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Feasibility, Safety, and Enjoyment during Wii Balance Board Exergame Training among Individuals with Sub-acute Stroke

Viabilidad, seguridad y diversión durante el entrenamiento con Wii Balance Board Exergame en personas con ictus subagudo

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Abstract

Introduction. Nintendo® Wii is a non-immersive virtual reality platform that works integrated with the Wii Balance Board as a biofeedback system for balance rehabilitation among post-stroke patients.

Objective. Primary objective was to evaluate the feasibility of employing Wii Balance Board training as a standalone treatment approach in clinical practice for sub-acute stroke patients. The secondary objective was to assess the enjoyment status during Wii Balance Board training and to calculate effect size for definitive study.

Method. The study design was pilot randomized control trial**.** We recruited 20 sub-acute stroke patients using a block randomization technique. The participants in the experimental group received Wii Balance Board training for 12 sessions up to 2 weeks. The control group participants received standard physiotherapy treatments for standing balance for 12 sessions until 2 weeks. Outcome measures were clinical-log documentation for feasibility testing, Exergame Enjoyment Questionnaire, mini-BESTest, and FIMs.

Results. The study's enrollment and retention rate was respectively 80% (n = 20) and 70% in each group (n = 7). The incidence rate of adverse events from Wii Fit training was reported to be 40% (n = 4), along with a moderate enjoyment rate (mean±sd=50.10 ± 14.69; n = 10). The experimental intervention did not offer significant benefits over control intervention (p = 0.539, 0.622; Cohen's d = -0.280, -0.224; 95% CI: -1.158 to 0.605, -1.101 to 0.658).

Conclusion. The Wii Balance Board-based exergames training can be considered a feasible and safe balance training approach among sub-acute stroke patients. However, exergames cannot replace standard care balance rehabilitation due to poor efficacy in short term.

Keywords

Balance; Exergames; feasibility; sub-acute stroke; virtual reality; enjoyment; Nintendo® Wii Fit Plus; non-immersive; safety; Wii Balance Board.

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Contribution of the authors
Sayan Pratihar: Conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, software, visualization, writing – original draft.
Shanmuga Priya R.P.: Project administration, resources, supervision, validation, writing – review & editing.

Resumen

Introducción. Nintendo® Wii es una plataforma de realidad virtual no inmersiva que funciona integrada con la Wii Balance Board como un sistema de biofeedback para la rehabilitación del equilibrio en pacientes después de un accidente cerebrovascular.

Objetivo. El objetivo principal era evaluar la viabilidad de emplear el entrenamiento con Wii Balance Board como un enfoque de tratamiento independiente en la práctica clínica para pacientes con apoplejía subaguda. El objetivo secundario era evaluar el estado de disfrute durante el entrenamiento con la Wii Balance Board y calcular el tamaño del efecto para un estudio definitivo.

Método. El diseño del estudio fue un ensayo piloto de control aleatorio. Reclutamos a 20 pacientes con AVC subagudo utilizando una técnica de aleatorización en bloque. Los participantes del grupo experimental recibieron entrenamiento en la Wii Balance Board durante 12 sesiones de hasta 2 semanas. Los participantes del grupo de control recibieron tratamientos estándar de fisioterapia para el equilibrio en posición erguida durante 12 sesiones de hasta 2 semanas. Las medidas de los resultados fueron la documentación clínica-log para las pruebas de viabilidad, el cuestionario de disfrute del exergame, el mini-BESTest y los FIMs.

Resultados. La tasa de matrícula y retención del estudio fue respectivamente del 80% (n = 20) y 70% en cada grupo (n = 7). Se informó que la tasa de incidencia de eventos adversos del entrenamiento Wii Fit fue del 40% (n = 4), junto con una tasa moderada de disfrute (promedio sd = 50,10 14,69; n = 10). La intervención experimental no ofreció beneficios significativos sobre la intervención de control (p = 0,539, 0,622; d = -0,280, -0,224 de Cohen; IC 95%: -1,15 a 0,60, -1,10 a 0,65).

Conclusión. El entrenamiento de exergames basado en la Wii Balance Board puede considerarse un enfoque factible y seguro para el entrenamiento del equilibrio entre pacientes con ACV subagudo. Sin embargo, los exerjuegos no pueden reemplazar la rehabilitación de equilibrio de atención estándar debido a su escasa eficacia a corto plazo.

Palabras clave

Equilibrio; Exergames; viabilidad; golpe subagudo; realidad virtual; disfrute; Nintendo® Wii Fit Plus; no inmersivo; seguridad; Wii Balance Board.

Introduction

Stroke is a critical health condition that contributes to global mortality and impairment. The 2022 Global Stroke Fact Sheet, published by the World Stroke Organization (WSO), revealed that a bulk of global burden of stroke, including all risk factors combined, account for 87.0% (84.2-89.8), and 89.0% of global stroke deaths and disability combined reside in low to middle income nations as measured by disability-adjusted life years (DALYs) from the past 20 years [1]. The crude stroke incidence varied from 108 to 172 per 100,000 individuals annually, whereas the crude prevalence ranged from 26 to 757 per 100,000 individuals per year in India. The monthly case fatality rates varied from 18% to 42% over the past 23 years in the country [2].

The typical abnormalities of stroke manifest as asymmetrical weight distribution, decreased range of stability, compromised postural control, impaired balance, and dysfunction in gait [3,4]. Standard neuro-rehabilitation methods generally focus clinical aims such as balance and mobility, while giving less attention to patient-centered outcomes such as enjoyment, motivation, and quality of life for individuals recovering from a stroke [5]. Balance training is now recognized as an essential intervention for people who have recently experienced a stroke. Research has demonstrated that engaging in standing balancing training, especially when combined with advanced technology, substantially improves functional balance, walking ability, and independence in everyday tasks [6].

The Exergames is a video gaming platform designed to facilitate exercise and promote user engagement and motivation for motor-cognitive training. It aims to boost balance and mobility, as well as improve visual perception and overall cognitive performance [7–9]. The Nintendo® Wii, used together with the Wii Balance Board, is a commercial video game equipment that employs non-immersive virtual reality technology to offer visual biofeedback for stroke recovery [10]. Wii Balance Board is a relatively low-cost, easily accessible tool that can be used in various settings [11].

Previous studies reported that Wii Balance Board-based exergame training was effective for improving patients' balance, postural stability, and reducing disability in clinical settings during the sub-acute stage of stroke [12,13]. However, the efficacy of Wii Balance Board training was estimated as an add-on intervention to standard physiotherapy treatments for post-stroke patients, which was discussed in most of the past studies [14–16].

