# **Implementation of an exergaming intervention to improve balance and reduce the risk of falling in individuals with knee osteoarthritis: a feasibility study**

## **Context of the study**

The context of this study is set as an intervention component of the thesis investigating the use of exergaming in individuals with knee osteoarthritis (OA). In this study, the Nintendo Wii Fit™ games and balance board system will be utilised as an exergaming intervention. This proposal was conceptualised and informed by two literature reviews which are part of the PhD thesis [1, 2]. From a methodological point of view, effects should be studied in a randomised controlled trials. However, before spending considerable resources for a randomised controlled trial, a feasibility of the programme using a single-arm trial should be tested first.

## **Background**

Over the last decades, a clear process of demographic ageing has been observed globally[3]. Osteoarthritis (OA) and falls and their impact on morbidity and mortality constitute major health concerns in this population [3, 4]. OA ranked 13th while falls ranked 12th as leading contributors to global years lived with disability[5]. Individuals with knee OA are at greater risk of falling compared with a non-OA group, and more than 50% of individuals with knee OA reported a fall during the previous year [6, 7]. Although it has been suggested that OA, as condition, is a risk factor for falls, the reason for falling in this population may be more specifically due to symptoms related to OA [8, 9].

Knee OA is characterised by pain, joint stiffness, muscle weakness, instability and functional impairments [10-12]. The interaction of these symptoms alters the integrity of the knee joint, which in turn influences balance. The decline in balance can be a result of both physiological changes due to the ageing process, and an impaired integration of somatosensory and neuromuscular information due to the presence of knee OA symptoms [13, 14]. The consequences of the joint changes and symptoms increase the propensity of individuals with knee OA to fall. Thus, it is important to consider the symptoms and related factors in managing balance impairment of individuals with knee OA.

Exercise is recommended as the first line of choice in clinical guidelines for management of knee OA [15]. International guidelines advocate individuals with knee OA to engage in physical activities and exercise programs to relieve the symptoms and to improve muscle strength, joint range of motion, and aerobic fitness [16, 17]. Doing exercise in a supervised group, practising Tai Chi, and participating in physical activities such as walking has been proven effective [18, 19]. However, there are alternative treatments that can be used that may provide possible therapeutic and rehabilitative effect in a novel and engaging way.

Exergaming (*exercise + gaming*), active video games or gamification showed potential use for improving postural balance in older adults [20-23]. Preliminary evidence supports using exergaming to improve balance, physical function, and reduce the risk of falling in this healthy older adult group [22, 23].Commercially available or off-the-shelf game-based system such as Nintendo Wii Fit™ and Sony X-box Kinect™ are popular since they are low-cost compared to other virtual reality tools [20, 21]. Studies have also shown increase exercise adherence due to the interaction and enjoyment components of which can increase exercise intentions [24, 25].

Despite the fun component of the games used in exergaming which simulates feedback and encourages individuals to perform exercises, parameters using exergaming to target improvements in balance have not yet been established [22, 23]. A narrative review was conducted to synthesise published evidence on Nintendo Wii Fit™ exergaming and evidence supports that the most commonly used protocols in playing Wii Fit™ game 30 minutes, three times weekly for six weeks; however firm recommendation was not achieved due to conflicting evidence on optimal dosage [1]. Some studies showed changes and potential improvements in balance outcome score after six and eight weeks of exergaming intervention, but these were investigated in healthy older adults [26-28].

The majority of published articles investigating the use of exergaming included healthy and patient population where the latter are mostly neurologic conditions such Stroke, Parkinson’s disease, and Multiple Sclerosis [29, 30]. The use of exergaming has not been explored in individuals with knee OA. Several games have been developed to increase physical fitness and balance, yet it is also unclear to which degree of usability, safety and acceptability of this exergaming programme in a knee OA group. Thus, a feasibility study is an important step to evaluate trial protocols and procedures before determining its effectiveness.

## **Objectives of the study**

This research aims to conduct an exergaming intervention using Nintendo Wii Fit™ games in individuals with knee OA. The primary objective is to determine the feasibility of implementing an exergaming balance intervention. The specific objectives are as follows:

1. To assess the recruitment of participants with knee OA in an exergaming balance intervention;
2. To estimate the compliance and retention rate of the participants with knee OA after completing an 8-week exergaming balance intervention;
3. To explore on participants’ perceptions and experiences after using the Nintendo Wii Fit™ as an exergaming intervention.

