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Home-Based Exercise Program Improves Balance and Fear of Falling in Community-Dwelling Older Adults with Mild Alzheimer's Disease: A Pilot Study

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Abstract.
Background/Objective: Balance problems are common in older adults with Alzheimer's disease (AD). The objective was to study the effects of a Wii-Fit interactive video-game-led physical exercise program to a walking program on measures of balance in older adults with mild AD.
Methods: A prospective randomized controlled parallel-group trial (Wii-Fit versus walking) was conducted in thirty community-dwelling older adults (73 ± 6.2 years) with mild AD. Home-based exercises were performed under caregiver supervision for 8 weeks. Primary (Berg Balance Scale, BBS) and secondary outcomes (fear of falls and quality of life) were measured at baseline, 8 weeks (end of intervention), and 16 weeks (8-weeks post-intervention).
Results: At 8 weeks, there was a significantly greater improvement (average inter-group difference [95% CI]) in the Wii-Fit group compared to the walking group in BBS (4.8 [3.3–6.2], $p < 0.001$), after adjusting for baseline. This improvement was sustained at 16 weeks (3.5 [2.0–5.0], $p < 0.001$). Analyses of the secondary outcome measures indicated that there was a significantly greater improvement in the Wii-Fit group compared to walking group in Activity-specific Balance Confidence scale (6.5 [3.6–9.4], $p < 0.001$) and Falls Efficacy Scale (–4.8 [–7.6 to –2.0], $p = 0.002$) at 8 weeks. However, this effect was not sustained at 16 weeks. Quality of life improved in both groups at 8 weeks; however, there were no inter-group differences ($p = 0.445$).
Conclusion: Home-based, caregiver-supervised Wii-Fit exercises improve balance and may reduce fear of falling in community-dwelling older adults with mild AD.

Keywords: Alzheimer's disease, balance, fear of falling, older adults

INTRODUCTION

Falls are associated with significant morbidity and mortality [1, 2]. More than 60% of patients with Alzheimer's disease (AD) fall annually, a rate three

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times greater than those without AD [3]. Falls in AD are associated with an increased rate of institutionalization [4]. Poor balance and gait abnormalities seen in AD are risk factors for falls [5]. AD patients score more poorly on tests of equilibrium and limb coordination compared to their cognitively intact peers, independent of age [6]. Shortened step length, increased double support time, increased stride length variability, and decreased gait speed are common gait abnormalities in AD [7]. Increased stride length variability is a proven risk factor for falls in patients with AD. These balance and gait impairments worsen with dual tasking potentially due to overlap in the brain areas involved in gait and certain cognitive tasks [8]. Gait and balance problems are potentially modifiable independent risk factor of falls [9]. Thus, we focused on an intervention that could improve balance and gait in patients with AD.

In a recent review of exercise programs in dementia, exercises that target strength training and balance were seen necessary for reducing falls [10]. Caregiver engagement and having multiple exercise options to choose from were noted to be important in this population. Exergames give the flexibility of choosing from a bank of multiple exercises targeting strength training and balance and hence may do better than traditional exercise programs in this population. In a systematic review of exercise studies in older adults, balance training exercises have demonstrated significant impact on preventing falls in cognitively intact older adults [11]. In deconditioned older adults at high risk of falls, even low intensity exercise has proven benefits [12]. However, there are very few studies examining the effect of balance training exercises as a strategy for improving balance in community-dwelling older adults with AD [13, 14].

In spite of many known benefits of exercise, many older adults continue to remain sedentary. A novel approach of engaging older adults in exercises would be to make the exercises fun, engaging, and easily accessible at home such as exergames. The use of exergames at home may help overcome some of the barriers to exercise such as fear of falling, lack of motivation, the effort and costs of traveling to exercise venues, and a preference for the privacy of the home environment [15, 16]. No study to date has explored a self-directed, caregiver-supervised exergames program for balance in community-dwelling patients with AD.