In recent years, only few studies reported its direct comparison as a standalone treatment approach against standard physiotherapy care during sub-acute phase of stroke. Though, those studies lack methodological quality, robust treatment efficacy, acceptability, and implementation of a novel intervention in clinical neuro-rehabilitation settings [17,18]. This creates a gap in understanding whether an independent Wii Balance Board training can be as effective as, or perhaps more effective than, standard physiotherapy cares. Recent systematic reviews and meta-analyses suggest that Wii-based interventions show promising result in previous studies, but still existing literature lacking significant effectiveness of the Wii Exergames training when compared to standard physiotherapy care therapies. Thus, there is a need for more rigorous and high-quality randomized controlled trials to establish their efficacy as standalone treatments [19,20].

On the other hand, a clear rationale related to standardized protocols for implementing Wii Balance Board training has led to variability in treatment dosage, the level of treatment intensity, and the calibration of the difficulty level in VR games, which are intended for future research [18,21]. It is necessary to thoroughly investigate the assessment of procedural safety during Wii Balance Board training and to develop a suitable method for gathering individual feedback on treatment experience and enjoyment associated with the specific Wii Fit Plus balance game [22]. Furthermore, implementing the Wii Balance Board as an isolated treatment in clinical settings could also present technical challenges, such as the need for adequate space, reliable equipment, technical support, and additional operational training to both clinicians and patients for effectively use of the device [23]. Therefore, this study would contribute to fulfill the existing literature gap through conducting a pilot trial that would provide initial data to inform the design of larger and the more definitive study.

The primary objective of this study was to assess the feasibility and procedural safety for the implementation of the Wii Balance Board exergame training as an independent therapeutic method in sub-acute stroke population to ensure a future definitive study. The secondary objective was to evaluate the patients' enjoyment level from the Wii exergame training. An additional secondary objective was included to investigate the preliminary efficacy along with the effect size calculation for the main definitive study in future.

Method

Study Design

This study employed an underpowered pilot randomized control trial (parallel arm) including the experimental group (EG) or Wii Balance Board training group and a control group (CG). The structure of the pilot study assumed a 15%-20% rate of actual power calculated two-tailed sample size of 125, α = 0.05, **β** = 80% (1- **β**). The study's participants were allotted equally (ratio of 1:1) by an independent researcher into EG and CG through a block randomization procedure (block size of 4, numerical sequence). Randomization was done using PC-based random allocation software (generated by an independent researcher who was not associated with the trial) and the computerized database concealment was followed until the intervention commenced. A blinded assessor conducted the outcome assessment, unaware of the original group allocation. The study adheres to CONSORT 2010 guidelines to report a pilot and feasibility trial [24].

Participants

Stroke patients admitted or registered to the SRM Medical College Hospital and Research Centre (SRM MCH&RC, Chennai, India) in the Department of Neurology Ward and Physical Medicine & Rehabilitation (PMR), as in-patients and out-patients, were screened daily depending on the specified inclusion criteria: 1.) males and females with an age group of 18 and above years; 2.) hemiparesis in the sub-acute phase of stroke (between 2 weeks to 24 weeks of the onset of illness) for the first time, including both ischemic and hemorrhagic conditions; 3.) ability to stand and walk a minimum of 3 meters distance, either independently or with the use of an assistive device (walker, quadruped/tripod cane); 4.) the subject's Mini-Mental State Examination (MMSE) score is equal to or greater than 18 (both mild cognitive and non-cognitive impairment patients); 5.) participants who possess the capability to comprehend spoken directives and view a visual screen; 6.) no previous VR-based rehabilitation training experience.

The exclusion criteria for this study included the following: 1.) use of AFOs and prosthetic devices in the lower limb; 2.) any congenital deformities affecting the lower limb and spine; 3.) severe spasticity in the lower limb muscles that limited the lower extremity range of motion to less than 80%; 4.) any current musculoskeletal injury, severe backache, or joint diseases that restrict weight bearing while standing; 5.) history of epilepsy/seizure episode; 6.) history of TIA, recurrent stroke, vestibular diseases, peripheral neuropathy, global aphasia, psychiatric disorders and dementia; 7.) pregnant women; 8.) history of severe cardiac and respiratory diseases; 9.) concomitant with any other associated neurological conditions, excluding those aforesaid.

Screening and Enrollment

The study protocol was approved by the SRM Institutional Ethical Committee, holding the reference number SRMIEC-ST0823-695 and the study was also registered under the Clinical Trial Registry of India (ctri.nic.in) with the registration number CTRI/2023/11/059464.

We assessed 25 stroke patients for the eligibility of recruitment in the hospital. Out of them, three patients did not fulfill the requirements for inclusion, and two patients were not qualified to be recruited due to meeting the criteria for exclusion. Finally, we successfully recruited a total of 20 sub-acute stroke patients who met the criteria for inclusion and exclusion. Out of the total number of recruited participants, 11 were from in-patient sources and 9 were from out-patient sources. The EG was comprised of 4 in-patients and 6 out-patients, while the control group included 7 in-patients and 3 out-patients. (Figure 1 - participants' flow chart). Everyone signed a document indicating their voluntary consent and comprehension of the provided information.

