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ORIGINAL RESEARCH

Effectiveness of Conventional Versus Virtual Reality–Based Balance Exercises in Vestibular Rehabilitation for Unilateral Peripheral Vestibular Loss: Results of a Randomized Controlled Trial

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Abstract

Objective: To compare the effectiveness of virtual reality–based balance exercises to conventional balance exercises during vestibular rehabilitation in patients with unilateral peripheral vestibular loss (UVL).

Design: Assessor-blind, randomized controlled trial.

Setting: Two acute care university teaching hospitals.

Participants: Patients with UVL (N=71) who had dizziness/vertigo, and gait and balance impairment.

Interventions: Patients with UVL were randomly assigned to receive 6 weeks of either conventional (n=36) or virtual reality–based (n=35) balance exercises during vestibular rehabilitation. The virtual reality-based group received an off-the-shelf virtual reality gaming system for home exercise, and the conventional group received a foam balance mat. Treatment comprised weekly visits to a physiotherapist and a daily home exercise program.

Main Outcome Measures: The primary outcome was self-preferred gait speed. Secondary outcomes included other gait parameters and tasks, Sensory Organization Test (SOT), dynamic visual acuity, Hospital Anxiety and Depression Scale, Vestibular Rehabilitation Benefits Questionnaire, and Activities Balance Confidence Questionnaire. The subjective experience of vestibular rehabilitation was measured with a questionnaire.

Results: Both groups improved, but there were no significant differences in gait speed between the groups postintervention (mean difference, −.03m/s; 95% confidence interval [CI], −.09 to .02m/s). There were also no significant differences between the groups in SOT scores (mean difference, .82%; 95% CI, −5.00% to 6.63%) or on any of the other secondary outcomes ($P>.05$). In both groups, adherence to exercise was high (~77%), but the virtual reality–based group reported significantly more enjoyment ($P=.001$), less difficulty with ($P=.009$) and less tiredness after ($P=.03$) balance exercises. At 6 months, there were no significant between-group differences in physical outcomes.

Conclusions: Virtual reality–based balance exercises performed during vestibular rehabilitation were not superior to conventional balance exercises during vestibular rehabilitation but may provide a more enjoyable method of retraining balance after unilateral peripheral vestibular loss.

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Unilateral peripheral vestibular loss (UVL) results in vertigo, dizziness, anxiety, gaze instability during head movement, and gait and balance impairment.[1-5] Vestibular rehabilitation is a safe and effective intervention for UVL.[6-8] Fundamentally, vestibular rehabilitation programs are motor learning programs requiring practice and feedback. The increasing prevalence of technology has produced opportunities for improving rehabilitation. Virtual reality, defined as computer simulation that combines computer graphics to create a realistic-looking world that can respond in real-time to a user's input (verbal commands or gestures) and modify the virtual world instantaneously, is one such technology.[9]

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In addition, forceplate technology has been used in the clinical setting to provide visual and auditory feedback of the center of pressure and has shown some promising results.[10,11] Developments in the gaming industry have resulted in a low-cost virtual reality system, an off-the-shelf virtual reality gaming system, the Nintendo Wii Fit Plus,[a] which incorporates a force platform. It provides accurate visual and auditory feedback of the body's center of pressure during virtual reality exercises and games.[12] It perturbs balance in order to retrain it. In a previous study,[13] we reported that patients with vestibular disease found the system highly usable, enjoyable, and motivating and were in favor of using it in balance rehabilitation. Recently, Sparrer et al[14] found evidence that the Wii Fit Plus used in the first 2 weeks after acute vestibular neuritis was effective in improving balance when compared with placebo, but to date, no randomized controlled trial has investigated the superiority of the system to conventional vestibular rehabilitation, nor its application in the home exercise environment. The aim of this study therefore was to investigate whether the Wii Fit Plus as a form of virtual reality presented a superior method of rehabilitation of balance during vestibular rehabilitation when compared with conventional balance exercises during vestibular rehabilitation, in adults with UVL.

Methods

The trial was an assessor-blinded, randomized controlled, parallel trial with a 1:1 allocation. Two university teaching hospitals were involved in the study, and ethical approval was obtained from each of the sites' research ethics committees. Patients attending the otolaryngology or neurology outpatient clinics were invited to participate. Inclusion criteria were a clinical diagnosis of unilateral peripheral vestibular hypofunction confirmed, where possible, with bithermal caloric irrigation and a canal paresis >20%. Where caloric testing was not available, the presence of a positive head thrust test, or head shaking after nystagmus, or direction-fixed spontaneous nystagmus (assessed with an infrared oculomotor recording system) was required. Participants also had 1 or more of the following subjective complaints for longer than 6 weeks: dysequilibrium, gait instability, vertigo/dizziness, or motion sensitivity. Participants were excluded if they reported previous vestibular rehabilitation, had bilateral vestibular pathology, central nervous system involvement, fluctuating disease (active Meniere's disease, migrainous vertigo), active benign paroxysmal positional vertigo, or other medical conditions in the acute phase. A pacemaker or epilepsy also excluded participation (as per Nintendo Wii safety guidelines). Written informed consent was obtained. The trial protocol was published.[15]

Randomization

A permuted, blocked randomization procedure was used to randomly assign participants at an individual level to 1 of 2 treatment arms: conventional vestibular rehabilitation or virtual reality-based vestibular rehabilitation (VR). A third party, who was not involved in the day-to-day running of the trial, used an online randomization program (www.randomization.com) to assign individual patients in advance of recruitment. Block size was 6, chosen randomly from a block size of 4, 6, or 8. Allocation was notified to the treating therapist by the randomizer using e-mail or phone, after participants provided informed consent and underwent baseline assessments.

