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Clinical feasibility of the Nintendo Wii™ for balance training post-stroke: a phase II randomized controlled trial in an inpatient setting

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Abstract

Objective: To investigate the feasibility and potential efficacy of the Nintendo Wii™ for balance rehabilitation after stroke.

Design: Phase II, single-blind, randomized controlled trial.

Setting: Inpatient rehabilitation facility.

Subjects: Thirty adults (mean age 63.6 (14.7) years) undergoing inpatient rehabilitation who were less than three months post-stroke and able to stand unsupported.

Interventions: Participants were allocated to a Balance Group, using the 'Wii Fit Plus' in standing, or Upper Limb Group, using the 'Wii Sports/Sports Resort' in sitting. Both groups undertook three 45 minute sessions per week over two to four weeks in addition to standard care.

Main measures: The primary focus was feasibility, addressed by recruitment, retention, adherence, acceptability and safety. Efficacy was evaluated by balance, mobility and upper limb outcomes.

Results: Twenty-one percent of individuals screened were recruited and 86% (n = 30) of eligible people agreed to participate. Study retention and session adherence was 90% and > 99%, respectively, at two weeks; dropping to 70% and 87% at four weeks due to early discharge. All participants reported enjoying the sessions and most felt they were beneficial. No major adverse events occurred. Wii use by the Balance Group was associated with trends for improved balance, with significantly greater improvement in outcomes including the Step Test and Wii Balance Board-derived centre of pressure scores. The Upper Limb Group had larger, non-significant changes in arm function.

Conclusions: A Wii-based approach appears feasible and promising for post-stroke balance rehabilitation. A larger randomized controlled trial is recommended to further investigate efficacy.

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Introduction

The management of balance deficits is an essential component of stroke rehabilitation. Reduced balance is common following stroke, negatively impacting the individual's independence and safety.[1] Up to 73% of people with stroke report falling during the first six months after leaving hospital.[2] Although there is currently no definitive approach for balance retraining after stroke, evidence supports the intensive practice of task-related activities.[3]

The Nintendo Wii™, a motion-controlled videogame system, has become an increasingly popular adjunct to rehabilitation therapy worldwide.[4] Preliminary evidence supports the feasibility of using the 'Wii Fit' in populations such as Parkinson's Disease,[5] Multiple Sclerosis,[6] and older adults.[7,8] These small studies have demonstrated high levels of adherence,[6,8] satisfaction,[5,7,8] and safety,[6-8] as well as improvements in selected balance outcomes.[5-8]

The utility of upper limb-based Wii interventions following stroke has been more comprehensively studied than the application of the 'Wii Fit' for balance training after stroke.[9-11] Two published studies have investigated the efficacy of the 'Wii Fit' following stroke.[12,13] Minimal information about feasibility, including safety, was reported in these studies and the participants were long-term stroke survivors. The results of these studies can therefore not be generalised to rehabilitation settings where the 'Wii Fit' is being increasingly incorporated. The limited evidence supporting Wii use for balance rehabilitation after stroke highlights the need for further investigation, particularly in a sub-acute population.

The primary aim of this study was to evaluate the feasibility of a Wii-based treatment approach in an inpatient stroke rehabilitation setting. The secondary aims were to investigate preliminary efficacy of this approach for improving balance, mobility and upper limb function. It was hypothesised that the intervention would be feasible, and that improvements in balance performance would be observed in the group undertaking a 'Wii Fit Plus'-based balance intervention.

Methods

A phase II, single-blind, randomized controlled trial was undertaken. The study was approved by the institutional Human Research Ethics Committee, and informed consent was obtained from all participants. Reporting was conducted in accordance with CONSORT[14] and recommendations for pilot studies.[15] Further details on the methodology have been documented elsewhere[16] and are summarised in the following sections.

All individuals with a diagnosis of stroke admitted to an inpatient rehabilitation facility in Melbourne, Australia were screened for eligibility and recruited consecutively. The inclusion criteria were: (i) 18 years and over; (ii) non-cerebellar stroke less than three months prior; (iii) able to stand unsupported for longer than 30 seconds; and (iv) have functional use of at least one upper limb. Exclusion criteria included: (i) medically unstable or other medical condition that could confound results; (ii) severe dysphasia, dyspraxia or cognitive impairment; (iii) anticipated length of stay less than three weeks. Following enrolment and baseline assessment, a minimisation procedure, based on the participant's Stroke Rehabilitation Assessment of Movement (STREAM) score,[17] was used to assign participants to either the Balance Group (intervention) or Upper Limb Group (active control). Allocation was concealed until the participant's score was entered into the Excel-based program. A sample size of 30 participants was chosen as a practical and appropriate size for a pilot study.[18]

Therapists involved in the standard care of participants and the outcome assessors were blinded to group allocation. Intervention sessions were undertaken in a closed room and participants were asked not to discuss details of the study intervention with their usual therapists or the assessor. Participants

were aware that both groups would be using the Wii, but were not provided with details of the group intervention differences.

