

Wii Fit for Balance Training in Elderly: A Systematic Review

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ABSTRACT

Falls due to poor balance are common in elderly people and can cause fractures, head injury, soft tissue trauma; and may even result in death from these complications. Balance training is one of the strategies used to prevent falls among the elderly population. Wii Fit is a new technological approach of balance training in the community dwelling elderly. The primary aim of this systematic review is to study the effectiveness of Wii Fit as a balance-training tool in older adults using various balance and fall risk assessment scales as outcome measures. Using selected keywords in English only, online literature search was conducted from 2009 to 2019. The initial search resulted in 312 articles. After screening, 14 full text articles were included for the final review and qualitative analysis. There is evidence that Wii Fit plus is a useful, cost-effective, user-friendly, less time consuming, home-based approach for reducing the risk of fall and improving the balance and physical performance in older adults. There are few or no adverse events of using Wii Fit. The commonly used outcome measures were 8 foot up and go test, activities-specific balance confidence scale, Berg balance scale, falls efficacy scale, postural sway, times up and go test and static and dynamic balance assessment tool.

Key Words: Postural balance, Rehabilitation, Video games, Virtual reality, Evidence-based medicine, Technology.

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INTRODUCTION

It is expected that by 2050, the population of elders (Age >60 years) will be more than two billion and most of them will be residing in Asia.¹ Elderly populations, who perform regular exercise of moderate intensity throughout the week, are more active and healthier than those with a sedentary lifestyle.² Balance is defined as the ability of the physiological systems to control bodily alignment in an upright position during static and dynamic postures and to maintain the centre of mass within the base of support.³ Aging results in a decreased quality and quantity of muscle fibers with low strength and power to bear weight or to maintain the body upright, decrease endurance and capacity to efficiently work in coordination with the nervous system.⁴ Elderly people have reduced potential and stamina for exercise, leading to a sedentary lifestyle that may result in a vicious cycle of muscle weakness and wasting.

This further contributes to poor stamina and mobility.^{2,5} Elderly populations have a higher risk of balance impairment, disturbed gait pattern and poor coordination of body movements, which may lead to falls or fear of fall.^{1,6} There are many consequences of impaired balance, which can adversely affect physical functioning. Falls related to impaired balance are considered more fatal than any other consequence; because falls are the main source of morbidity among the geriatric population.⁷ The frequency of falls increases with age and an estimated one-third of the older adults had at least one fall over the year.⁹ Most falls accidents happen when walking. Falls may result in further problems like fear of more falls, psychological disturbances, isolation, activity limitations, and increased financial burden for the family.^{8,9} Hip fractures as a result of fall can further limit the participation of community dwelling older adults. These fractures may prove to be fatal or even if non-fatal, may result in prolonged hospitalisation of individuals.^{10,11}

Management of falls and the resulting morbidities require substantial involvement of healthcare professionals. It can result in extra burden for the rehabilitation professionals and prolonged therapy sessions, which are usually not followed up by community-dwelling older adults.^{12,13}

Different approaches to manage balance impairment and postural instability in community dwelling older adults have been recommended. These include specially designed exercise

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programmes for targeted muscle's strength, endurance, stretching,¹⁴ sensory feedback training, vestibular rehabilitation with reaction time training, cognitive exercises,¹⁵ frequent proprioceptor's stimulation around muscles and joints,¹⁶ tai-chi,¹⁷ environmental modification with proper ergonomics, and circuit training.¹⁸

These interventions improve balance, increase the quality of life (QOL), and reduce the risk of falls.^{19,20}

The virtual reality-based rehabilitation is a recent technology with a sensory feedback approach that targets and challenges the vision, hearing, vestibular system and proprioceptors at a time in three-dimensional landscapes.²¹ Different gaming consoles are available in the market for entertainment and clinical use. Wii Fit was launched as software, specifically for balance rehabilitation with strengthening and endurance of core muscles. It has different yoga poses and generalised fitness games. Compared to other virtual reality exergaming tools, Wii Fit is inexpensive and with easy instructions for use at home. Each game consists of different levels, which can be unlocked when previous levels are completed. The higher levels require more precise and accurate muscle activity, motor control, and good reaction time.