Exergames are interactive video games that involve physical activity [17]. The Nintendo Wii-Fit® exergame uses a balance board that senses shifts in weight to provide aerobics, strength, and balance training [18]. This gaming system is widely available, is easy to use, has the potential for home use, and may provide a mechanism for sedentary older adults to safely add exercise to their lifestyle. In our pilot study, residents of an assisted living facility with mild to moderate AD used supervised Wii-Fit exercise as a safe and feasible means to improve balance [19]. Exergames have been used as a home-based exercise under unsupervised conditions in healthy older adults [20, 21]. However, no such studies have been done in community-dwelling patients with AD. We hypothesized that home-based caregiver supervised Wii-Fit exercises would be safe and improve balance more than the walking program in older adults with mild AD. Thus, the primary objective of this pilot study was to study the effects of an 8-week home-based caregiver supervised Wii-Fit program on balance in community-dwelling older adults with mild AD. The secondary objectives were to explore the effects of the exercise program on fear of falling, functional state, quality of life, and cognition in the same subjects.

METHODS

Study design and participants

A 16-week home-based, caregiver supervised, prospective randomized controlled parallel-group pilot trial was conducted to compare the effects of the Wii-Fit program to the walking program on balance and fear of falling with 8 weeks of intervention followed by 8 weeks of detraining. The protocol was approved by the appropriate Institutional Review Board and the study was conducted in compliance with guidelines on human experimentation from June 2010 to December 2014. Community-dwelling older ($\geq$60 years) adults ($n = 30$) with AD (Diagnostic and Statistical Manual DSM-IV TR criteria [22]), a Mini-Mental State Exam (MMSE) score $\geq$18, with history or fear of falling in the past year, and had a caregiver were included in the study. Subjects using wheel chairs or walkers for mobility or having absolute contraindications to exercise per American College of Sports Medicine guidelines were excluded [23]. The sample size was *a priori* determined for the primary outcome measure of BBS using information from a previous study. Assuming a common SD of 3.3 for BBS change for both groups, a sample size of 24 (12 per group) was necessary to detect a difference between BBS improvement of 5 points in the Wii-Fit group versus a 1-point improvement in the control group with a power of 0.80 using a two-sided alpha of 0.05. Twenty percent attrition was projected based on our previous experience, which inflated the required sample size to 30 with 15 subjects in each group.

Study procedure

IRB approval was obtained for a HIPAA waiver to allow pre-screening of subjects after their initial telephone contact with the study team. The medical center's electronic medical records were reviewed for the pre-screening. Recruits that met the pre-screening criteria by the electronic medical record review were invited for the baseline visit. All recruitment was done at the medical center. Consent was obtained from subjects that met the cut-off score for the UCSD Brief Assessment of Capacity to Consent (UBACC) [24]. Assent from subjects, and consent from caregivers was obtained for subjects that did not meet the cut-off on UBACC. Additionally, all caregivers provided a written informed consent for their own participation in the study. After the consent, all subjects were reviewed for the diagnosis of mild AD. The study physician determined the diagnosis of mild AD based on the clinical history and DSM-IV TR criteria. All subjects also underwent an MMSE assessment. Those with scores $\geq$18 were included in the study. Demographics and anthropometric data along with all the primary and secondary outcomes measures were assessed at the baseline visit. Subjects and their caregivers were trained to use Wii-Fit over one to two sessions to learn about the program, and to ensure their willingness to participate. Subjects were randomized using a randomized block design to the Wii-Fit exercise ($n = 15$) and walking control groups ($n = 15$) using sealed envelopes prepared by the statistician.

Role of research assistants

After randomization, a research assistant made home visits to the Wii-Fit group to set up the device and trained the subject and their caregiver about its use. The research assistants followed up with phone calls one day after installation, one week after starting the program, and then every two weeks to troubleshoot problems, provide encouragement, and identify any adverse events. Adverse events were defined as study related adverse events such as falls, dizziness, and pain during exercise. These were identified by open ended questions and specific inquiries. Subjects were also queried for serious adverse events such as emergency room visits and hospitalizations via telephone calls.