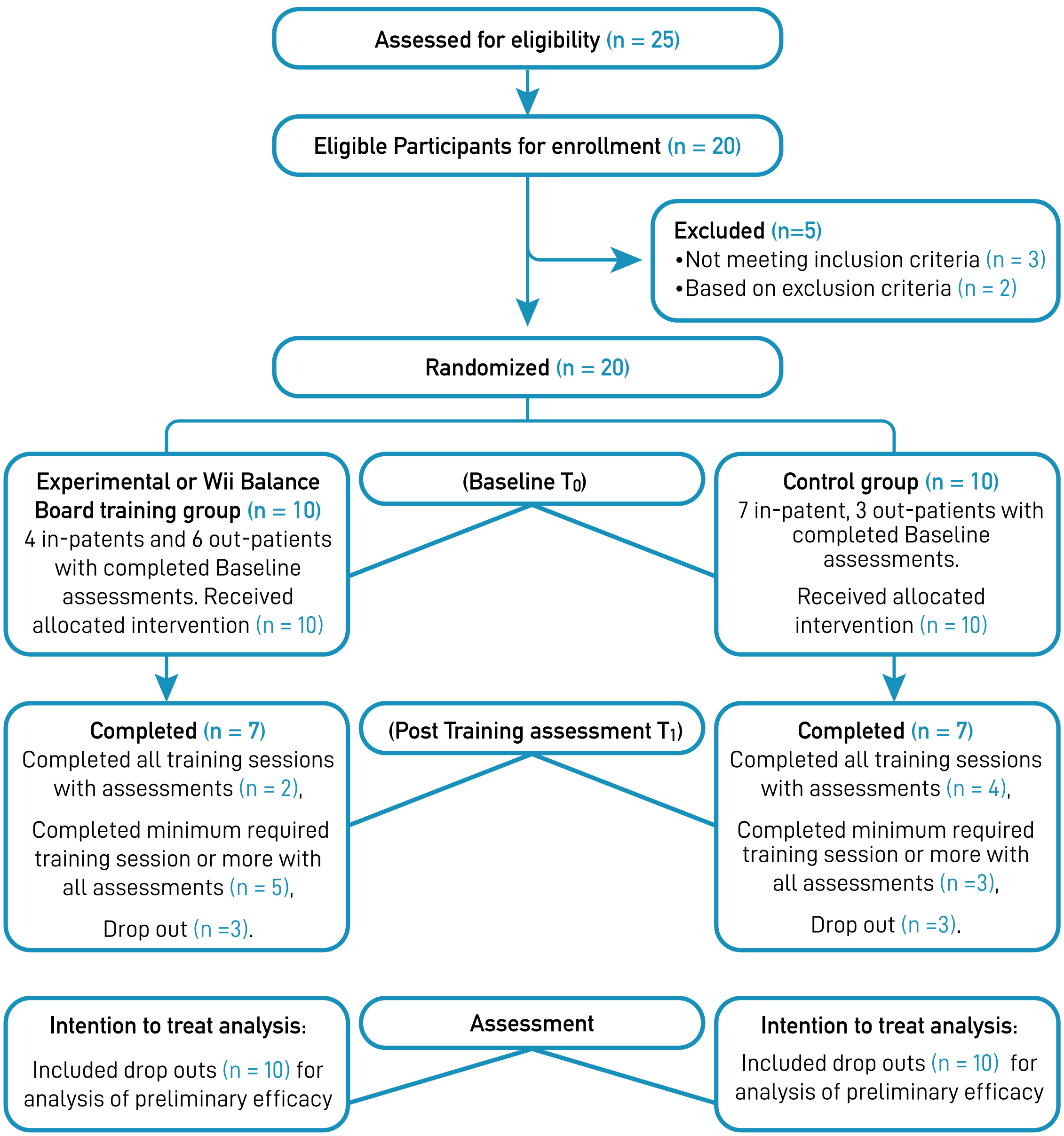

Figure 1. Participants' flow chart.

Intervention

The experimental intervention was conducted at the Department of Physical Medicine & Rehabilitation (SRM MCH&RC). The participants in the EG received virtual reality-oriented Nintendo® Wii Fit Plus standing balance training on the Wii Balance Board, connected to a projector screen (Figure 2). At the beginning, the vital signs, including blood pressure, pulse rate, respiratory rate, and SPO_2 of the participants were monitored to confirm their hemodynamic status before and after each training session to estimate any unexpected rise in stress level and for predicting any harmful cardiovascular events [25]. The frequency and dosage of the training sessions were considered as follows: 6 sessions in a week for 2 weeks; a total 12 training sessions was administered. Two selected Wii Fit Plus balance games such as table tilt and ski slalom (particularly target standing balance involves multidirectional weight shifts and stabilization) were played in the training for 30 minutes (i.e., 14 minutes each game with 2 minutes of rest period in between at level-1/beginner stage). Next at level-2/advanced stage, a total of 40 minutes of session (i.e., 18 minutes of each game with 4 minutes of rest period). Finally, at level-3/pro stage, a total period of 50 minutes of session (i.e., 22 minutes of each game with 6 minutes of rest period). The increase in training levels depended on the progression of game challenges. There were 2 minutes of warm-up with active-assisted ROM exercises of the upper limb as well as the lower limb before starting training and 2 minutes of cool-down by resting on a chair after the completion of every training session. In order to ensure a comprehensive understanding of the game-play concept and game controls on the Wii Balance Board, all participants had practice sessions lasting at least 30 minutes with the selected games prior to commencing the main training. For safety concerns, our participants were given a choice of using assistive devices like a cane or walker while stepping on, standing, or playing games on the Wii board as per their requirements. However, we encouraged our participants to minimize using the assistive devices while playing games on the Wii board. We also enforced manual assistance by two therapists during the training sessions to prevent fall incidents. We did not include any other specialized physiotherapy treatments in the experimental protocol except the Wii Balance Board training.

(A) Table Tilt game play (B) Ski slalom game play

Figure 2. Wii Fit Plus standing balance training on the Nintendo® Wii Balance Board.

The participants in the CG got standard physiotherapy care for standing balance, which was administered as follows: exercise 1, weight shifting while standing on floor with feet apart (side to side, forward and backward); exercise 2, single-leg stance for both affected and unaffected; exercise 3, wobble board standing exercises for dynamic balance; exercise 4, perturbation training (unpredictable pushes or pulls while standing on floor). Each exercise was executed for the duration of 10 minutes (a single exercise consisted of two 5-minute bouts including 30 sec. of rest interval). Interval period was 2 minutes in between two exercises. Before commencing the training, a one-minute warm-up activity was performed and a one-minute cool-down period was planned after completion of the training session. The total treatment duration was 50-minute per session for a total of 12 training sessions, occurring 6 sessions in a week up to 2 weeks, which was administered in the Department of Physiotherapy (SRM MCH&RC). See the Control Group exercise regimen in Table 1.

Table 1. Control Group exercise regimen.

Exercise Prescription Regimen	Details
Warm-Up	1 minute of light warm-up activities before commencing the exercises including A-ROM exercises of upper and lower limbs.
Exercise 1	**Weight Shifting (Standing on Floor with Feet Apart):** Side-to-side, forward, and backward weight shifting. Duration: 10 minutes.
Exercise 2	**Single-Leg Stance (Affected and Unaffected Sides):** Supported single-leg stance, progressing to unsupported single-leg stance. Duration: 10 minutes.
Exercise 3	**Wobble Board Standing Exercises (Dynamic Balance):** Standing exercises on a wobble board to improve dynamic balance. Duration: 10 minutes.
Exercise 4	**Perturbation Training (Standing on Floor):** Unpredictable pushes or pulls to challenge balance, starting with therapist support. Gradual decrease in the level of assistance over time. Duration: 10 minutes.
Rest Intervals	2 minutes of rest period between two individual exercises.
Cool-Down	1 minute of cool-down activities after completing the exercises by sitting on a chair.
Total Duration per Session	50 minutes per session.
Frequency of Sessions	6 sessions per week for 2 weeks (total of 12 sessions).

