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Clinical Rehabilitation

Improvement in balance using a virtual reality based stepping exercise: a randomized controlled trial involving individuals with chronic stroke

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Abstract:

Objective: To study the clinical effectiveness and the usability of a virtual reality based intervention compared to conventional physical therapy in the balance recovery of individuals with chronic stroke.
Design: Randomized controlled trial
Setting: Outpatient neurorehabilitation unit
Participants: Twenty individuals with chronic stroke.
Interventions: Participants were randomly assigned to either an experimental group or a control group. The intervention consisted of 20 one-hour sessions, 5 sessions per week. The experimental group combined thirty minutes with the virtual reality-based intervention with thirty minutes of conventional training. The control group underwent one hour conventional therapy.
Main measures: Balance performance was assessed at the beginning and at the end of the trial using the Berg Balance Scale, the balance and gait subscales of the Tinetti Performance-Oriented Mobility Assessment, the Brunel Balance Assessment, and the 10-Meter Walking Test. Subjective data were collected from a feedback questionnaire at the end of the trial.
Results: The results revealed a significant group-by-time interaction in the scores of the Berg Balance Scale ($p<0.05$) and in the 10-Meter Walking Test ($p<0.05$). Post-hoc analyses showed greater improvement in the experimental group, also in the Brunel Balance Assessment ($\chi 2=2.5$, $p<0.01$). The feedback score was 55.7±3.4 (range: 15-65).
Conclusions: The training of the stepping strategy through VR interventions that satisfy the motor learning principles can enhance the balance recovery in individuals with chronic stroke. Subjective data also revealed positive results regarding presence, comfort, and enjoyment.

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Results: The results revealed a significant group-by-time interaction in the scores of the Berg Balance Scale ($p<0.05$) and in the 10-Meter Walking Test ($p<0.05$). Post-hoc analyses showed greater improvement in the experimental group: 3.8±2.6 vs 1.8±1.4 in the Berg Balance Scale, -1.9±1.6 s vs. 0.0±2.3 s in the 10-Meter Walking Test, and also in the number of participants who increased level in the Brunel Balance Assessment ($\chi 2=2.5$, $p<0.01$). The feedback score was 55.7±3.4 (range: 15-65).

Conclusions: Virtual reality interventions can be an effective and usable resource to enhance the improvement of balance in individuals with chronic stroke.

Improvement in balance using a virtual reality based stepping exercise: a randomized controlled trial involving individuals with chronic stroke

Introduction

Initial reports point out that the introduction of virtual reality technology in the rehabilitation process can provide therapists with new and effective tools for the treatment of individuals with stroke[1] and for their assessment with objective data.[2] According to these reports, these interventions can also provide extra motivation, which has been associated with an increase in the adherence to the treatment.[3] In the last few years, an increasing number of studies have focused on motor rehabilitation. Great efforts have been made on the rehabilitation of the upper limb.[1, 4] However, the application to balance rehabilitation has not been exploited to the same extent[5]. But still, several studies involving balance rehabilitation can be found in the literature. Weiss et al. adapted a chroma key system for rehabilitation. This system has been used in different pathologies with different objectives, including balance rehabilitation in individuals with stroke.[6] Moreover, systems that are based on force platforms have been used in rehabilitation programs to assess and improve balance.[7-9]

Basing on the existing evidence, we developed a virtual reality-based exercise to train balance and postural control disabilities that individuals with stroke can present. The exercise has been previously tested in non-randomized stroke population with promising results.[10, 11] This paper describes a randomized controlled trial that studies the clinical effectiveness and the usability of the experimental intervention to improve standing balance in individuals with chronic stroke through the training of step strategy.