Study intervention

Subjects in both groups exercised under caregiver supervision for 30 min five days/week for 8 weeks. The Wii-Fit group performed exercises from five categories of the Wii-Fit program: yoga, strength training, aerobics, balance games, and training plus, which includes more complex exercise tasks. Each session in the Wii-Fit included a warm up, exercise, and cool down phase. During the warm up and cool down phases, subjects walked for 5 min at a self-selected comfortable pace using the program's 'basic walk' activity. The exercise phase was designed to be participant centric. The study physician set up the components of the exercise program based on knowledge from our prior studies of which exercises could be completed by this population with respect to ability and safety. Exercises were deliberately chosen from the balance, aerobic, strength training, and yoga components. The specific exercises in each category were picked based on their ease of use and subject preference expressed in our prior clinical work. All subjects started each exercise at level one. Upon mastery, subsequent levels were opened automatically by the program. Subjects were encouraged to choose one or more exercises from every Wii-Fit category during each session. Research assistants did an initial home-visit to set-up the program at the patient's home and trained the subject and their caregiver on the use of the program. Caregivers were instructed to help the subjects in setting up the instruments if needed and supervise them during each exercise session. They were also instructed to help the subjects record the activities performed daily in their activity diary. Subjects in the walking program were instructed to walk for 30 min at their self-selected pace either indoors or outdoors for five days of the week. Subjects were advised to walk in an uninterrupted block of activity and not cumulative over the day. Subjects maintained an activity diary with the assistance from the caregivers wherein they recorded the day they exercised and time spent exercising during each session.

All outcomes were measured at baseline, 8 weeks (end of intervention), and at 16 weeks (8-weeks post intervention) by an outcomes assessor, who was not part of the study interventions but was aware of the group assignments. The primary outcome was the Berg Balance Scale (BBS), which assesses balance impairments in older adults, and is a good measure of static and dynamic stability [25]. It consists of 14 tasks performed in a standardized order with each task scored on a five-point scale according to quality or time ranging from "0" (lowest level of function) to "4" (highest level). The maximum score is 56. BBS has good test-retest reliability (0.95) and inter-rater reliability (0.72) in community-dwelling older adults with mild to moderate AD [26].

The secondary outcome measures included fear of falling, quality of life, cognition, and functional state. Fear of falling is an important psychological consequence that develops in subjects who fall. Activities-specific Balance Confidence (ABC) scale measures fear of falling and self-confidence to maintain balance [27]. Subjects rate their confidence in maintaining balance while engaging in 16 non-hazardous activities of daily living. Lower scores indicate greater fear of falling. The test-retest reliability is 0.92 with Cronbach's alpha of 0.96 in cognitively intact community-dwelling older adults [27]. Falls Efficacy Scale (FES) is a 10-item rating scale which assesses the confidence of subjects in performing activities of daily living. Scores range from 10 to 100, with lower scores indicating greater confidence in maintaining daily living activities [28]. FES has also been shown to have a good reliability ($\alpha = 0.89$) in cognitively impaired population [29].

Quality of Life-AD (QOL-AD) is a 13-item scale which assesses quality of life from the subject's perspective in older adults with AD. It assesses subject's physical condition, mood, interpersonal relationships, ability to participate in meaningful activities, financial situation, and overall assessment of self, and quality of life as a whole. It is rated on a four-point scale, with 1 being poor and 4 being excellent. Total scores range from 13–52 with higher scores indicating higher QOL. This scale has been evaluated and shown to have a good reliability ($\alpha = 0.84$) in cognitively impaired population [30].

Modified Mini Mental (3MS) is a global screening for cognitive function that covers orientation to time and place, registration, recall, simple language, and construction. Test-retest reliability ranges from 0.91 to 0.93 [31]. The total score places the individual on a well-accepted scale of cognitive function. Different versions were used at each testing occasion to minimize practice effects. An MMSE score derived from 3MS was used in the inclusion criteria of the study.

Katz's Activities of Daily Living (ADL) assesses a subject's independence in performing basic tasks of daily living such as bathing, eating, toileting, dressing, grooming, and ambulation. Each task is further divided in questions of ability to do things. The score ranges from 0–24 with higher scores indicating a higher level of function [32]. This scale is widely used in geriatrics and in research studies involving cognitively intact and impaired populations. A recent report of factor analysis of Katz ADL found that there was no need for normalization of the scale according to cognitive decline [33]. Lawton and Brody's Instrumental Activities of Daily Living (IADL) assesses the subject's independence in performing hierarchical activities, which include ability to prepare meals, handling finances, ability to use telephone, shopping for grocery or personal items, performing household work, ability to do the laundry, ability to take responsibility of one's own medication, and mode of transportation. The score ranges from 0–23 with higher scores indicating higher level of function [34].

Statistical analyses

Subject demographics and baseline characteristics were compared using *t*-tests (continuous data) and Fisher's exact tests (categorical data).