Intensity	One single exercise consists of two 5-minute bouts including 30 sec. of rest interval. **Warm up:** Low intensity: Gentle movements to increase circulation without causing fatigue. **Exercise 1:** Low intensity (Progressing to moderate): Patients should shift their weight in a controlled manner, aiming for a perceived exertion of 9-11 on the Borg RPE Scale (Rating of Perceived Exertion). Gradually increase to moderate intensity (12-14 on Borg RPE) as the patient's stability improves and the level of assistance decreases. **Exercise 2:** Low to moderate intensity: Begin with moderate support and progress to minimal or no support as balance improves. Target a perceived exertion of 10-14 on the Borg RPE Scale, gradually increase as the patient's stability improves and the level of assistance decreases. **Exercise 3:** Low intensity (Progressing to moderate): Exercises should be challenging but achievable, with a focus on maintaining balance with slight wobble. Aim for a perceived exertion of 9-11 on the Borg RPE Scale. Gradually increase to moderate intensity (12-14 on Borg RPE) as the patient's stability improves and the level of assistance decreases. **Exercise 4:** Low to Moderate intensity: Start with low intensity (perceived exertion 9-11 on Borg RPE) and gradually increase to moderate intensity (12-14 on Borg RPE) as the patient's stability improves and the level of assistance decreases.

However, there was no constraint on the routine medical care, the routine physiotherapy treatments, or other associated services in the hospital during the conduction of the trial for the participants in both groups.

Outcome Measures

The primary outcome of feasibility and safety was measured with the recruitment capability and retention rate, treatment compliance, adherence rate, and adverse events through clinical research log documentation. The secondary outcome of patient enjoyment was evaluated by the Exergame Enjoyment Questionnaire or EEQ at the end of the trial. EEQ measures both the exergames-related enjoyment status and the user's experience from playing an exergame [26]. Additional secondary outcome measures for assessing balance control and functional independence measurement were evaluated by the mini version of the balance evaluation system test scale or mini-BESTest scale (inter-rater ICC = 0.87 to 0.98) and the functional independence measure scale or FIMs (ICC = .87) [27,28]. The measurements of both the mini-BESTest scale and FIMs were taken first at baseline (T_0) while recruitment of samples and post-test (T_1) after either completion of the minimum required training sessions or more as per intervention protocol (adhere to 70% benchmark adherence rate of total training sessions for the generalization of feasibility) [29].

Statistical Analysis

We conducted the statistical data analysis using IBM® SPSS® version 27 software. We utilized both the Shapiro-Wilk test and the Q-Q plot to verify the normal distribution of the dataset of outcome variables. We performed the paired samples t-test to evaluate the variation between dependent variables within the experimental and control groups. Independent t-test was utilized for analyzing treatment efficacy comparing between the groups. Regression models with interaction terms for moderation and mediation analysis with control variables using Hayes' PROCESS macro in SPSS. Pearson correlation analysis was performed to determine relationship between participants' adherence and treatment enjoyment. We carried out the entire analysis using a statistical significance threshold of 0.05. We subjected data on usefulness to descriptive statistical analysis.

Use of AI in the manuscript

We utilized an AI language model, ChatGPT, version 3.0, developed by OpenAI (2020) in this paper [30]. The AI was used to assist in generating initial drafts of the text, specifically focusing on enhancing texts readability and ensuring clarity and coherence. The generated text was reviewed and edited by the research team to ensure accuracy, relevance, and alignment with the overall narrative of the paper. The use of ChatGPT helped in efficiently generating well-structured text and in articulating complex ideas, thereby enhancing the clarity of the contexts in such a way that does not breach the original study findings and interpretation of results.

Results

Feasibility

A monthly screening was carried out for stroke patients, with the following numbers observed: 9 patients in the initial month, 3 patients in the subsequent month, 8 patients in the third month, and 5 patients in the fourth month. In the first month, we were able to register 8 patients; in the second, 3 patients; in the third, 4 patients; finally, in the fourth, 5 patients. The recruitment process for this study commenced on November 3, 2023, and the final baseline assessments concluded on February 16, 2024. The outcome assessments were carried out between 16th November 2023 and 29th February 2024. The average time frame from screening to participant enrollment in this study was 24 hours. Table 2 displays the basic demographic characteristics of the participants in both groups.

The enrollment percentage for qualifying screens was 80% (n = 20). All enrolled participants across both groups attended a minimum of one session. The mean attendance of our participants during the period of two-week intervals stayed at 9 out of the total 12 sessions in both groups. Five participants achieved a minimum of 8 or more consecutive sessions with all assessments, meeting the 70% benchmark adherence rate for total training sessions [29], whereas only two participants completed all designated training sessions and required assessments in the EG. In contrast, four participants successfully attended all the training sessions and three participants completed with minimum required training sessions or more along with completion of required assessments in the CG. The study experienced a dropout rate of 30% in both the EG (n = 3) and CG (n = 3). Three participants from the EG who dropped out were all registered outpatients, while in the CG, one inpatient and two registered outpatients dropped out. The study found that 70% of the planned assessments were completed in both study groups. The average time period required to complete the entirety of assessment visits per participant was around 30 minutes in both groups.

Table 2. Primary Characteristics of Participants.

Characteristics	Experimental Group (n=10)	Control Group (n=10)
Age (in years)	*55 ± 7.40 (min: 45; max: 66)	*59.40 ± 10.03 (min: 37, max: 74)
Sex (male, female)	#6(60%), 4(40%)	#8(80%), 2(20%)
Post-stroke duration (in weeks)	*5.20 ± 4.89 (min:2; max:16; range:14)	*6.30 ± 4.27 (min: 2, max:14; range: 12)
Type of stroke (Hemorrhagic/ Ischemic condition)	#4(40%), 6(60%)	#8(80%), 2(20%)
Cognition Status: Mini-Mental State Examination Score (MMSE)	*21 ± 2.0 (min: 18, max: 24)	*21.60 ± 2.87 (min: 18, max: 26)
Mobility Status: Cane/manual assistance/ quadruped cane Usage/ Independent	#0% cane, 40% manual assistance, 50% quadruped cane, 10% independent	#10% cane, 60% manual assistance, 30% quadruped cane, 0% independent

Note. Values are presented as *mean ± standard deviation, minimum, maximum, and range, #N(%).

The compliance rate for the treatment in EG was found to vary based on the Exergame difficulty levels of the distinct exergames. For Game-I at the beginner level, the compliance rate was 89.07%, while for Game-II it was 75.83%. At the advanced level, Game-II received a rating of 75.16%, but no one was able to make progress in Game-I at that stage. The gameplay-related events in EG are statistically described in Table 3.

Table 3. Game-play events in Experimental Group.

