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COMPARISON OF EFFECTS OF TRAINING IN A VIRTUAL ENVIRONMENT WITH AND WITHOUT PHYSIOTHERAPEUTIC INTERVENTION IN CHRONIC STROKE PATIENTS

Study Protocol

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1. Background

Stroke is the leading cause of death in some countries and the leading cause of disablity in the world (Roger 2012; Adamson 2004; *The Internet Stroke Center* 2016), significantly contributing to the increase in public health costs. In Brazil, approximately 50% of the people affected present some degree of disability (Carmo 2015) and are dependent on others due to the injury (Allen 2009; Corrêa 2005).

Patients present less symmetry between lower limbs and difficulty in weight bearing on the affected side in standing position, with consequente change in the motor function, balance and gait (Trindade 2011).

Actually there are several approuches to rehabilitation and, between then, virtual reality (VR) - technology that promotes human-computer interaction in an created environment (Laver, 2012) – is expanding in the treatment of post-stroke balance disorders, because VR promotes a motivated, challenging, task-specific and repetitive training (Chen 2016, Laver 2012; Yatar 2015; Joo 2010; Saposnik 2011). The commercial equipment Nintendo Wii Fit®, promote anterior, posterior and lateral excursiono f the center os pressure, allowing greater postural control and symmetry, besides, providing cognitive demand of the decision making to perform the motor task effectively (Crosbie, 2007; Broeren, 2008; Joo, 2010; Cameirão, 2011).

Some studies report the possibility of using this system at home, where the training could be carried out autonomously by the patients themselves, without a physiotherapist directing the training (Yatar 2015; Sugarman 2009; Deutsch 2009). However, as suggested by Yatar in 2015, this issue still controversial - different authors cite the possibility of training without supervision of the physiotherapist but discuss the lack of evidence, questioning the need of the presence of the physiotherapist intervening in the treatment, in order to guarantee patient motivation and safety (Joo 2010, Borghese 2013, Laufer 2014). Thus, there is a need to clarify the role of physical therapist assistance during balance training through VR in comparison to that performed without intervention.

2. Purpose

The aim of this study is to compare the effects of a balance training program in a virtual environment (using a gaming system with balance board device) with and without

verbal/manual physiotherapeutic intervention, on the motor function, balance and gait in chronic stroke patients.

3. Methods

It will be a prospective, single blinded, randomized clinical trial, performed at Center of Research of the Department of Speech Therapy, Physical Therapy and Occupational Therapy of São Paulo University.

Forty chronic stroke patients will be randomly in control and experimental group, 20 each one. Both groups conduct 14 training sessions, twice a week, for seven weeks. Each session will consist a 30 minute-global-exercise series including stretching, muscle strength and axial mobility exercises. After this, both groups will perform 30 more minutes of balance training using eight Wii Fit® games which stimulate motor and cognitive functions.

Patients will be assessed at the beginning, in the end and 60 days after the end of the treatment (follow-up).

3.1 Participant allocation

Patients will be randomized in two groups: Experimental Group or Control Group. Each participant must sign the Consent Form.

Forty patients will be selected according to the following criteria:

Inclusion Criteria:

- hemiparetic status resulting from a single stroke at least 6 months earlier;

- the ability to walk 10 m independently with or without an assistive device;

- a Montreal Cognitive Assessment (MoCA) score of ≥ 20;

- the absence of a musculoskeletal condition that could potentially affect the ability to stand or walk safely;

- absence of serious visual impairment or a hearing disorder;

- muscle strength ≥ 3 in lower limbs;

- ability to understand and follow simple instructions.

Exclusion Criteria:

- severe dementia or aphasia;
- hemispatial neglect, ataxia or any other cerebellar symptom;
- inability to stand without minimal assist;
- uncontrollable medical complications;
- participation in other studies or rehabilitation programs.

3.2 Procedures

3.2.1 Assessments

Both groups will be assessed before treatment, after treatment and after 60 days of the end of the treatment (follow-up).

Primary outcomes:

- The lower limb subscale of the Fugl-Meyer Assessment (FMA-LE): FMA-LE is a subscale measuring lower limb motor recovery. It examines movement and coordination of the hip, knee, and ankle in the supine, sitting, and standing positions. Each item is scored on a 3-point scale (0, cannot perform; 1, partially performs; 2, performs fully). The score range is 0 to 34, with higher scores indicating better lower limb motor performance (Fugl-Meyer, 1975; Maki, 2006).
- Balance Evaluation Systems Test (BESTest): Balance Evaluation Systems Test (BESTest) measures balance. It includes 36 items that evaluate performance of
- 6 balance systems: biomechanical constraints, stability limits/verticality, anticipatory postural adjustments, postural responses, sensory orientation, and stability in gait (Horak, 2009).
- 6-minute walk test: The 6MWT is a practical simple test. This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes (the 6MWD). The 6MWT has been used as a measure of functional status of patients (Britto, 2006).