Both groups undertook a Wii training program in addition to their standard multidisciplinary care. Wii sessions were provided three times per week for a minimum of two and a maximum of four weeks, dependent upon, and reflective of, the typical inpatient length of stay. Sessions were individually supervised by a physiotherapist and ran for approximately 45 minutes, consistent with usual therapy schedules. Standard care primarily consisted of physiotherapy and occupational therapy in both individual and group settings.

Balance Group participants undertook standing balance activities using the 'Wii Fit Plus' package. A possible 18 of 66 activity options were utilised, and are detailed elsewhere.[16] Activity selection and progression was individualised to the participant's balance ability. The variety of tasks included both static poses (e.g. yoga deep breathing) and more dynamic activities such as weight-shifting (e.g. ski slalom) and stepping (e.g. jogging). Therapeutic challenge was also increased by varying the task complexity (e.g. speed requirements and dual-tasking) and decreasing external support (e.g. reducing hands-on assistance and cueing).

Upper Limb Group participants used the 'Wii Sports' and/or 'Wii Sports Resort' packages in a seated position. An active control group was chosen to balance group equivalence in time spent receiving a novel treatment approach. Activities were primarily chosen based on participants' upper limb function (e.g. boxing or cycling for gross upper limb movement, and bowling or archery for dexterity). Individuals were encouraged to use their affected upper limb and task difficulty and duration was increased progressively as appropriate.

Feasibility was the primary outcome of interest and encompassed recruitment, retention, adherence, acceptability and safety. A screening log was used to record study recruitment and retention. Adherence was represented by session attendance and the length of treatment sessions. Additionally, a therapy log was used to quantify the duration and type of standard therapy received. Acceptability was evaluated by participants at the end of each session by the completion of 5-point Likert scales rating enjoyment, ease-of-use and perceived helpfulness of the intervention on recovery from 'strongly disagree' (1) to 'strongly agree' (5). Overall impressions at the end of the study, including a comparison to their usual physiotherapy, were also rated. Safety encompassed: (i) documentation of any adverse events, including falls both within the treatment sessions and during the study period; (ii) pain and fatigue ratings before and after each session using an 11-point visual analogue scale (VAS);[19,20] and (iii) rating of perceived exertion after each session using the BORG scale (rated 6-20).[21] Furthermore, independence in the ability to navigate the Wii menus and interact with the gaming activities was recorded.

Efficacy outcomes were assessed at baseline, two weeks and four weeks. The primary clinical outcomes of interest were the Step Test,[22] with the affected leg in stance position, and the Functional Reach Test.[23] Secondary outcomes assessed were: (i) the Timed Up and Go;[24] (ii) Wii Balance Board-derived centre of pressure measures of static and dynamic balance;[25] (iii) the Short Falls Efficacy Scale – International;[26] (iv) the Upper Limb – Motor Assessment Scale;[27] and (v) the STREAM.[17] Further details on the measurement properties and rationale for their selection can be found in the protocol paper.[16]

Descriptive statistics were used to summarise baseline characteristics and feasibility data. The Shapiro-Wilk test and visual inspection of histograms were used to evaluate data distribution. Independent t-tests, Mann-Whitney U tests or Chi-square tests were conducted for comparisons at baseline and for between-group comparisons of feasibility outcomes. Change scores (mean, (SD)), between-group differences in change scores (mean, 95% CI) and effect sizes (Cohen's *d*) were calculated for efficacy outcomes, and repeated measures analysis of variance (ANOVA) was used to evaluate within and between group changes. Statistical analysis was undertaken using the SPSS for Windows, version 21.0 (SPSS Inc, Chicago, IL) and the level of significance was set at 0.05.