Events	N% or Mean±SD (n=7)
Level attained in games (Game I, Game II)	Game I: 100% beginner level, 0% advanced level, 0% pro level. Game II: 100% beginner level, 100% advanced level, 0% pro level.
Attempted game-play duration (in minutes) at Beginner level (Game I, Game II)	124.71 ± 27 (min: 80; max:152), 31.85 ± 20.07 (min: 8; max: 72)
Attempted game-play duration (in minutes) at Advanced level (Game I, Game II)	(*N/A), 94.71 ± 41.51 (min:37; max:148)
No. of sessions played at Beginner level (Game I, Game II)	10 ± 1.49, 3 ± 1.77
No. of sessions played at Advanced level (Game I, Game II)	(*N/A), 7 ± 1.77

Note. all the values are reported as per minimum attendance of 8 or more training sessions, analysis is made without dropout data, *N/A= Game level not achieved.

$$\left[\text{Formula of calculating treatment specific compliance rate in Experimental Group} = \frac{\textit{Actual total play times at various levels of Wii Fit games throughout the sessions}}{\textit{Total prescribed duration ofgameplay at different levels of Wii Fit games throughout the sessions}} \times 100\%\right]$$

The control group demonstrated a treatment-specific compliance rate of 83% for all balance exercises, as measured by the successful execution and completion of individual balance exercises.

$$\left[\text{Formula of calculating treatment specific compliance rate in Control Group} = \frac{\textit{Actual total duration of executed balance exercises throughout the sessions)}}{\textit{Total prescribed duration of balance training throughout the sessions}} \times 100\%\right]$$

The exercise training related events in CG are elaborated in Table 4.

Table 4. Control Group training events.

Events		Mean±SD (n = 7)
Average number of attempted bouts in individual exercise throughout the trial sessions	Exercise 1	20 ± 4.46
	Exercise 2	20 ± 4.59
	Exercise 3	20 ± 5.04
	Exercise 4	20 ± 4.56
Average duration of performed exercises throughout the entire trial sessions by the participants (Mean/SD values are in minute)		529 ± 98.12

Note. All the values are reported as per minimum attendance of 8 or more training sessions, analysis is made without dropout data.

Safety

Four participants in the EG reported adverse events, including sudden onset of pain in the ankle joint, knee joint, and calf muscles, after a few training sessions. No complaints were made regarding accidental falls. In contrast, two participants reported experiencing similar knee and ankle pain after the training sessions in CG. Nevertheless, the reported adverse events were minor as confirmed by the specialized physician and did not result in any significant difficulties thereafter to be engaged with the interventions. The majority of the participants (80%, n = 8) encountered challenges in maintaining proper foot placement within the foot marker of the Wii Balance Board, resulted in stepping out of the foot markers during playing the exergames.

Enjoyment

The participants expressed a moderate level of overall enjoyment during engaging in Wii Balance Board training, as shown by their responses on the Exergame Enjoyment Questionnaire (EEQ), with a mean score of 50.10 ± 14.69 (n = 10). Pearson's correlation analysis reveals that participants' enjoyment ratings after playing the exergames is strongly associated with better adherence to the treatment sessions in the EG (r = 0.984, p = <0.001), see Table 5.

Table 5. Correlation between adherence rate and patient reported Exergames related enjoyment ratings in Experimental Group (n=10).				
Variables	**Pearson Correlation (r)**	**p- value**	**95% Confidence Intervals**	
			Lower	**Upper**
Adherence rate – Exergames enjoyment rate	0.984	<0.001	0.923	0.996

Note. p-value indicates two tailed significance.

Preliminary Efficacy

The statistical analysis was performed by the original assigned groups (both EG and CG) based on the intention-to-treat analysis principle. There were significant improvements in Mini-BESTest and FIM scores for both the experimental (EG) and control groups (CG) at post-test (T_1) compared to baseline (T_0). Intra-group analysis revealed large, statistically significant improvements in standing balance and functional independence for both EG (p = 0.003, 0.005; Cohen's d = -1.277, -1.162) and CG (p = 0.002, 0.004; Cohen's d = -1.336, -1.193) (see Table 6 and Figure 3).

Table 6. Comparison of balance control and functional independence measurements within groups.

Outcome Measures	**Experimental Group (n = 10)**						**Control Group (n = 10)**					
	T_0(n = 10)	**T_1 (n = 10)**	**p-value**	**Cohen's d**	**95% CI**		**T_0(n=10)**	**T_1 (n = 10)**	**p-value**	**Cohen's d**	**95% CI**	
					Lower	**Upper**					**Lower**	**Upper**
Mini-BESTest	12.70 ± 4.05	15.20 ± 5.35	0.003	-1.277	-2.108	-0.409	13.50 ± 3.83	16.70 ± 5.35	0.002	-1.336	-2.186	-0.450
FIMs	99.80 ± 10.27	101.60 ± 11.02	0.005	-1.162	-1.958	-0.329	103.30 ± 15.53	104.70 ± 16.14	0.004	-1.193	-1.998	-0.351

Note: Data are reported as mean ± standard deviation, T_0 = Pre Test, T_1 = Post Test. N= number of participants in each group p-values are indicative of the statistical significance (<0.05) of a paired samples t-test. Cohen's d indicates the effect size with 95% CI. The analysis is performed by including dropout participants' data, assuming the same value measured at baseline for the post-test assessments.

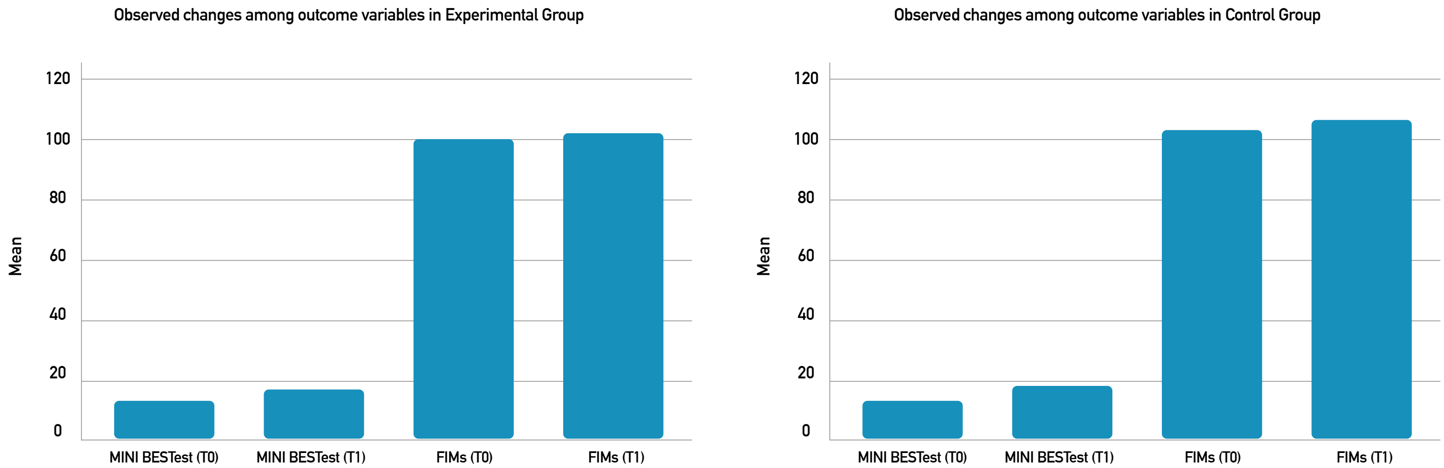

Figure 3. Statistical Bar graph for observed changes in outcomes within in Experimental and Control Group.