List of abbreviations:

DVA	**dynamic visual acuity**
LogMAR	**logarithm of the minimum angle of resolution**
SOT	**Sensory Organization Test**
UVL	**unilateral peripheral vestibular loss**
VR	**virtual reality-based**

Interventions

Both groups underwent 6 weeks of vestibular rehabilitation. The interventions were tripartite consisting of gaze stabilization exercises, balance exercises, and a graded walking program (supplemental appendix S1, available online only at http://www.archives-pmr.org/). The gaze stabilization exercises and the walking program were similar for both groups. The balance exercises were the differentiating feature. Balance training in the conventional group was based on a progression of conventional exercises derived from the literature and the authors' clinical practice,[16-19] and patients were provided with a foam balance mat for their home exercise program.[b] Balance training in the VR group was developed during pilot work.[13] Participants in the VR group were loaned a Wii Fit Plus for use at home and were loaned a rocker board that transforms the Wii Board from a stable to an unstable surface (Frii Board, Swiit Game Gear) (see supplemental fig S1, available online only at http://www.archives-pmr.org/). Both balance programs were designed to conform to the known neurophysiological principles underpinning balance dysfunction in UVL and its subsequent recovery,[20-23] and incorporating motor learning principles.[24] Both balance programs lasted 15min/d for 5 days a week and were progressive. Initial training in all exercises was provided in the clinic during weekly treatment sessions. Participants received weekly exercise booklets, designed to look the same, which incorporated an exercise diary (see supplemental appendix S1). A minimum of 4 sessions at the clinic (and a maximum of 7) was stipulated for those participants who lived geographically far away from the treatment site or who started the program at a higher level, or both. This was left to the discretion of the individual treating therapists and was deemed to reflect customary clinical practice. Interventions were provided by senior physiotherapists at the sites. All therapists had completed postgraduate training in vestibular rehabilitation and had an average of 6 years of experience in the rehabilitation of vestibular disorders.

Outcome measures

Outcome measures were administered by the blinded assessor at baseline, 8 weeks, and 6 months. The primary outcome measure was self-preferred gait speed (m/s) at 8 weeks. Gait speed was measured with a computerized 3-dimensional gait analysis system,[c] described elsewhere.[25] This is considered the criterion standard method of gait analysis.[26] The secondary endpoint was at 6 months. Secondary outcome measures were as follows:

Gait parameters: Gait parameters measured included speed, step length, step width, and percentage of gait cycle spent in double support during (1) self-preferred gait speed, (2) walking with head turns (as per the Dynamic Gait Index task[27]), and (3) walking with eyes closed (distance, 3.75m). For the eyes closed task, the amplitude of displacement (cm) over 3.75m.was also measured. The Dynamic Gait Index, a validated and reliable measure of gait function in patients with UVL, was also assessed.[27]