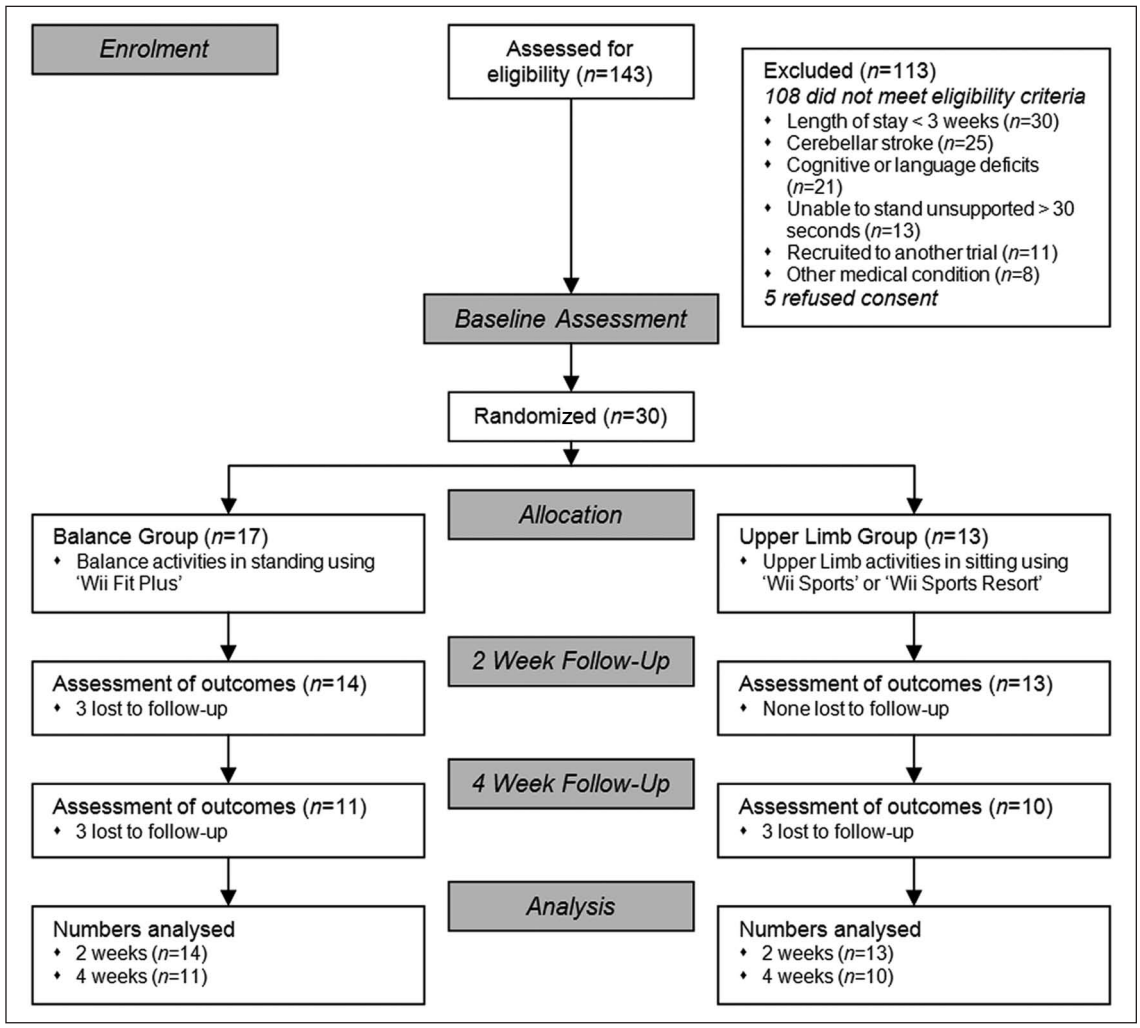

Figure 1. Study flow diagram based on CONSORT.

Results

One hundred and forty-three consecutive admissions with stroke were screened from September 2010 to September 2012 (Figure 1); 108 were ineligible, five declined consent, and 21% ($n = 30$) were recruited. Three participants in the Balance Group withdrew from the study prior to the two week assessment, one due to lack of interest, one became medically unwell, and one was discharged. A further three participants in each group were discharged prior to the four week assessment.

The mean (SD) age of participants was 63.6 (14.7) years and the time from stroke onset was 24.8 (18.1) days. The demographic variables and efficacy outcomes were similar between the groups at baseline (Table 1). Participants withdrawing from the study prior to the two week assessment did not significantly differ from remaining participants. The six participants discharged home prior to the four week assessment had significantly better baseline Timed Up and Go ($P = 0.023$), Upper Limb STREAM ($P = 0.018$), Total STREAM ($P = 0.022$), and Step Test