Changes from baseline at 8 and 16 weeks in primary and secondary outcomes were analyzed using repeated measures mixed model analyses of covariance. Group (Wii-Fit and walking) and time (8 and 16 weeks) as well as the interaction between the two were independent variables; the dependent variable's baseline measure was included as a covariate. In *post-hoc* analyses, groups were compared in terms of the changes from baseline at 8 and 16 weeks using *t*-tests derived from model-based contrasts. Additionally, comparisons were made to separately assess improvements within each group. For BBS, the primary endpoint, a sensitivity analysis to investigate bias due to missing data for subjects ($n = 6$) who dropped out of the study was performed by carrying forward baseline values to conservatively impute missing data as no change. Two-sided p-values less than 0.05 indicated statistical significance. Since there was only one primary endpoint, p-values were not adjusted; however, the higher than nominal experiment-wise Type I error rate should be kept in mind particularly for the exploratory analyses of secondary endpoints [35]. Data were analyzed using SAS Enterprise Guide v5.1 (SAS, Cary, SC).

RESULTS

The screening, enrollment, and participation flow are depicted in Fig. 1. A total of 106 subjects were

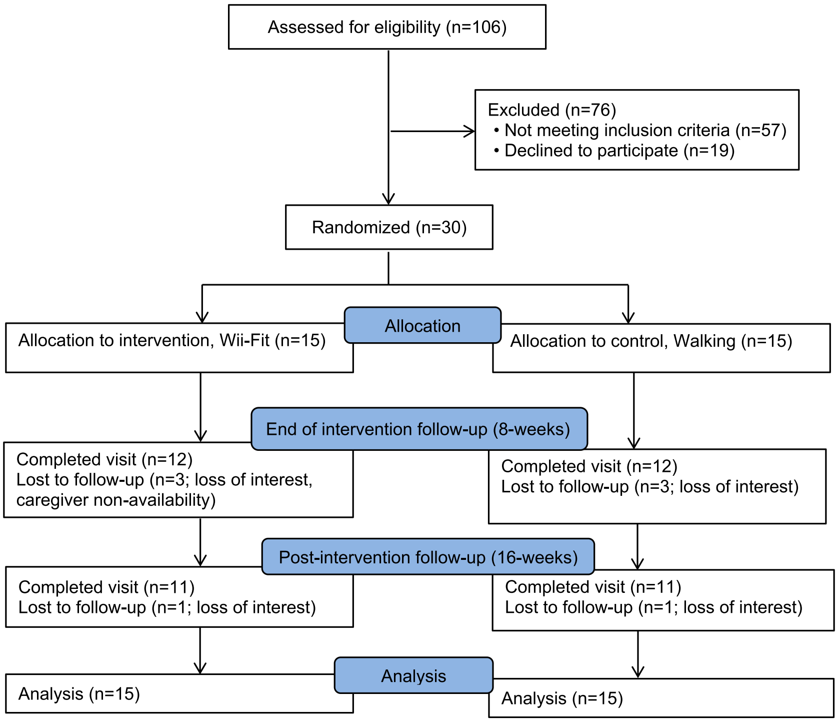

Fig. 1. Screening, enrollment, and participation.

assessed for eligibility of which 57 failed to meet the inclusion and exclusion criteria, and 19 were not interested in participation. Thirty subjects were deemed eligible and randomized. Twenty-four subjects completed the 8-week visit and 22 completed the 16-week visit. Six subjects dropped out of the study and did not attend any of the follow-up visits; two did not attend the final 16-week visit. Two subjects dropped as their caregivers were not able to dedicate the necessary time, and four others dropped due to loss of interest. The demographic characteristics of the study are presented in Table 1. The mean (SD) age of the subjects was 73.0 (6.2) years, 63% were males, and 77% were non-Hispanic Caucasian. There were no significant differences between the two groups with regard to age, gender, race, and anthropometry (Table 1). There were also no significant differences between the two groups with regards to comorbidities, number of comorbidities, and number of medications (Table 1).

There were no significant differences at baseline between the two groups with regards to primary or secondary outcome measures (Table 2). There were four adverse events, but they were deemed to be not study related. There were no study-related adverse events. Total time spent exercising in the Wii-Fit group was 1,253 (444) min while in the walking group was 985 (211) min. Total number (mean ± SD) of exercise sessions in the Wii-Fit group was 38±2 while in the walking group was 37±6. There was no statistically significant difference between the two groups regarding the total time spent exercising ($p = 0.072$) (Table 2) or the number of exercise sessions ($p = 0.452$) which is analogous to 95% and 93% adherence, respectively, given the target of 40 sessions. There was no correlation with session duration and balance improvement ($r = 0.02$, $p = 0.95$), but there is a strong correlation with number of sessions and balance improvement ($r = 0.75$, $p = 0.005$).