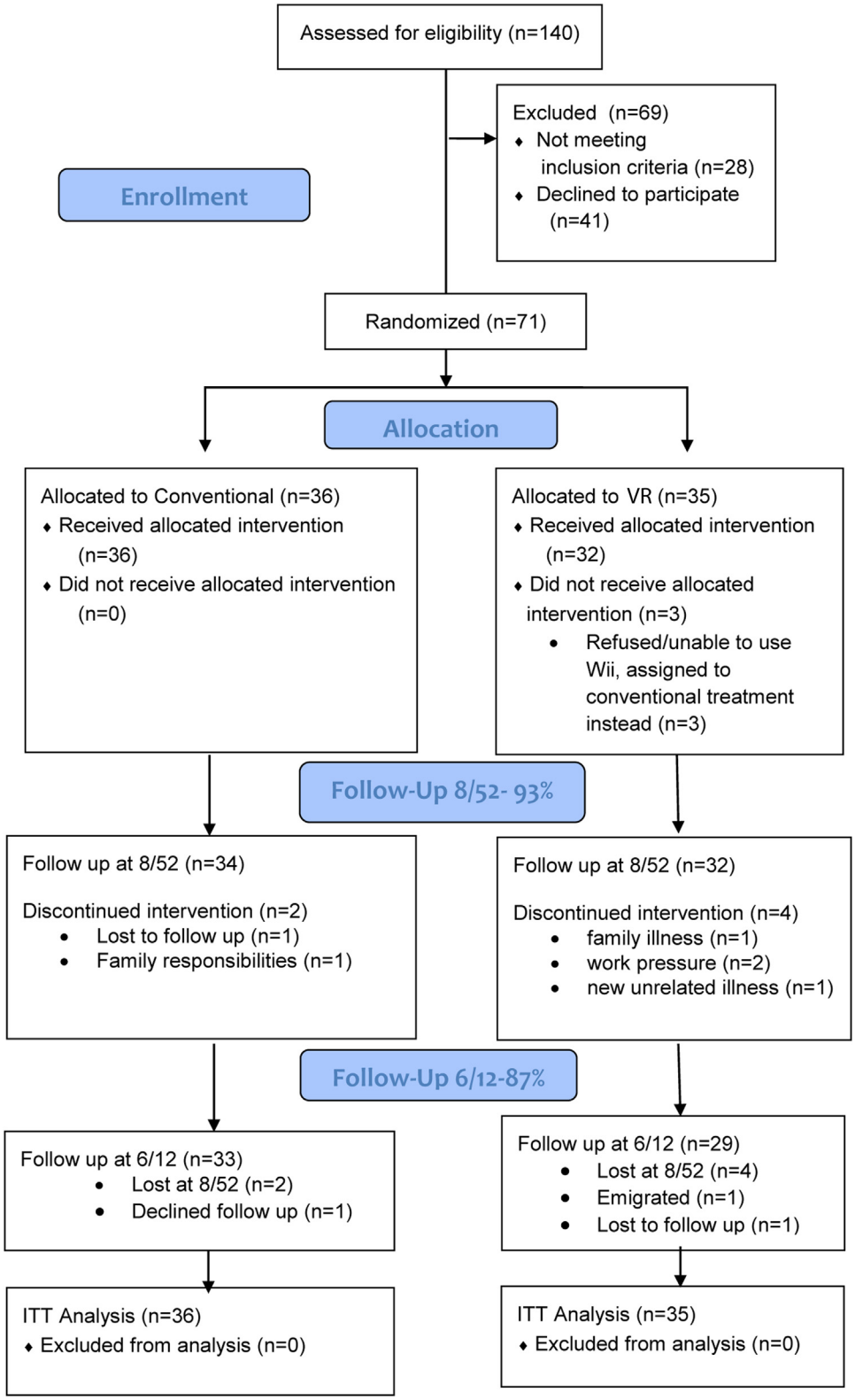

Fig 1 Consolidated Standards of Reporting Trials flow diagram of trial. Abbreviation: ITT, intention to treat. Follow up indicates the percentage of participants followed up at the time points indicated.

Standing balance: Balance was measured using the Equitest's Sensory Organization Test (SOT).[d] This is a form of computerized dynamic posturography that is validated and reliable.[28-32] The composite score, a summary percentage score of balance under 6 sensory conditions, with higher scores indicating better balance, was analyzed. In addition, the sensory ratios of conditions 5/1 and conditions 4/1, which indicate the ability to use vestibular and visual systems, respectively, were calculated.[32,33]

Table 1 Baseline characteristics of participants

Characteristics	Conventional (n=36)	VR (n=35)
Age (y)	50.47±15.53	57.83±13.6
Sex		
Men	13	14
Women	23	21
Years since first onset of symptoms Mean (SD)	4.63±4.99	5.85±8.27
Diagnosis		
Vestibular neuritis	22 (61.1)	26 (74.3)
Vestibular schwannoma	11 (30.6)	6 (17.1)
Postsurgery	8 (73.0)	2 (33.3)
Watch and scan	3 (23.0)	4 (66.7)
Ramsay Hunt syndrome	1 (2.9)	1 (2.9)
Meniere's disease	2 (5.6)	1 (2.9)
Labyrinthectomy	0 (0)	1 (2.9)
Side affected		
Left	24 (66.67)	18 (51.4)
Right	12 (33.33)	17 (48.5)
Diagnosis made by:		
Caloric weakness (n=30)	13 (36.1)	17 (48.6)
% caloric weakness	58.9±29.0	49.5±30.0
MRI (vestibular schwannoma)	11 (30.6)	6 (17.1)
Clinical diagnosis; positive head thrust test or presence of head-shaking nystagmus	12 (33.3)	12 (34.3)
No. of comorbidities		
None	9 (25)	5 (14.3)
1–2	19 (52.7)	17 (48.6)
3–5	8 (22.2)	12 (34.3)
No. complaining of:		
Dizziness	27 (75.0)	27 (77.0)
Oscillopsia	22 (64.7)	21 (61.7)
Gait problems	34 (94.5)	30 (85.7)
Dysequilibrium	33 (91.7)	33 (94.3)
Falls	15 (42.9)	11 (31.4)

NOTE. Values are mean ± SD, n, or n (%).
Abbreviation: MRI, magnetic resonance imaging.

Dynamic visual acuity (DVA): A computerized DVA system[e] was used to measure DVA (in units of LogMAR [logarithm of the minimum angle of resolution]) during horizontal head movement at a velocity of 150°/s. The system consisted of a gyroscope secured to the head to measure the angular velocity of head rotation. The character was an optotype "Ш", the size of which was changeable and represented different values of LogMAR (from −0.3 to 1.0 LogMAR), and was presented randomly on a monitor in 1 of 4 orientations (right, left, up, or down). Static visual acuity was determined first. This was taken as the lowest LogMAR value at which the orientation of 3 of 5 optotypes could be correctly identified. Visual acuity was then measured during active horizontal head movement and DVA calculated as the difference between static and dynamic tests.