Table 1. Baseline characteristics.*

	BG (*n*=17)	ULG (*n*=13)
Demographics		
Age, mean (SD), yrs	61.9 (13.6)	65.9 (16.2)
Male gender, *n* (%)	8 (47%)	9 (69%)
Height, mean (SD), cm	165.8 (9.7)	170.9 (7.8)
Body mass, mean (SD), kg	70.6 (14.2)	77.0 (8.6)
Stroke details		
Left-sided lesion, *n* (%)	7 (41%)	7 (54%)
Stroke type, infarct, *n* (%)	12 (71%)	8 (62%)
OSCP classification		
TACS, *n* (%)	2 (11.8%)	2 (15.4%)
PACS, *n* (%)	9 (52.9%)	9 (69.2%)
LACS, *n* (%)	6 (35.3%)	2 (15.4%)
Time since stroke, mean (SD), days	25.4 (16.4)	24.2 (20.8)
Comorbidities		
Hypertension, *n* (%)	11 (64.7%)	11 (84.6%)
Ischaemic heart disease, *n* (%)	0	4 (30.8%)
Diabetes, *n* (%)	2 (11.8%)	3 (23.1%)
Dyslipidaemia, *n* (%)	5 (29.4%)	4 (30.8%)
Atrial Fibrillation, *n* (%)	2 (11.8%)	3 (23.1%)
Smoking history, *n* (%)	2 (11.8%)	7 (53.8%)
Previous stroke, *n* (%)	3 (17.6%)	2 (15.4%)
Functional state		
mRS, median (IQR)	3.0 (3.0–4.0)	4.0 (3.0–4.0)
FIM (on rehab admission)	69.0 (49.2–85.5)	74.0 (60.5–82.0)
MMSE, median (IQR), /30	26 (24–28)	26 (21–27)
STREAM, median (IQR), /100	84 (33–100)	77 (49–94)
Step Test (affected stance), median (IQR), *n*	3.0 (0–9.0)	7.0 (3.5–11.0)
Functional reach, mean (SD), cm	28.2 (5.8)	27.7 (9.0)

BG, Balance Group; ULG, Upper Limb Group; SD, standard deviation; IQR, interquartile range; OSCP, Oxford Community Stroke Project; TACS, Total Anterior Circulation Syndrome; PACS, Partial Anterior Circulation Syndrome; LACS, Lacunar Syndrome; mRS, Modified Rankin Scale; FIM, Functional Independence Measure; MMSE, Mini-Mental State Exam; STREAM, Stroke Rehabilitation Assessment of Movement.

*Independent t-tests, Mann-Whitney U tests or Chi-Square tests were used for between-group comparisons of baseline data with $P < 0.05$.

(unaffected) ($P = 0.004$) scores than the 21 retained participants.

At the two week assessment, all participants had completed six training sessions, with the exception of one Upper Limb Group participant, who completed five training sessions. The total Wii intervention time in the Balance Group was greater than the Upper Limb Group at two weeks ($P = 0.034$); however, there were no significant between-group differences at four weeks ($P = 0.642$) (Table 2). The main reasons for missed or shortened sessions were fatigue or therapy schedule issues, such as late arrival or conflicting appointments. The amount of standard physiotherapy and occupational therapy received did not differ significantly between the two intervention groups at either assessment point ($P = 0.208$-0.477).

Four (13%) participants reported previously using the Nintendo Wii™, and 67% ($n = 20$) reported no prior computer game playing experience. All

Table 2. Session details for Wii intervention and standard care.*

	Week 2		Week 4	
	BG (*n*=14)	ULG (*n*=13)	BG (*n*=11)	ULG (*n*=10)
Wii session number	6.0 (0)	5.9 (0.3)	10.3 (1.2)	10.6 (1.4)
Wii session time, hrs	4.1 (0.6)	3.7 (0.4)**	7.1 (1.2)	6.9 (1.2)
PT+OT session number	20.1 (4.5)	18.6 (5.9)	36.7 (12.6)	32.7 (6.9)
PT+OT session time, hrs	18.1 (3.8)	16.1 (5.1)	33.2 (9.3)	28.8 (5.7)

BG, Balance Group; ULG, Upper Limb Group; PT, physiotherapy; OT, occupational therapy.
*Independent t-tests used for between group comparisons of session times; data presented as mean (SD).
**Significant between-group difference for session time ($P = 0.034$).

participants rated their overall experience of the Wii sessions to be enjoyable and over 90% ($n = 25$ of 27) found the system easy to use (see online supplement Figure S1). All Balance Group participants and 77% ($n = 10$ of 13) of Upper Limb Group participants felt the sessions were beneficial for their recovery. All participants found the Wii sessions to be 'as enjoyable as' or 'more enjoyable than' their standard physiotherapy. Acceptability ratings did not differ between the intervention groups ($P = 0.160$-0.297).

No major adverse events or falls occurred within the intervention sessions. Four participants in the Balance Group and two in the Upper Limb Group had falls on the ward during the study period that did not result in any serious injuries. Fifteen of the 30 participants reported pre-existing pain during one or more of their intervention sessions that was unchanged or varied by no more than one point on the 11-point VAS following the sessions. An increase in pain of 2 points or greater (range 2-5) was reported following seven of the 130 Balance Group intervention sessions, while over the 123 Upper Limb Group sessions only two episodes of pain that increased by 2 points were reported. Balance Group participants tended to report low back or leg pain, whereas the Upper Limb Group reported shoulder and neck pain. No pain increase lasted more than 24 hours. Similar self-reported fatigue levels on an 11-point VAS were reported at the start of the treatment sessions; however, the Balance Group had a significantly greater increase in post-session fatigue (from 3.0 to 3.8; $P = 0.002$). There was no significant between-group difference ($P = 0.075$) in perceived exertion during intervention sessions (median 11.2 and 10.8 in the Balance Group and Upper Limb Group, respectively).