Among the completers ($n = 24$), there was a significant group-by-time interaction for the primary outcome measure BBS ($p = 0.048$, Fig. 2). *Post-hoc* analysis showed that the change in BBS from baseline for the Wii-Fit group significantly differed from that in the walking group at both 8 and 16 weeks. After adjusting for baseline BBS score, the average inter-group differences (95% CI) were 4.8 (3.3–6.2; $p < 0.001$) at 8 weeks and 3.5 (2.0–5.0; $p < 0.001$) at 16 weeks. Intra-group analysis showed significant improvements in BBS in the Wii-Fit group at 8 weeks (5.8 [4.8–6.8], $p < 0.001$) and 16 weeks (5.4 [4.4–6.4], $p < 0.001$), and in the walking group at

Table 1
Descriptive characteristics of Wii-Fit and Walking groups

	All Participants ($n = 30$)	Exercise group ($n = 15$)	Control group ($n = 15$)	p-value
Age, mean (SD)	73.0 (6.2)	72.1 (5.3)	73.9 (7.1)	0.439
Male, n (%)	19 (63.3)	10 (66.7)	9 (60)	0.705
Race, n (%)				0.390
Non-Hispanic Caucasian	23 (76.7)	10 (66.7)	13 (86.7)	
Non-Hispanic African-American	7 (23.3)	5 (33.3)	2 (13.3)	
Education, n (%)				>0.999
High school diploma	26 (87)	13 (87)	13 (87)	
Some college	2 (7)	1 (7)	1 (7)	
Bachelor's degree	2 (7)	1 (7)	1 (7)	
Anthropometry				
Height (inches), mean (SD)	67.9 (2.4)	67.6 (2.6)	68.1 (2.3)	0.533
Weight (lbs.), mean (SD)	181 (28.8)	178.5 (34.8)	183.5 (22.2)	0.647
Body mass index (kg/m^2), mean (SD)	27.0 (3.8)	26.1 (4.5)	27.9 (3.0)	0.206
Comorbidities, n (%)				
Hypertension	28 (93)	13 (87)	15 (100)	0.483
Diabetes	8 (27)	4 (27)	4 (27)	>0.999
Hyperlipidemia	27 (90)	13 (87)	14 (93)	>0.999
Coronary Artery Disease	8 (27)	4 (27)	4 (27)	>0.999
Degenerative joint disease	5 (17)	3 (20)	2 (13)	>0.999
Depression	17 (57)	8 (53)	9 (60)	>0.999
Number of comorbidities, median (IQR)	7 (6, 8)	6 (6, 8)	7 (6, 8)	0.672
Medications, n (%)				
Cholinesterase Inhibitors	17 (57)	8 (47)	9 (53)	>0.999
Antidepressants	18 (60)	8 (53)	10 (67)	0.710
Memantine	2 (7)	1 (7)	1 (7)	>0.999
Number of medications, median (IQR)	8 (7, 9)	8 (7, 8)	8 (7, 10)	0.703

Table 2
Baseline outcome measures in Wii-Fit and Walking groups

Variables	All Participants ($n = 30$) Mean (SD)	Wii-Fit group ($n = 15$) Mean (SD)	Walking group ($n = 15$) Mean (SD)	p-value[a]
Primary end point				
Berg Balance Scale (BBS)	46.1 (2.4)	46.5 (2.4)	45.8 (2.5)	0.457
Secondary end points				
Activities Specific Balance Scale (ABC)	82.3 (6.6)	83.2 (6.1)	81.4 (7.3)	0.460
Falls Efficacy Scale (FES)	16.6 (2.9)	16.7 (3.1)	16.5 (2.9)	0.809
Modified Mini-Mental (3MS)	86.6 (6.0)	87.5 (3.6)	85.7 (7.8)	0.423
Mini-Mental State Exam (MMSE)	22.9 (2.2)	23.3 (2.2)	22.7 (2.3)	0.524
Activities of Daily Living (ADL)	23.3 (1.2)	23.4 (1.1)	23.2 (1.4)	0.658
Instrumental Activities of Daily Living (IADL)	18.3 (3.3)	18.4 (2.4)	18.3 (4.0)	0.913
Quality of Life-AD (QOL-AD)	37.0 (3.2)	36.8 (3.5)	37.2 (3.0)	0.739

[a]Comparison of Wii-Fit and Walking groups used t-test or Wilcoxon rank sum test.

