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A Prospective, Randomized Trial to Evaluate the Efficacy of Virtual Reality Treatment Versus Traditional Balance Treatment in Patients with Stroke

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Abstract: Recovery from stroke needs different time and speed in every case depending on the brain capacity of neural plasticity. Based on neurophysiological researches high repetition of practice is required to induce neuroplastic changes and functional recovery of motor deficits. However, data from earlier studies shows that stroke patients generally perform a very limited number of movement repetitions in traditional therapy sessions. Virtual Reality therapy was found to be beneficial in improving trunk, hand, upper and lower extremity functions. However, reviews found no definitive conclusions regarding balance. The present study focuses on evaluating the efficacy of Nintendo Wii™ on balance and gait functions of stroke patients. Twenty one hemiparetic stroke patients were randomly assigned to either control or therapy groups. Effectiveness was evaluated by Fugl-Meyer balance subtest, Functional Ambulation Categories (FAC), Romberg (R), sharpened Romberg (SR), one-legged stance (OLS), six-meter walking test (6MWT) and timed up and go test (TUG). The analysis revealed a significant effect of training with Nintendo Wii™ for FAC $z = 0.0267$, FMBS $z = 0.0046$, OLST2 $z = 0.0068$ and OLS1 $z = 0.0067$ (affected side). The control group demonstrated improvement in R ($z = 0.0474$) and SR ($z = 0.0411$). In both groups improvement was detected in functional mobility and 6MWT (control group $z = 0.0069$, Wii groupz = 0.0123). No significant differences were found between groups. Findings of the current study support that balance treatment with Nintendo Wii™ is similarly effective method to improve static balance and functional mobility when compared with conventional therapy.

Key words: Nintendo Wii™, stroke, dynamic balance, rehabilitation, video game.

1. Introduction

Recovery of stroke patients is extremely heterogeneous and depends on the capacity of neural plasticity [1].

Balance between cell-intrinsic mechanisms and extrinsic regulatory molecules, that are controlled by activity-dependent processes of different kinds of interaction with the external world [2, 3] are behind the plastic properties of the brain [1]. Observational data showed that stroke patients generally perform a very limited number of movement repetition in traditional therapy sessions [4]. One proposed method for increasing the time of movement repetition is the virtual reality (VR) training. VR training is supposed to be a specific model of task-oriented motor learning. It is generally defined as technological intervention that alters properties of the physical world using multisensory stimulus, immediate sensory feedback on patients' movement and grading. Findings from animal studies suggested that optimalisation of motor learning [5-7] can be reached throughout immediate feedback and grading of tasks. Effectiveness of task specific training has been proven in the domains of activity. Walking speed and distance are increased [8]. In addition, research with animals and humans indicates that intensive task-oriented practice [1] induces cortical reorganisation [9, 10]. Training in Enriched

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Environment (EE) results in better performance of functional tasks than training in basic environments [7, 11, 12]. Also EE has been found to strongly promote functional motor recovery [1, 6, 7, 12]. Wii-based balance training has been found to be capable of stimulating cerebral plasticity [1, 14, 15]. Also changes in the reorganization of neural networks were observed in neurological diseases by VR [16]. VR therapy has been proven to be beneficial in body function and structure according to the International Classification of Functioning, disability and health model (ICF). It contributes to better hand [16], upper [17] and lower extremity functions [18]. Insufficient evidence was found about the effect on gait function and balance [6, 7]. A small number of randomized controlled trials (RCT) exist without clear evidence that virtual reality is more effective than "conventional therapy" (CT) in improving walking ability. As well as walking ability is one of the key element of the activity of daily living (ADL). This study focuses on evaluating the efficacy of Nintendo Wii™ on balance and gait functions in stroke patients. The purpose of this RCT was to compare VR therapy to conventional balance treatment (CBT) among hemiparetic stroke patients. We hypothesized that in patients with mild to moderate spasticity, balance training with Nintendo Wii could be superior to conventional interventions resulting in better outcomes of balance and gait functions.

2. Methods

This study received approval from the Human Research Ethics Committee of the University of Debrecen under process number HRB/052/00514-2/ 2013.

2.1 Study Design

A randomized controlled clinical trial was carried out at the Department of Medical Rehabilitation and Physical Medicine, Faculty of Medicine, University of Debrecen. Participants were randomly allocated to a control and an experimental group by draw. The flow of this study is shown in Fig. 1. The participants were evaluated in two visits: the first one for screening within one week before the randomization, the second one week after the last therapy session.

