

# Clinician's Commentary

Jennifer Robertson, Janice Eng, and Chihya Hung are to be commended for conducting a clinical trial on the effects of functional electrical stimulation (FES) on gait and balance for individuals recovering from stroke. Stroke rehabilitation is a major emphasis of physical therapy, yet despite the activity limitations and participation restrictions associated with this common condition, evidence for physical therapy outcomes is only just beginning to accumulate. For this reason, trials that report data on the effects of specific physical therapy interventions are valuable. One of the positive findings of Robertson et al.'s study was that some stroke patients showed improvements in toe clearance during the swing phase of gait after four sessions of FES training. Others showed improvements in balance function. Changes in gait speed and balance confidence, as measured on the Activities-specific Balance Confidence Scale (ABC),<sup>1</sup> were not found to be significant in this small sample of community-based persons living with stroke.

Robertson et al.'s paper highlights the challenges of reporting and conducting controlled trials on the effectiveness, efficacy, or outcomes of physical therapy interventions post-stroke. One of the biggest challenges is to recruit a sufficiently large sample to detect statistically and clinically significant effects of a given intervention. Robertson et al. tested a convenience sample of 15 chronic stroke patients; as they point out in their paper, a sample of 59 participants would have been required to identify changes in balance with FES as measured by the ABC. It is also possible that effect sizes might have been larger in a more acute sample of stroke patients, given that most recovery occurs in the first 6 months following an infarct or haemorrhage. In addition, the effect sizes might have been larger if patients had received a dosage of therapy greater than 8 hours spread over a 1-month period.

Another challenge is to select the research design most appropriate to address the research questions under consideration. Robertson et al. used a before–after study design in which all stroke patients were measured before and after four 2-hour sessions of physical therapy that incorporated FES training. While this design allows change scores to be reported, it does not control for practice effects or for the specific effects of physical therapy; changes in performance can occur that are not attributable to the specific interventions used (in this case, FES). The non-specific effects of being treated or tested and/or the effects of the passage of time may contribute to the changes noted. For this reason, some

advocate the use of randomized controlled clinical trial (RCT) designs, in which patients are randomly allocated to one or more physical therapy interventions or to a no-treatment comparison group. By comparing the relative changes in two or more such groups, researchers can obtain more information on the specific effects of therapies such as FES. Nevertheless, sometimes it can be useful to report data from small samples using a before–after design, in order to gain effect-size data that can then be used to determine the sample size required for a large-scale RCT.

Yet another challenge is to determine the most appropriate measurement tools to quantify balance. Robertson et al. used the ABC as a measure of balance confidence and fear of falling, and the Berg Balance Scale (BBS) to measure balance. The extent to which these tools measure similar or different constructs remains open to question. Moreover, one of the underlying assumptions of the study was that improving toe clearance during the swing phase of gait using FES would reduce the risk of trips and falls. Trips and falls were not monitored, however, and doing so would require a comprehensive method of data collection. The gold standard for collecting data on falls is the annual falls calendar, a tool whereby patients record the frequency and outcomes of falls on a daily basis for 12 months.<sup>2</sup> Implementing a 12-month data-collection process would be time consuming; nevertheless, if the aim is to understand the nexus between balance and falls, such a method would probably be worth the investment of resources.

Conducting trials that measure the effects of physical therapy interventions is challenging, yet such trials are very much needed. Robertson et al. are to be commended for embarking on the ambitious task of quantifying how physical therapy incorporating FES can affect gait and balance. Their well-written paper adds valuable information that can be used in clinical practice. Clinical trial guidelines, such as those documented by the Consolidated Standards of Reporting Trials (CONSORT) statement,<sup>3</sup> provide further information on optimal methods for reporting the findings of RCTs of physical therapy and other interventions.

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