Wii Fit is an innovative and interactive device that challenges postural control by the complexity of the task and the environment. It is a reliable and valid tool for assessment of standing balance in the elderly.^{22,23}

The aim of this systematic review was to assess the usefulness of Wii Fit as a balance-training tool in the elderly population. The results may be of clinical importance for the future development of clinical guidelines regarding balance dysfunction in community-dwelling older people.

METHODOLOGY

The systematic review is reported in accordance with the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines.²⁴ This review title was prospectively registered on JBI website (http://joannabriggs.org/research/registered_titles.aspx).

The eligibility criterion for this systematic review was based on the PICOS criteria.

Participants were healthy older adults (>60 years), who had Wii Fit training alone or Wii Fit training along with exercise therapy. Treatment time lasted for at least of three weeks' duration. Comparison was made with traditional balance exercises along with/or without Wii Fit training or no intervention at all. Outcome was balance improvement and fall risk/prevention assessment using various scales and tools. Only randomised controlled trials (RCTs) were included.

Two authors independently searched six electronic databases. These included five global (Web of Science, Google Scholar, Medline, Literature Latino-Americana e do Caribe em Ciências da Saúde (LILACS) and Physiotherapy Evidence Database) and

the local Pakistani database PakMedinet (<http://www.pakmedinet.com/>). We limited the search to studies published between 2009 and 2019 only. The time limit was set because Wii Fit Plus was officially launched in 2009.²⁵ Keywords used for the literature search included: Wii Fit, elderly, aged, geriatrics, virtual reality, postural balance, virtual reality, geriatrics, community-dwelling older adults, elderly population, frail adults, virtual reality, Wii Fit plus, exergaming, gaming technology postural balance, postural instability, fall, clinical trial, and randomised controlled trial using a combination of Boolean operators. The reference list of the selected articles was explored for additional studies. The search was restricted to English only.

After literature search, studies were screened and selected according to the predefined PICOS format. The level of evidence for each study was graded by using Oxford Centre for Evidence-based medicine guidelines to evaluate the strength of the included RCTs.²⁶

Studies were excluded, if the age of the participants was less than 60 years or they had other health conditions like neurological disorders, fractures, amputations, cognitive impairments or were unable to stand and walk for short distances. Studies in non-English languages, abstracts only, non-RCTs, and primary intervention other than Wii Fit training were also excluded. The PRISMA flow chart of the literature search is presented in Figure 1.²⁴

There were two primary outcomes. One was to measure improvement in balance by 8-ft up and go, activities-specific balance confidence scale (ABCS), Berg balance scale (BBS), Tinetti (Static and Dynamic), neurocom sensory organization test, limits of stability (LOS), timed up and go test (TUG), Romberg test, the centre of gravity/position (COG/P), postural sway, functional reach test (FRT). Second was to assess the fall risk/prevention: measured by Tinetti's falls efficacy scale, unipedal test with eye opened and closed, and physiologic profile assessment scale.

Secondary outcomes were to document the commonly used balance assessment tools in measuring outcomes of balance training, adverse events related to the use of Wii Fit for balance training, and improvement in the health-related quality of life (HRQOL)

RESULTS

The initial search resulted in 312 articles. Titles were screened and duplicates were excluded. The remaining 170 articles were assessed for eligibility; and further 106 were excluded, since they did not meet the pre-defined PICOS criteria. Fourteen randomised controlled trials, involving 678 participants, were included in the final qualitative review. It was not possible to comment on the gender distribution as two studies did not mention it.²⁷⁻²⁹ Table I mentions the interventions, characteristics, study duration, outcomes, and strength of evidence for each study.

