

# **Exergaming to improve balance and decrease the risk of falling in individuals with knee osteoarthritis**

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## Abstract

**Background:** The benefits of exercise to improve balance and reduce the risk of falls is well-recognised in the older-adult literature. However, little attention is paid to people with osteoarthritis (OA) of the knee. While there is evidence of an increasing number of falls in adults with knee OA, the contributing factors for falling has not been substantially investigated. Exergaming (exercise and gaming) is useful in improving balance in a range of health conditions, yet there is limited research regarding its application to people with knee OA.

**Aim:** The primary aim of this thesis was to investigate the feasibility and acceptability of exergaming using Nintendo Wii Fit™ to improve balance and reduce the risk of falls in individuals with knee OA. Secondary aims were to identify the risk factors for falls in adults with knee OA and to examine the strength of relationship between falling and clinical characteristics such as dynamic balance, pain, instability, muscle strength, and physical function in adults with knee OA.

**Methods:** The main study utilised a mixed-methods, explanatory sequential study design (quantitative followed by qualitative design) to determine the feasibility of exergaming. Nested in this thesis were two literature reviews and a cross-sectional study, all conducted to inform the design of the main study. A systematic review was conducted to identify published evidence on the risk factors for falls in adults with knee OA. The findings from the systematic review informed the risk factors for falls explored in the cross-sectional study. A narrative synthesis of exergaming literature using Nintendo Wii Fit™ was conducted to determine dosage and parameters of the exergaming intervention in the main study.

**Results:** Findings from the systematic review included moderate evidence for impaired balance, decreased knee muscle strength, an increasing number of symptomatic joints, and the presence of comorbidities as risk factors for falls in individuals with knee OA. Conflicting evidence was found for knee pain. Impaired proprioception, knee instability, and use of walking aids had limited evidence for being significantly associated with increasing risk for falls. In the cross-sectional study, 31 out of 63 (49%) participants with knee OA reported at least one fall in the previous 12 months. For participants with knee OA and history of falling, dynamic balance, knee muscle strength, and performance of

physical function were significantly reduced when compared to participants with knee OA and no history of falling ( $p < 0.05$ ). Lower dynamic balance measured by the Composite Score (OR 0.86, 95% CI 0.73–0.98,  $p = 0.049$ ) and weaker quadriceps muscles strength (OR 0.70, 95% CI 0.44–0.91,  $p = 0.028$ ) showed positive association with an increased risk of falling. Whereas, poorer physical function measured with the Timed Up and Go test, showed increased risk of falling by almost two-fold (OR=1.65, 95% CI 1.85–4.21,  $p = 0.006$ ).

The main study found that it is feasible and acceptable to use Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling in adults with knee OA. The pre-defined feasibility criteria such as recruitment, retention, and compliance were successfully met. This was affirmed by the participants' views on the procedures of the study in terms of the frequency and duration of the assessment and intervention sessions, which they reported to be acceptable. The study demonstrated that it is safe to use Nintendo Wii Fit™ as an exergaming tool as there were no adverse events reported throughout the study period. There were encouraging results in the key outcome measures such as increasing muscle strength, balance, and performance of physical function sufficient to support the conduct of a future randomised controlled trial (RCT). Participants enjoyed playing Wii Fit™ games and found exergaming motivating and interactive in spite of some barriers with the use of technology.

**Conclusion:** This thesis highlights the risk factors for falls and the potential of exergaming to improve balance and decrease the risk of falling in individuals with knee OA. It is essential to understand the mechanism underlying the occurrence of falls in knee OA by identifying modifiable risk factors which can be mitigated. The potential use of exergaming as a balance tool and the assessment of knee OA symptoms that are critical to increasing falls risk can provide valuable information for both clinicians and fall prevention program developers. Findings coming from feasibility study are encouraging, and support the need to conduct a full-scale RCT.

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## Publications and research outputs

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**Manlapaz DG**, Sole G, Jayakaran P, Chapple CM. (2017). Exergaming to improve balance and decrease the risk of falling in individuals with knee osteoarthritis. *Australia New Zealand Clinical Trial Registry*. Online protocol registration: ACTRN 12617000154303(<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=372182&isReview=true>).

