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Designing a Double-Blind Clinical Trial to Compare the Effects of Nintendo Wii on Ankle Spasticity in Subjects with Stroke

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Original Article

Abstract

Introduction: Spasticity is one of the well-known consequences of stroke. Todays, virtual reality systems are known as a standard therapy method in neurologic disorders such as stroke. Nintendo Wii is a motion-controlled game system which provides an alternative form of repetitive task training in an interactive enriched environment. Despite the direct relationship between the motor pattern and spasticity, former studies have not considered the effect of spasticity on balance and movement of patients experiencing a stroke. Given the above-mentioned issues, this study seeks to evaluate the effect of Nintendo Wii on ankle spasticity in patients with a stroke.

Materials and Methods: This study was a double-blind randomized controlled trial. Based on the inclusion and exclusion criteria, the subjects selected were randomly divided into the two standard therapy and standard therapy plus Nintento Wii groups. Modified Ashworth scale (MAS), H-Reflex latency, H_{max}/M_{max} Ratio, Timed Up and Go (TUG) test, and 36-Item Short Form Health Survey questionnaire (SF-36) as outcome measures were assessed by a blinded physiotherapist and a neurologist at the beginning of the first session and at the end of the last session. Standard therapy included weight bearing, stretching, and active exercises. In addition to the standard therapy, the trial group received 30 minutes of Nintendo Wii game. the data analysis was conducted by SPSS software. T-test and paired t-test were used for the normal data distribution and Mann-Whitney U test and Wilcoxon test for the abnormal data distribution.

Conclusion: This study sought to introduce a new and cost-effective treatment tools which can be used at home to improve function among the stroke survivors.

Keywords: Spasticity, Nintendo Wii, Stroke, Ankle, Electromyography

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Introduction

Spasticity is one of the most well-known movement disorders following a stroke (1). Elimination of pain factors, use of anti-spasticity patterns, use of range of motion (ROM) and stretching exercises, use of ankle splints at night and while standing, nerve control using botulinum, and the use of oral drugs such as tizanidine, baclofen, and benzodiazepines, are among the methods of prevention and treatment of spasticity and contracture with the most scientific evidence (2,3). Recent studies suggest task-oriented, purposeful, engaging, progressive, adaptive, and focused training to facilitate post-stroke movement recovery (2,4). Today, virtual reality (VR) gaming systems are recognized as a standard treatment for many neurological diseases, including stroke (2). Nintendo Wii is a motion game system in which different, purposeful training is performed repetitively and in an interactive environment (5). Although there seems to be a direct relationship between spasticity and movement pattern, previous studies have not considered the effect of spasticity on

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controlling balance and movement in patients with stroke. Given this, the present clinical trial study is designed aiming to reveal the challenge of the effect of this type of game on ankle joint spasticity and to design a treatment protocol and test the effect of Nintendo Wii on ankle joint spasticity in patients with stroke.

Materials and Methods

This study was a double-blind (participant and rater) and prospective randomized clinical trial registered on the Iranian Registry of Clinical Trials (IRCT) with code IRCT20200101045970N3 and ethics code IR.MUI.RESEARCH.REC.1399.309. This study conducted to examine the effect of 12 sessions of Nintendo Wii treatment on ankle spasticity in patients with stroke compared to the control group. Thus, 30 men and women with a history of their first unilateral stroke participated in the study. The study inclusion criteria included confirmation by a neurologist through the findings of computed tomography scan (CT-Scan) or Magnetic resonance imaging (MRI) and also, according to the Modified Ashworth Scale (MAS) (6) spasticity score of greater than or equal to 2 in the ankle joint. According to the Persian version of the Mini-Mental Status Exam (MMSE), individuals had to have a good cognitive status (more than 24) and be able to maintain a standing position without the use of assistive devices for at least 30 seconds (7,8). People with a history of heart attack or high-risk heart disease and other neurological disorders such as neuropathy, epilepsy, seizures, and diabetes mellitus (DM) were excluded from the study (8,9). Individuals taking botulinum or other oral antispasmodics (10), participating in other physiotherapy interventions, and having contracture and rigidity in the plantar flexor muscles could not enter the current trial design.

Individuals with stroke who had referred to private and public centers in Isfahan, Iran were invited to enter the study through announcements. The objective of the trial was explained to the volunteers and written and official consent was obtained from all of them and then the subjects were randomly entered into one of the study groups using the blocking method.

In the next step, the patients who met the inclusion criteria were invited to attend the super-specialty neurology clinic located in Isfahan. Before starting the test, biographical information including age, sex, height, weight, and disease-related characteristics such as the involved side, duration of the disease, type of stroke, and location of injury were extracted from the patient and clinical findings, respectively.