Methods

All the eighty-three outpatients who had sustained a stroke and were attending a rehabilitation program were the potential participants in this study. The inclusion criteria were 1) hemiparesia; 2) age ≥ 40 years old and ≤ 70 years old; 3) chronicity >

six months; 4) absence of cognitive impairment (Mini-Mental State Examination[12] cut-off > 23); 5) able to follow instructions; and 6) ability to maintain stride-standing position for 30 s without holding onto or assistance from another person as specified in the Brunel Balance Assessment, section 3, level 7.[13] The exclusion criteria were 1) individuals with severe dementia or aphasia (Mississippi Aphasia Screening Test[14] cut-off < 45); 2) individuals whose visual or hearing impairment did not allow the possibility of interaction with the system; 3) individuals with hemispatial neglect; and 4) individuals with ataxia or any other cerebellar symptom.

The clinical trial was conducted through the specialized neurorehabilitation service of a large metropolitan hospital. All participants agreed to take part in the study and provided an informed consent. Ethical approval for the study was granted by the Institutional Review Board at Hospitales NISA, Spain.

All of the subjects were randomly assigned to a group. The randomization schedule was computer-generated using a basic random number generator. The allocation sequence was concealed from an independent researcher. Each participant underwent a total of twenty one-hour rehabilitation sessions, five days a week for four weeks. In each session, the participants belonging to the control group underwent one hour of conventional physiotherapy (Appendix A). In this group, exercises were administered consecutively in single ten-minute repetitions and one-minute breaks were allowed between the repetitions. Participants belonging to the experimental group combined 30 minutes of conventional therapy with 30 minutes of training with the virtual rehabilitation system (Appendix B) in that order. In this group, the exercises of conventional therapy were administered consecutively in single five-minute repetitions and the training with the virtual rehabilitation system consisted of three nine-minute repetitions with one and a half minute breaks between them.

The participants were assessed by the same blinded therapist at the beginning and end of the training with a battery of standardized clinical tests that included the Berg Balance Scale[15] as a primary outcome, and the gait and balance subscales of the Tinetti Performance-Oriented Mobility Assessment,[16] the Brunel Balance Assessment, and the 10-Meter Walking Test[17] as secondary outcomes (Table 1).

Insert Table 1 about here

In addition to the motor scales, an adaptation of the Short Feedback Questionnaire[18] was also used as a secondary outcome to obtain information about the subjective responses of the participants to the virtual experience.

Data analysis

Demographical and clinical comparisons between the experimental group and the control group were performed with independent sample t-tests and Chi-squared or Fisher exact tests, as appropriate. Repeated measures analyses of variance (ANOVAs) with time (before and after treatment) as the within-subjects factor and treatment option (control vs. experimental) as the between-subjects factor were performed for the quantitative scales. The main effects of time, treatment option and the time-treatment option interaction effects were evaluated. For each repeated measures ANOVA, we present the partial eta squared (η^2_p) as a measure of effect size; values may range between 0 and 1, with higher values representing higher proportions of variance explained by the independent variable. Simple contrasts were conducted for each significant time main effect to determine the source of the significant difference. A Chi-

square test was performed to compare the percentage of participants from the two groups who improved their level in the Brunel Balance Assessment after treatment.

The α level was set at 0.05 for all analyses. All analyses were computed with SPSS for Mac, version 15 (SPSS Inc., Chicago, USA).

Results

After the inclusion-exclusion criteria, a final consecutive sample of twenty-two participants remained from the total pool (Figure 1). Sample size requirements were estimated according to preliminary studies (power=70%, α=0.05, loss rate=10%).[10, 11] One subject from the experimental group who suffered a recurrent stroke and one subject from the control group who developed epilepsy dropped out of the treatment; consequently, their data are not included (Table 1).

Insert Figure 1 about here

Insert Table 1 about here

No significant differences in demographical (age, gender, education, weight, height, body mass index) or clinical (chronicity, etiology) data at inclusion were detected between the groups (Table 1). An independent t-test also revealed no significant difference in the clinical scales at the baseline ($p>0.05$).