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## Conference presentations:

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## Table of Contents

Abstract	i
Acknowledgments	iii
Publications and research outputs	v
Table of Contents	vii
Appendices	xiv
List of Tables	xv
List of Figures	xvii
List of Abbreviations	xix
<b>CHAPTER 1: Introduction</b>	<b>1</b>
1.1 Chapter overview	1
1.2 Background	1
1.2.1 The ageing population	2
1.3 Knee osteoarthritis	6
1.4 Falls	9
1.4.1 Falls and balance	12
1.4.2 Falls and knee osteoarthritis	13
1.5 Exergaming	14
1.6 Research objectives	17
1.7 Thesis organisation	19
1.8 Significance of the study	21
<b>SECTION ONE</b>	<b>22</b>
<b>CHAPTER 2: Risk factors for falls in adults with knee osteoarthritis: a systematic review</b>	<b>23</b>
2.1 Chapter overview	23
2.2 Background	23
2.3 Methods	24
2.3.1 Protocol	24
2.3.2 Eligibility criteria	24
2.3.3 Literature search and study selection	25
2.3.4 Quality assessment	25
2.3.5 Data extraction and synthesis	26

2.3.6 Level of evidence	27
2.4 Results	27
2.4.1 Study selection	27
2.4.2 Methodological quality	29
2.4.3 Study characteristics	31
2.4.4 Fall definition and reporting	36
2.4.5 Identified risk factors	36
2.4.5.1 <i>Intrinsic risk factors</i>	38
2.4.5.2 <i>Extrinsic risk factors</i>	39
2.4.6 Sub-group analysis	39
2.4.7 Level of evidence	40
2.5 Discussion	42
2.5.1 Identified risk factors	42
2.5.2 Falls in knee OA	45
2.5.3 Strengths and limitations	45
2.6 Conclusion	46
2.7 Relationship of the study to thesis	46

### **CHAPTER 3: Factors associated with risk of falling in adults with knee**

<b>osteoarthritis: a cross-sectional study</b>	<b>47</b>
3.1 Chapter overview	47
3.2 Background	47
3.3 Methods	48
3.3.1 Study design	48
3.3.2 Sample size	49
3.3.3 Ethical approval	49
3.3.4 Recruitment and screening of participants	49
3.3.5 Study setting	50
3.3.6 Eligibility of participants	50
3.4 Materials and procedures	51
3.4.1 Dependent variable	51
3.4.2 Independent variables	52
3.4.3 Outcome measures for the independent variables	53
3.4.3.1 <i>Knee injury and Osteoarthritis Outcome Score (KOOS)</i>	53

3.4.3.2 <i>Knee Outcome Survey-Activities of Daily Living Scale for knee instability (KOS-ADL)</i>	54
3.4.3.3 <i>Sensory Organization test (SOT)</i>	55
3.4.3.4 <i>Hand-held dynamometer</i>	58
3.4.3.5 <i>Timed-Up and Go Test</i>	59
3.4.4 Procedures	59
3.5 Data management and analysis	62
3.5.1 Data management	62
3.5.2 Data analysis	63
3.6 Results	65
3.6.1 Participants characteristics	65
3.6.2 Comparison between faller and non-faller group with knee OA	66
3.6.3 Association between clinical characteristics of individuals with knee OA and history of falling	69
3.7 Discussion	71
3.7.1 Characteristics of falls in individuals with knee OA	71
3.7.2 Differences in the characteristics of fallers and non-fallers	72
3.7.3 Association between clinical characteristics of individuals with knee OA and history of falling	73
3.7.4 Limitations	75
3.8 Conclusion	76
3.9 Relationship of the study to thesis	76
<b>SECTION TWO</b>	<b>77</b>
<b>CHAPTER 4: A narrative synthesis of Nintendo Wii Fit™ gaming protocol in addressing balance among healthy older adults: what system works?</b>	<b>78</b>
4.1 Chapter overview	78
4.2 Background	78
4.3 Methods	79
4.3.1 Data sources	79
4.3.2 Study selection	80
4.3.3 Data extraction	80
4.3.4 Data analysis	81
4.4. Results	81
4.4.1 Study selection	81