Nine of the 17 Balance Group participants required close supervision or physical assistance for most treatment sessions. Only one participant in the Upper Limb Group required hands-on assistance for most of the sessions, however 8 of 13 required regular prompting to understand and interact with the gaming activities. Seven of 17 Balance Group participants and 7 of 13 Upper Limb Group participants were able to independently navigate the menus by the third treatment session.

Both groups improved significantly over time in the primary outcome measures (Step Test and Functional Reach Test). At baseline, the Balance Group Step Test data were non-normally distributed (6 of 14 participants scored zero). Step Test scores did not differ between groups at baseline ($P = 0.239$), but a significant group x time interaction in favour of the Balance Group ($P = 0.002$) associated with a relatively large effect size ($d = 1.54$; Table 3) was seen at four weeks. The Functional Reach data also did not differ between groups at baseline; however, a non-significant trend ($P = 0.066$) towards greater improvement in the Balance Group was found at the two week assessment associated with a moderate to high effect size ($d = 0.75$; Table 4).

Improvements were observed in the majority of secondary outcomes over time in both groups. The Balance Group participants demonstrated greater improvements in Wii Balance

Table 3. Efficacy outcomes (baseline to four weeks).

Outcome measures	Week 0		Week 4		Within-group difference (Week 4 - Week 0), Mean (SD)		Between-group difference, Mean (95% CI)	Effect size (Cohen's *d*)
	BG (*n*=11)	ULG (*n*=10)	BG (*n*=11)	ULG (*n*=10)	BG	ULG	BG-ULG	
Primary outcomes								
Step Test (affected)[a], *n* mean (SD)	2.7 (3.8)	7.4 (6.0)	10.1 (4.7)	8.9 (5.4)	7.4 (4.7)	1.5 (2.7)	5.9 (2.3 to 9.4)*	1.54
median (IQR)	0 (0–7.0)	7.5 (3.0–10.0)	10.0 (7.0–15.0)	8.5 (5.0–12.3)				
Functional Reach, cm	28.1 (6.4)	28.3 (9.6)	31.1 (6.5)	31.1 (9.0)	3.0 (5.6)	2.8 (7.9)	0.2 (–6.0 to 6.4)	0.03
Secondary outcomes								
Step Test (unaffected)[b], *n*	4.2 (3.1)	6.1 (5.8)	9.0 (4.2)	9.7 (4.7)	4.8 (3.0)	3.6 (2.8)	1.2 (–1.5 to 3.9)	0.41
Timed Up and Go, s[b]	30.3 (15.9)	32.0 (32.2)	19.2 (15.5)	16.0 (11.9)	–11.2 (10.3)	–16.0 (21.1)	4.8 (–10.8 to 20.4)	0.29
STREAM, /100								
Upper Limb	70.5 (26.9)	69.4 (21.0)	85.5 (20.4))	92.5 (17.0)	15 (13.4)	23.1 (17.9)	–8.1 (–22.5 to 6.3)	–0.51
Lower Limb	74.6 (30.4)	86.0 (10.2)	89.1 (19.7)	96.0 (8.6)	14.5 (18.8)	10.0 (11.1)	4.6 (–9.7 to 18.8)	0.29
Mobility	59.9 (16.0)	68.7 (19.3)	83.1 (14.5)	85.0 (11.7)	23.2 (13.4)	16.3 (17.2)	6.9 (–7.1 to 20.9)	0.45
Total	68.2 (21.2)	72.9 (15.5)	85.8 (13.9)	91.1 (10.7)	17.6 (13.7)	18.2 (15.7)	–0.6 (–14.0 to 12.9)	–0.04
Upper Limb - Motor Assessment Scale								
/18, raw score	9.5 (6.9)	9.0 (4.8)	13.6 (4.4)	14.1 (3.2)	4.1 (5.2)	5.1 (3.5)	–1.0 (–5.1 to 3.08)	–0.23
/100, Rasch conversion[c]	56.7 (39.5)	57.8 (25.6)	80.5 (21.2)	83.7 (15.1)	23.8 (30.3)	25.7 (17.7)	–2.0 (–25.0 to 21.0)	–0.08
Falls Efficacy Scale - International, /28[d]	16.6 (4.8)	19.3 (7.0)	11.3 (3.2)	13.0 (3.4)	–5.3 (4.1)	–6.3 (6.2)	1.0 (–3.8 to 5.8)	0.19
Wii Balance Board-derived COP measures								
Eyes open COP velocity, cm/s	1.90 (0.76)	1.54 (0.38)	1.59 (0.49)	1.54 (0.42)	–0.31 (0.40)	0.00 (0.25)	–0.31 (–0.62 to 0.00)*	–0.93
Eyes open mediolateral COP velocity, cm/s	0.94 (0.45)	0.60 (0.13)	0.71 (0.27)	0.59 (0.16)	–0.23 (0.29)	–0.01 (0.11)	–0.22 (–0.42 to 0.02)*	–1.00
Eyes open anteroposterior velocity, cm/s	1.45 (0.60)	1.29 (0.33)	1.28 (0.41)	1.31 (0.38)	–0.17 (0.33)	0.02 (0.21)	–0.19 (–0.45 to 0.07)	–0.69
Eyes closed COP velocity, cm/s	2.89 (1.30)	2.62 (0.82)	2.29 (0.70)	2.36 (0.67)	–0.60 (0.97)	–0.26 (0.39)	–0.34 (–1.03 to 0.35)	–0.46
Eyes closed mediolateral COP velocity, cm/s	1.38 (0.99)	0.89 (0.34)	0.94 (0.38)	0.76 (0.22)	–0.44 (0.73)	–0.13 (0.20)	–0.31 (–0.81 to 0.19)	–0.58
Eyes closed anteroposterior velocity, cm/s	2.21 (0.84)	2.27 (0.70)	1.91 (0.60)	2.12 (0.61)	–0.30 (0.61)	–0.16 (0.27)	–0.14 (–0.58 to 0.30)*	–0.30
Mediolateral weight shifting, *n*	7.2 (3.5)	8.1 (3.4)	10.9 (4.0)	10.1 (2.3)	3.7 (2.8)	2.0 (1.9)	1.7 (–0.5 to 3.9)	0.71