The participants were evaluated on the first day of the physiotherapy program just before the intervention and on the last day after the end of the physiotherapy program.

The physiotherapists performed MMAS, Timed Up and Go (TUG), and 36-Short Form Health Survey (36-SF) and the neurologist performed the Nerve Conduction Velocity (NCV) tests. These individuals were unaware of the groupings. According to the Functioning, Disability and Health (ICF) model, spasticity was examined at the levels of body structure and function, social activity and participation, and life satisfaction (11).

MMAS: The body structure and function level, spasticity, and muscle tone were assessed using this criterion which has good validity and reliability (11). In this method, spasticity has a score of 0-4 and describes the resistance that is felt against the passive movement of a limb in a joint, over the full ROM and for one second. This test was performed while the patient was lying on the bed in a supine position with perfectly straight knees, and the experienced physiotherapist tested the ankle spasticity and reported the score based on the amount of stiffness he felt (6).

Hmax/Mmax Ratio, H-reflex latency, and M-wave were recorded with the help of the NCV device for objective recording of neural characteristics of spastic muscle. H-reflex latency and Hmax/MmaxRatio were measured by the experienced neurologist who was unaware of the subjects and treatment groups. To perform the test, the patient lay in the supine position on the bed with his leg hanging from the edge of the bed (12). After preparing the skin, the tibial

nerve in the popliteal fossa was stimulated while the receptor electrode was located on the gastrocnemius muscle between the inner malleolus and the inner tibial epicondyle. The ground electrode was also placed between the stimulator and receiver electrodes. Nerve stimulation was performed according to Braddom and Johnson method with a duration of 1 millisecond and a frequency of 5 Hz, and then the maximum amplitude obtained from the H-reflex and M-wave was measured and the H-reflex latency was recorded (12) (Figure 1).

Figure 1. H-reflex and M-wave measurement test

TUG test: This fast and easy test is of a high internal and external reliability (13) and is used to assess the level of activity. The TUG test was applied to examine the patient's ability to perform sequential motor tasks related to walking and spinning (11), in which the patient had to stand up from a chair without help, walk around a distance of 3 meters, and then return and sit on the chair again. The time elapsed was recorded using the stopwatch by the physiotherapist who was uninformed of the grouping (Figure 2).

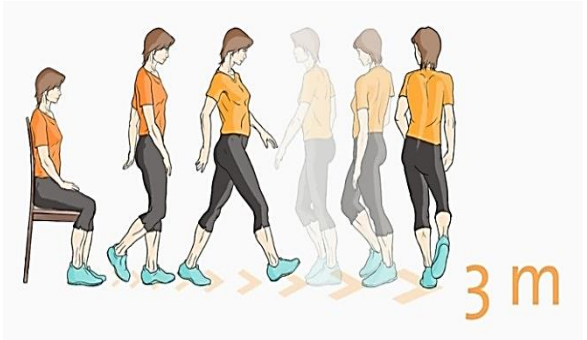

Figure 2. Timed Up and Go (TUG) test

36-SF Questionnaire: To assess patient participation, the 36-SF questionnaire, whose validity and reliability had already been proven, was used. This questionnaire examines the level of community health as part of the results of medical studies in both physical and mental parts (14).

Interventions: Participants in the control and intervention groups received treatment with valid scientific evidence to reduce spasticity (2). The limb positioning was performed in the form of antispastic patterns, ROM exercises, and functional stretching for 30 minutes, three sessions per week for 12 sessions. In addition to receiving routine treatment, the intervention group received 30 minutes of Nintendo Wii game three times a week for 12 sessions in the same session after a 5-minute break. All games were played standing on the balance board of the device without the use of assistive devices.

Exercises: The patient lay on the bed in the supine position and the gastrocnemius muscle of the patient was stretched manually by the therapist with a straight knee and for the soleus muscle with a bent knee. Each stretch lasted 30 seconds and repeated 5 times for each leg (Figure 3).

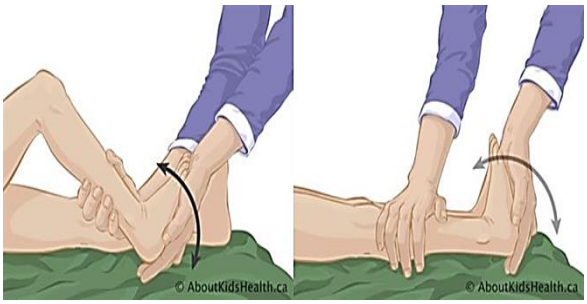

Figure 3. Stretching of the gastrocnemius and soleus muscles

On the parallel bars (to increase the patient's safety) while weight bearing on one foot, the patient touched four rows of Lego arranged at different heights with the toes of the other foot and then changed the support foot. This movement was performed in 3 sets and each set with 10 repetitions. Finally, on the parallel bars, if the patient bore weight on one leg, he lifted the other foot from two rows of Lego (like walking),

put the heel on the ground, and then while bending the knee, he lifted his foot from the Lego again and pulled back and put his toes on the ground. This movement was performed in 3 sets and each set with 10 repetitions for each leg.