4.4.2 Study participants and characteristics _____	81
4.4.3 Nintendo Wii Fit™ protocol _____	89
4.5 Discussion _____	95
4.5.1 Gaming selection and setting _____	95
4.5.2 Dosing and progression of exercise _____	96
4.5.3 Safety and technical issues _____	97
4.5.4 Outcome measures _____	98
4.5.5 Limitations _____	98
4.5.6 Recommendations _____	98
4.5 Conclusion _____	99
4.6 Relationship of the study to thesis _____	99
<b>SECTION THREE _____</b>	<b>100</b>
<b>CHAPTER 5: Exergaming to improve balance and decrease the risk of falling in adults with knee osteoarthritis: a feasibility study _____</b>	<b>101</b>
5.1 Chapter overview _____	101
5.2 Background _____	102
5.3 Methods _____	103
5.3.1 Study design _____	103
5.3.2 Ethical approval _____	105
5.3.3 Recruitment _____	105
5.3.4 Eligibility of participants _____	105
5.3.5 Study setting _____	107
<b><i>Part 1: Quantitative Phase</i> _____</b>	<b>108</b>
5.4 Quantitative phase: methods _____	108
5.4.1 Interventions _____	108
5.4.1.1 <i>Usual care</i> _____	108
5.4.1.2 <i>Exergaming intervention</i> _____	108
5.4.2 Assessors _____	114
5.4.3 Primary outcome measure: feasibility outcomes _____	114
5.4.4 Secondary outcome measure: clinical outcomes _____	115
5.4.4.1 <i>Physiologic Profile Assessment</i> _____	116
5.4.4.2 <i>Short form Falls Efficacy Scale-I</i> _____	120
5.4.5 Assessment procedure _____	121

5.4.6 Data management and recording _____	123
5.4.7 Data analysis _____	124
5.5 Quantitative phase: results _____	125
5.5.1 Demographics _____	125
5.5.2 Primary outcome measure: feasibility outcomes _____	126
5.5.2.1 <i>Recruitment</i> _____	126
5.5.2.2 <i>Retention</i> _____	128
5.5.2.3 <i>Compliance</i> _____	128
5.5.2.4 <i>Safety</i> _____	129
5.5.3 Secondary outcome measure: clinical outcomes _____	129
5.5.3.1 <i>KOOS</i> _____	132
5.5.3.2 <i>KOS-ADL for knee instability</i> _____	132
5.5.3.3 <i>Balance Composite Scores</i> _____	133
5.5.3.4 <i>Knee muscle strength</i> _____	133
5.5.3.5 <i>Timed Up and Go test</i> _____	134
5.5.3.6 <i>Physiologic Profile Assessment</i> _____	135
5.5.3.7 <i>FES-I</i> _____	135
5.6 Quantitative phase: discussion _____	136
5.6.1 Feasibility of exergaming _____	136
5.6.2 Preliminary changes in outcome measures _____	137
<b>Part 2: Qualitative Phase</b> _____	<b>141</b>
5.7 Qualitative phase: methods _____	141
5.7.1 Data Source _____	141
5.7.2 Interview guide development _____	141
5.7.3 Setting _____	142
5.7.4 Focus group discussion _____	143
5.7.5 Data analysis _____	144
5.7.6 Ensuring rigour _____	145
5.8 Qualitative phase: results _____	146
5.8.1 Participants description _____	146
5.8.2 Qualitative findings- feasibility _____	147
5.8.2.1 <i>Theme 1: Feasibility from participant's perspective</i> _____	148
5.8.2.2 <i>Theme 2: Safety while doing exergaming</i> _____	149
5.8.3 Results of the general inductive approach _____	150