Table I: Characteristics of Included Studies.

| Author | Year Published | Participants | Study duration | No. of participants | Details of Wii Fit Intervention | Comparator | Outcomes Measures | Mean/median score | Main Outcomes and result | Level of evidence |
|------------------------|----------------|--|----------------|---------------------|--|---|---|--|--|-------------------|
| Rendon <i>et al.</i> | 2012 | Older adult >60 years | Six weeks | 40 | Games consist of Lunges, twist and single leg extension under the supervision of the physiotherapist. The exercise program consisted of three sessions a week for six weeks. | No intervention | 8-ft up and go and ABC | In the Wii Fit group, median change (Min-Max) in 8FUG 1.0 (-1.9-3.7), ABC 6.9 (-1.9-20.0) In the control group, median change (Min-Max) in 8FUG -0.2 (-2.63-4.47), ABC 1.3 (-31.2-40.9) | There was a significant decrease in median scores of Wii Fit interventions in 8-ft up and go and ABC (P<0.05). | 1b |
| Franco <i>et al.</i> | 2012 | Older adults >60 years, 25 (78%) Females and 7 (22%) males | Three weeks | 32 | Wii Fit Group (supervised Nintendo® Wii + home exercising) performed 2 sessions consisting of 10-15 min of active game play per week for 3 weeks | G2 - Matter of the Balance group (Exercise consists of 30 to 45 min of exercise twice a week for 3 weeks) G3- (no intervention) | BBS; TFE Scale; SF-36; self-reported Wii Fit enjoyment scale | The mean changes in scores± S.D were Berg Scale (3.55 ± 5.03), Wii Fit, MOB, (3.45 ± 2.50), and control group (1.1 ± 2.99) | Interventions did not significantly improve SF-36 (p=0.256), Tinetti's Falls Efficacy Scale (p=0.913) and BBS (p=0.837). 81% of the participant enjoyed playing Wii Fit program | 1b |
| Toulotte <i>et al.</i> | 2012 | Older adult >65. 22(61%) Females and 14(39%) males. | Twenty weeks | 36 | G2: Wii Fit training One hour per week for 20 weeks G3: Adapted physical therapy+ Wii Fit training; One hour per week for 20 weeks G4: no intervention | G1: Adapted physical therapy; One hour per week for 20 weeks G3: Adapted physical therapy+ Wii Fit training; One hour per week for 20 weeks G4: no intervention | Unipedal test with the eye open and closed; Tinetti (static and dynamic); position of center of gravity (COG) | In G1, post mean scores± S.D: Unipedal test post scores with eye opened 8.7 ± 5.2* Unipedal test post scores with eye closed 11.5 ± 2.8* Tinetti static 13.5 ± 0.89* Tinetti dynamic 3.0 ± 0.21 COG 14.2 ± 5.8 In G2, post mean scores± S.D: Unipedal test post scores with eye opened 14.5 ± 2.1 Unipedal test post scores with eye closed 15.0 ± 5.0 Tinetti static 13.2 ± 0.67* Tinetti dynamic 3.8 ± 0.67 COG -12.5 ± 2.2* In G3, post mean scores± S.D: Unipedal test post scores with eye opened 14.6 ± 3.0* Unipedal test post scores with eye closed 17.2 ± 4.8* Tinetti static 13.6 ± 0.67* Tinetti dynamic 2.7 ± 0.47* COG -4.8 ± 1.9* | Marked improvement seen in the Tinetti test scale for static position (p<0.05) in G1, G2, and G3. Tinetti test scale for dynamic position (p<0.05) showed improvement in G1 and G3. Performance in Unipedal test (p<0.05) shows significant change in G1 and G3. COG shows improvement in (p<0.05) G2 and G3. | 1b |
| Mailloet <i>et al.</i> | 2012 | Older adults >65. 27(84%) Females and 5(16%) males. | Twelve weeks | 32 | The Wii Fit training intervention comprised 10 games of 1-hour, twice a week for 12 weeks under the supervision of the physiotherapist | No intervention | 8-foot Up and Go | In the training group, 8-foot Up and Go pre and post changed mean score (S.D) -0.94(0.62) In the control group, 8-foot Up and Go pre and post changed mean score (S.D) 0.48 (1.05) | Marked improvement in intergroup outcome measure of balance and agility level (p<0.05). | 1b |
| Ray <i>et al.</i> | 2012 | Older adult with average age of 75. 58(66%) females and 29(34%) males. | Fifteen weeks | 87 | The Wii group (Wii balance board + weighted vest) performed 45 min session three times per week for 15 weeks under the supervision | G2 consist of fitness exercise led by fitness professional G3 no intervention | 8 foot up and go test; "NeuroCom Sensory Organization Test": limits of stability (LOS) and COP and, postural sway recorded in control, visual, auditory and cognitive distractors | There was a significant pretest (7.2 ± 1.4) post-test (6.7 ± 1.4) comparison for 8-foot Up and Go* (p = 0.017) in both intervention group. | Significant improvement and greater reduction in the intervention group (Wii group) for 8-ft up-and-go test. No significant difference between groups for COP or LOS measures; all groups showed a significant improvement in COP parameters over time | 1b |
| Jorgensen <i>et al</i> | 2013 | Older adults >65 years, 40(69%) Females and 18(31%) males. | Ten weeks | 58 | Wii Fit intervention consisted of two sequences; balance-training exercise and muscle exercise sequence. | In control group, wearing copolymer shoe insoles can improve their postural balance | CoP velocity; TUG (3 m); FES; adverse event reporting scale | CoP mean change (95% CI): 0.23mm ² /s (-4.1; 4.6) TUG mean change (95% CI): -1.4 (-2.5; -0.4) FES mean change (95% CI): -1.2 (-2.2; -0.1) | Marked improvement in Wii Fit on the parameters of TUG (p<0.01), FES(p<0.03), not on CoP velocity (P=0.92). No adverse events reported in this trial. | 1b |