Subjective measures: The Vestibular Rehabilitation Benefits Questionnaire,[16,17] Activities Balance Confidence Questionnaire,[18,19] and Hospital Anxiety and Depression Scale[20] were patient-reported outcome measures. All have been validated for use in vestibular disease.[34-38] Patient satisfaction with treatment was evaluated by means of a 5-item questionnaire developed by the researchers that asked participants to rate, on a 5-point Likert scale, their level of enjoyment, motivation, adherence, tiredness, and difficulty with the gaze stabilization, balance, and walking exercises, respectively. Preliminary analysis of this questionnaire returned a Cronbach alpha of .82.

Adherence: Self-reported adherence to the vestibular rehabilitation program was quantified using the returned exercise booklets, which had a diary incorporated (see supplemental fig S2, available online only at http://www.archives-pmr.org/). A percentage adherence score was generated by summing all the exercises reported as completed and expressing them as a percentage of the total exercises prescribed for each week. An average was then obtained for the 6 weeks. Incomplete data sets were analyzed on a worst case scenario where the nonreturned diaries were scored as zero adherence for that week.

Sample size calculation

The sample size calculation is reported elsewhere.[15] Based on a 2-sample *t* test, 36 participants per group were required to detect a

gait speed difference of 0.1m/s (with a common SD of .15m/s) with 80% power and an alpha of $P=.05$.[39]

Statistical methods

Statistical analysis was performed using Stata 11 statistical software.[f] Intention-to-treat analysis and per-protocol analyses were performed.[40,41] Baseline data were examined for comparability. Where there were missing data, the last observation was carried forward. Data were summarized using means, SDs, and 95% confidence intervals for continuous variables; median and interquartile ranges for nonnormal continuous or ordinal data; and percentages for categorical data. Per-protocol analyses were performed excluding patients with major deviations from the treatment protocol (defined as <50% adherence with treatment) and those with missing data.[42] Data were examined for normality using the Shapiro-Wilk test. Linear regression modeling was used to investigate between-group effects on outcomes, including baseline levels of the outcome and adjusting for baseline imbalances of known predictor variables. Results were reported as the adjusted mean differences between the groups and their confidence intervals.[43] Poisson regression was used where data were nonnormal. The null hypothesis was rejected if $P<.05$. Within-group comparisons against baseline were examined only for trends, as the main hypothesis was investigating the superiority of the virtual reality-based vestibular rehabilitation.[44]

Results

Recruitment to the study commenced in January 2011 and ceased in April 2013. A total of 71 participants were recruited. The last 6-month follow-up was completed on October 4, 2013. The flow of participants through the study is shown in figure 1.

A total of 140 individuals met the inclusion criteria; 41 of them declined to participate, and 28 were excluded by the exclusion criteria (epilepsy, n=2; pacemaker, n=3; asymptomatic, n=11; central nervous system abnormality, n=4; previous vestibular rehabilitation, n=4; unable to use a Wii, n=4). Therefore, 71 participants were randomly allocated to either the conventional group (n=36) or the VR group (n=35). Three participants (2 women aged 73y and 80y, and 1 man aged 73y) allocated to the VR group found the Wii Fit Plus too difficult to use and were crossed over to the conventional group at the end of their first treatment. Ninety-three percent and 87% of participants were followed up at 8 weeks and 6 months, respectively. Baseline data are shown in table 1. All baseline characteristics were comparable, with the exception of age. Individuals in the VR group were on average 7.3 years older than those in the conventional group (57.83y vs 50.47y). Age was therefore included as a covariate in the analyses.

In the intention-to-treat analysis (on outcomes at 8wk and at 6mo), the last-observation-carried-forward method was used for the 6 participants (8.5%) who had not completed the study and who had missing data at 8 weeks (see fig 1). The adjusted mean differences between the groups for outcomes at 8 weeks and 6 months are shown in tables 2 to 4. Individual baseline and 8-week scores are shown in figure 2.

Primary outcome: gait speed

Self-preferred gait speed improved from baseline to 8 weeks in both groups (see table 2 and fig 2A). The regression model,

Table 2 Comparison of primary and secondary outcome measures for both groups (conventional group and VR group) at baseline and primary endpoint (8wk) and 6 months