5.8.3.1 <i>Theme 1: Exergaming boosts motivation</i>	151
5.8.3.2 <i>Theme 2: Interactions in exergaming</i>	152
5.8.3.3 <i>Theme 3: Barriers of exergaming</i>	153
5.9 Qualitative phase: discussion	155
5.10 Integrated discussion	157
5.10.1 Strengths and limitations	160
5.10.2 Recommendations	162
5.10.3 Design of the future exergaming study	163
5.11 Conclusion	165
<b>CHAPTER 6: General discussion and conclusion</b>	<b>166</b>
6.1 Chapter overview	166
6.2 Summary of the thesis findings	166
6.2.1 What are the risk factors that contribute to falls in individuals with knee OA?	169
6.2.2 Is exergaming feasible and acceptable in improving balance and decreasing the risk of falling in individuals with knee OA?	171
6.3 Strengths and limitations	173
6.4 Research implications	174
6.5 Clinical implications	175
6.6 Conclusion	176
<b>References</b>	<b>178</b>
<b>Appendices</b>	<b>196</b>

## Appendices

- Appendix A:** Publications
- Appendix B:** Conference proceedings
- Appendix C:** Poster presentations
- Appendix D:** Preferred Reporting Items for Systematic reviews and Meta-Analyses
- Appendix E:** Protocol registration: systematic review
- Appendix F:** Search strategy for the systematic review
- Appendix G:** Data extraction form for the systematic review
- Appendix H:** Protocol registration: cross-sectional study
- Appendix I:** Ethical approval and Maori Consultation for cross-sectional study
- Appendix J:** Poster/Advertisement for the cross-sectional study
- Appendix K:** Agreement for talent release for cross-sectional
- Appendix L:** Assessment forms for cross-sectional study
- Appendix M:** Sensory Organization Test result using NeuroCom Equitest® system
- Appendix N:** Protocol registration: feasibility study
- Appendix O:** Ethics approval and Maori consultation forms (feasibility study)
- Appendix P:** Baseline Assessment form (feasibility study)
- Appendix Q:** Participant's Wii intervention kit
- Appendix R:** Focus group discussion script
- Appendix S:** Focus group codes

## List of Tables

<b>Table 1.1</b> Categories of falls risk factors.....	11
<b>Table 1.2</b> Summary of the supplementary studies and the main study.....	18
<b>Table 2.1</b> Quality scores of the included studies .....	30
<b>Table 2.2</b> Summary of the characteristics of reviewed studies.....	32
<b>Table 2.3</b> Summary of findings for risk factors for falls in individuals with knee OA.....	37
<b>Table 2.4</b> Summary of the sub-group analysis.....	41
<b>Table 2.5</b> Summary of the strength of evidence of the risk factors of falls in knee OA.....	41
<b>Table 3.1</b> Inclusion and exclusion criteria used in the study.....	51
<b>Table 3.2</b> Questions to collect falls characteristics of the participants.....	52
<b>Table 3.3</b> Independent variables and outcome measures of the study.....	53
<b>Table 3.4</b> Sensory organisation test six conditions and sensory cues in NeuroCom Equitest® Balance Manager System .....	57
<b>Table 3.5</b> Participants' falls characteristics.....	66
<b>Table 3.6</b> Comparison of demographic characteristics of fallers and non-fallers with knee OA .....	67
<b>Table 3.7</b> Comparison of independent variables between fallers and non-fallers with knee OA .....	68
<b>Table 3.8</b> Results of the association between each independent variable and outcome measure falls in knee OA.....	69
<b>Table 3.9</b> Result of multivariate analysis comparing falls and selected clinical characteristics of knee OA adjusted for all potential confounders .....	70
<b>Table 4.1</b> Summary of included studies .....	84
<b>Table 4.2</b> Extracted Wii gaming protocol .....	90
<b>Table 4.3</b> Dosing of Nintendo Wii Fit™ exergames from included articles.....	93
<b>Table 5.1</b> Inclusion and exclusion criteria used in the study.....	107
<b>Table 5.2</b> Description and movement requirements of the main balance games used in the study.....	110
<b>Table 5.3</b> Summary of Wii Fit™ protocol and games used in the study.....	111
<b>Table 5.4</b> Selection of Wii Fit™ game as part of progressing the exergaming programme.....	113