Repeated measures ANOVA at the beginning and at the end of the clinical trial revealed that both groups significantly improved their scores in the Berg Balance Scale ($p<0.01$, $\eta^2_p=0.6$) and in the 10-Meter Walking Test ($p<0.05$, $\eta^2_p=0.2$) during the therapy (time effect) (Table 2). No group effect was detected for any outcome, which confirms the comparability of the two groups. In addition, significant group-by-time

interactions were detected in the scores of the mentioned scales ($p<0.05$, $\eta^2_p=0.2$; and $p<0.05$, $\eta^2_p=0.2$, respectively), indicating that the experimental group showed effective gains in balance (Berg Balance scale) and gait velocity (10-Meter Walking Test) attributable to the intervention. With respect to these variables throughout the therapy, post-hoc analysis showed greater improvement in the experimental group when compared to the control group (3.8±2.6 vs. 1.8±1.4, and -1.9±1.6 s vs. -0.0±2.3 s, respectively).

Insert Table 2 about here

For the Brunel Balance Assessment, three participants from the experimental group and only one participant from the control group increased their level on this scale at the end of treatment. Two participants from the experimental group increased one level, and another participant increased from level 9 (section 3) to level 12. The only participant in the control group who improved, scored 9 at baseline and 10 at the end of treatment.

The global usability score was 55.7±3.4 (range 49-61). According to these results, participants described the experience as enjoyable (4.1±0.6), felt a marked sense of presence during their virtual experience (4.3±0.9), were aware of their success (3.9±1.0), and showed good control of their movements in the virtual scenario (3.8±0.4). Moreover, the participants perceived the virtual environment as being realistic (3.7±0.8), understood the computer feedback quite well (4.5±0.5), and considered the therapy to be useful (4.7±0.5). None of the participants experienced any significant side effect during their performance. In fact, the scores regarding comfort (4.6±0.7), dizziness (4.8±0.4), visual discomfort (5.0), and disorientation (4.4±1.1) were

high. Overall, the participants did not perceive great difficulties while performing the task (3.6±0.8) or using interface devices (4.3±0.7).

Discussion

According to our results, the experimental training using a virtual reality-based stepping exercise is effective and represents a usable resource for improving balance and gait speed in stroke population. Patients in the experimental group showed statistically significant improvements in the Berg Balance Scale and in the 10-Meter Walking Test compared to the conventional group. In addition, a significant number of patients from the experimental group decreased their balance disability as measured by the Brunel Balance Assessment. The discrete nature of this scale, the ceiling effect detected in our sample, and the limited period of treatment could have prevented even greater differences in improvement between the two groups.

The clinical improvements reported here confirm the positive relationship between balance function and other aspects of functional mobility and gait previously published.[6, 19] The stepping exercise replicates the load-unloading sway strategy at the hip increasing its speed and precision. These abilities are important for many daily activities, such as walking (one-leg support phase).[20] Previous studies also suggest the importance of balance ability besides muscle strength as an important determinant of performance in gait functions in individuals with stroke.[21]

The results in the Tinetti tests could be explained by the psychometric properties of these scales. Five of the twenty participants had already reached the maximum value of the balance subscale in the initial assessment, and six of them had already reached the maximum in the gait subscale. However, none of the participants had reached the top score in the Berg Balance Scale. This could explain the different sensitivity of the two

tests in detecting changes in the condition of the participants. These effects are consistent with previous non-randomized studies,[10, 11] which have also revealed training-related benefits in more objective measures such as computerized dynamic posturography.[11] The specificity of the stepping exercise could also explain the changes detected in the speed (10-Meter Walking Test) but not in the quality of gait (gait subscale of the Performance-Oriented Mobility Assessment).

Our results suggest that the virtual reality-based intervention can promote the acquisition of the motor strategies needed to perform the fast and safe postural changes that are necessary to confront the changing environmental stimuli that threaten stability. This training can directly improve stability and balance and indirectly improve the safety and gait speed of the chronic stroke population. Although there is a great body of research supporting the benefits of balance rehabilitation, there is still no consensus in what the best practices are. From a clinical point of view, one of the challenges is to identify methods and environments that promote motor learning, taking into account the particular clinical condition of individuals and their chronicity. It has been proved that learning-dependent brain changes, especially in the chronic stages, are driven by meaningful, motivating, skillful, challenging, and rewarding practice. Novel virtual reality-based interventions could promote skill acquisition, not only of balance but also of gait.[6, 22] However, the transfer of the improvement acquired in the trained skill to activities of daily living or even to other very similar tasks remains a challenge for rehabilitation programs.