In the intervention group, the games were played while the patient was standing on the balance board. The patients had already received the necessary training by the physiotherapist and were monitored by them during play. In each session, 3 games out of 5 games were selected with the participation of the physiotherapist and the patient's preference, and if necessary and at the patient's request, he was given a 5-minute break between the games. The games were played at a distance of three meters from the screen (Figure 4).

Figure 4. Selected games of the Nintendo Wii system

Randomization: Since the number of the required samples was less than 100, the blocking system was used to randomize the samples. The required number of samples and groups, which was two groups in the present study, was provided to the software. The software then randomly placed the samples in one of the two control or intervention groups and presented them in the table.

Blinding strategy: The physiotherapist responsible for evaluating patients, as well as the neurologist, were aware of the study process, but were unaware of the grouping as well as the details of the treatment protocol.

The individuals who were willing to participate in the study were fully informed of the details of the treatment goals, but were unaware of the treatment procedure. After signing the consent form, the patients entered the study process and then entered one of the groups based on the random blocking system. At this stage, the researcher explained the treatment details to each person and they were free to decide whether to continue or leave the study without any obligation. The program for the other group was not explained to any of the patients to avoid any treatment bias. Moreover, the time and place of treatment of both groups were the same, and they would only visit on separate days.

To analyze the data, first the normal distribution of variables was investigated using Shapiro-Wilk test. Then t-test and paired t-test were utilized for data with normal distribution and Mann-Whitney U and Wilcoxon tests for data with an abnormal distribution. $P < 0.05$ was considered as the significant level. Finally, the data were analyzed in SPSS software (version 20, IBM Corporation, Armonk, NY, USA).

At the end of the study, the drop in participants was displayed in the form of a CONSORT chart.

Discussion

Spasticity is the most well-known complication after a stroke (1), which leads to movement disorders and affects the life of the patient and those around him in the long run. Prevention and treatment of this lesion are one of the most important treatment goals in any country (15). The use of purposeful and engaging exercises in the form of VR systems is now recognized as the standard treatment for neurological patients (2).

The present trial design showed the extent to which these games can improve the spasticity of patients with stroke and to what extent they can change the level of patients' performance in the daily functions and their social role.

Limitations

None.

Recommendations

None.

Conclusion

None.

Acknowledgments

The present clinical trial study registered on the Iranian Registry of Clinical Trials (IRCT) with code IRCT20200101045970N3 and ethics code IR.MUI.RESEARCH.REC.1399.309 and was taken from a dissertation of the Master of Physiotherapy approved by the School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran. The authors would like to appreciate Mr. Milad Ataeian, Master of Physiotherapy, for his contribution to data collection. The Clinical Council and the Vice Chancellor for Research and Technology of Isfahan University of Medical Sciences and all the patients who cooperated in the implementation of this research project are also appreciated.

Authors' Contribution

Ehsan Ghasemi: study design and ideation, attracting financial resources for the study, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be sent to the journal office, responsibility for maintaining the integrity of the study process from the beginning to publication, and responding to the referees' comments; Narges Yousefi: study design and ideation, data collection, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be sent to the journal office, responsibility for maintaining the integrity of the study process from the beginning to publication, and responding to the referees' comments.

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This clinical trial registered on the Iranian Registry of Clinical Trials (IRCT) with code IRCT20200101045970N3 and ethics code IR.MUI.RESEARCH.REC.1399.309 and was based on the secondary analysis of part of the information extracted from the dissertation of the Master of Physiotherapy, which was funded by Isfahan University of Medical Sciences. Isfahan University of Medical Sciences has not commented on the data collection, analysis, and reporting, manuscript preparation and final approval of the article for publication.

Conflict of Interest

The authors declare no conflict of interest. Dr. Ehsan Ghasemi attracted funding for basic studies related to this article from Isfahan University of Medical Sciences and has been working as an assistant professor of physiotherapy at this university since 2006. Narges Yousefi has been a master's degree student in physiotherapy at the School of Rehabilitation Sciences, Isfahan University of Medical Sciences since 2018.

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