The inter-group analysis indicates that there were no significant differences in the improvement of balance control (Mini BESTest) and functional independence status (FIMs) between the EG and CG at post intervention (T1). Additionally, the treatment efficacy was found to be limited (p = 0.539, 0.622; Cohen's d = -0.280, -0.224; 95% CI: -1.158 to 0.605, -1.101 to 0.658). The findings indicate the experimental intervention did not offer a significant benefit over the control intervention in this preliminary investigation (see Table 7).

Table 7. Comparison of balance control and functional independence measurements between the Control Group (n=10) & Experimental Group (n=10).

Outcome Measures	Groups	Mean ± SD	t- value	Mean Differ-ence	p-value	95% CI of Difference		Cohen's d	95% CI	
						Lower	Upper		Lower	Upper
Mini BESTest (T_0)	Experimental	12.70±4.05	-0.453	-0.80	0.656	-4.50	2.90	-0.203	-1.079	0.679
	Control	13.50±3.83								
Mini BESTest (T_1)	Experimental	15.20±5.34	-0.627	-1.50	0.539	-6.52	3.52	-0.280	-1.158	0.605
	Control	16.70±5.35								
FIMs (T_0)	Experimental	99.80±10.27	-0.594	-3.50	0.560	-15.87	8.87	-0.266	-1.143	0.619
	Control	103.30±15.53								
FIMs (T_1)	Experimental	101.60±11.02	-0.501	-3.10	0.622	-16.08	9.88	-0.224	-1.101	0.658
	Control	104.70±16.14								

Note. T_0 = Pre Test, T_1 = Post Test. N= number of participants in each group. p-values are indicated a statistical significance (<0.05) of the Independent samples t-test. The t-value indicates the T-Statistics. Cohen's d refers to the point estimate of effect size with 95% CI. The analysis is performed with intention to treat analysis including dropout participants' data.

The moderation analysis in the EG revealed that exergame difficulty level was a significant predictor of participants' adherence (β = 2.183, p = 0.000) and balance improvement (β = 7.505, p = 0.025), but not functional independence (β = 12.683, p = 0.225). However, exergame difficulty level did not significantly moderate the relationship between exergame training and adherence (β = 0.000, p = 1.000), balance (β = 3.571, p = 0.290), or functional independence (β = 2.571, p = 0.818), with no significant influence from covariates (age, sex, MMSE), as it can be seen in Table 8.

Table 8. Moderation analysis for interaction of Exergame difficulty level with Exergame training and intervention's outcomes, adherence with control variables in Experimental Group.

Outcome Variables	Predictors	Coefficient (β)	Standard Error	t	p-value
Balance	Intervention (Pre-Post)	2.500	1.485	1.683	0.116
	Exergame difficulty level	7.505	2.956	2.539	0.025
	Intervention * Exergame difficulty level	3.571	3.241	1.102	0.290
	Age (Covariates)	0.109	0.121	0.895	0.387
	Sex (Covariates)	0.539	1.827	0.295	0.773
	MMSE (Covariates)	-0.034	0.711	-0.048	0.963
Functional independence	Intervention (Pre-Post)	1.800	5.006	0.360	0.725
	Exergame difficulty level	12.683	9.961	1.273	0.225
	Intervention * Exergame difficulty level	2.571	10.923	0.235	0.818
	Age (Covariates)	-0.021	0.409	-0.052	0.960
	Sex (Covariates)	0.173	6.157	0.028	0.978
	MMSE (Covariates)	-0.932	2.396	-0.389	0.704
Adherence	Intervention (Pre-Post)	.000	.212	.000	1.000
	Exergame difficulty level	2.183	.423	5.166	.000
	Intervention * Exergame difficulty level	.000	.463	.000	1.000
	Age (covariates)	-.006	.017	-.333	.744
	Sex (covariates)	-.573	.261	-2.192	.047
	MMSE (Covariates)	.949	.102	9.332	.000

Note. Coefficient (β): direction and magnitude for interaction of Exergame's difficulty level, Standard Error: precise estimation of coefficient, p-value is significant at 0.05.

Further moderation analysis in EG using different types of stroke showed that it did not significantly predict balance outcome (β = -1.063, p = 0.672), but it did predict functional independence status (β = 20.201, p < 0.001). Though, no major moderating effect by stroke types was seen to influence the association between the exergame intervention and balance (β = 1.250, p = 0.746) or functional independence outcomes (β = 2.000, p = 0.766). Higher cognitive function as measured by MMSE was linked to improved balance (β = 1.614, p = 0.018), but not for functional independence (β = -1.142, p = 0.289), as shown in Table 9.

Table 9. Moderation analysis for interaction of types of Stroke with Exergame training and intervention's outcomes with control variables in Experimental Group.

Outcome Variables	Predictors	Coefficient (β)	Standard Error	t	p-value
Balance	Intervention (Pre-Post)	2.500	1.852	1.350	0.200
	Stroke type	-1.063	2.455	-0.433	0.672
	Intervention * Stroke type	1.250	3.779	0.331	0.746
	Age (covariates)	0.209	0.156	1.338	0.204
	Sex (covariates)	2.213	2.117	1.045	0.315
	MMSE (Covariates)	1.614	0.594	2.717	0.018
Functional independence	Intervention (Pre-Post)	1.800	3.220	0.559	0.586
	Stroke type	20.201	4.270	4.731	0.000
	Intervention * Stroke type	2.000	6.573	0.304	0.766
	Age (covariates)	-0.337	0.271	-1.240	0.237
	Sex (covariates)	4.220	3.682	1.146	0.272
	MMSE (Covariates)	-1.142	1.033	-1.105	0.289

Note. Coefficient (β): direction and magnitude for interaction of Stroke types, Standard Error: precise estimation of coefficient, p-value is significant at 0.05.

A mediation analysis in EG revealed that the exergame compliance rate (Game I & II at various difficulty levels) served as a mediator for the impact of individual participant's characteristics (age, sex, MMSE) on balance outcomes (β = 0.304, p<0.001) and functional independence measures (β = −0.604, p = 0.044, as it can be seen in Table 10.

In the control group, types of stroke did not moderate the effects of standard balance training on balance (β = 2.125, p = 0.650) or functional independence (β = −0.125, p = 0.994). Treatment compliance significantly mediated the relationship between standard balance training and improvements in functional independence (β = 0.097, p = 0.044), but not balance outcomes (β = 0.012, p = 0.400), as shown in Tables 11 and 12.

