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Review

Walking measures to evaluate assistive technology for foot drop in multiple sclerosis: A systematic review of psychometric properties

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ABSTRACT

Background: Foot drop in people with multiple sclerosis (pwMS) often managed with assistive technologies, such as functional electrical stimulation and ankle foot orthoses. No evidence synthesis exists for the psychometric properties of outcomes used to evaluate the efficacy of these interventions.

Objective: This systematic review aimed to identify the outcome measures reported to assess the benefits of assistive technology for pwMS and then synthesize the psychometric evidence in pwMS for a subset of these measures.

Methods: Two searches in eight databases were conducted up to May 2017. Methodological quality was rated using the COSMIN guidelines. Overall level of evidence was scored according to the Cochrane criteria.

Results: The first search identified 27 measures, with the 10 m walk test, gait kinematics and Physiological Cost Index (PCI) most frequently used. The second search resulted in 41 studies evaluating 10 measures related to walking performance. Strong levels of evidence were found for the internal consistency and test-retest reliability of the Multiple Sclerosis Walking Scale-12 and for the construct validity for Timed 25 Foot Walk. No psychometric studies were identified for gait kinematics and PCI in pwMS. There was a lack of evidence for measurement error and responsiveness.

Conclusion: Although a strong level of evidence exists for some measures included in this review, there was an absence of psychometric studies on commonly used measures such as gait kinematics. Future psychometric studies should evaluate a wider range of walking related measures used to assess the efficacy of interventions to treat foot drop in pwMS.

1. Introduction

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the central nervous system that typically strikes adults [1]. There is a wide variability among the symptoms, with gait impairments being one of the most common [2]. People with MS (pwMS) rate the impairment of their gait as being an inhibiting factor in their everyday life, sometimes even in relatively early stages of the disease [3,4].

One of the most common gait impairments is foot drop, which is the reduced dorsiflexion of the ankle during the swing phase of gait, potentially leading to trips or falls. Foot drop can be caused by weakness of the dorsiflexor muscles, impaired neural control causing co-contraction of agonist and antagonist muscles and increased tone in the plantarflexor muscles [5]. In pwMS foot drop can also be caused by increased motor fatigability, which is described as the exercise-induced reduction in the ability of the muscles to produce force or power [6]. Two common interventions to treat foot drop are functional electrical stimulation and ankle foot orthoses. The most commonly used ankle foot orthoses restrain the movement of the foot and thus reduce foot drop, but they do not allow active control of the ankle, which may result in an abnormal gait pattern [7]. On the contrary, functional electrical stimulation involves electrical stimulation that is applied to the common peroneal nerve, eliciting the desired contraction to produce ankle dorsiflexion during the swing phase of gait. The advantage of functional electrical stimulation is that it facilitates a more normal gait pattern, increases walking speed and decreases the physiological cost of gait [8,9].

The effects of functional electrical stimulation and ankle foot orthoses on walking performance is currently evaluated via a wide variety of outcome measures including, for example, timed walking tests [e.g. 6-min Walk test (6MWT), Timed 10-m Walk (10mWT), Timed 25 Foot Walk (T25FW)] or patient or clinician reported instruments and rating scales [e.g. Multiple Sclerosis Walking Scale-12 (MSWS-12), Hauser Ambulation Index (HAI), Dynamic Gait Index (DGI)]. Instrumental motion analysis techniques are also used to objectively quantify the gait pattern. A comprehensive assessment of three-dimensional kinematics

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and kinetics can reveal minimal changes that cannot be observed visually [10]. For this reason, three-dimensional (3D) gait analysis is widely used to discriminate between normal and abnormal gait patterns and to evaluate responses to interventions in a variety of populations, such as stroke [11], cerebral palsy [12] and Parkinson's disease [13,14].

The outcome measures used to assess the efficacy of interventions such as assistive technology to treat foot drop need to be valid, reliable and responsive to change. Several studies have evaluated the psychometric properties of outcome measures used to assess the effects of ankle foot orthoses and functional electrical stimulation to treat foot drop (e.g. Goldman et al. [15], Stellman et al. [16], Learmonth et al. [17,18]). However, no systematic review exists that has evaluated both the evidence and the methodological quality of studies describing the psychometric properties of such outcome measures.

We, therefore, aimed to (i) identify studies that evaluated the effects of ankle foot orthoses and functional electrical stimulation in pwMS and then (ii) synthesize the available psychometric evidence for the designated subset of, walking performance, effort of walking and lower limb function, outcome measures identified. In so doing, we hoped to augment the evidence-base available to optimize the appropriate selection of outcome measure(s) to evaluate the efficacy of assistive technology to treat foot drop in pwMS.

2. Methods

2.1. First search: overview of outcome measures

The purpose of the first search of the literature was to identify those studies that assessed the effects of either functional electrical stimulation or ankle foot orthoses used to treat foot drop in pwMS. From these studies we identified the outcome measures used and the frequency of their use.