Outcome	Baseline		8wk*		6mo		Difference Between Groups†			
	Conv (n=36)	VR (n=35)	Conv (n=36)	VR (n=35)	Conv (n=36)	VR (n=35)	8wk*		6mo	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean (95% CI)	*P**	Mean (95% CI)	*P*
Gait speed (m/s)	1.28±0.18	1.22±0.22	1.38±0.16	1.31±0.20	1.40±0.19	1.34±0.19	−0.03 (−0.09 to 0.02)	.23	−0.03 (−0.09 to 0.04)	.38
Dynamic Gait Index (/24)	19.44±3.01	19.48±3.67	22.38±1.92	22.13±2.33	22.39±1.78	22.14±2.36	−0.25 (−1.14 to 0.65)	.59	−0.08 (−0.99 to 0.82)	.86
SOT (%)	52.58±12.27	55.8±15.40	65.53±14.74	68.23±14.03	65.44±14.54	67.24±15.05	0.82 (−5.00 to 6.63)	.78	1.20 (−4.77 to 7.16)	.69
Activities Balance Confidence Scale (%)	64.49±20.38	64.82±18.74	81.54±14.07	74.33±21.25	83.03±16.79	79.28±20.33	−6.18 (−13.19 to 0.82)	.08	−3.08 (−11.07 to 4.92)	.45
Vestibular Rehabilitation Benefits Questionnaire Total (%)	37.86±17.48	40.27±13.80	17.48±14.76	22.4±16.15	16.91±16.41	21.42±16.62	4.17 (−2.76 to 11.11)	.23	2.78 (−4.66 to 10.22)	.75
DVA affected side (LogMAR)	0.2 (0.2)‡	0.2 (0.2)‡	0.2 (0.2)‡	0.2 (0.2)‡	NM	NM	−0.04 (−0.32 to 0.23)§	.76	NM	NM
DVA nonaffected side (LogMAR)	0.2 (0.2)‡	0.2 (0.1)‡	0.15 (0.15)‡	0.2 (0.2)‡	NM	NM	−0.31 (−0.31 to 0.27)§	.27	NM	NM
Hospital Anxiety and Depression Scale score total (/42)	11.94±7.68	13.15±7.78	8.61±7.32	10.77±7.72	NM	NM	1.13 (−1.35 to 3.60)	.91	NM	NM

Abbreviations: CI, confidence interval; Conv, conventional group; NM, outcome not measured at 6/12.

* Primary endpoint.

† Regression analyses adjusted for baseline levels of the dependent variable and age.

‡ Median (interquartile range).

§ Poisson regression, differences between groups reported as the log of expected counts of DVA score.

Table 3 Between-group differences of gait parameters in 3 gait tasks: self-preferred speed, walking with head turns, and walking a distance of 3.75m with eyes closed

	Baseline		8wk*		Difference Between Groups†	
	Conv (n=36)	VR (n=35)	Conv (n=36)	VR (n=35)	8wk*	
Gait Task Outcome	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean (95% CI)	P*
Self-preferred speed						
% GC in DS	22.91±2.99	23.45±3.53	21.69±2.65	22.54±3.10	.50 (.29 to 1.30)	.21
Stride length (m)	1.29±0.15	1.25±0.18	1.36±0.13	1.30±0.17	−.03 (−.06 to .01)	.16
Step width (m)	0.16±0.04	0.16±0.05	0.16±0.03	0.16±0.04	.01 (−.001 to .02)	.08
Gait with head turns						
Gait speed (m/s)	1.14±0.18	1.10±0.21	1.25±0.19	1.20±0.21	−.02 (−.07 to .05)	.63
% GC in DS	25.14±3.58	25.52±4.73	23.90±3.65	24.98±4.29	.89 (−.32 to 2.10)	.15
Stride length (m)	1.18±0.17	1.15±0.19	1.25±0.15	1.20±0.19	−.04 (−.08 to .005)	.08
Step width (m)	0.17±0.04	0.17±0.05	0.16±0.03	0.16±0.05	.005 (−.007 to .02)	.40
Gait with eyes closed						
Gait speed (m/s)	0.91±0.24	0.86±0.29	1.08±0.23	0.99±0.29	−.05 (−.13 to .03)	.22
% GC in DS	29.28±6.02	30.78±8.20	25.76±4.90	28.15±6.49	1.39 (−.75 to 3.53)	.16
Stride length (m)	1.07±0.20	1.02±0.28	1.18±0.19	1.09±0.26	−0.03 (−.10 to .03	.32
Step width (m)	0.19±0.06	0.20±0.07	0.18±0.05	0.18±0.06	.002 (−.02 to .02)	.80
Amplitude of displacement 3.75m (cm)	10.38 (14.35)‡	19.21 (17.6)‡	7.48 (14.20)‡	10.01 (13.9)‡	.06 (−.33 to .44)§	.78

Abbreviations: CI, confidence interval; Conv, conventional group; DS, double support; GC, gait cycle.
* Primary endpoint.
† Regression analyses adjusted for baseline levels of the dependent variable.
‡ Median (interquartile range).
§ Poisson regression.

including age and baseline gait speed as covariates, showed that there were no significant differences between the groups in self preferred gait speed at 8 weeks (mean difference, −.03m/s; 95% confidence interval, −.09 to .02; $P=.23$).

Primary endpoint: secondary outcomes

There were no significant differences between the groups at the primary endpoint on any gait task or parameter ($P>.05$; see table 3). The Equitest SOT scores improved in both groups from baseline to 8 weeks (see fig 2B).There were no significant differences between groups (adjusted mean difference, .82%; 95% confidence interval, −5.00 to 6.63; $P=.78$) at 8 weeks (see table 2). Subscore ratios of the SOT also showed no significant differences between the groups at 8 weeks ($P>.05$) (see table 4).

DVA data were not normally distributed. Improvement in DVA was seen in both groups for both rotations of the head toward the affected side and toward the nonaffected side. Poisson regression analysis showed that there was no significant difference between groups at 8 weeks ($P>.05$) (see table 2).