Secondary outcomes:

- Limits of Stability: The Limits of Stability subtest quantifies the maximum distance a person can intentionally displace their center of pressure (COP) from start position of midline COP centered over the base of support to eight targets.

Location and movement of the COP was indicated by a cursor display projected on a screen in front of the subject. As targets were highlighted, the subject was to move the COP cursor quickly and accurately as possible towards a target located on the Limits of Stability perimeter and hold position as close to the target as possible. The parameters include COP movement velocity and directional control (% to target).

- Rhythmic Weight Shift: The Rhythmic Weight Shift quantifies the subject's active weight shift ability by moving the COP cursor to match velocity and direction of a moving visual target in the medial- lateral (ML) and anterior-posterior (AP) directions at three different velocities.

- Stroke specific quality of life scale: Stroke Specific Quality of Life Scale is a self-report assessment that includes 12 stroke specific subscales with 49 items. The Stroke Specific Quality of Life Scale attempts to capture the domains of stroke specific QOL that are insufficiently assessed with generic QOL measures. The 12 subscales, which are unidimensional, are Energy, Family Role, Language, Mobility, Mood, Personality, Self-Care, Social Roles, Thinking, Upper Extremity Function, Vision, and Work-Productivity. Participants responded to each item on a 5-point scale. Domain scores are the averages of the item scores, and the total score is the average of the domain scores. All summary scores therefore range from 1 to 5. Higher scores indicate better function (Williams, 1999; Lima, 2006; Lima, 2008).

3.2.2 Training

Both groups will participate of 14 individual treatment sessions, with physiotherapist supervision, twice a week, for seven weeks. Each treatment session will be composed of 30 minutes of regular physical therapy (equal to both groups), based on stretching, strenght and mobility exercises, followed by 30 minutes of balance training using a gaming system with balance board device (eight games of Nintendo Wii Fit®, for games per session).

Differences between groups are based on the type of physiciotherapist’s role in the training:

Virtual Reality Training Without Physiotherapeutic Intervention (Experimental Group) will perform a balance training program in a virtual environment (using a gaming system with balance board device - eight games of Nintendo Wii Fit®, for 14 sessions)

without verbal/manual physiotherapeutic intervention. Initially, phyisiotherapist will provide instructions about the rules and strategies of how to play the game and control the avatar. Then the patient will be invited to start the game, and in the two attempts of the training no manual or verbal assistance will be provided by the physiotherapist. Physiotherapist participation during training will be restricted to ensuring patient safety, providing motivational verbal stimuli, and replicating the feedback provided by the game at the end of each attempt.

Virtual Reality Training With Physiotherapeutic Intervention (Control Group) will perform a balance training program in a virtual environment (using a gaming system with balance board device - eight games of Nintendo Wii Fit®, for 14 sessions) with verbal and manual physiotherapeutic intervention. Initially, phyisiotherapist will provide instructions about the rules and strategies on how to play the game and control the avatar. Then the patient will be invited to start the game, and in the first attempt of the training physiotherapist will provide manual and verbal assistance, providing corrections on movement speed, direction, aceleration, amplitude, rhythm and coordination, necessary to achieve game goals (avoiding compensatory movements). In the second attempt, no manual or verbal assistance will be provided by the physiotherapist (only ensuring patient safety and providing motivational verbal stimuli, and replicating the feedback provided by the game), allowing the patient to organize his or her performance.

There will be eight games (four per session) by Nintendo Wii Fit®, selected according to the motor requirements of static and dynamic balance.

3.3 Statistical Analysis

Demographic data and clinical characteristics of the control and experimental groups will be compared using the unpaired T-test.

Results of the primary and secondary measures will be analyzed after normality test (Kolmogorov-Smirnov test), with repeated measures of variance (ANOVA), one for each dependent variable, using as a factor group (GC and GE) and the three evaluations (before treatment, after treatment and follow up), the last measure being repeated (2x3 RM-ANOVA).

The Tukey Post Hoc Test will be performed to verify any differences between effects with significance.

Significance level adopted: 5%.

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