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Original article

Effects of oculomotor and gaze stability exercises on balance after stroke: Clinical trial protocol

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ABSTRACT

Background: The inability to maintain balance after stroke is an important risk factor for falling and relates to decreased potential for recovery. The vestibular system and gaze stability contribute respectively to postural stability and to maintain balance. Rehabilitation may be more effective with domiciliary training.
Objective: This trial aims to verify if balance impairment after stroke improves with a domiciliary oculomotor and gaze stability training program.
Methods: Individuals older than 60 years, discharged after suffering brain stroke with referral to the physiotherapy department, will be assessed for orthostatic balance. Patients with stroke diagnosis 3–15 months before recruitment, positive Romberg test and able to walk 3 m alone are invited to participate in this randomized controlled trial. Participants will be allocated in two intervention groups through block randomization, either the current rehabilitation program or to a supplemental intervention focused on oculomotor and gaze stability exercises to be applied at home twice a day for three weeks. Primary outcome measures are the Motor Assessment Scale, Berg Balance Scale and Timed Up and Go Test. Trial registration: ClinicalTrials.gov (NCT02280980).
Results: A minimum difference of four seconds in the TUG and a minimum difference of four points in BBS will be considered positive outcomes.
Conclusions: Oculomotor and gaze stability exercises may be a promising complement to conventional physiotherapy intervention after brain stroke, improving the balance impairment.

Introduction

Stroke is one of the major causes of long-term disability in the adult; balance deficits occurring after stroke are strongly associated with more severely impaired motor function and a decrease in recovery potential.[1,2]

In patients who have had strokes with inability to maintain balance, either in a static or in a dynamic way, it could be associated with the impairment to select reliable sensory information from different sources (visual, vestibular and somatosensory systems) in order to maintain postural stability using a correct motor pattern.[3,4] Both postural imbalances after stroke and gait disorders are important risk factors for falls.[5] The high incidence of falls in these patients is well documented in the literature, as well as its social and economic impact.[6]

The vestibular system contributes to postural stability and visual stabilization through the vestibulo-spinal reflex (VSR) and the vestibulo-ocular reflex (VOR), respectively.[7]

VOR is the first mechanism of gaze stability. During head movements, the VOR stabilizes gaze (eye position in space), generating eye movements of equal speed and opposite direction to the movement of the head[8] to allow an adequate visual acuity,[9] while the VSR contributes to maintain postural stability activating contraction of the antigravity muscles.[7]

Gaze stability is needed to coordinate the movements of the head, trunk and pelvis during walking.[10] Individuals after stroke have been described to exhibit abnormal coordination of axial segments and pelvic rotations during head rotation, which can contribute to changes in balance during gait.[11] The decrease in stability of the trunk and head after stroke also causes a lack of quality in visual information, which may cause impaired balance.[11]

Abbreviations: VSR, vestibulo-spinal reflex; VOR, vestibulo-ocular reflex; BBS, Berg Balance Scale; TUG, Timed Up and Go Test; RCT, randomized controlled trial; MAS, Motor Assessment Scale.

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Gaze stability exercises have been described to improve postural stability in healthy young adults,[12] improve balance and subjective confidence to carry out the activities of daily life in a healthy elderly population[13] and to decrease the perception of disability in individuals with unilateral vestibular deficit.[14] It has been suggested that VOR adaptation exercises have influence on the alignment of the head, resulting on improvements in the overall perception of balance, expanding the limits of stability.[15] The improvements achieved with these exercises in different clinical conditions were not associated with gender,[16] age[16,17] and time of onset of symptoms,[17] therefore it may be assumed that they can be used both in chronic conditions and in the elderly.[17]

Oculomotor and gaze stability exercises are easy to learn, therefore, after supervised training, they can be performed at home,[13] autonomously or with minimal supervision, as a complement to institution-based rehabilitation programs. Domiciliary training programs allow exercising at least twice a day, seven days a week, giving ground to quicker, more complete recovery.