2.1.1. Search strategy and study selection

A comprehensive search of eight databases, including MEDLINE (1963-5/2017), CINAHL (1969-5/2017), EMBASE (1974-5/2017), SCOPUS (1963-5/2017), PsycINFO (1963-5/2017), AMED (1967-5/2017), SPORTDiscus (1963-5/2017) and Web of Science (1967-5/2017) was conducted in order to identify the articles that met the inclusion criteria. The search strategy included synonyms and keywords for functional electrical stimulation (e.g. 'Functional Electrical Stimulation', 'foot drop stimulation' and 'common peroneal stimulation') and ankle foot orthoses (e.g. 'Ankle Foot Orthoses' and 'splints') and the population of interest (e.g. 'multiple sclerosis' and 'demyelinating disease'). The full strategy has been included as Supplementary material.

The inclusion criteria for this search were: a) studies that have assessed the use of functional electrical stimulation or ankle foot orthoses to treat foot drop in pwMS and b) studies that included outcome measures that evaluate function, walking performance, fatigue and quality of life (QoL). The exclusion criteria were: a) studies that used other forms of electrical stimulation (i.e. not functional) and those that evaluated orthoses for other joints than the ankle, b) studies that were reviews (i.e. systematic, meta-analysis, etc.), conference abstracts and editorials and c) studies in languages other than English, Greek or Dutch.

Two independent researchers (GA, MvdL) were involved in the screening of the articles for inclusion. After exclusion of irrelevant articles based on the titles and abstracts, the full-text of the remaining articles was examined for their eligibility. Reference lists of articles included in the review were searched for potentially relevant articles that were not retrieved in the original search. If any differences in opinion existed, consensus was made through discussion and a third reviewer (TM) was available if consensus between the primary two reviewers was not reached. From the eligible articles, we extracted the outcome measures that were employed to assess the effects of functional electrical stimulation or ankle foot orthoses and recorded the frequency of these measures being used.

2.2. Principal search: systematic review of the psychometric properties of outcome measures

The second and principal search was conducted to identify studies that evaluated the psychometric properties of outcome measures that assess walking performance, effort of walking and lower limb function in pwMS.

2.2.1. Search strategy and study selection

A similar protocol for the second search was followed as the one described above. A comprehensive search of MEDLINE (1976-5/2017), CINAHL (1995-5/2017), SCOPUS (1999-5/2017), EMBASE (1974-5/2017), PsycINFO (1963-5/2017), AMED (1967-5/2017), SPORTDiscus (1963-5/2017) and Web of Science (1967-5/2017) databases was conducted by combining the outcome measures of walking performance, effort of walking and lower limb function which were identified in the first search. The search strategy included keywords and synonyms of the population of interest (see first search), a subset of the identified outcome measures (e.g. '3D gait analysis', '10 m walk test', etc.) and a search filter for identifying studies evaluating measurement properties, developed by Terwee et al. [19]. The full search strategy is included as Supplementary material.

The inclusion criteria for our second search were: studies that assessed the psychometric properties of a subset of the outcomes identified in the first search, namely those assessing walking performance, lower limb function and effort of walking. Although we acknowledge the importance of outcome measures such as QoL and fatigue, we decided to restrict the outcome measures in this review to those measures that are potentially directly affected by the use of functional electrical stimulation and ankle foot orthoses. Further, the psychometric evidence for fatigue measures used in MS has been the subject of a previous review [20]. The exclusion criteria were: a) studies that were reviews (e.g. systematic and meta-analyses), abstracts from conferences or editorials, and b) full texts in peer reviewed journals published in languages other than English, Greek or Dutch. The procedures used to select the final set of papers were the same as those described for the first search.

2.3. Methodological quality

The methodological quality of the studies identified in the second search was assessed using the Consensus-based Standards for the selection of Health Measurement Instruments (COSMIN). We chose the COSMIN checklist since is used to obtain a score for the methodological quality of a study evaluating one or more measurement properties of a particular outcome measure [21,22]. The COSMIN checklist has been assessed for the inter-rater agreement and reliability of each item, with the percentage agreement being appropriate, but the kappa coefficients for each item being relatively low [23]. However, to overcome low inter-rater agreement in scoring items, we familiarized with the grading process and developed specific guidelines as recommended by the developers of COSMIN. The COSMIN-checklist consists of nine boxes (internal consistency, reliability, measurement error, content validity, structural validity, construct validity, cross-cultural validity and responsiveness) with each box including 5–18 items. The reviewer selects the measurement properties evaluated in the study and scores the specific item-lists with 'poor', 'fair', 'good' or 'excellent' depending on the design and execution. The lowest score from the rated items determines the methodological quality of the measurement property [24]. Two reviewers (GA, MvdL) used the COSMIN checklist to rate the methodological quality of the measurement properties in all studies. Any disagreements in ratings were resolved through discussion.