2.2 Participants

21 hemiparetic stroke patients took part in the study, ten in the control and eleven in the experimental group.

2.3 Inclusion Criteria

Patients with residual hemiparesis caused by stroke with mild to moderate spasticity in lower extremity muscles (MAS 1-3), good muscle strength (at least 3 in a five point rating scale) in the antigravity muscles (gluteal muscles—medius and maximus—and femoral quadriceps) and independent walking ability indoor with or without assistive device were included.

2.4 Intervention

Patients met the inclusion criteria after the initial evaluation were randomly allocated to 2 groups. Both groups participated in 30 minutes balance therapy per day every weekday in a two-week period. The control group received conventional balance therapy focusing on trunk stabilization (Proprioceptive Neuromuscular Facilitation) and weight shifting in light of patients' ability in the same time frame. The experimental group was assigned to balance training with Nintendo Wii™ Fit gaming system to practise balance and improve postural gait stability. During the intervention, four games were carried out in order to train balance and coordination (Heading, TableTilt, Penguin Slide and Tight Rope) each was repeated three times under the supervision of a physiotherapist. Besides this, both groups were treated with conventional physical therapy (muscle strengthening, endurance exercise and practicing functional movements) for one hour every weekday.

2.5 Measurements

Effectiveness was evaluated by functional mobility,

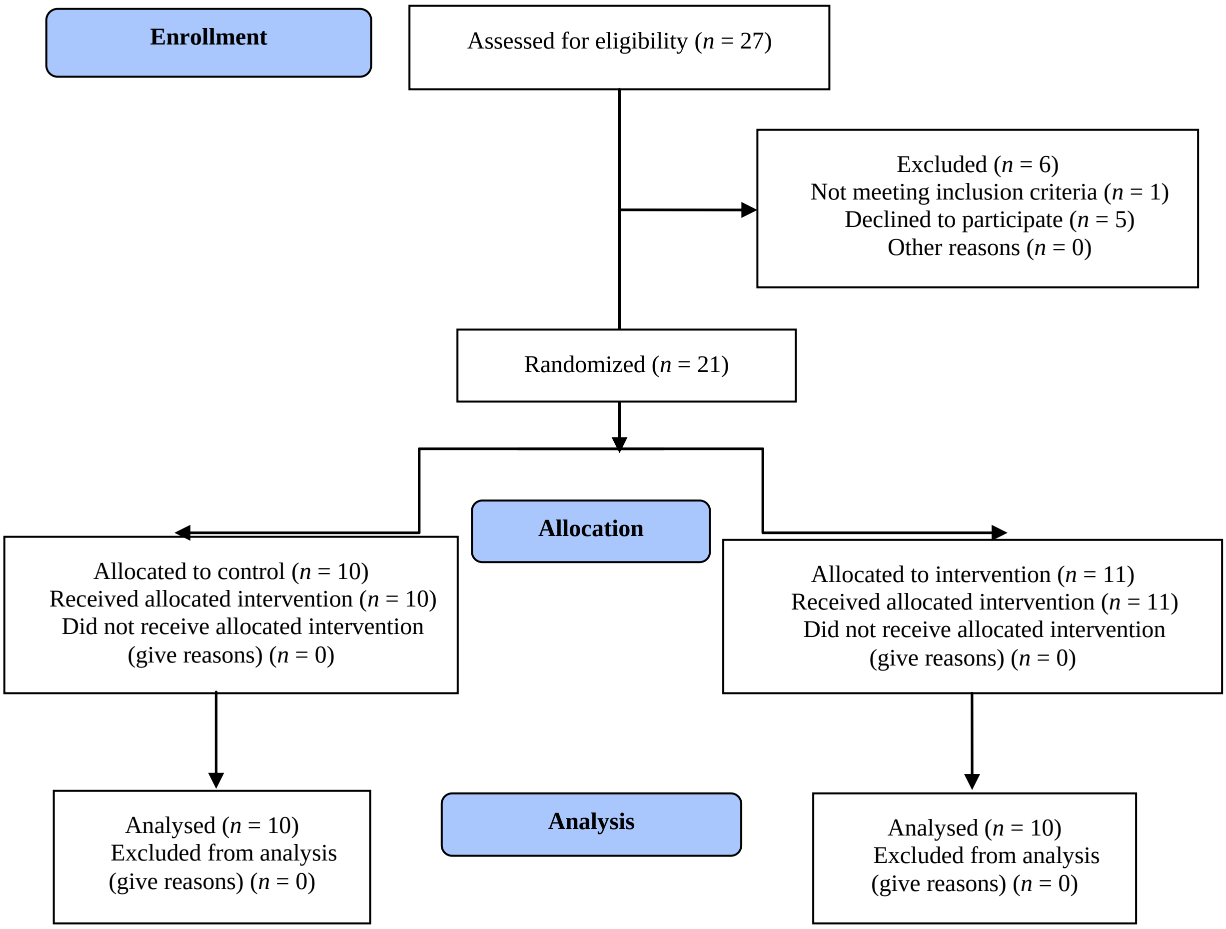

Fig. 1 Four phase flow-diagram for study design, showing the number of patients enrolled, screened, randomized and analysed.