<b>Table 5.5</b>	Feasibility outcomes definition and criteria for the success of the study.....	115
<b>Table 5.6</b>	List of clinical domains and corresponding outcome measures.....	116
<b>Table 5.7</b>	Application of outcome measures across the different time points.....	122
<b>Table 5.8</b>	Characteristics of participants at entry to trial.....	126
<b>Table 5.9</b>	Descriptive summary of the clinical outcome scores and results of comparing baseline (A1), week 8 (A2), and post-intervention (A3) assessments.....	131
<b>Table 5.10</b>	Physiologic Profile Assessment falls risk scores obtained from the NeuRA FallScreen®.....	135
<b>Table 5.11</b>	Focus group guide key questions and probing questions. ....	142
<b>Table 5.12</b>	Participants demographics and falls characteristics. ....	147
<b>Table 5.13</b>	Summary of the themes and sub-themes with other direct quotes from the participants to support the emergent themes using template analysis.....	150
<b>Table 5.14</b>	Summary of the themes and sub-themes with corresponding quotes from the participants to support the emergent themes. ....	154

## List of Figures

<b>Figure 1.1</b> Rankings of years lived with disability per 10,000 individuals for all ages and gender under non-communicable, musculoskeletal disorders and injuries.....	4
<b>Figure 1.2</b> The focus of the thesis in each of the areas of knee osteoarthritis, falls, and exergaming.....	19
<b>Figure 1.3</b> Research framework showing the contributions of the supplementary studies.....	20
<b>Figure 2.1</b> Flow of the study selection.....	28
<b>Figure 3.1</b> Schematic diagram of recruitment of participants from the community.....	50
<b>Figure 3.2</b> NeuroCom Equitest® Balance Manager System .....	56
<b>Figure 3.3</b> Set-up and position of the participant on the EquiTest® balance system.....	60
<b>Figure 3.4a</b> Measuring quadriceps muscle in sitting position.....	61
<b>Figure 3.4b</b> Measuring hamstrings muscle in prone position .....	61
<b>Figure 3.5</b> Summary of the tests and measures conducted during the assessment of participant. ....	62
<b>Figure 3.6</b> Schematic diagram showing the different statistical analysis to answer the research questions of the study.....	64
<b>Figure 4.1</b> Results and flow of the study selection.....	82
<b>Figure 5.1</b> Schematic diagram of the quantitative and qualitative component of the study.....	104
<b>Figure 5.2</b> Participants playing Nintendo Wii Fit™ during school exergaming session.....	112
<b>Figure 5.3</b> Sample postural sway trace on a graphing paper with corresponding measurements in millimetres with eyes open (EO) and eyes closed (EC).....	118
<b>Figure 5.4</b> Sample of falls risk graph generated from NeuRA FallScreen®. ....	119
<b>Figure 5.5</b> Summary of the assessment procedure conducted in the feasibility study.....	123
<b>Figure 5.6</b> Flowchart of recruitment, retention, and study procedure.....	127
<b>Figure 5.7</b> The overall compliance rate of exergaming sessions.....	129
<b>Figure 5.8</b> The changes of each KOOS subscale scores.....	132
<b>Figure 5.9</b> Changes in Composite Scores.....	133
<b>Figure 5.10</b> Changes in muscle strength .....	134

<b>Figure 5.11</b> The mean TUG scores from baseline to post intervention assessment.....	134
<b>Figure 5.12</b> Framework of increasing engagement and acceptance.....	160
<b>Figure 5.13</b> Flow of the future study .....	164
<b>Figure 6.1</b> Summary of the significant findings of the studies included in the thesis...	166