The secondary objective is to estimate changes in the outcome measure scores mainly for balance and risk of falling. As a feasibility study, effectiveness will not be evaluated instead feasibility outcomes and estimation of changes in the key outcome measures will be presented.

## **Significance of the study**

The proposed project will be an essential preliminary step towards investigating the usability of Wii Fit™exergaming as a balance intervention and as part of a fall prevention program for individuals with knee OA. Findings from this study will inform the design of the future intervention protocol and explore the acceptability of the exergaming intervention in this patient population.

**Methods**

***Study design***

A mixed-methods, explanatory sequential study design will be conducted for piloting the Nintendo Wii Fit™ exergaming program in individuals with knee OA [31]. This design emphasises quantitative analysis, which is followed by interviews or observations (qualitative) to help in analysing the findings [31]. The quantitative part will be a one-way repeated measures design, while the qualitative part will be a focus group discussion. *Figure 1* shows the flow and the two components of the study while *Tables 1* shows the summary of the outcome of interest, criteria for success, outcome measures and plan of analysis.

Assessment 1

Assessment 2

Assessment 3

Eligible participants (N=12)

8 weeks

Usual care

8 weeks

Wii Fit™ intervention

Focus Group

Discussion

*Figure 1. Schematic diagram of the quantitative (intervention) and qualitative (focus group discussion) part of the study.*

## ***Ethical considerations***

## Ethical approval will be sought from the Southern Health and Disability Ethics Committee, and research consultation with Māori will be undertaken.

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| *Table 1. Summary of the outcomes, criteria, and plan of analysis of the study* | | | |
| **Outcome of interest** | **Criteria for success** | **Outcome measures** | **Plan of Analysis** |
| ***Feasibility outcomes\**** | | | |
| Recruitment | Recruit of at least 12 participants | Number of participants recruited over 3-month period | Descriptive statistics |
| Retention | Retain at least 75% of the sample | Number of participants post-intervention assessment |
| Compliance | >50% of the participants will complete exergaming intervention for at least two out three sessions per week | Attendance and proportion of participants that completed the intervention |
| Safety | No adverse events/harms during the related to the study or due to intervention | Number of recorded adverse events /harms related to the study\*\* |
| ***Measures related to knee OA symptoms, balance and falls risk*** | | | |
| *Self- reported outcome measures* | | | |
| Pain  Joint stiffness  Physical function  Quality of life | Positive changes in outcome measure scores from baseline to post-intervention assessment | Knee Osteoarthritis Outcome Score | Mean, Median, Interquartile ranges, Median difference, and 95% confidence interval |
| Instability | Knee Outcome Survey – Activities of Daily Living Scale |
| Fear of falling | Short FES-I |
| *Instrumented outcome measures* | | | |
| Balance | Positive changes in outcome measure scores from baseline to post-intervention assessment | Sensory Organisation Test using *NeuroCom SMART Equitest* | Mean, Median, Interquartile ranges, Median difference, and 95% confidence interval |
| Strength | Hand-held Dynamometer |
| Proprioception | Physiological Profile Assessment |
| Falls risk |
| *Physical performance measures* | | | |
| Physical function | Positive changes in outcome measure scores from baseline to post-intervention assessment | Timed Up and Go test | Mean, Median, Interquartile ranges, Median difference, and 95% confidence interval |
| ***Participants’ perceptions and experiences*** | | | |
| Perceptions and experiences (i.e. usability, acceptability, satisfaction) | Positive experiences with the use of exergaming program | Semi-structured interview (focus group) | Thematic Content Analysis |
| *\*Definition of feasibility outcomes and success, cessation of the study is presented in outcome measures section of this proposal*  *\*\*Adverse events and harms is defined in outcome measures section of this proposal* | | | |

## ***Participants***

*Inclusion criteria.*Participants aged 18 years old and above with knee OA meeting the clinical criteria of the American College of Rheumatology [32] and history of falls over the past 12 months will be recruited. A fall is defined as an event in which person unintentionally comes to rest on the ground or other lower level [33]. Following the National Institute for Health Care Excellence (NICE) guidelines and Health Quality and Safety Commission New Zealand (HQSC-NZ) recommendation on assessing falls in older people [34]. To determine the history of falls, participants will be asked the following questions:

1. *Have you slipped, tripped or fallen in the last year? If yes, how many fall/s?*
2. *Can you get out of a chair without using your hands?*
3. *Have you avoided some activities because you are afraid you might lose your balance?*

These questions were adapted from “Ask, Assess, Act” of HQSC-NZ. We included the number of falls in the past year in the question following the NICE guidelines to assess the frequency, context and characteristics of the falls [34].