In addition, according to the results of the usability questionnaire, the virtual rehabilitation exercise was highly motivating and immersive, and it actively involved the participants in their rehabilitation.

The limitations of our study must be taken into account when analyzing the results. First, although the sample size was similar to other studies,[1] twenty-two participants can be considered a small sample. Second, because the study does not include follow-up data, the persistence of the benefits provided by the virtual training cannot be evaluated. However, previous non-randomized studies revealed maintenance of gains one month after the training in all the scales.[10, 11] Finally, the characteristics of the sample are inherently linked to the specialized neurorehabilitation center where the study took place, which could restrict the generalizability of the results. Despite these limitations, this randomized controlled trial has demonstrated the clinical effectiveness and the usability of virtual reality as an adjunct in stroke rehabilitation at chronic stage.

Clinical messages

- Virtual reality based interventions that promote motor learning mechanisms may offer additional benefits to balance recovery compared with conventional therapy in hemiparetic individuals with chronic stroke.
- Virtual task-oriented exercises can be enjoyable and motivating, as well as usable.

Appendix A – Description of the conventional balance intervention

The conventional balance training consisted of one-on-one exercises including: 1) static standing exercises in different positions (Romberg position, tandem stance, single stance, etc.) using verbal, visual, and perceptual cues to increase weight bearing to the affected lower limb; 2) task-specific reaching exercises involving ankle and hip strategies to increase limits of stability and balance confidence; 3) stepping tasks to increase weight transfer and improve stepping strategies which are essential to avoid falls; 4) static and dynamic balance exercises including arm activities during functional tasks to improve balance self-confidence in daily activities; and 5) walking exercises under different conditions (obstacle course, indoor and outdoor walking, stair climbing, etc.).

At the beginning of the session of each participant, an experienced physical therapist established the difficulty of each exercise according to his/her particular needs, condition, and evolution along the program.

Appendix B – Description of the virtual rehabilitation intervention

The virtual rehabilitation intervention was based on providing audiovisual feedback while performing a stepping task, which was graduated in difficulty according to the motor condition of each participant.

The general hardware set-up consisted of a standard computer, an audio-visual output system, and a motion tracking system. The output system consisted of a video display and an audio system. The virtual rehabilitation system enabled positional audio, thus providing 3D audio stimuli with a proper configuration of speakers. With regards to the motion tracking system, two OptiTrack FLEX:C120 (NaturalPoint, OR) cameras at 100 Hz were used to estimate the 3D position of two reflective spherical markers, which were fixed to the participants' insteps using Velcro strips (Figure 2).

Insert Figure 2 about here

The exercise immersed the participants in a 3D virtual environment. In the virtual world, the participants' feet were represented by two shoes that mimicked their movement in the real world. Initially, both shoes appeared in the center of the virtual environment inside a circle, around which some items rose from the ground. The objective of the task was to reach the items with one foot while maintaining the other foot within the circle. In order to facilitate the understanding of the task and the perception of presence in the virtual world, both the environment and the avatar were very simple and were also powered with visual cues. A third-person view, which allowed the participants to see the virtual items all around them, was used.

A management tool allowed therapists to define the training sessions by adding different repetitions and configuring their duration and break times. The level of difficulty of the exercise was also configurable by tuning a set of parameters, such as distance, lifetime, size, region of appearance, and number of simultaneous items. This way, the session could be customized for each participant, adapting the training to his/her particular combination of impairments. In addition, the management tool allowed therapists to define pre-established levels of difficulty (Table 3) and the system automatically increased or decreased the level of difficulty depending on the participant's performance.