| | | | | | | | | | | |
|-------------------------|------|--|-------------|----|---|--|--|---|---|----|
| Cho <i>et al.</i> | 2014 | Older adult >65 years | Eight weeks | 32 | Wii balance board game included ski slalom, table tile and balance bubble (24 sessions, 8 weeks, 30 min each) | No intervention | Romberg test with eyes open and closed using biorescue. | In the Wii Fit group: COP with open eye pre and post mean±S.D Pre 95.1±10.7 Post 44.9±6.6* COP with closed eye pre and post mean±S.D Pre 104.1±20.4 Post 35.6±7.6* In Control Group: COP with open eye pre and post mean±S.D Pre 99.6±11.6 Post 114.5±51.2 COP with closed eye pre and post mean±S.D Pre 109.9±15.3 Post 72.5±20.9 | Wii Fit training is effective at improving the (p<0.05) balance of the elderly | 1b |
| Park <i>et al.</i> | 2015 | Older adult >65 years. 19(79%) females and 5(21%) males. | Eight weeks | 24 | Wii balance board games included Soccer Heading, Snowboard Slalom, and Table Tilt. The subjects spent 10 min on each game for a total of 30 min per session. They performed their exercises for 30 min 3 times a week for 8 weeks | Ball exercises group: Performed exercises for 30 min 3 times a week for 8 weeks | Sway length, sway speed and TUG | Sway length post mean change ±S.D: -5.5±7.122 (p-value 0.07) Sway speed post mean change ±S.D 0.0±0.29 (p-value=1.00) TUG post mean change ±S.D: -1.7±6.64 (p-value=0.53) | Between the two groups effects revealed that the virtual reality game exercise resulted in a greater reduction of sway length than the ball exercise. | 1b |
| Fu <i>et al.</i> | 2015 | Older adult >65 years. 39(69%) females and 21(31%) males. | Six weeks | 60 | Wii Fit balance board games included Soccer Heading, Table Tilt and Balance Bubble. All exercises were performed in a one-hour session, thrice a week for 6 weeks. | The conventional physiotherapy program consisted of lower limb strengthening, tandem standing and walking, walking in sideway, stepping exercise. All exercise was performed in one hour session thrice a week for 6 weeks. | PPA: incidence of fall | In Wii Fit group: Posttest mean score of PPA: Contrast sensitivity 17.4±1.6 Proprioception 2.2±1.0 Quadriceps strength 5.8±0.8 a Reaction time 315.3±74.2 a Postural sway 1042.0±317.2 a In conventional physiotherapy group: Post test mean score of PPA: Contrast sensitivity 17.3±1.5 Proprioception 2.6±1.0 Quadriceps strength 5.1±0.6 a Reaction time 338.9±87.6 a Postural sway 1330.8±3510.4 | Wii Fit group respond significantly on the parameter of strength, reaction time, postural sway and decreasing number of falls | 1b |
| Nicholson <i>et al.</i> | 2015 | Older adults more than 65 years. 14(34%) males and 27(66%) females | Six weeks | 41 | Participants in the Wii group were encouraged to complete 3 x 30 min Wii Fit sessions per week for six weeks. Participants undertook all gaming unsupervised within the community hall of their retirement village. | Participants in the intervention group were encouraged to play selected balance games from Wii Fit Plus for at least 30 min three times per week for six weeks. Eight games from the balance and training plus components of Wii | TUG: single leg balance, lateral reach (left and right) and Icon FES | In Wii group mean score change: TUG -0.61 (0.79) Functional reach (cm) 2.47 (5.08) Functional reach left (cm) 2.24 (4.79) Functional reach right (cm) 1.77 (4.88) SLS left (s) 2.68 (11.73) SLS right (s) 2.89 (11.6) Icon FES 0.58 (1.55) In comparator group mean score change: TUG -0.14 (0.88) | Wii Fit group reported significant improvements in Timed Up-and-Go, left single-leg balance and lateral reach (left and right) | 1b |