Table 10. Mediation analysis for mediation relationship of Exergames compliance between participant characteristics (covariates) and outcomes in Experimental Group.

Outcome Variable	Predictor	Unstandardized Coefficient (B)	Standardized Coefficient (β)	p-value
Balance	Game-I (Beginner) compliance	0.304	2.382	< .001
	Game-II (Beginner) compliance	0.006	0.023	0.950
	Game-II (Advanced) compliance	-0.005	-0.042	0.843
	Age (Covariates)	.268	.404	.025
	Sex (Covariates)	9.470	.993	< .001
	MMSE (Covariates)	-3.667	-1.489	.042
Functional independence	Game-I (Beginner) compliance	-.604	-2.182	.044
	Game-II (Beginner) compliance	-.927	-1.725	.040
	Game-II (Advanced) compliance	0.212	0.843	0.068
	Age (Covariates)	-1.100	-.762	.036
	Sex (Covariates)	5.251	0.253	0.430
	MMSE (Covariates)	17.668	3.303	.029

Note. Unstandardized Coefficient (B) = actual magnitude effect of Exergame compliance, Standardized Coefficient = strength of compliance effects across variables, P-Value is set at 0.05 significance level.

Table 11. Moderation analysis for interaction of types of Stroke with standard balance training and outcomes with control variables in Control Group.

Outcome Variables	Predictors	Coefficient (β)	Standard Error	t	p-value
Balance	Intervention (Pre-Post)	3.200	1.827	1.751	0.103
	Stroke type	3.767	2.537	1.485	0.161
	Intervention * Stroke type	2.125	4.568	0.465	0.650
	Age (covariates)	-0.091	0.102	-0.896	0.386
	Sex (covariates)	-1.150	2.369	-0.486	0.635
	MMSE (Covariates)	0.589	0.380	1.551	0.145
Functional independence	Intervention (Pre-Post)	1.400	6.225	0.225	0.826
	Stroke type	15.558	8.642	1.800	0.095
	Intervention * Stroke type	-0.125	15.563	-0.008	0.994
	Age (covariates)	0.409	0.348	1.178	0.260
	Sex (covariates)	-1.393	8.071	-0.173	0.866
	MMSE (Covariates)	2.408	1.294	1.861	0.086

Note. Coefficient (β): direction and magnitude for interaction of Stroke types, Standard Error: precise estimation of coefficient, p-value is significant at 0.05.

Table 12. Mediation analysis for mediation relationship of training compliance between participant characteristics (covariates) and outcomes in Control Group.

Outcome Variable	Predictor	Unstandardized Coefficient (B)	Standardized Coefficient (β)	p-value
Balance	Intervention (Pre-Post)	3.200	0.664	0.109
	Training compliance	0.012	0.357	0.400
	Age (Covariates)	-0.157	-0.319	0.214
	Sex (Covariates)	0.437	0.037	0.867
	MMSE (Covariates)	0.193	0.112	0.803
Functional independence	Intervention (Pre-Post)	1.400	0.091	0.812
	Training compliance	0.097	0.879	0.044
	Age (Covariates)	-0.065	-0.041	0.864
	Sex (Covariates)	8.369	0.222	0.309
	MMSE (Covariates)	-1.395	-0.253	0.562

Note. Unstandardized Coefficient (B) = actual magnitude effect of training compliance, Standardized Coefficient = strength of compliance effects across variables, P-Value is set at 0.05 significance level.

Discussion

Study Feasibility

The study had a convenient access to the specific demographic of stroke patients in the study hospital. The swift progression from screening to enrollment highlights the efficiency of our recruitment procedure, ensuring the study's feasibility. All participants who enrolled attended at least one session, indicating their initial interest and accessibility towards Wii Balance Board exergame training. The monthly fluctuation in the number of patients screened and enrolled in our study may reflect the inherent variability in patient availability and willingness to participate in the study. Patient recruitment process is often influenced by factors such as patient readiness and logistical considerations [31].

The adherence rate over a two-week interval was noteworthy for both groups. This further highlights the feasibility of Wii Balance Board intervention by emphasizing the potential of gamified rehabilitation to patient engagement and adherence [32]. The completion of all designated training sessions was lower in the EG compared to the CG. This discrepancy could be attributed to the newness and perceived complexity of the Wii exergame protocol, which could have presented challenging learning process for specific individuals, potentially impacting overall adherence in the EG [33]. The planned completion rate of assessments in both groups was remarkable, indicating the trial's feasibility and verifying that the study design, including the scheduling and execution of assessments, was well tolerated by participants. The consistent duration of assessments across groups also indicates that the procedures were standardized and there were no significant time-related biases that could have influenced the study results.

We found that the difficulties related to out-patients' involvement were more prominent in the study. Logistical considerations, such as transportation challenges, scheduling conflicts including personal factors such as competing responsibilities in family, were the major obstacles as reported by our outpatient participants for drop out from the study as well as in achieving sustained adherence and successful completion of the required assessments. Given its well-structured environment and ample resources, the hospital setting naturally offered a greater degree of practicality for in-patient participating in the trial, because they had more efficient access to rehabilitation programs and faced less logistical challenges in comparison to outpatients [34]. Thus, they faced these difficulties only after being discharged from the hospital, which was the main reason for the dropout among in-patient participants.

Conversely, stroke out-patients, particularly those from rural areas in India, often face more formidable obstacles to maintaining regular involvement in rehabilitation sessions and social activities [35]. It is mostly because they lack access to suitable transportation, potential discomfort with commuting, and disruptions in their routine medical care after being released from the hospital [36].

A higher degree of compliance with Game-I at the beginning stage might be linked to the task's simplicity and accessibility, which probably matched with the participants' abilities and comfort levels. Appropriately challenging exergames tailored to the user's ability level can enhance involvement and compliance in rehabilitation environments [37]. In contrast, the lower rates of compliance noted for Game-II at both the beginner and advanced levels indicate that this game may have presented greater difficulty or lacked participant engagement. Demanding tasks of an excessive nature might result in dissatisfaction and diminished desire, ultimately leading to a decline in adherence to the intervention for a post stroke patient [38]. The cognitive and physical demands for playing the particular exergame might have exceeded participants' expectations, resulting in decreased adherence to the prescribed intervention protocol [39].

