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Appraisal Trial Protocol

Ballistic strength training compared with usual care for improving mobility following traumatic brain injury: protocol for a randomised, controlled trial

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Abstract

Introduction: Traumatic brain injury is the leading cause of disability in young adults aged 15 to 45 years. Mobility limitations are prevalent, and range in severity from interfering with basic day-to-day tasks to restricting participation in higher level social, leisure, employment and sporting activities. Despite the prevalence and severity of physical impairments, such as poor balance and spasticity, the main contributor to mobility limitations following traumatic brain injury is low muscle power generation. Strengthening exercises that are performed quickly are termed 'ballistic' as they are aimed at improving the rate of force production and, hence, muscle power. This is compared with conventional strength training, which is performed slowly and aims to improve maximum force production, yet has limited impact on mobility. Research question: In people recovering from traumatic brain injury: (1) is a 12-week ballistic strength-training program targeting the three muscle groups critical for walking more effective than usual care at improving mobility, strength and balance; and (2) does improved mobility translate to better healthrelated quality of life? Design: A prospective, multi-centre, randomised, single-blind trial with concealed allocation will be conducted. Participants and setting: Participants will be patients with a neurologically based movement disorder affecting mobility as a result of traumatic brain injury. Patients will be recruited during the acute phase of rehabilitation (n = 166), from brain injury units in large metropolitan hospitals in Melbourne and Sydney, Australia. Intervention: For 12 weeks, participants in the experimental group will have three 60-minute sessions of usual physiotherapy intervention replaced by three 60-minute sessions of strength training (ballistic strength, gait). The three key muscle groups responsible for forward propulsion will be targeted: ankle plantarflexors, hip flexors and the hip extensors. Initial loads will be low, to facilitate high contraction velocities. Progression to higher loads will occur only if participants can perform the exercises ballistically. The control group will have their three 60minute sessions of usual physiotherapy intervention (balance, strength, stretch, cardiovascular fitness, gait) standardised so that all participants have equivalent therapy time. Both groups will continue to receive usual rehabilitation. Outcome measures: The primary outcome will be mobility, measured using the High Level Mobility Assessment Tool. The secondary outcomes will be walking speed, muscle strength, balance and health-related quality of life. Walking speed will be measured using the 10-m walking

test. Strength will be measured by a 6 repetition maximum, seated, single leg press test. Balance will be measured as the single limb support time. Health-related quality of life will be measured using the Assessment of Quality of Life. Outcomes will be measured at baseline (0 months), at completion of the intervention phase (3 months), and 3 months after cessation of intervention (6 months). Baseline measures will be completed prior to randomisation. Assessors blinded to group allocation will perform all measures. Analysis: Baseline characteristics of participants will be determined according to group, using descriptive statistics. The proportion of patients compliant with the intervention will be calculated according to group and compared using Fisher's exact test. Compliance with the intervention will be defined as those who have satisfactorily completed at least 80% of the allocated sessions (29 of 36 sessions). The between-group difference for all outcomes will be estimated using analysis of covariance, adjusting for baseline High Level Mobility Assessment Tool score, age, gender and length of post-traumatic amnesia. Analyses will be conducted on an intention-to-treat basis. Discussion: Strength training in neurological rehabilitation is highly topical because muscle weakness has been identified as the primary impairment leading to mobility limitations in many neurological populations. This project represents the first international study of ballistic strength training after traumatic brain injury. The novelty of ballistic strength training is that the exercises attempt to replicate how lower limb muscles work, by targeting the high angular velocities attained during walking and higher level activities.

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