When Wii Fit training compared with no intervention, there was a significant difference ($p > 0.05$) between the post-treatment score of the control and treatment groups in improving the static and dynamic balance in the Wii Fit group as assessed by ABCS, Romberg test and 8 foot up and go test. While these studies documented the only statistically significant difference in the Wii Fit training group, it does not provide insight regarding the extent of improvement in clinical outcomes of the control group.²⁷⁻²⁹

One study reported that there was no significant difference ($p > 0.05$) on the BBS, TFE and health-related quality of life, using SF-36 outcome scores when comparing Wii Fit supervised training with the matter of balance group exercise. Compared with ball exercises, there were statistically significant differences in Wii Fit assessed on the parameters of sway length and sway speed.³⁻³⁰

One study of 58 older adults (Wii Fit group and control group wearing copolymer shoe insoles for 10 weeks) focused on adverse events along with other parameters of COP, TUG and FESI. No adverse events were reported in this trial.³¹ Apart from reducing the risk of fall, Wii Fit also improved the balance, physical performance and lower limb strength. Limitations included female's preponderance and recruiting older adults with ideal functioning of musculoskeletal function and postural balance.

One study reported results of Wii Fit training combined with adapted physical therapy in a sample of 36 participants. They assessed various positions of static and dynamic balance using Tinetti test scale, unipedal test, and COG. Wii Fit training along with adapted physical therapy group was superior to other groups in all study parameters.³²

One study demonstrated significant improvement ($p < 0.05$) in lower limb strength, reaction time, postural sway and decreasing number of falls in the Wii Fit training group. Limitations of the study were a modest sample size and difficult level of exercise for frail adults.³³

Three studies compared Wii Fit exercises with the control group (consisting of fall prevention education and conventional program) for 6-8 weeks.³⁴⁻³⁶ Outcome measures used included TUG, single leg balance, lateral reach (left and right), Icon FE, BBS, FES and FRT. The results of all three trials showed significant ($P > 0.05$) improvement in physical parameters, such as balance control, reaction time and muscle strength for the Wii Fit groups. However, one study reported exacerbation of back pain in two participants.³⁶

Two studies reported the results of RCTs of five weeks duration in which weekly sessions of Wii Fit exercises were compared to the control group.^{37,38} The control group was asked to monitor their daily activities categorized into light, medium and heavy. Static and dynamic balance improved significantly ($p > 0.05$) in the experimental group.³⁷ Limitations

of these studies included a modest sample size and unclear assessment of the home practice of the interventions.