*Exclusion criteria.*Exclusion criteria will include the presence of another concomitant lower extremity musculoskeletal condition, inflammatory arthritis, the presence of neurological diseases, previous history of lower limb joint replacement, the presence of cognitive deficits, and those with a vestibular problem. A participant who is receiving the current intervention or included in an ongoing study as well as with the previous history of using exergaming will also be excluded.

***Sample size***

As per recommendation of estimating the sample size of a feasibility study, 12 participants are needed in a group [35]. Twelve participants will be recruited and will be the basis for the recruitment criteria for success of this feasibility study.

***Recruitment and study setting***

Participants will be recruited from Dunedin by community advertising. Inclusion criteria will be used to screen the participants for eligibility. If a respondent is interested in joining the study, they will undergo screening by telephone before attending the research centre at the School of Physiotherapy. Recruitment will be from August to October 2017. The potential participants will receive study information and will be given time to decide and an opportunity to ask questions regarding the study before signing an informed consent form. The assessment and intervention sessions will be done at the Balance Clinic of School of Physiotherapy and in a set-up Exergaming room, respectively. The duration of both assessment and intervention will be approximately 60 minutes.

***Procedure***

Eligible participants will have three assessment sessions (baseline, after eightweeks and after 16 weeks) and two intervention phases (usual care and Wii Fit™ intervention). After completion of baseline assessment, the participants will continue with usual care for the next eight weeks. As part of their usual care, participants will be given exercise instructions and home exercise program. Before embarking on the next phase of the intervention, participants will be assessed at eight-week. Participants will perform 45 to 60 minutes of exergaming, three times per week for an eight-week period. The games were informed by the result of the narrative synthesis [1]. This will include Table Tilt, Soccer Heading and Penguin Slide (Table 2)*.* Aside from being the most commonly used games, these were chosen due to their focus on weight shifting which is a component of postural balance. To monitor adherence, participants will be followed-up through phone calls.

*Table 2. Game Title and Description*

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| **Game Title** | **Description** |
| Table Tilt | Participants shift their weights on the forward and backwards and from side to side to direct a ball on-screen into a hole for points. The difficulty of the goal increases as more balls are navigated into the hole. Game ends when the time runs out |
| Soccer Heading | Participants shift weight left or right to head soccer balls on the screen. The game ends when time runs out. |
| Penguin Slide | Participants shift their weight right or left to tilt an iceberg and slide a penguin back and forth to catch fish for points. More rapid weight shifts make the tosses the penguin up to catch more fish. The game ends when time runs out. |

A training session will be provided to a Physiotherapists who will be doing the intervention. The training will help the assigned Physiotherapist to be familiar with the operation of Wii Fit™ games and system. The study will utilise the Nintendo Wii Fit™ Balance Board. The balance board which measures 8.5’’ x 6’’ x 2’’ is an accessory for the Nintendo’s Wii video game console. It has a white top and a grey bottom, shaped like a weighing scale. The balance board is a wireless console run by 2 AA batteries and can support up to 300 lbs. The balance board contains several multiple pressure sensors that measure a player’s centre of balance and the body mass index (BMI). The balance board will be calibrated before the commencement of the study.

***Focus group***

A qualitative study design will be conducted post intervention to explore participant's perceptions and experiences. A focus group discussion method will be employed as it facilitates an in-depth and interactive discussion [36]. A semi-structured interview technique will be utilised. An interview guide questions will be developed and piloted following recommended guidelines [36, 37]. The interview guide questions will also be peer-reviewed by the research team. The guide questions will include an introduction, key issues, transitions and probing questions. A summary and ending questions will be provided to conclude the discussion. The focus group discussion will be audio-recorded and transcribed verbatim.

**Outcome measures**

The feasibility will be evaluated based on recruitment, retention, compliance and safety. Table 3 shows specific definitions and criteria for success of the study. The study will be terminated before completion if one major adverse event. Cessation the study will be based on the incidence of adverse events and harms during the implementation of the study. In this feasibility study, adverse events and harms are defined as untoward events directly caused by the intervention.