Participants who were unable to progress beyond a specific level were required to maintain the same training volume and methods as outlined in the original protocol. No modifications were implemented to the length, intensity, or organization of the training sessions in response to individual advancement. Although this method guaranteed uniformity in the training procedure, it is conceivable that individuals who showed stagnation in the progression of games difficulty may not have obtained the complete intended advantage of the intervention, which could have contributed to the observed disparities between the experimental and control groups [40]. This highlights a potential area for future research, where adaptive training methods could be implemented. For instance, dividing a prolonged gameplay session into multiple short bouts with specific rest intervals, and providing practice sessions before intervention that target not only level 1 game but also level 2 and level 3 games, would better accommodate individual ability development. Furthermore, continuous positive reinforcement during gameplay session could also better enhance the compliance rate of exergame training [41].

By comparison with the control group's higher overall compliance rate can be ascribed to the regimented character of standard balance exercises, which are probably more predictable and familiar to the participants [42]. Due to their well-recognized effectiveness and routine use, standard care rehabilitative exercises were linked to greater compliance than new or gamified treatments [43].

Procedural Safety

The study's reported types of musculoskeletal discomforts are not uncommon in balance training and exergame-based interventions due to muscular weakness persisted in the involved side limb along with improper posture while using platforms like the Wii Balance Board, as reported in similar past studies where participants engaged in repetitive and weight-bearing activities [44]. The absence of more serious adverse events, such as accidental falls, indicates that the safety protocols was implemented successfully in reducing the hazards linked to the exergame intervention, that supports procedural safety of the Wii Balance Board intervention. These adverse occurrences might have been influenced by the difficulties encountered by 80% of the participants in maintaining correct foot placement on the Wii Balance Board. Prior studies have emphasized the significance of correct posture and foot placement in balance training, especially when employing virtual reality platforms, since incorrect placement might result in compensatory movements and increased load on the affected lower limbs [45].

Participants' Enjoyment to Exergame training

The moderate levels of enjoyment reported by EG participants are crucial for understanding the overall adherence and engagement in the Wii exergame intervention as statistically significant positive correlation ($p = <0.001$) is evident between enjoyment levels and training adherence. The findings also suggest a reason for increased rates of dropout and comparatively low degree of commitment in the experimental group. Hence, there is the need of creating exergames that are both physically appropriate and enjoyable for sub-acute Stroke [46].

Preliminary Efficacy of Wii Balance Board Exergame training

The large treatment effects obtained with in both the EG and CG (Cohen's $d > 1$) suggest that both the Wii Balance Board Exergame training and standard standing balance training were successful to improve standing balance and functional independence in the short term. Nevertheless, the comparisons between the groups demonstrated limited effectiveness (Cohen's $d < 0.3$), which indicate any disparities between the interventions were negligible and lack clinical significance. Thus, the finding shows that exergaming can be effective but its benefits may not always surpass those of standard balance training methods, especially in the short term [47]. Furthermore, the results emphasize the possibility of exergame-based interventions to be used as a supplement to conventional therapies [48]. It would be important to know that their additional benefits may be restricted when directly compared to conventional approaches for sub-acute stroke [49].

The Exergame difficulty levels could be considered a strong predictor ($\beta = 7.50$, $p = 0.025$) on adherence rate and balance improvement, although they did not significantly moderate the predictive relationship between exergame training and adherence, balance, or functional independence in this study. Moreover, they could not influence the functional independence outcome suggesting that while appropriately challenging exergames could enhance motor skills in stroke patients, but they might not directly impact functional independence status [50,51]. Additionally, age, sex, or cognitive function did not significantly influence balance outcomes that indicates exergame difficulty levels could independently influence adherence rate and balance outcome in this pilot study.

Types of stroke also significantly influenced the prediction of effect on functional independence status, but did not predict balance in EG. Conversely, the absence of moderating effects between balance training and its outcomes in the control group suggests that although exergames may need to be customized for specific stroke types to maximize functional independence, standard balance training does not appear to need such customization to achieve positive results [52].

Higher MMSE scores were associated with enhanced balance among various types of stroke in the EG groups. Hence, it could be proposed that cognitive status played major role in how well the participants got benefit from the Wii exergame training [53]. In contrast, MMSE did not substantially influence outcomes in CG, emphasizing a possible benefit for individuals even with lesser cognitive reserve who might demonstrate easy improvement with traditional balancing training [54].

In both groups, training compliance rate was a crucial mediator of gaining outcomes. In the EG, exergames compliance mediated the impact of participant characteristics on both balance and functional status efficiently (p>0.001, 0.044) as compared to the CG intervention. This underscores the need of maintaining high levels of engagement in such forms of innovative intervention to gain optimal results [55].

Nevertheless, a rigorous statistical analysis with large samples is required in the definitive study for exploring how these predictors impact on balance and functional enhancement.

Limitations and Considerations

Inadequate distribution of sexes, unequal representation of hemorrhagic/ischemic stroke, and in-patient/outpatient strokes in the current study were the major limitations of this pilot study. Enhancing the credibility of the findings, the definitive studies should aim to achieve a better allocation of sex, ischemic and hemorrhagic stroke, and in-patient/out-patient stroke among each group. Given that after practice time point data collection was not carried out, it is challenging to quantify the impact of game learning just after involving in practice sessions of exergames. Hence, appropriate methods to measure those learning skills are warranted among stroke patients to identify how their initial skills differ immediately after practice session. Uniformity in the training procedure, without considering individual advancement, might have led to suboptimal outcomes. Therefore, future studies should consider modification in the Wii exergame training protocol, which better match the patient's cognitive and physical capabilities. We were only able to measure the short-term outcomes immediately after completion of the trial, but the same could not be possible on long term follow-up due to financial constraint and logistic reasons like communication breakdown with our participants. Hence, it would be essential to conduct the definitive study with long-term follow-up assessment to measure any long-term benefits. The repercussions of study's drop out would impede the efficacy of the results. To effectively overcome dropout barriers, it would be essential to use strategies such as offering transportation assistance, offering incentives, facilitating remote session access, or modifying the intervention to better align with the patient's home environment in future research. Implementing the Wii Balance board training in clinical practice would be significantly influenced by reported adverse events and stepping out episodes. Therefore, developing clinical guidelines for the use of the Wii Balance Board in stroke rehabilitation may help standardize its use and ensure consistent safety practices across different settings. Reasonable amount of enjoyment would impede the effectiveness of Wii balance board training. Hence, the exergames training should be framed in such a way to ensure its interactive terms with the stroke patients.

Conclusion

This pilot study demonstrates that Wii Balance Board exergame training is a feasible and generally safe rehabilitation approach for individuals with sub-acute stroke, with high initial compliance, and moderate enjoyment rate. The Wii Balance Board Exergame training produced significant improvements in balance and functional independence within the experimental group. However, no significant differences were observed when comparing the efficacy of Wii balance board training to standard balance training, indicating the need for further investigation to enhance overall efficacy rigorously. The current findings indicate that although exergames show potential, they should be combined with traditional balance training to maximize therapeutic results.

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