A sample size of 87 healthy older people was reported, with three arm groups: G1 (experimental group) performed Wii balance board exercises with weighted vest; Group 2 received fitness exercise led by fitness professional; Group 3 did not receive any intervention. The outcome measures used were 8 foot up and go test, NeuroCom Sensory Organization Test, limits of stability, LOS, COP and postural sway. The Wii Fit group and Fitness group showed significant improvement on 8-ft up-and-go test in pre and post time of assessment, but Wii fit group had greater mean difference than the Fitness group.¹⁰ A modest sample size, majority of females, lack of information about the dropout rate and no description of random allocation are the drawbacks of the study.

The Template for Intervention Description and Replication (TIDieR) checklist is an extension of consort 2010 and was published in 2014. This checklist and guideline were developed to help improve completeness in the reporting of interventions in research studies. None of the studies in this review published after 2014 reported and followed the TIDieR checklist.^{3,33-39}

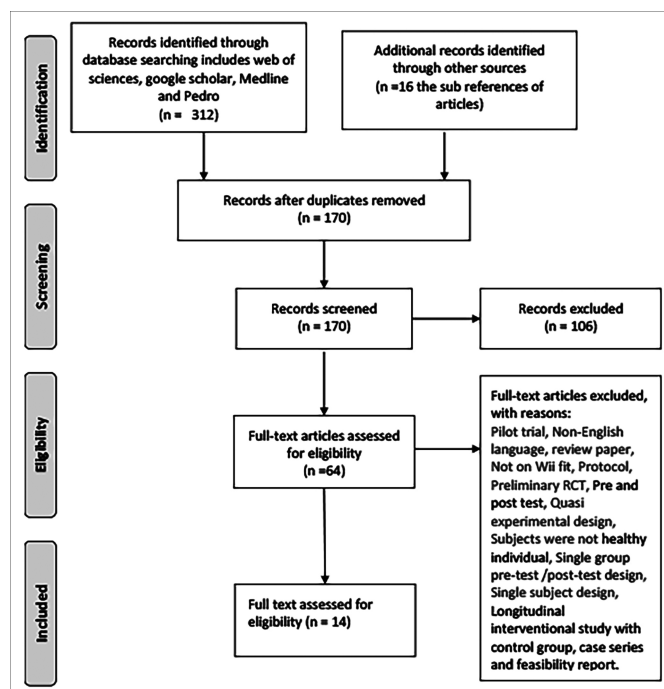


Figure 1: PRISMA flow diagram for literature search.

DISCUSSION

This systematic review provides evidence that Wii Fit is a useful tool for balance training in the elderly population. There has been a growing interest in using commercial video games rehabilitation in a range of conditions, including stroke, cerebral palsy, Parkinson's disease, balance training, weight loss, and aging.⁴⁰ The Wii Fit system is cost-effective

and one of the top-selling video console games of all time.⁴¹ Wii Fit designed to improve postural control in static and dynamic position. The reported benefits of engaging older adults in Wii Fit exergaming include improved range of motion, feelings of social connectedness in their peer groups⁴² and enhanced quality of life.³⁰