BG, Balance Group; ULG, Upper Limb Group; SD, standard deviation; IQR, interquartile range; STREAM, Stroke Rehabilitation Assessment of Movement; COP, centre of pressure.

[a]All measures presented as mean (SD) unless otherwise indicated, [b]data from one BG participant not included for analysis as participant unable to complete baseline assessment independently; [c]raw score converted to interval-scaled score (0-100) derived from Rasch analysis by Miller et al.[27], [d]lower score indicates less concern about falling.
*Significant ($P < 0.05$) time x group interaction using repeated-measures ANOVA.

Table 4. Efficacy outcomes (baseline to two weeks).

Outcome measures[a]	Week 0		Week 2		Within-group difference (Week 2 – Week 0), Mean (SD)[b]		Between-group difference, Mean (95% CI)	Effect size (Cohen's *d*)
	BG (*n*=17)	ULG (*n*=13)	BG (*n*=14)	ULG (*n*=13)	BG	ULG	BG-ULG	
Primary outcomes								
Step Test (affected), *n*, mean (SD)	4.8 (5.2)	7.4 (5.6)	8.8 (6.0)	11.1 (6.4)	4.1 (3.9)	3.7 (5.2)	0.4 (–3.2 to 4.0)	0.09
median (IQR)	3.0 (0–9.0)	7.0 (3.5–11.0)	9.5 (3.8–13.0)	10.0 (6.5–14.5)				
Functional Reach, cm	28.2 (5.8)	27.7 (9.0)	32.2 (6.1)	28.2 (10.2)	3.5 (5.0)	0.5 (2.6)	3.0 (–0.2 to 6.2)	0.75
Secondary outcomes								
Step Test (unaffected), *n*	6.1 (4.0)	6.8 (5.3)	8.4 (5.2)	9.9 (5.9)	2.8 (2.0)	3.2 (3.4)	–0.4 (–2.6 to 1.8)	–0.14
Timed Up and Go, s[c]	24.4 (15.1)	28.1 (28.9)	19.2 (14.4)	20.7 (24.9)	–6.4 (7.6)	–7.4 (11.2)	1.0 (–6.8 to 8.8)	0.10
STREAM, /100								
Upper Limb	75.0 (30.9)	72.6 (21.7)	85.7 (22.5)	88.5 (16.3)	8.9 (13.5)	15.8 (14.6)	–6.9 (–18.0 to 4.2)	–0.49
Lower Limb	79.7 (28.5)	87.3 (10.1)	87.1 (21.8)	95.4 (7.8)	7.1 (9.3)	8.1 (9.7)	–1.0 (–8.5 to 6.5)	–0.11
Mobility	66.3 (17.7)	68.8 (18.1)	82.0 (15.9)	80.9 (13.0)	15.7 (9.7)	12.1 (9.8)	3.6 (–4.1 to 11.3)	0.37
Total	73.7 (23.2)	74.9 (14.9)	84.9 (16.7)	88.2 (10.9)	10.6 (9.8)	13.4 (11.6)	–2.8 (–11.3 to 5.7)	–0.26
Upper Limb - Motor Assessment Scale								
/18, raw score	10.4 (6.6)	9.4 (5.0)	12.9 (5.1)	13.2 (4.7)	2.5 (3.6)	3.8 (2.5)	–1.3 (–3.7 to 1.2)	–0.41
/100, Rasch conversion[d]	61.9 (38.0)	59.7 (25.6)	76.7 (27.2)	79.1 (22.7)	14.3 (22.2)	19.2 (9.7)	–4.9 (–18.7 to 8.9)	–0.29
Falls Efficacy Scale - International, /28[e]	16.8 (4.4)	18.2 (6.6))	12.1 (3.5)	14.6 (5.7)	–4.9 (5.1)	–3.5 (5.2)	–1.4 (–5.5 to 2.7)	–0.27
Wii Balance Board-derived COP measures								
Eyes open total COP velocity, cm/s	1.78 (0.80)	1.54 (0.36)	1.74 (0.86)	1.56 (0.39)	0.04 (0.23)	0.02 (0.22)	0.20 (–0.16 to 0.20)	0.10
Eyes open mediolateral COP velocity, cm/s	0.80 (0.42)	0.64 (0.19)	0.75 (0.47)	0.61 (0.17)	–0.07 (0.18)	–0.04 (0.14)	–0.03 (–0.16 to 0.10)	–0.19
Eyes open anteroposterior velocity, cm/s	1.42 (0.68)	1.27 (0.31)	1.40 (0.70)	1.31 (0.38)	0.09 (0.18)	0.04 (0.22)	0.05 (–0.11 to 0.21)	0.25
Eyes closed total COP velocity, cm/s	2.56 (1.25)	2.56 (0.84)	2.53 (1.15)	2.19 (0.69)	–0.03 (0.75)	–0.37 (0.51)	0.33 (–0.18 to 0.08)	0.52