Insert Table 3 about here

Before their first training session, each participant received instruction in the common usage of the system, watched a demo, and finally carried out a test session. The most fitting level of difficulty for each participant was determined in this session basing on their motor condition. During the trial, the exercise automatically increased the level when the participants performed the activity with a success rate of 80% or more and decreased the level with a lower success rate of 20%.

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Tables

Table 1 Characteristics of the participants

Issue	Control group (n=10)	Experimental group (n=10)	Significance
Gender (n, %)			
Male	5 (50%)	4 (40%)	NS (p=0.6)
Female	5 (50%)	6 (60%)	
Age (years)	55.0 ± 11.6	58.3 ± 11.6	NS (p=0.5)
Education (years)	13.0± 3.9	10.7 ± 4.3	NS (p=0.2)
Weight	72.8±13.0	80.1±11.9	NS (p=0.2)
Height	1.62±0.1	1.66±0.1	NS (p=0.4)
Body mass index	27.8±4.8	28.8±3.1	NS (p=0.5)
Etiology (n, %)			
Ischemic stroke	6 (60%)	7 (70%)	NS (p=0.6)
Haemorrhagic stroke	4 (40%)	3 30%)	
Chronicity (days)	587.6±222.1	407.5±232.4	NS (p=0.1)

The table shows the characteristics of the participants. Age, education, and chronicity are defined in terms of mean and standard deviation. Etiology and gender are also expressed as a percentage of the total number of participants. *p<0.05, **p<0.01. NS: non-significant.

Table 2 Clinical data

	Before treatment	After treatment	Difference (95% CI)	Significance (p, effect size)
Berg Balance Scale				
Control	44.4±7.0	46.2±5.7	1.8±1.4 (0.8 to 2.8)	GxT*(F=4.5, p=0.047, η^2_p=0.2); T**(F=35.6, p=0.000, η^2_p=0.6)
Trial	47.2±6.7	51.0±4.6	3.8±2.6 (1.9 to 5.6)	
Tinetti Performance-Oriented Mobility Assessment - Balance				
Control	13.8±1.7	13.2±1.9	-0.6±1.7 (-1.8 to 0.6)	NS
Trial	14.0±3.0	15.2±0.8	1.2±2.4 (-0.5 to 2.9)	
Tinetti Performance-Oriented Mobility Assessment - Gait				
Control	10.8±2.8	10.3±1.7	0.5±2.0 (-1.9 to 0.9)	NS
Trial	10.1±2.0	10.7±1.8	0.6±0.7 (0.1 to 1.1)	
10-Meter Walking Test (s)				
Control	17.0±10.9	17.0±10.1	0.0±2.3 (-1.7 to 1.6)	GxT*(F=4.4, p=0.048, η^2_p=0.2); T*(F=4.7, p=0.043, η^2_p=0.2)
Trial	13.4±6.4	11.5±5.3	-1.9±1.6 (-3 to -0.7)	
Brunel Balance Assessment				
Control				(χ^2 =2.5, p=0.007)
Level ≤ 9	2 (20%)	1 (10%)	-1	
Level = 10	1 (10%)	2 (20%)	1	
Level = 11	3 (30%)	3 (30%)	0	
Level = 12	4 (40%)	4 (40%)	0	

Trial			
Level ≤ 9	2 (20%)	1 (10%)	-1
Level = 10	0 (0 %)	0 (0 %)	0
Level = 11	2 (20%)	1 (10%)	0
Level = 12	6 (60%)	8 (80%)	2

Numerical data of the scales and tests. Repeated measures analyses of variance (ANOVAs) were performed for the quantitative scales. The results are given in terms of mean and standard deviation, within group mean difference with 95% confidence interval and partial eta squared (η^2_p). Chi-square test was performed for the Brunel Balance Assessment, and their results are given as the number of participants and percentages of the total sample. CI: confidence interval. G: group effect. T: time effect. GxT: group-by-time effect. *p<0.05, **p<0.01. NS: non-significant.

