comparing change scores with an external standard. The MCID is not an invariable characteristic of a measurement instrument but may depend on the perspective from which minimal importance is considered and the baseline values on the measurement instrument under study (de Vet et al., 2007). Because of the lack of a standard measurement of MCID, combined distribution-based and anchor-based measures of MCID are recommended (Copay et al., 2007).

The rationale for calculating MDC and MCID rather than comparing baseline and follow-up scores between a randomly distributed control and experimental group because the differences of change scores between a control and experimental group could not determine the measurement errors of the assessment tools and minimal threshold for clinically important changes. Determining MDC and MCID values for the *PBS* is important for clinical decision making in children with CP due to the widespread use of the *PBS* in research and practice. However, no studies have measured the clinimetric properties of the *PBS*. Therefore, the purpose of this study was to examine the validity of the *PBS* and its clinimetric properties, including responsiveness, MDC, and MCID, in children with CP.

2. Methods

2.1. Participants

Children with CP were recruited from the rehabilitation clinics of three hospitals for a follow-up study. All participants were independently examined by a physiatrist and by a physical therapist to determine whether they met inclusion criteria for the study: diagnosis of CP, age between 1 and 6 years, and *Gross Motor Function Classification System* (*GMFCS*) level I–IV. The exclusion criteria were *GMFCS* level V, progressive neurological disorder, genetic or metabolic disorder, or severe concurrent illness or disease not typically associated with CP (e.g., traumatic brain injury or active pneumonia). Of the 48 children from a convenience sample initially recruited for the study, three were lost to follow up (including one due to active medical problems and two due to lost contact). Finally, 45 children with CP were enrolled. The CP diagnosis and subtype of the child were ascertained by the physiatrist based upon parent interview (e.g. history taking), clinical examinations of children, and chart review (medical chart, brain imaging, or laboratory tests). The *GMFCS* level was classified by either the physiatrist or the physical therapist based upon parent interview (e.g. history taking), clinical evaluations, and progress and