Eyes closed mediolateral COP velocity, cm/s	1.14 (0.87)	0.93 (0.39)	0.97 (0.52)	0.77 (0.28)	–0.22 (0.52)	–0.16 (0.28)	–0.06 (–0.39 to 0.27)	–0.14
Eyes closed anteroposterior velocity, cm/s	2.01 (0.86)	2.20 (0.70)	2.14 (0.98)	1.88 (0.60)	0.16 (0.54)	–0.31 (0.39)	0.47 (0.09 to 0.85)*	1.00
Mediolateral weight shifting, *n*	7.5 (3.6)	8.2 (3.1)	10.4 (3.0)	10.2 (2.7)	2.3 (2.5)	2.1 (1.5)	0.2 (–1.5 to 1.9)	0.10

BG, Balance Group; ULG, Upper Limb Group; SD, standard deviation; IQR, interquartile range; STREAM, Stroke Rehabilitation Assessment of Movement; COP, centre of pressure.
[a]All measures presented as mean (SD) unless otherwise indicated, [b]calculations based on only those participants completing the two week assessment, [c]data from one BG participant not included as participant unable to complete baseline assessment independently; [d]raw score converted to interval-scaled score (0-100) derived from Rasch analysis by Miller et al[27], [e]lower score indicates less concern about falling.
*Significant ($P < 0.05$) time x group interaction using repeated-measures ANOVA.

Board-derived measures with small to large effect sizes (d = 0.30-1.00) at four weeks (P = 0.007-0.048; Table 3). Larger, non-significant improvements in the upper limb subscale of the STREAM and the Upper Limb – Motor Assessment Scale in the Upper Limb Group compared to the Balance Group were found at the two and the four week assessments.

Discussion

To the authors' knowledge, this study is the largest randomized clinical trial investigating the use of the Nintendo Wii™ for balance retraining after stroke. The findings from this study suggest that additional training using the Wii is a feasible, safe and acceptable approach for inpatient stroke rehabilitation. Information gained from this study will help to inform the methodology of a larger study. The improvements seen in clinical outcomes show promise for the potential efficacy of this approach, with evidence of task-specificity in results obtained for the two different training groups.

Although a Wii-based approach was found to be feasible for participants in this study, it may be suitable for just a portion of people undertaking inpatient stroke rehabilitation. Only 30 of 143 individuals screened were recruited, however the reasons for exclusion were primarily due to constraints in the study design and not an inability to participate in a Wii-based training protocol. Adherence to, and enjoyment of, the Wii sessions was high and this is consistent with previous studies where Wii-based protocols were used in upper limb training following stroke,[9,10] and balance training in older adults.[7,8] Although not specifically asked, several participants in this study expressed an interest in continued Wii use post-discharge. However, the current study was not designed to evaluate longer term acceptability or adoption of the technology.