## List of Abbreviations

ABC	Activities-Specific Balance test
ACR	American College of Rheumatology
ADL	Activity of Daily Living
AMED	Allied and complementary Medicine
BBS	Berg Balance Scale
BMI	Body Mass Index
CDP	Computerised Dynamic Posturography
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COG	Centre of Gravity
COM	Centre of Mass
COP	Centre of Pressure
CS	Composite Score
DM	Donald Manlapaz
ES	Equilibrium Score
GBD	Global Burden of Disease
HHD	Hand Held Dynamometer
HR	Hazard Ratio
ICC	Intraclass Correlation Coefficient
KOOS	Knee Osteoarthritis Outcome Score
KOS-ADL	Knee Outcome Survey-Activities of Daily Living Scale
KP	Knowledge of Performance
KR	Knowledge of Results
LR	Likelihood Ratio
MCID	Minimal Clinically Important Difference
MK	Mandeep Kaur
NICE	National Institute for Health and Care Excellence
NM	Normala Mesbah
NZ	New Zealand
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
OR	Odds Ratio

PICOS	Population, Interventions, Comparators, Outcomes and Study designs
PPA	Physiologic Profile Assessment
PPM	Physical Performance Measure
PR	Prevalence Ratio
PRISMA	Preferred Reporting Items for Systematic reviews and Meta- Analyses
ProFaNE	Prevention of Falls Network European
QoL	Quality of Life
RCT	Randomised Controlled Trial
RPE	Rate of Perceived Exertion
RR	Relative Risk ratio
SD	Standard Deviation
SEM	Standard Error of Measurement
SOT	Sensory Organisation Test
SPSS	Statistical Package for Social Sciences
TUG	Timed Up and Go Test
VR	Virtual Reality
WHO	World Health Organisation
WOMAC	Western Ontario and McMaster Universities osteoarthritis index
YLD	Year Lived with Disability

# CHAPTER 1

## Introduction

### 1.1 | Chapter overview

The focus of this thesis was to bring into perspective exergaming as an intervention to improve balance and reduce the risk of falling in individuals with knee osteoarthritis (OA). This chapter encapsulates the background on the two pressing issues faced by an ageing population: the burden of knee OA and the impact of an increasing number of falls. It begins with a brief discussion of the current scenario of the ageing population, which subsequently unfolds into the three core areas discussed in this thesis: knee OA, falls, and exergaming. Essential concepts are described to highlight the gaps and establish the overlapping issues of knee OA and falls, with exergaming offering a potential solution. The structure of the thesis and significance of the study are presented at the end of this chapter.

### 1.2 | Background

Rapid ageing has prompted novel and creative approaches to healthcare delivery. The integration of virtual reality (VR) into rehabilitation and medicine has demonstrated potential use to achieve the requirements of an effective intervention (Lange, Flynn, & Rizzo, 2009; Pirovano, Surer, Mainetti, Lanzi, & Borghese, 2016; Skjæret et al., 2016). One of the most recognised VR tools in rehabilitation is exergaming, a term coined for the combination of exercise and gaming (Sinclair, Hingston, & Masek, 2007; Staiano & Calvert, 2011). Exergaming has been shown to be useful in rehabilitation and physiotherapy for a range of health conditions, and for promoting physical activity, enhanced balance, and improved motor coordination (Bonnechere, Jansen, Omelina, & Van Sint Jan, 2016; Skjæret et al., 2016). However, research regarding its application to knee OA is limited.

### 1.2.1 | The ageing population

There is a paradox in the drive to extend life. Ageing is a natural process defined as the accumulation of uncompensated deficits that increase the chances of illness or disease (Mitnitski, Mogilner, & Rockwood, 2001). It is an integral part of living yet it is typically accompanied by physiological changes and increased prevalence of chronic diseases (World Health Organization, 2015). Adding years to life comes with health and socioeconomic burdens that have significant consequences for the quality-of-life (QoL) of an ageing population (Baltes & Carstensen, 2008; Bloom, Canning, & Fink, 2010). Every country in the world will experience a substantial increase in the size of the population aged 60 years and above between 2015 and 2030 (World Health Organization, 2015). In New Zealand (NZ), the population is steadily ageing. The current 14% proportion of 65 years and above has a 90% probability of increasing to 22-25% by 2041 (Statistics New Zealand, 2014).