Subjective measures

There were no significant differences between the groups at 8 weeks or at 6 months for the Vestibular Rehabilitation Benefits Questionnaire or the Hospital Anxiety and Depression Scale and their subscores, nor for the Activities Balance Confidence Questionnaire ($P>.05$) (see tables 2–4 and fig 2C,D). The VR group reported significantly more enjoyment ($P=.001$) with the balance component of the program and significantly less tiredness ($P=.03$) after, and less difficulty with the balance exercises ($P=.009$).

Adherence

There were complete sets of diaries in 83% of participants. Adherence was 78.5% in the conventional group and 77.1% in the VR group, and there were no significant differences between the groups ($P>.05$, Mann-Whitney U test).

Adverse events

A total of 3 study-related adverse events occurred. Only 1, recurrence of low back pain, was attributed to the Wii Fit Plus. The other 2 were exacerbations of neck pain and severe nausea and both were considered related to the gaze stabilization exercises.

Per-protocol analysis

The per-protocol analysis was performed on 61 participants. No significant differences were found between the groups on any outcome measures at either time point ($P>.05$).

Discussion

This trial was the first to investigate whether virtual reality-based vestibular rehabilitation using the Wii Fit Plus for balance exercises was superior to conventional vestibular rehabilitation. It was also the first to use the Wii Fit Plus in a home exercise program. We hypothesized that the Wii Fit Plus would have a superior effect on physical outcomes because it provided visual and auditory feedback of balance control. However, no superior effect on balance, gait, and subjective outcome measures over the short- or long-term was found. We found that gait speed improved in both

Table 4 Comparison of primary and secondary outcome measure subscores for both groups (conventional group and VR group) at baseline and primary endpoint (8wk) and 6 months

	Baseline		8wk*		6mo		Difference Between Groups†			
	Conv (n=36)	VR (n=35)	Conv (n=36)	VR (n=35)	Conv (n=36)	VR (n=35)	8wk*		6mo	
Outcome	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean (95% CI)	*P**	Mean (95% CI)	*P*
Subscore										
VRBQ symptom (%)	36.87±17.85	40.35±13.39	20.95±16.30	26.11±16.64	20.44±18.10	25.53±17.17	2.09 (−4.72 to 8.90)	.54	1.88 (−5.79 to 9.56)	.63
VRBQ quality of life (%)	37.91±20.57	40.16±21.73	14.14±19.11	18.78±20.62	14.47±20.01	17.34±19.05	5.13 (−4.00 to 14.26)	.26	2.08 (−7.14 to 11.29)	.65
VRBQ anxiety (%)	25.32±25.51	25.05±21.90	16.53±19.59	19.14±17.32	14.52±18.71	18.32±19.57	1.35 (−8.19 to 10.89)	.78	3.46 (−4.56 to 11.49)	.39
VRBQ dizziness (%)	47.66±22.29	52.26±17.83	29.99±22.05	35.51±24.73	29.19±24.18	35.00±24.11	1.69 (−6.01 to 9.40)	.66	2.27 (−8.27 to 12.80)	.67
VRBQ motion-provoked dizziness (%)	38.65±21.84	40.04±19.56	18.92±16.82	24.64±18.90	19.02±18.80	24.07±20.95	4.64 (−3.11 to 12.40)	.24	3.12 (−5.76 to 11.99)	.49
SOT C4/C1 (ratio)	0.65±0.23	0.71±0.21	0.83±0.16	0.84±0.09	0.78±0.22	0.78±0.19	−0.01 (−0.07 to 0.05)	.70	−0.01 (−0.11 to 0.09)	.85
SOT C5/C1 (ratio)	0.20±0.22	0.26±0.27	0.38±0.30	0.43±0.30	0.38±0.27	0.40±0.28	0.02 (−0.10 to 0.13)	.27	0.002 (−0.12 to 0.12)	.97
HAD Anxiety (/21)	7.00±4.70	7.64±4.31	5.53±4.95	6.32±4.05	NM	NM	0.37 (−1.16 to 1.90)	.63	NM	NM
HAD Depression (/21)	4.94±3.39	5.5±3.91	3.11±2.83	4.29±4.01	NM	NM	0.49 (−0.79 to 1.77)	.45	NM	NM

Abbreviations: C1, condition 1 of the SOT; C4, condition 4 of the SOT; C5, condition 5 of the SOT; CI, confidence interval; Conv, conventional group; HAD, Hospital Anxiety and Depression Scale; NM, not measured; VRBQ, Vestibular Rehabilitation Benefits Questionnaire.

* Primary endpoint.

† Regression analyses adjusted for baseline levels of the dependent variable.

groups (average: .09m/s in VR group, 0.1m/s in conventional group), a magnitude of improvement that is in agreement with other studies[16,17,45] using conventional vestibular rehabilitation. The adjusted mean difference of −.03m/s at the primary endpoint between the groups was not significant. Importantly, the 95% confidence interval (−.09−.02m/s) did not include the predetermined, clinically important difference of 0.1m/s, indicating that the trial was adequately powered. The secondary outcome of balance was arguably the next most important outcome measure, as the mode of balance exercises was the only difference between the groups. Similarly, no superior effect was evident in composite SOT scores, with both groups improving (on average by 12%). The improvement by both groups was similar in magnitude to that reported by other studies (Pavlou et al,[33] 12%−20%; Meli et al,[46] 9.62%). In contrast, a previous study[11] using forceplate technology similar to the Wii Fit Plus found a superior effect on standing balance when compared with conventional treatment. Other important secondary outcomes of symptoms of dizziness and vertigo, DVA, balance confidence, and balance-perturbing gait tasks showed no significant between-group differences. The per-protocol analysis supported the intention-to-treat analysis, also demonstrating a lack of superiority of virtual reality-based balance exercises. The nonsignificant findings in the primary and secondary outcomes remained at the longer-term follow-up of 6 months.

