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Effects of treadmill training with load addition on non-paretic lower limb on gait parameters after stroke: A randomized controlled clinical trial

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ABSTRACT

The addition of load on the non-paretic lower limb for the purpose of restraining this limb and stimulating the use of the paretic limb has been suggested to improve hemiparetic gait. However, the results are conflicting and only short-term effects have been observed. This study aims to investigate the effects of adding load on non-paretic lower limb during treadmill gait training as a multisession intervention on kinematic gait parameters after stroke. With this aim, 38 subacute stroke patients (mean time since stroke: 4.5 months) were randomly divided into two groups: treadmill training with load (equivalent to 5% of body weight) on the non-paretic ankle (experimental group) and treadmill training without load (control group). Both groups performed treadmill training during 30 min per day, for two consecutive weeks (nine sessions). Spatiotemporal and angular gait parameters were assessed by a motion system analysis at baseline, post-training (at the end of 9 days of interventions) and follow-up (40 days after the end of interventions). Several post-training effects were demonstrated: patients walked faster and with longer paretic and non-paretic steps compared to baseline, and maintained these gains at follow-up. In addition, patients exhibited greater hip and knee joint excursion in both limbs at post-training, while maintaining most of these benefits at follow-up. All these improvements were observed in both groups. Although the proposal gait training program has provided better gait parameters for these subacute stroke patients, our data indicate that load addition used as a restraint may not provide additional benefits to gait training.

1. Introduction

Impaired gait represents a significant contributor to long-term disability and care burden after stroke [1]. Restoring efficient, independent functional walking is one of the main goals of rehabilitation after stroke and many patients are guided toward achieving faster gait speed and better gait patterns [2].

Hemiparetic gait is characterized by marked lower limb asymmetry [2–5]. Stroke patients prefer to bear weight on the non-paretic limb [3], which generates more work and strength than the paretic limb [6] with resulting changes in angular and spatiotemporal gait parameters [3]. Reduced single support time in the paretic limb can be observed. On the contrary, paretic swing time is increased due to the inadequate propulsion of the hip and ankle flexors of this limb [3,7]. This deficit also promotes reduced peak knee flexion on swing, with a reduced ankle dorsiflexion during this phase [7]. As consequences of asymmetry, can occur damages in dynamic balance control, cumulative musculoskeletal injury to the non-paretic limb and gait inefficiencies [5].

Considering the strong preference to using the non-paretic lower limb, interventions that encourage the use of the paretic lower limb should be explored [6]. To this end, restraining the movement of the non-paretic limb – based on the constraint-induced movement therapy (CIMT) – may be favorable to increase the use of the paretic lower limb [8]. CIMT has as key components the massive practice of functional activities, the restraint of non-paretic limb and behavioral strategies to increase the transfer of learning to daily activities (“transfer package”). Promising results

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have been shown in motor function and functionality of the paretic upper limb [9], with few studies about this therapy for lower limbs [8].

Regnaux and colleagues [10] proposed the use of load as a restraint for the non-paretic lower limb during gait of subacute stroke patients. In that study, improved gait speed, cadence, paretic step length, weight-bearing on paretic limb and joint excursion of the paretic limb were observed after restraining the non-paretic limb by using an ankle mass in a single session of treadmill training. In a more recent study, Bonnyaud and colleagues [11] used the same protocol but for chronic stroke patients, and did not observe specific effects of the restraint on gait parameters of the paretic limb.

It is important to note that only the CIMT restraint component was used in these studies [10,11] and only immediate effects were investigated. Thus, the aim of this study was to evaluate the effects of adding load to treadmill gait training as a multisession intervention on the spatiotemporal and angular gait parameters, for both paretic and non-paretic lower limbs of subacute stroke patients.

2. Methods

2.1. Design

This is a randomized trial with a parallel design, conducted under CONSORT recommendations, at the Laboratory of Intervention and Analysis of Movement of the Federal University of Rio Grande do Norte/Brazil.