This clear process of demographic ageing observed globally presents both opportunities and challenges. Increased life expectancy, due partly to the success of health interventions, has resulted in many countries facing both short- and long-term health challenges (World Health Organization, 2015; Baltes & Carstensen, 2008). In developed countries like the United States of America, Australia, and NZ, there is an increase in the number of older adults because of advances in health care and scientific research (Bloom, Canning, & Fink, 2010; Bryant, Teasdale, Tobias, Cheung, & McHugh, 2004). The increased older population in developing countries is mostly the result of significant reductions in mortality at younger ages, particularly during childbirth and from prevalent diseases (World Health Organization, 2015).

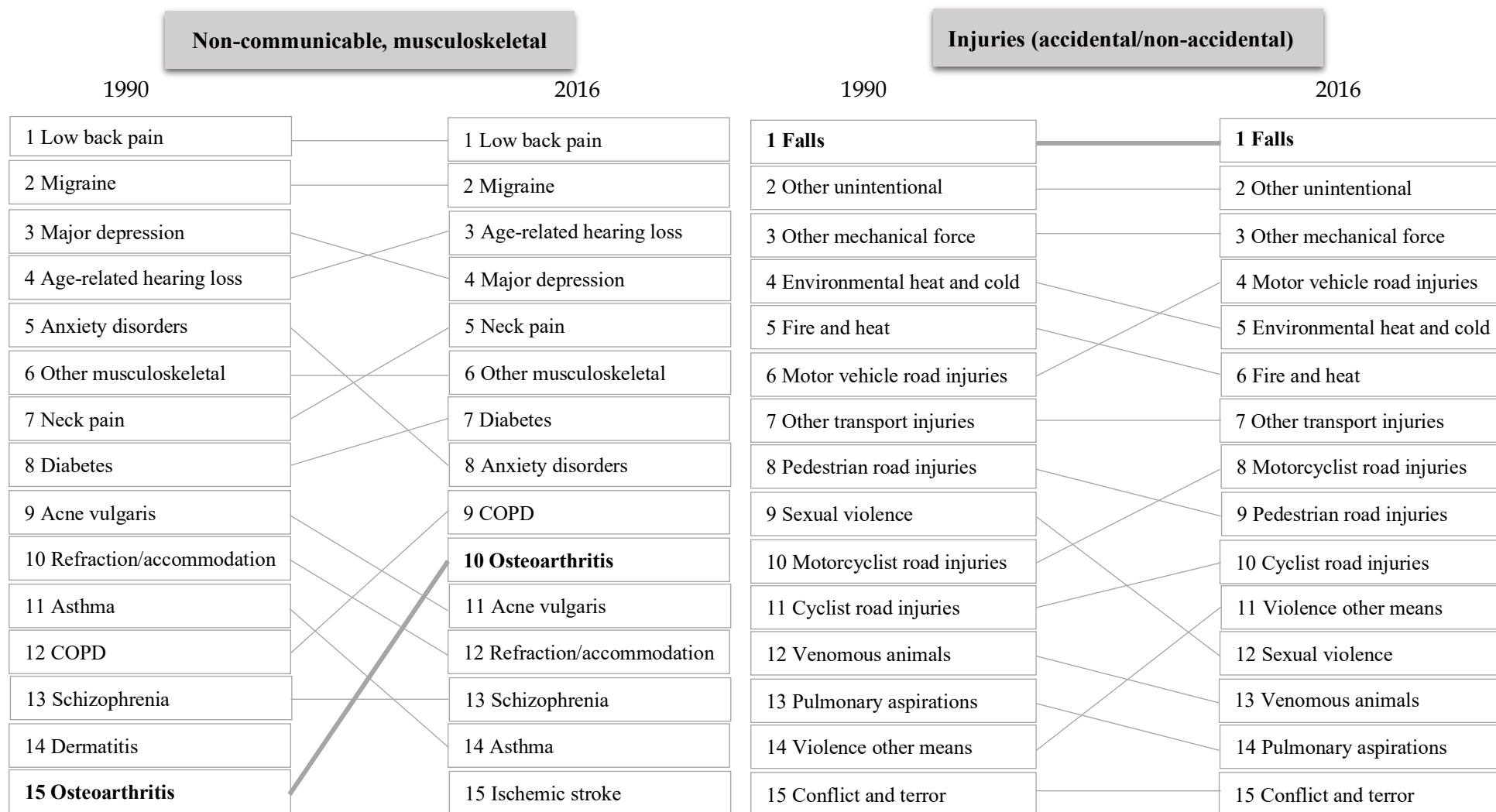
With increasing age, numerous underlying physiological changes may lead to impairments which in turn contribute to disability. The International Classification of Functioning, Disability and Health (ICF) model defines disability as a result of negative interaction between a person with a health condition and that person's personal and environmental factors (World Health Organization, 2001). Moreover, the ICF model conceptualises the domains at different levels namely impairments, activity limitations, and participation restrictions applied in different conditions.