A high level of adherence was reported by both groups: 78.5% in the conventional group and 77.1% in the VR group ($P=.86$). This was an important finding because adherence has been found to affect outcome. Yardley and Kirby[47] measured adherence and found that greater adherence resulted in a greater improvement in symptoms in a home-based vestibular rehabilitation program. The patients in the vestibular rehabilitation arm of that trial reported a mean adherence rate of only 37.5%, which is much lower than the adherence rate in the present study. Therefore in the present trial, the similar adherence levels in the groups suggested that adherence was not a confounder.

The only significant superior finding was in the satisfaction questionnaire, in which the VR group reported significantly more enjoyment, less fatigue, and less difficulty with the balance exercises. These results should be viewed with caution because they are a post hoc analysis of individual scores on an as yet unvalidated questionnaire.

There were minimal adverse events, suggesting that the Wii Fit Plus can be used safely at home by this population. The observation that no falls occurred was important because patients with UVL are at risk for falls.[48]

Three individuals in the VR group crossed over to the conventional group because of difficulty using the Wii Fit Plus, and all were older than 70 years. We have previously reported that older patients reported less usability of the Wii Fit Plus.[49] The cost-effectiveness of the Wii Fit Plus, although not formally investigated in this study, should be considered. The Wii Fit Plus is more expensive than the foam balance mat. Furthermore, therapists reported that training the VR group took more time. Thus the opportunity costs of implementing the Wii Fit Plus in treatment may preclude its use, particularly if superior benefits are not evident.

During the course of the trial, Sparrer[13] published a study that investigated the use of the Wii Fit Plus in the early acute phase (0−5d) after vestibular neuritis and found that the Wii Fit Plus was superior to placebo. This is the only other study that has used the Wii Fit Plus in vestibular rehabilitation, but its methodological