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| **Feasibility outcome** | **Definition** | **Criteria for the feasibility of the study** | | |
| **Feasible** | **Feasible with modification** | **Not feasible** |
| Recruitment | Number of participants recruited in three months | 12 participants | 6-11participants | <5 participants |
| Retention | Number of participants retained post-intervention | >75% of recruited participants | 50% -75% of recruited participants | <50%  recruited participants |
| Compliance | Number of days per week performed the intervention | >60% performed the intervention thrice per week | >60% performed the intervention twice per week | >60% performed the intervention once per week |
| Safety | Number of adverse events/harm related to the study or intervention | No harms and adverse effect | Reported adverse event/harms resulted not directly caused by the intervention | Reported adverse event/harms resulted directly caused by the intervention |

Table 3. Criteria for success of the feasibility study.

Adverse events will be mitigated by training the participants on how to use the system, giving clear instructions on the objective of the games and reporting incident resulting in harm or personal injury to participants during testing or intervention according to the University of Otago Health and Safety assessment procedures. The Physiotherapist and assessor will also have a valid Cardiopulmonary Resuscitation (CPR) certificate.

***Primary outcome measures***

Table 4 shows the primary and secondary outcome measures related to balance, falls risk and knee OA symptoms to be used in the study.

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| Table 4. Primary and secondary outcome measures of the study | |
| **Variable** | **Outcome measures** |
| *Primary outcome measures* | |
| Balance | Sensory Organisation Test using *NeuroCom SMART Equitest system, version 8.6.0* |
| Falls Risk | Physiological Profile Assessment |
| *Secondary outcome measures* | |
| Pain, stiffness, symptoms, knee related quality of life | Knee injury and Osteoarthritis Outcome Score |
| Knee instability | Knee Outcome Survey – Activities of Daily Living Scale |
| Knee muscle strength | Hand-held dynamometer using *Nicholas MMT, Model 01160* |
| Physical function | Knee injury and Osteoarthritis Outcome Score  Timed Up and Go Test (TUG) |
| Fear of Falling | Short Fall Efficacy Score – International |

*Postural balance and sway*

Postural balance and sway will be measured using the standard Sensory Organization Test (SOT) [38]. The standard SOT will be administered using the NeuroCom SMART Equitest system, version 8.6.0 *(NeuroCom, A Division of Natus, Clackamas, OR)*. The SOT protocol is consists of three 20-second trials under six different sensory testing conditions [39]. The participant will stand upright on a fixed or movable platform and surround, with the eyes closed or open. Instructions and safety procedures such as the wearing of the harness will be done before proper administration of the test. There will be two variables to be obtained in this assessment, the equilibrium and composite scores. Equilibrium balance expressed as percentage balance will be indicative on how a participant will stay within a certain sway envelope or limit of stability while the composite score will measure the participant’s overall level of performance score in SOT. A percentage score near 100% means minimal sway while a decreasing percentage means that the sway is near the limit of stability [38].

*Falls risk*

Falls risk will be determined using the Physiologic Profile Assessment (PPA) [40], which includes five validated measures of physiological function. Visual contrast sensitivity will be assessed using the Melbourne Edge Test [41]. Proprioception will be measured using a lower limb-matching task. Errors will be recorded in degrees using a protractor inscribed on a vertical clear acrylic sheet (60 × 60 × 1 cm) placed between the legs. Quadriceps strength will be measured isometrically in the dominant leg, with the angles of the hip and knee at 90° with patients seated [40]. The best of three trials will be recorded in kilogrammes. Simple reaction time will be measured in milliseconds using light as the stimulus and a finger-press as the response. Previous studies used PPA as an outcome measure for individuals with knee OA [42].