The therapist supervising the sessions was additional to the standard inpatient service and acceptability from the therapists' perspective was not evaluated. Although set up only took several minutes, over half of the participants required assistance during their sessions. In practice, consideration may need to be given to the use of therapy assistants, carers, or group-based sessions as alternative ways of providing Wii training sessions for those individuals requiring assistance.

Importantly, no major adverse events occurred within the treatment sessions in this feasibility study. It is unlikely that the falls reported outside of the intervention sessions were related to study participation as the incidence of falls (20%) were well within the range previously reported in inpatient stroke rehabilitation settings (14 to 65%).[2] It is unclear whether the frequency and level of pain reported in this study was similar to that expected within typical balance training therapy. Mild and short-lasting pain incidents have previously been associated with 'Wii Sports'[10] and 'Wii Fit'[7,8] activities. It is evident that pain should be carefully monitored and activities adapted where necessary. The small increase in fatigue reported in this study was not clinically significant.[20] Participants rated their perceived exertion as 'fairly light',[21] consistent with reports in healthy populations engaging in the Wii-based activities.[28]

This phase II study was not powered to detect significant changes in clinical outcomes. As expected during inpatient rehabilitation after stroke, where individuals are undertaking active therapy, the participants improved over time in most outcomes. A clear trend for greater improvement in the Balance Group in many of the balance-related outcomes was observed; however, the low participant numbers and data distribution suggest caution with the interpretation of efficacy. Change scores for the Step Test were beyond the reported minimal detectable change.[29] Although Step Test scores were not different between groups at baseline, a larger proportion of participants in the Balance Group were unable to perform this test initially, therefore floor effects and data distribution may have influenced the results. Change scores for the Functional Reach were below the reported minimal detectable change,[29] and may have been influenced by a ceiling effect. The clinical relevancy of improvements in the Wii Balance Board-derived measures is difficult to interpret. Interestingly, greater improvements in upper limb outcomes were found in the Upper Limb Group, potentially

highlighting task-specific training effects of the different treatment approaches.

The higher number of significant results obtained at four weeks suggests that a longer intervention period may be more effective. Kwakkel et al. suggested that 16 hours of additional therapy is required for meaningful changes in function after stroke.[30] Four weeks may not have been long enough to detect clinically significant changes in balance; however, the current findings also indicate that average patient stay, scheduling and activity tolerance should be considered in planning future studies.

There were several limitations in the current study. Firstly, feasibility was evaluated in a select group of people from a single inpatient facility, and therefore may not reflect the populations and environments in other rehabilitation settings. The retention period may not have been sufficient to detect meaningful changes and a number of participants were discharged prior to the four week assessment. The chosen outcome measures demonstrated floor and ceiling effects, and may therefore have not have been adequately responsive to change in this sample. Finally, the use of an upper limb active control group did not allow for a comparison of the intervention to standard balance treatment. Despite these limitations this study provides important findings on clinical feasibility and will help to inform future trials.

It is recommended that future studies be adequately powered to draw more definitive conclusions on treatment efficacy. For example, based on the Functional Reach scores at two weeks, a sample size of 110 participants (allowing for 20% drop out rate) would provide at least 80% power to detect a significant difference of 3cm (P = 0.05, two-sided). However, the treatment effect sizes of the two primary outcomes in this study varied markedly over the two assessment time points, possibly impacted by the attrition of participants with less severe impairments, as well as floor and ceiling effects of the chosen outcome measures. The largest effect size was found in the Step Test at four weeks, reflecting the smallest possible sample may be 25 participants. Inpatient-based studies may consider employing a three week assessment point, an extended post-discharge treatment duration and longer term follow-up. Outcome measures should reflect the task-specificity of the intervention and be sufficiently sensitive to change. Further exploration of the utility of Wii Balance Board-derived measures and outcomes such as the Berg Balance Scale may be recommended. A cost-analysis could be included in a larger study, where the intervention protocol could be carried out by a therapy assistant and/or involve higher participant-to-therapist ratios. Finally, future studies may consider the use of a standard balance training control group as a comparison.

Our results suggest that additional training exercises using the Wii are feasible and safe in inpatient stroke rehabilitation. Furthermore, specific activities targeted at balance training using the 'Wii Fit Plus' are potentially effective for improving standing balance in this population. With the capacity to provide engaging and varied activities, the Wii could prove to be an accessible and valuable adjunct to current therapy regimes; however, a more definitive clinical trial is warranted.

Clinical messages

- A Wii-based treatment approach appears to be feasible and safe for use in inpatient stroke rehabilitation.
- 'Wii Fit Plus' training, as an adjunct to standard therapy, shows promise for improving balance-related outcomes post-stroke.
- A larger trial is recommended to further evaluate efficacy.

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Conflict of interest

The authors declare that there is no conflict of interest.

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