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The minimal clinically important difference for the Gait Profile Score

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ABSTRACT

The minimally clinically important difference (MCID) is an important concept for interpreting the results of clinical research. This paper proposes a rationale for defining an MCID for the Gait Profile Score (GPS) based on an analysis of the difference in median GPS for children classified at different levels of the Functional Assessment Questionnaire. A strong linear correlation between median score and FAQ level was found. An MCID of 1.68 is therefore suggested, reflecting the mean difference between adjacent FAQ levels. Comparison of this value with (i) the standard deviation of GPS from typically developing children (1.48) and (ii) the percentage of the difference between the median GPS for each FAQ level and that for typically developing children offers further support to suggest that 1.68 is an appropriate figure.

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1. Introduction

There is an increasing emphasis in clinical research into establishing whether outcomes are clinically meaningful as well as statistically significant. The concept of minimal clinical important difference [MCID [1]] is widely accepted but there is little consensus on precise definitions [2,3]. The range of methods has been divided into anchor based methods, which compare a new measure to other measures of clinical evidence, and distribution based methods which are based on its statistical or psychometric properties [3]. Both have limitations, anchor based methods, in validating one measure on the basis of another, have the potential to be “circular in logic and fraught with potential bias” [2]. Distribution based methods “cannot address the question of clinical importance, which is central to the concept of MCID” [2].

None of the existing measures of gait quality [4–7] have had an MCID defined. Oeffinger et al. [8] reported a six year multi-centre study to define MCID for range of measures of walking function but did not include any gait quality indices. The Gait Profile Score [GPS [4,5]] represents the root mean square (RMS) difference between a

particular gait trial and averaged data from people with no gait pathology. It has an advantage over the other indices as it is comprised of a number of gait variable scores (GVSS) representing an equivalent RMS difference for different kinematic variables. These can be displayed as a bar chart known as the Movement Analysis Profile (MAP). The aim of this paper is thus to define an MCID for the GPS.

The cross-sectional approach is an anchor based method that compares groups that are different in terms of a clinically relevant disease related criterion [3]. Within clinical gait analysis two such criterion measures of functional mobility are widely used. The Functional Assessment Questionnaire [FAQ [9]] is a 10 point scale (6–10 describe functional walkers with 10 being most able) which was designed specifically to be used as an outcome measure. The Gross Motor Function Classification System [GMFCS [10,11]] is designed for children with cerebral palsy (CP) with five levels (functional walkers are classified within levels I–III, with I being the most able). Both scales were derived by clinicians to define groups of children whose physical function is clinically different and both were developed independently of any consideration of instrumented gait analysis (IGA). The GMFCS was derived using a Delphi process involving 48 clinicians from a range of backgrounds [10]. It is more difficult to establish the construct validity of the FAQ from the original publication [9] but this has now been cited over 100 times reflecting widespread acceptance within the clinical research community (and thus high face validity). They

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