This trial aims to verify if balance impairment after stroke improves with a domiciliary oculomotor and gaze stability training program for senior patients.

Methods

Design

Non-blinded, randomized controlled trial (RCT) (Fig. 1).

Patient population

Individuals older than 60 years, discharged after suffering brain stroke with referral to the physiotherapy department outpatient clinic of a tertiary care hospital (Centro Hospitalar de Lisboa Central).

Outcome measures

Primary outcome measures are:

1. The variation in the Berg Balance Scale (BBS) score from baseline after suffering a brain stroke up to three weeks of intervention and its association to the home-based program of oculomotor and gaze stability exercises, and
2. The variation in the Timed Up and Go Test (TUG) from baseline after suffering a brain stroke up to three weeks of intervention and its association to the home-based program of oculomotor and gaze stability exercises.

Participants

Recruitment

Individuals are eligible for the trial if they fulfill the following inclusion criteria:

- Brain stroke diagnosed 3–15 months prior to recruitment,
- Verified presence of impaired balance (positive Romberg test), and
- Ability to walk at least 3 m alone with or without an assistive device.

Individuals are not eligible if:

- The balance problems are previous to the brain stroke,
- The ability to perform the proposed exercises is compromised by severe osteo-articular disease, or
- They had previous experience with oculomotor or gaze stability exercises.

Randomization

After the initial assessment, participants will be allocated in two intervention groups through block randomization with stratification by age, functionality and balance. Three age groups will be considered: 60–69 years, 70–79 years and ≥80 years. Patients will be stratified by their functionality into three categories, according to the score of the Motor Assessment Scale (MAS): major dependence (score below 16), moderate dependence (score between 17 and 32) and minor dependence (score over 33), and by their balance into two categories, according to the predictive cut-off points for falling using TUG[18] and BBS[19]: no risk of falling (TUG < 14 s and BBS > 45) or with risk of falling (TUG > 14 and/or BBS < 45).

Sample size

The sample size was estimated considering the ability to identify (power 90% and confidence 90%) either a minimum increase of four points in BBS[20] or minimum decrease of four seconds in TUG.[20,21] The estimated minimum sample size to detect four seconds of difference in the TUG in individuals with the target population characteristics is 18 elements. The estimated minimum sample size to detect a difference of 4 points in BBS in individuals with the target population characteristics is 66 elements, thus this will be the estimated target sample size.

Study procedures

After checking for eligibility criteria, the patients will be invited to participate and informed, written consent will be obtained.

Participants will have a baseline assessment with MAS (to access the level of dependence), BBS and TUG (to access balance). Furthermore, demographic and clinic information will be collected by interview and confirmed by consulting the previous clinical records (when available), including the date of the stroke, location, laterality and etiology, and participants will be asked about previous balance problems, treatments with oculomotor or gaze stability exercises, severe osteo-articular problems, gait ability, number of falls after stroke, and present therapies.

The rehabilitation program for stroke patients, in this unit, is customized according to the patient problems and based on the professional's clinical reasoning supported in the knowledge of neurophysiology, motor control, biomechanics and motor learning theories,[22] using a mixture of components from several different approaches.[23]

Participants will be randomly assigned to either the usual rehabilitation program only or to the program with a supplemental intervention, to be applied at home for three weeks, as used in the study of Morimoto and colleagues.[12]

Participants in the supplemental intervention group will be taught a set on oculomotor and gaze stability exercises (Table 1) and will receive a leaflet and a logbook. When the participants have difficulties in learning or performing the exercises by themselves, a caregiver will be required to collaborate.

The supplemental exercises will be reviewed every week with the participants to check the compliance with the home program, to clarify doubts and to register difficulties or possible adverse effects.

After three weeks, every participant will be submitted to a balance assessment (BBS and TUG) and will be asked about the number of falls that occurred. The participants in the supplemental intervention group will be asked to return the logbook to the investigators.

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