8 weeks (1.0 [0.0–2.0], $p = 0.051$), and 16 weeks (1.9 [0.8–2.9], $p = 0.001$). Additionally, when the missing outcomes data for the eight subjects (four in each group) were imputed as no change in a sensitivity analysis (intent-to-treat approach), the effect of exercise decreased, but was still statistically significant: the average inter-group differences (95% CI) were 3.5 (1.7–5.4, $p = 0.001$) at 8 weeks and 2.5 (0.6–4.3, $p = 0.011$) at 16 weeks.

There was a significant improvement (average inter-group difference [95% CI]) in the ABC scale in the Wii-Fit group compared to walking group (6.5 [3.6–9.4], $p < 0.001$) at 8 weeks. However, this effect was not sustained at 16 weeks (2.0 [–1.0–5.1], $p = 0.182$). There was a significant improvement in the FES in the Wii-Fit group compared to walking group (–4.8 [–7.6 to –2.0], $p = 0.002$) at 8 weeks. However, this effect was not sustained at 16 weeks (–2.2 [–5.1–0.7], $p = 0.129$). There was significant intra-group improvement in the QOL-AD both in the Wii-Fit group (1.7 (0.6–2.8), $p = 0.005$) and the walking group (1.1 (0.0–2.3) $p = 0.048$) at 8 weeks. These effects were not sustained at 16 weeks. There was also significant intra-group improvement in the IADLs both in the Wii-Fit group (1.7 (0.7–2.6), $p = 0.002$) and the walking group (1.0 (0.1–1.9), $p = 0.039$) at

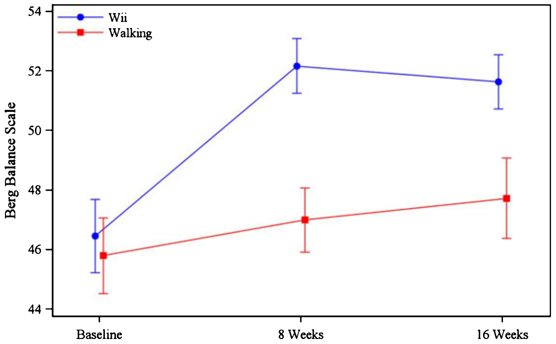

Fig. 2. Berg Balance Scale over time in Wii-Fit and Walking groups (Observed Mean ± 2 SE). Wii-Fit and Walking groups significantly differed in terms of change from baseline at 8 weeks ($p < 0.001$) and 16 weeks ($p < 0.001$).

8 weeks, and in the Wii-Fit group (2.0 (1.0–3.0), $p < 0.001$) and the walking group (1.3 (0.3–2.2), $p = 0.013$) at 16 weeks. There were no significant inter-group or intra-group differences for any of the other secondary outcomes (Table 3).

DISCUSSION

The main objective of our pilot home-based, caregiver-supervised study was to compare the effects of Wii-Fit exercises to walking on balance in community-dwelling older adults with mild AD. This study establishes the feasibility of using Wii-Fit in a home setting under caregiver supervision in community-dwelling older adults with mild AD. At 8 weeks, subjects in the Wii-Fit group showed significantly greater improvement in their balance compared to the Walking group. The improvement in BBS is both statistically and clinically significant. Minimally detectable change in BBS is dependent on factors such as their baseline BBS score. Donoghue et al. found that a change of 4 points is clinically significant if the baseline BBS scores ranged from 45–56 in community-dwelling patients ($n = 118$, aged over 65 years) [36]. Our study population's baseline BBS scores is similar to Donoghue et al. and had a 5.8-point improvement in BBS. This improvement was sustained at 8-weeks post-intervention. The Wii-Fit group also showed significantly greater improvement in the fear of falling measures compared to the walking group. The adherence to the program as measured by the amount of time spent exercising was slightly better in the exercise group compared to the control group. Although not statistically significant, there was a trend toward significance. Time spent exercising by the two groups would likely influence the outcome. The Wii-Fit group did spend slightly more total

Table 3

Changes from baseline (8 or 16 weeks minus baseline) in outcomes for Wii-Fit (exercise) and Walking (control) groups and differences between the two groups