2.2. Subjects

Community-dwelling stroke adults were recruited by convenience (by personal invite or advertise) from secondary and tertiary health care units (university clinics, neurologic care centers and after discharge from reference hospitals) from Natal/Brazil. Participants (aged 21–70 years) should have a clinical diagnosis of their first stroke (ischemic or haemorragic) which resulted in walking deficits (gait speed less than 0.8 m/s) [12], until 1 year after the onset of stroke, ability to walk 10 m independently (without walking aids) and understand simple motor commands. No participant presented exclusion criteria previously defined: instability of heart conditions and other adverse clinical conditions affecting balance and/or gait, pain and/or discomfort that could impede completion of the training, or expressive changes in blood pressure [13] before, during or after training. Each individual provided written informed consent prior to participation. This study was approved by the local ethics committee and registered as a clinical trial (ClinicalTrials.gov).

2.3. Experimental set up

Participants were randomly allocated for treadmill training with an ankle load (experimental group) or without the load (control group), with both undertaking daily training for two consecutive weeks (9 sessions) at the laboratory. During this period, participants were also instructed to perform load discharge exercises every day at home and encouraged to increasing use of the paretic limb during daily activities. This represented the behavioral strategies ("transfer package"), according to CIMT concepts. Load discharge exercises involved the transfer of body weight on the paretic limb in both the anteroposterior and laterolateral direction in the standing position, consisting of 3 sets of 10 repetition in each direction.

Participants were not actively involved in any kind of physical activity/rehabilitation for lower limbs during the study period. All the participants were instructed to use their usual footwear during the training. No participant used gait orthosis.

The nine training sessions (for experimental and control groups) consisted of 30-min treadmill training [14], with breaks for rest at the 10th and 20th minutes. Participants used a harness for stabilization (without unweighting) while they walked on a treadmill [14]. On first day, they were instructed to hold on to the front bar of the treadmill with the non-paretic hand, being encouraged to withdraw this support on subsequent days. The speed of the treadmill was set at the highest comfortably tolerated [14,15], which could be increased at the beginning of each new therapy session once the subject stopped using the support of the treadmill bar. Previously-trained therapists monitored posture and body alignment of participants, but without providing manual assistance. Verbal corrections and incentives were given as deemed necessary.

The experimental group performed treadmill training (equal to the control group), but using a mass attached around the non-paretic ankle, with load equivalent to 5% of the individual body weight. The load selected was similar to that used by Regnaux and colleagues [10] and is in accordance with our pilot data.

2.4. Data acquisition and analysis

At baseline, sociodemographic, clinical and anthropometric data were assessed using an identification form and neurological status was evaluated by the National Institute of Health Stroke Scale (NIHSS) [16].

Kinematic gait analysis was performed using a motion analysis system (Qualisys Motion Capture System, Qualisys Medical AB, Gothenburg, Sweden). Eight cameras and 38 passive markers were used, according to a previous study [15]. Data were captured at a frequency of 120 Hz by the QTM 2.6 acquisition software (Qualisys Medical AB, Gothenburg, Sweden). All recordings were low-pass filtered using a Butterworth filter with a 6-Hz cutoff. Later, data were processed using Visual 3D software (Visual3D Standard, C-Motion, Rockville, MD).

Data were processed and analyzed for at least five walking trials. During the walking trials, participants walked shoes along the 8-m walkway with self-selected speed [15] and without load.

Gait events (heel contact and toe-off) were defined based on the graphic representation of markers placed on the calcaneus or head of the fifth metatarsus on the Z-axis (vertical) in Visual3D software [17], for both feet.

Spatiotemporal and angular gait parameters were investigated. Primary outcomes were: speed [m/s], symmetry ratio of swing time [swing time of paretic limb/swing time of non-paretic limb] and ankle range of motion (ROM) [°] of non-paretic limb in the sagittal plane. Secondary outcomes were: paretic and non-paretic step length [m], ankle ROM [°] of paretic limb, hip and knee ROM [°] of paretic and non-paretic limbs in the sagittal plane.

Gait parameters were recorded before the interventions (baseline), immediately after interventions (post-training) and 40 days after the end of interventions (mid-term follow-up).

Before, during and after each training session, heart rate and arterial blood pressure were monitored by the therapists, using a digital sphygmomanometer (Fisomat Confort III®) and a heart rate monitor watch (Polar Care®). During training, therapists should record complaints of pain and discomfort, if present.

2.5. Sample size calculation

According to sample size calculation and using a symmetry ratio of swing time as the primary outcome measure [18], a minimum of 16 subjects would be required for each group, to detect group differences of 0.12 in the symmetry ratio (standard