dynamic and static balance test. All participants completed the Fugl-Meyer balance subtest (FMBS), Functional Ambulation Categories (FAC), one-legged stance (OLS), Romberg (R), sharpened Romberg (SR), six-meter walking test (6MWT) and timed up and go test (TUG). The primary outcomes were the Fugl-Meyer balance subtest, Functional Ambulation Categorization (FAC) and measurement of functional mobility (6MWT, TUG). The secondary outcomes were the static balance tests (R, SR, OLS).

2.6 Statistical Analysis

Data analysis was done by the Statistical Package in the Social Science (SPSS system) version 18. Scores of clinical scales, age and sex were summarized using non-parametric statistics, reporting mean, standard deviation (SD), min and max. The data were compared between the two groups using Mann-Whitney U test at baseline for verifying the homogeneity of the two groups and at the end of treatments for assessing the potential differences in changes. Also data were analyzed for differences in the changes within groups by Wilcoxon signed rank test. In all analyses, the null-hypothesis was rejected when the probability value was less than (or equal to) 0.05.

3. Results

3.1 Epidemiological and Clinical Characteristics of the Patients

21 stroke patients participated in the study 14 men ($N = 7$ in the Wii group) and 7 ($N = 4$ in the Wii group) women. The mean age was 59.45 years (range 37 to 78 years). All participants had spastic hemiparesis, twelve

of them on the right-side (7 and 5 in Wii and control groups, resp.). There were no significant imbalances between groups with respect to gender and affected side. Patients randomized to the control and Wii groups were almost at the same age (mean age 58.11 years versus 60.55 years) and did not have significant differences in the static (R, SR,) and dynamic balance function (FMBS and TUG) at baseline. There were small differences between the control and the Wii groups in the OLST1, OLST2 and walking distance (6MWT). The control group achieved 4 and the Wii group presented 3 in FAC at baseline. However, the differences between the two groups were not significant in these parameters. Baseline characteristics are presented in Table 1.

3.2 Primary and Secondary Outcomes

The analysis revealed a significant effect of training with Nintendo Wii™ for FMBS z = 0.0046 and FAC z = 0.0267. Moreover, meaningful improvement was found in secondary outcomes, OLST2 z = 0.0068 and OLS1 z = 0.0067 (affected side) as well. The control group demonstrated improvement in static balance, R (z = 0.0474) and SR (z = 0.0411). In both groups, we observed an improvement in functional mobility, 6MWT (control group z = 0.0069, Wii group z = 0.0123) (Table 2).

We didn't find significant differences between groups. Remarkable improvement was detected in OLST1 (139.5 versus 91.5 z =0.1840), OLST2 (121.5 versus 109.5 z =0.9714) in the therapy group with larger non-significant changes in OLST1. Significant improvement was found in FAC (127.5 versus 103.5 z =0.5973), but the changes were not significantly higher and FMBS (141.4 versus 89.5 z =0.1352) with greater non-significant changes in the therapy group. We found meaningful improvement in R (114 versus 116 z = 0.5854) and SR (109 versus 122 z = 0.3949) in the control group. However, the changes were not superior above the training group. Significant improvement was

Table 1 Baseline epidemiological data of 21 spastic hemipateric stroke patients.

	Control group *n* = 10	Wii group *n* = 11	Significance Mann-Whitney U test (z)
FMBS	10 ± 2.54	8.36 ± 2.20	0.1105
FAC	3.9 ± 0.88	3.36 ± 0.67	0.1690
OLST1 (affected side)	6.1 ± 9.904	2.45 ± 2.84	0.8855
OLST2 (non-affected side)	9 ± 11.33	3.91 ± 4.72	0.1886
R (sec)	19.5 ± 13.95	19.27 ± 14.89	0.9352
SR (sec)	6.05 ± 9.53	4.28 ± 5.38	0.9713
6MWT	162.55 ± 126.4	150.7 ± 83.56	0.6983
TUG (sec)	19.74 ± 9.92	17.91 ± 10.59	0.3071

Note: FMBS = Fugl-Meyer balance subtest, FAC = Functional Ambulation Categories, Romberg (R), sharpened Romberg (SR), OLST = one-legged stance test, 6MWT = six-meter walking, TUG = timed up and go test.