	Change at 8 weeks (Intervention period) Mean and 95% CI				Change at 16 weeks (Post-intervention period) Mean and 95% CI			
	Exercise	Control	Difference[a]	*p*-value[b]	Exercise	Control	Difference[a]	*p*-value[b]
Primary end point								
BBS	5.8	1.0	4.8	<0.001*	5.4	1.9	3.5	<0.001*
	4.8 to 6.8	0.0 to 2.0	3.3 to 6.2		4.4 to 6.4	0.8 to 2.9	2.0 to 5.0	
Secondary end points								
ABC	5.6	–0.9	6.5	<0.001*	1.3	–0.7	2.0	0.182
	3.6 to 7.7	–2.9 to 1.2	3.6 to 9.4		–0.8 to 3.5	–2.8 to 1.4	–1.0 to 5.1	
FES	–3.7	1.1	–4.8	0.002*	0.5	2.7	–2.2	0.129
	–5.7 to –1.7	–0.9 to 3.1	–7.6 to –2.0		–1.6 to 2.5	0.6 to 4.7	–5.1 to 0.7	
3MS	–0.4	–0.6	0.1	0.946	0.4	–2.0	2.4	0.123
	–2.6 to 1.7	–2.7 to 1.6	–3.0 to 3.2		–1.8 to 2.6	–4.2 to 0.2	–0.7 to 5.5	
MMSE	0.7	–0.1	0.8	0.264	0.6	–0.5	1.1	0.147
	–0.3 to 1.7	–1.1 to 0.9	–0.7 to 2.2		–0.5 to 1.6	–1.6 to 0.5	–0.4 to 2.6	
ADL	0.2	0.1	0.1	0.708	0.1	0.3	–0.2	0.499
	–0.2 to 0.5	–0.3 to 0.4	–0.4 to 0.6		–0.3 to 0.5	–0.1 to 0.6	–0.7 to 0.4	
IADL	1.7	1.0	0.7	0.316	2.0	1.3	0.7	0.267
	0.7 to 2.6	0.1 to 1.9	–0.7 to 2.0		1.0 to 3.0	0.3 to 2.2	–0.6 to 2.1	
QOL-AD	1.7	1.1	0.6	0.445	0.5	–0.6	1.1	0.166
	0.6 to 2.8	0.0 to 2.3	–1.0 to 2.2		–0.6 to 1.7	–1.8 to 0.6	–0.5 to 2.8	

[a] All means are estimates from a repeated measures model of 8- and 16-week change from baseline. Difference reflects exercise group change minus control group change and is adjusted for corresponding baseline measure. [b] *p*-values comparing Exercise and Control groups are model-based. *unadjusted *p*-value significant at <0.05; BBS, Berg Balance Scale; ABC, Activities Specific Balance Scale; FES, Falls Efficacy Scale; 3MS, Modified Mini-Mental State Exam; MMSE, Mini-Mental State Exam; ADL, Activities of Daily Living; IADL, Instrumental Activities of Daily Living; QOL-AD, Quality of Life-AD.

time exercising than the Walking group. This could have affected the balance improvements found but it also supports the possibility that the fun and interactive aspects of exergames promotes engagement. The Wii-Fit program could have helped the balance in several ways in this study. Many of the exercises performed particularly those in the balance category have similar tasks in the BBS such as weight transfer, functional reach, and body rotations. Motor learning and practice effect could improve static balance, dynamic balance, postural control, and other components of balance. Some of the exercises used increase strength which could improve the performance on BBS tasks. Improved self-efficacy and mastery with successful performance of the Wii-Fit program could also contribute to improvement in balance. There are several reasons why exergames may be a better alternative than other modalities of exercise in AD. The multimedia platform, the presence of a virtual trainer, easy to follow instructions, and real-time feedback to their bodily movements may engender higher engagement to exergames than traditional exercise programs in patients with AD. Transportation and economic barriers to exercise disproportionately impact those with AD. Home-based exergame programs have the potential to break the transportation and economic hurdles. Lack of adherence to long-term exercise program is a huge problem. The gaming format was interactive, required mental and physical tasking, and could be considered fun. Having an exercise program readily available that could be easily and safely performed by the patient at-home with supervision by a caregiver is important to sustain long-term adherence and exergames provide this.