Wii Fit plus is considered a form of exer-gaming and provides real time visual biofeedback to the player. It consists of Wii console and a balance board connected by Bluetooth.^{9,43} The sensors detect the body position and motion in space. The participant stands over the balance board to play the games, while moving the body in anterior, posterior, left and right sway and maintaining the centre of pressure within the base of support. The game is played with an on screen avatar called Mii. The Mii character reflects the speed, direction and acceleration of movements performed by the participants in three dimensions. It provides a visual feedback of the body movements, which aids the participant to perfectly execute the exercise. Each user can have a separate Mii with their own names and many participants can play the games, simultaneously. Their personal data and playing record were saved and represented visually as graph charts.^{27,44} Assessment of balance improvement noticed in outcome tools needs adequate knowledge of clinometric properties. These properties are potentially overlooked or not properly reported in clinical practice.^{45,46} Minimal detectable change and coefficient of variation percent for tools commonly used to assess balance is required while using the Wii Fit. Thus, it may provide the basis to detect the real change above measurement error in upgrading the everyday clinical practice.

POEM (Patient-oriented evidence that matters) is a useful strategy to focus on upgrading the practice. Wii Fit helps in the prevention of falls by engaging elderly people living in the community and improving their balance ability in the short term but there is only one study portraying the effects of follow up at one year.³³ There is a need for research to document the long-term outcomes of balance training in the elderly using Wii Fit.

Blinding of participants in an intervention, like Wii Fit, is not possible since every participant can accurately guess whether he/she is in the Wii Fit or the control group. Some studies report that the assessment of balance impairment with the Wii Fit balance board is not as accurate as the traditional balance assessment tools, although it can significantly improve the balance and postural instability in the elderly.^{47,48}

Randomised controlled trials that adhere to the highest standards for external and internal validity are important to make the best decisions for patients. Thus, it is necessary to rule out confounders and sources of bias. Factors such as blinding, allocation concealment and randomisation are important in minimising bias in clinical trials, but even some

of the best-designed trials in rehabilitation seem to have some risk of bias.⁴⁹ For example, randomisation is a method based on the chance of allocating the subject into a treatment group that cannot be predicted easily. Few studies were at low bias, according to the risk of the bias assessment tool.^{27,28,30,32-33,36}

In a randomised controlled trial, allocation concealment is a useful strategy to hide the method for allocating a participant into a treatment group so that this knowledge cannot be used. Adequate concealment of the assignment serves to prevent participants in the study from selecting treatment assignments.^{28,30,33,34} QoL consists of physical, psychological, and mental health. There is evidence that QoL in the elderly is improved by engaging in physical activity and exercise. In elderly population.^{30,50} These gains in QoL are more pronounced when the Wii Fit activities are performed in groups.⁵¹

The use of Wii Fit for the elderly is generally safe. Studies reported very few or no adverse events. One study in this review reported adverse effects like back pain, which lead to the patients to drop out from the study. However, this did not require medical attention.^{48,51} Another study reported that one person dropped out from the trial reporting that it was physically too difficult to continue. Wii Fit balance training program can be safely followed at home without the formal supervision of a healthcare professional.³⁶ This systematic review favours using Wii Fit as a balance-training tool in the elderly. Based on strength-of-recommendation taxonomy, the evidence would be graded as level A.⁵²

The limitations of the review were that it included only RCTs on the use of Wii Fit for balance training published in the English language. This might have missed research published on this topic in languages other than English.

CONCLUSION

We conclude that in healthy older adults without any cognitive or neurological diseases, Wii Fit is an effective virtual reality approach for balance training. This intervention requires less time per session compared to traditional physical therapy treatment. Moreover, it is user-friendly, engaging, cost-effective and can be delivered at home without the need for supervision by a trained rehabilitation professional. Given the growing popularity of the technological approach as Wii Fit intervention, it would be important for the rehabilitation field to replicate these findings as high quality randomised clinical trials with large sample size and equal distribution of males and females.

CONFLICT OF INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

AF: Gave the idea, performed the literature review, wrote the first draft, gave approval of the final version and agreed

to be accountable for all parts of the work.

FAR: Interpreted the results, revised the manuscript critically and gave approval of the final version and agreed to be accountable for all parts of the work.

SNBN: Did the literature search, analysed and interpreted the results, revised the manuscript critically and gave approval of the final version and agreed to be accountable for all parts of the work.

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