Table 2 Summary training effect for therapy and control group—primary and secondary outcomes.

	Wii group			Control group		
	1st measurement	2nd measurement	*P*	1st measurement	2nd measurement	*P*
FMBS	8.36 ± 2.20	9.82 ± 2.04	0.0046	10 ± 2.54	10.8 ± 1.93	0.0872
FAC	3.36 ± 0.67	4 ± 1.09	0.0267	3.9 ± 0.88	4.5 ± 1.17	0.0842
OLST1	2.45 ± 2.84	6.18 ± 8.097	0.0067	6.1 ± 9.904	7.7 ± 11.96	0.0872
OLST2	3.91 ± 4.72	8.64 ± 10.698	0.0068	9 ± 11.33	17.72 ± 12.73	0.0632
R	19.27 ± 14.89	24.9 ± 10.26	0.0843	19.5 ± 13.95	27.2 ± 9.17	0.0474
SR	4.28 ± 5.38	9.73 ± 9.52	0.1302	6.05 ± 9.53	13.65 ± 13.47	0.0411
6MWT	150.7 ± 83.56	194.7 ± 93.35	0.0123	162.55 ± 126.4	202.7 ± 133.45	0.0069

Note: FMBS = Fugl-Meyer balance subtest, FAC = Functional Ambulation Categories, Romberg (R), sharpened Romberg (SR), OLST = one-legged stance test, 6MWT = six-meter walking.

found in 6MWT (125.5 versus 105.5 z = 0.7509) in both groups. Wii Fit training and conventional balance therapy was similar in improving walking distance.

4. Discussion

In general, both groups showed improvement in balance. The intra-group analysis revealed significant improvement in all of the primary outcome scales' score (FMBS, FAC, 6MWT), OLST1 and OLST2 in the therapy group. Compare to conventional balance therapy, Wii Fit gaming is effective on walking ability (FAC) and functional balance (FMBS) improvements in our study group. In an earlier study, partial benefits were observed in walking ability recovery on the follow-up [19]. There is low and very low evidence that VR therapy improves walking ability [6, 7, 13, 19]. According to our findings, training with Nintendo Wii™ on postural balance probably had positive effects on reducing the need for aids and/or supervision during walking for avoiding the risk of falling [19].

Both groups showed significant improvement in functional mobility (6MWT). Regarding this, we didn't detect statistically significant differences between the groups, maybe because auditory and visual feedback similarly improves overall independence [20]. An earlier review showed insufficient evidence to draw conclusions on whether a virtual reality approach was more effective in improving gait speed than conventional therapy [6, 7]. Also a meta analysis for physical therapy poststroke didn't find significant effect on comfortable gait speed, maximum gait speed and walking ability [13, 14]. Findings of the current study support that a video game-based therapy could be effective in enhancing balance and walking speed (6MWT) similarly to a conventional balance therapy.

Similarly to our findings, Barcala and co-workers found significant improvement in functional mobility, static and functional balance in their RCT, but no statistically significant differences between the experimental and control group [21]. Contrary to our findings, an RCT showed that improvements in functional balance were significantly higher in Wii group [22]. Also Wii Fit training proved to be more effective than usual balance therapy in improving functional balance (Berg Balance Schale) and independence in activity of daily living (Barthel index) [19]. A review presented by Lohse and coworkers demonstrated significant moderate advantage in activity [13, 14, 19].

5. Conclusion

The purpose of this study was to investigate the efficacy of balance training on functional balance using video game-based intervention. Although it is difficult to draw clinical implication based on the results of small sample size, it is possible the balance treatment with Nintendo Wii is similarly effective method to improve static balance and functional mobility comparing to conventional therapy.

In conclusion, a Wii-based approach is promising for post-stroke balance rehabilitation. The therapy performed with a Nintendo Wii could be an alternative way to treat balance among stroke patients because of its several advantages: cost effectiveness, usage in out-patient rehabilitation and more fun to do (which is important for the patient's engagement in the therapy). Motivation of the patients is important throughout the rehabilitation process and repetition is also crucial (for plasticity). Several questions remain unclear about intensity, timing, and mode of action. A larger randomized controlled trial is recommended to further investigate.

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