Although this is the first study of home-based exergames in community-dwelling patients with AD, our results are in keeping with other home-based traditional exercise studies. In a single arm study of community-dwelling older adults with dementia, 6 months of home-based, caregiver-enhanced, tailored balance exercises improved balance, and reduced fear of falls [37]. This study differed from our study with regards to the subjects they included (any type of dementia), and had slightly lower average MMSE, and performed home visits by physical therapists. Average MMSE may be important as those who completed the study had higher average MMSE than those who dropped out (21.7 ± 3.9 versus 19.1 ± 4.2). The adherence rates in both studies were around 80%. In another randomized controlled trial (RCT) of 6 months of home-based, caregiver-supervised traditional exercise program (Otago program) in community-dwelling older adults with AD, a significant improvement was noted in the exercise group on functional reach, and fall risk score compared to the control group (education sessions on dementia and aging) [13]. This study differed from our study with regards to the subjects in the exercise group who had slightly lower average MMSE, and a higher drop-out rate of 42% [13]. The adherence rate in the exercise group for those who completed the study was similar in both studies. Another RCT with 4 months of home based, caregiver-supervised, traditional exercise program (strength and balance training with 30 min of brisk walking) in community-dwelling older adults with AD ($n = 40$), found a similarly significant improvement in the exercise group on Timed Up and Go, functional reach, and sit-to-stand tests compared to the control group (usual treatment) [13]. Home-based caregiver supervised exercise programs have shown to improve balance in community-dwelling older adults with dementia.

Exergames have been used as a home-based exercise program under unsupervised conditions in healthy older adults [20, 21]. In a 6-week, single arm study of healthy community-dwelling older adults ($n = 10$), balance, as measured by sway characteristics, improved significantly with a home-based unsupervised exergames training program [21]. In a three-arm home-based (step-mat training, Kinect, and control arms), 16-week RCT of healthy community-dwelling older adults, the step-mat training showed significantly greater improvement in fall risk, proprioception, reaction time, executive functioning, and sit-to-stand performance over the control arm while the Kinect arm improved muscle strength, and vision over the control arm [20]. Exergames have been used as a home-based exercise programs in populations with chronic obstructive pulmonary disease, non-small cell carcinoma of lung, multiple sclerosis, and systemic lupus erythematosus in uncontrolled studies [38–41].

The major strength of the study is the study design, a randomized parallel-group trial comparing the widely available exergame to walking (most commonly used exercise strategy) in older adults. The other strengths include that it was a home-based exercise program, and that there was a post-intervention follow-up to study the sustainability of effects of exercise. However, the current study has several limitations. This was a pilot study and was only *a priori* powered to address one primary outcome measure BBS and did not consider other outcomes as functional status and quality of life. Measures such as gait speed and lower extremity strength were also not included as outcome measures. Hence, improvements in gait speed and lower extremity strength with use of Wii-Fit cannot be learned from this study. These measures need to be included in future studies. Another major limitation was the lack of blinding of the outcomes assessor. However, all outcomes were measured by an outcomes assessor who was not part of the study interventions but was aware of the group assignments. The assessor also did not have access to the previous measurements at each visit. In spite of all these precautions, there could have been a bias toward the intervention group. There was also failure to strictly monitor the intensity of the exercises in each group. Subjects in the walking group walked at their self- selected pace. So, we expect the intensity to be mild to moderate. However, a specific measure to assess exercise intensity was not included. Subjects that would have done exercises at higher intensity may have had better outcomes. As the subjects had to perform the exercises five days of the week, the day of the week the exercise was performed and number of minutes spent exercising were the only two items recorded in the log to avoid patient and caregiver burden. Physical activity level prior to entry in the study was not recorded and is another limitation of the study. Those that had higher level of physical activity at baseline could have been better motivated to do the exercises. Data on number of falls in the previous year prior to entry into the study was not recorded and is another limitation of the study. This study was conducted prior to the publication of guidelines indicating that 12 weeks may be the effective duration of exercise needed to effect change in balance in older adults [42]. In order for Wii-Fit to be recommended as a home-based exercise program, a longer duration study with larger sample size is needed with enrollment of diverse ethnic groups, focusing primarily on balance exercises, and systematically measuring effects on incidence of falls and fall related injuries.

Conclusion

This pilot study supports that the home-based caregiver supervised Wii-Fit exercise program could improve balance and may reduce fear of falling in community-dwelling older adults with mild AD.

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