***Secondary outcome measures***

*Knee pain, stiffness, function and quality of life (KOOS)*

The Knee injury and Osteoarthritis Outcome Score (KOOS) will be administered to assess knee pain and function. KOOS consists of 5 subscales: pain, other symptoms, Activities of Daily Living (ADL), sport and recreation function (Sport/Rec) and knee-related Quality of Life (QOL) [43]. KOOS is intended to be used for a knee injury (e.g. ACL) that can subsequently result in posttraumatic OA but is also used in the knee OA group [43, 44]. An advantage of the KOOS is the inclusion of two different subscales of physical function relating to daily life, and sport and recreation. This enhances the instrument’s validity for patients with a wide range of current and expected physical activity levels. In knee OA, KOOS has high test-retest reliability [43]: ICCs for the pain subscale range from 0.85-0.93 and the function subscale from 0.75-0.91 [44]. Following the recommendation of KOOS on computing the scores, each subscale score will be calculated independently. The mean score of the individual items will be calculated by dividing it by 4 (the highest possible score for a single answer option). Excel spreadsheets with formulae to calculate subscale scores are available for download ([www.koos.nu](http://www.koos.nu)) [43].

*Knee instability*

A self-report using a question from the Knee Outcome Survey – Activities of Daily Living Scale will be used in measuring knee instability [45]. The Knee Outcome Survey was developed as a patient-reported instrument for the measurement of functional limitations commonly experienced by individuals who have various pathological disorders of the knee, including osteoarthritis. Item 6 of the survey related to instability will be used. An ordinal scoring system was used to assign a value to the responses, with a lower level of function resulting in a lower score [45].

*Knee muscle strength*

To measure the muscle strength, a handheld dynamometer *(Nicholas MMT, Model 01160, Lafayette Instruments, Lafayette, Indiana)* will be used. This device is valid and highly reliable for testing between trials and days [46]. A hand held dynamometer provides a reliable, quantitative method as compared to manual muscle testing in patients with knee OA [47]. The testing will be done in two positions – in prone for knee flexors (hamstrings) and in siting for knee extensors (quadriceps). In both positions, strength will be measured at 0-20° flexion and 70-90° flexion. The participant will be instructed to hold (isometrics) maximally and match the pressure given for 4 seconds without moving the limb [47]. The measurement will be recorded in kilogrammes (kg).

*Physical performance measure*

The OARSI recommends a set of performance-based tests of physical function that are best suited for individuals diagnosed with hip and knee OA [48]. One of the recommended tests is the Timed Up and Go Test (TUG). We decided to use this simple test to easily assess function, particularly a participant’s mobility. Considering the number of assessments included in the study, and wishing to avoid the burden of a long assessment for the participant, TUG will be the only physical performance measure to be used. This test measures the time (seconds) taken to rise from a standard chair (seat height approximately 44 cm), walk 3 metres at their pace, turn, walk back to the chair, and then sit down, wearing regular footwear [49, 50]. Use of their usual walking aid is allowed and recorded if required. TUG used for older adults has an inter-rater reliability of ICC = 0.98 -0.99 and an intra-rater reliability of ICC = 0.97-0.98 [49, 51].

*Fear of falling*

The Short Falls Efficacy Scale-International (FES-I) will be used to assess fear of falling. FES-I is a seven-item shortened version of the FES-I [52, 53]. The psychometric properties of the Short FES-I were as good as the FES-I [53, 54]. The Short FES-I produce a score for each participant by summing the fear experienced across a range of seven common activities of everyday life. The tool will be administered through participant’s self-reported experience [54].

**Data Analysis**

Descriptive statistical analysis will be used to describe the feasibility outcomes, participant’s characteristics and baseline measurement scores. The sample size of this feasibility study will be too small to test for significant differences. However, medians, interquartile ranges, median differences and confidence intervals as suggested by Bonett and Price will be performed to see changes in the outcome measures [55]. General Inductive approach and content analysis will be employed to identify important themes from the post-intervention interview [36, 56]. The audio-recorded interviews will be transcribed verbatim, and each piece of the transcription will be checked against audio records to ensure accuracy. A discussion with the research team will be conducted to conferred on the general themes that will emerge to ensure consistency and fidelity of the findings. Microsoft Excel 2016 will be used to encode the data while Statistical Package for the Social Sciences (SPSS) version 22.0 will be used to analyse the data.

**Study Timeline:**

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| **Activity** | **Jun** | **Jul** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** |
| Ethics, pilot testing |  |  |  |  |  |  |  |  |  |
| Recruitment |  |  |  |  |  |  |  |  |  |
| Intervention |  |  |  |  |  |  |  |  |  |
| Analysis of data |  |  |  |  |  |  |  |  |  |
| Results |  |  |  |  |  |  |  |  |  |
| 1st draft |  |  |  |  |  |  |  |  |  |

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