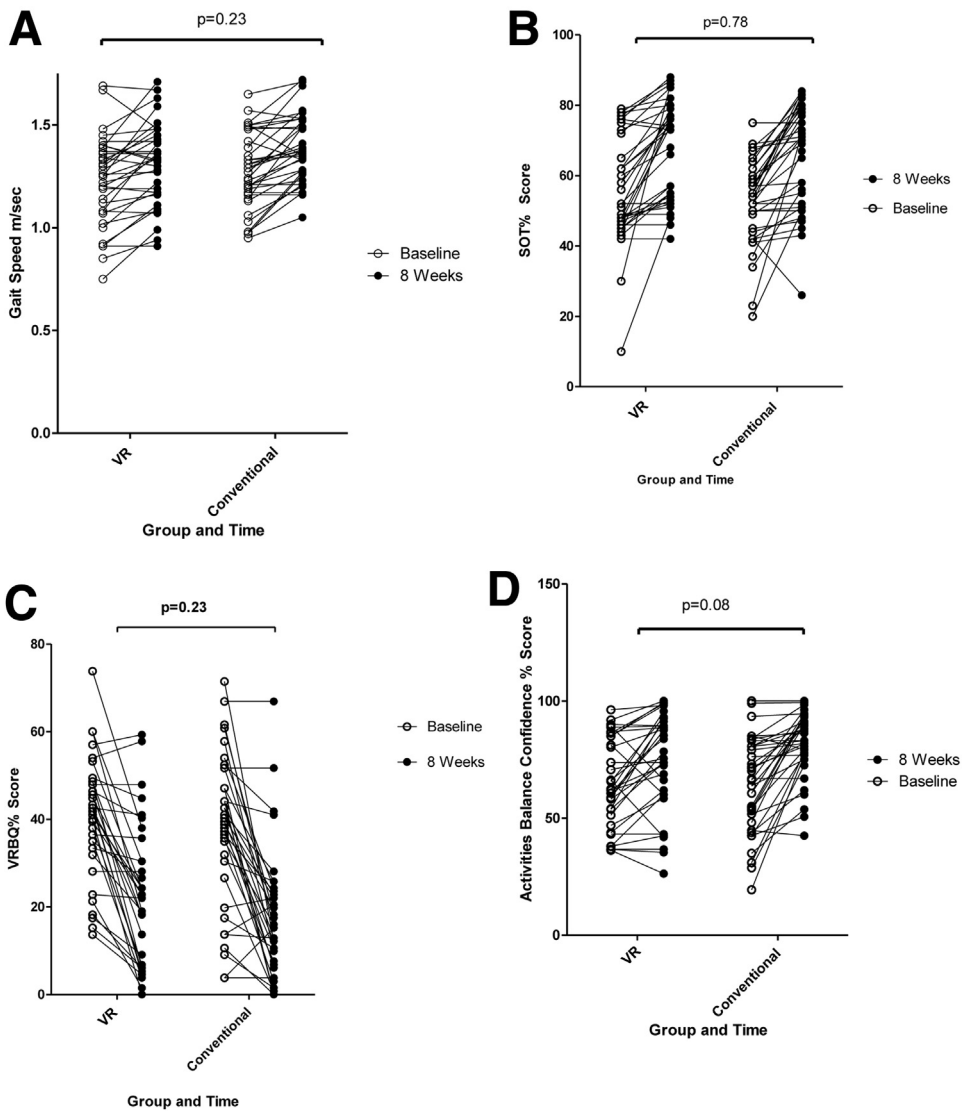

Fig 2 Raw scores for each participant at baseline (open circles) and 8 weeks (filled circles) stratified by group (VR and conventional treatment group) for primary outcome of (A) gait speed, (B) composite score of the SOT, (C) Vestibular Rehabilitation Benefits Questionnaire (VRBQ), and (D) Activities Balance Confidence scores.

differences preclude any comparisons to the present study. Two recent systematic reviews[49,50] in the area of using virtual reality in balance rehabilitation, albeit using heterogeneous populations, concluded that the evidence is weak at present, and 1 of the reviews, by Booth et al,[50] performed a meta-analysis that found no evidence for superiority of virtual reality interventions to improve balance when compared with conventional therapies. The findings of the present study are in agreement with these findings.

Study limitations

Blinding of the therapists and participants was not feasible in the study but must be considered a limitation of the study. The interventions were tripartite (gaze stabilization exercises, balance exercises, walking program), which meant it was not possible to estimate the contribution of each to the overall effects. It was considered unethical to omit the gaze stabilization exercises because of their evidence base.[7,21] Future studies might be able to investigate the relative contributions of each of the components to improvement.

Conclusions

This trial found that virtual reality-based balance exercises in vestibular rehabilitation were not superior to conventional balance exercises during vestibular rehabilitation, in patients with UVL, over the short- or long-term, but may present a more enjoyable and less difficult method of balance retraining. Future generations are likely to have expectations of technology to provide them with feedback during exercise, and this trial can be viewed as an initial investigation of using a low-cost, off-the-shelf, user friendly, virtual reality—based alternative to a more conventional method of retraining balance during vestibular rehabilitation. This trial will add to the rapidly expanding body of evidence pertaining to virtual reality and electronic gaming systems in vestibular rehabilitation.

Suppliers

a. Nintendo Wii Fit Plus; Nintendo.
b. Sissel Balance Fit Pad; Physio Needs.
c. Computerized 3-dimensional gait analysis system; Vicon Motion Systems Ltd.
d. Equitest's Sensory Organization Test; NeuroCom, a division of Natus.
e. Computerized DVA system; Micromedical Technologies.
f. Stata 11 statistical software; StataCorp LP.

Keywords

Dizziness; Gait; Postural balance; Rehabilitation; Vestibular diseases; Virtual reality exposure therapy

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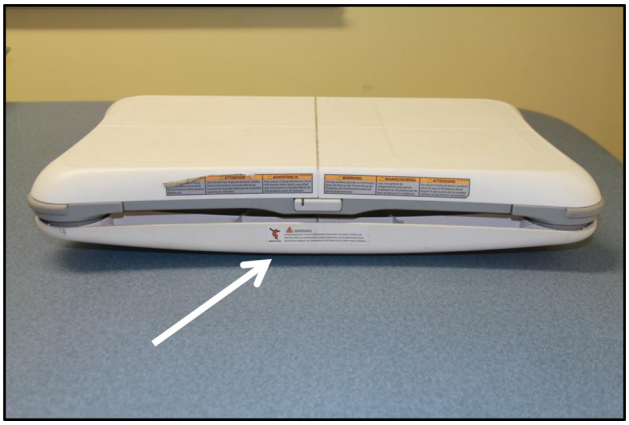
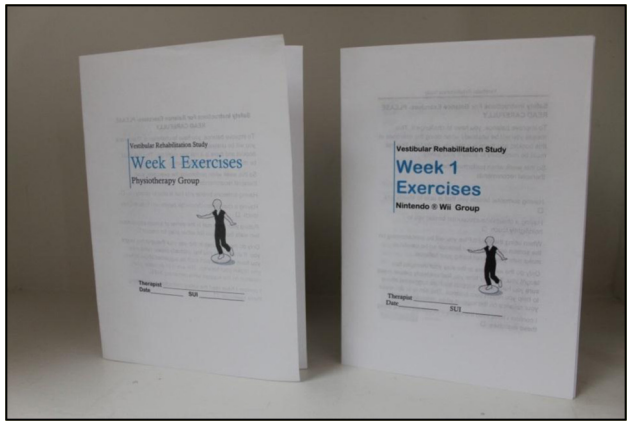


Supplemental Fig S1 Frii Board (Swiit Game Gear), an accessory for the Nintendo Wii Fit Plus balance board that attaches to the underside of the balance board (shown by white arrow) and converts it into an unstable surface.



Supplemental Fig S2 Example of the exercise book and diaries for the groups.