Table 3 Difficulty levels

Level	Number of simultaneous items (n)	Distance to item (cm)		Item lifetime (s)		Item size (cm)	
		min	max	min	max	min	max
1	1	30	30	5	10	15	20
2	1	40	40	10	10	15	20
3	1	50	50	10	10	15	20
4	1	50	50	10	10	10	10
5	1	50	50	3	3	10	10
6	2	50	50	10	10	15	20
7	2	50	50	10	10	10	10
8	2	50	50	3	3	10	10
9	3	60	60	3	3	10	10

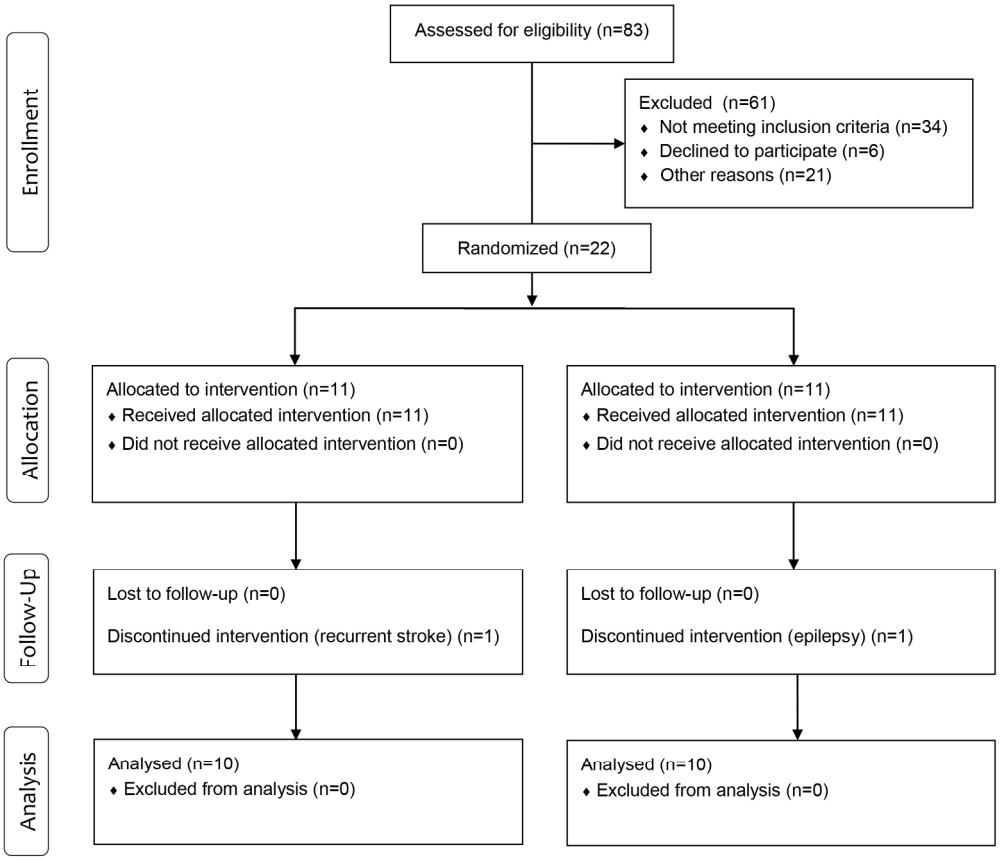
The table shows the specifications of nine different levels of difficulty. The features considered to configure the levels were the number, distance, size, and lifetime of the items. Distance was defined from the center of the virtual environment to the item. Lifetime defined the time since the item appeared to it disappeared.

Figures

Figure 1 – Flow diagram of the study

Figure 2 – Patient training with the system

The figure shows a participant training with the system. The patient wears two reflective markers that are located by the two infrared cameras of the set-up. The positions of the markers in the real world are transferred to the virtual world, where they are represented by two shoes that mimic the movements of the patient's feet.



196x169mm (300 x 300 DPI)

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568x353mm (72 x 72 DPI)