The accumulation of impairments due to comorbidities experienced by the ageing population negatively impacts on their activities of daily living (ADL). In fact, the number of impairments increases considerably with age where most people above the age of 65 have more than one chronic condition (Wolff, Starfield, & Anderson, 2002). Individuals with multiple chronic conditions have more complex health care needs and may have a more rapid decline in health status, higher likelihood of disability, and lower QoL than those with a single chronic condition (Fortin, Dubois, Hudon, Soubhi, & Almirall, 2007; Wolff, Starfield, & Anderson, 2002). For instance, a recent study in NZ explored multi-morbidity patterns and prediction of hospitalisation and all-cause mortality in the older population, showing multi-morbidity is associated with increased healthcare utilisation (Teh et al., 2018). Their findings support the idea that personalised care should be based on the differences between the patterns of multi-morbidity and observed associated health outcomes. Thus, patient-centred intervention and tailored management must be given to individuals with multiple coexisting diseases.

Cognizant with the scenario of an ageing population, there are many health issues that are expected to pose challenges to the healthcare system. Two of these issues are OA, which is the most common musculoskeletal joint disease (Helmick et al., 2008; Lawrence et al., 2008), and falls, which is the most common cause of injury and hospitalisation (World Health Organization, 2004; Shumway-Cook et al., 2009).

The Global Burden of Disease Study (GBD) is a comprehensive worldwide observational epidemiological study and describes mortality and morbidity from major diseases, injuries, and risk factors to health at global, national, and regional levels (Lozano et al., 2013). The GBD 2016 provides a comprehensive assessment of cause-specific mortality for 264 causes in 195 locations (Wang et al., 2016). Figure 1.1 shows the global ranking of years lived with disability (YLD) per 10,000 individuals for all ages and gender under categories of non-communicable, musculoskeletal disorders and injuries. OA is ranked 10<sup>th</sup> with a total 2.02% YLD, while falls remain the number one cause of injuries with a total of 2.35% YLD in 2016.





**Figure 1.1** Rankings of years lived with disability (YLD) per 10,000 for all ages and gender under non-communicable, musculoskeletal disorders and injuries (generated from Institute for Health Metrics and Evaluation data visualisation, *Global Burden of Disease study, 2016*).

There are several reasons why OA and falls continue to be a burden in this population. First, ageing is considered as primary risk factor for developing OA (Anderson & Loeser, 2010) while occurrence of falls increased directly with age (Felson, 2013; Sousa et al., 2016). Moreover, it is unlikely these can be prevented entirely since there is such a wide variety of risk factors for both OA and falls (Ambrose, Paul, & Hausdorff, 2013). Protective factors such as exercise and healthy lifestyle can be addressed, but many risk factors such as gender, age, and genetics are not modifiable (Deandrea et al., 2010). Although there is a wide range of devices and palliative medicines available that relieve pain and improve QoL for patients, there is no pharmaceutical product that halts or reverses the onset of OA (Felson, 2013). On the other hand, the causes of falls are multifactorial and unpredictable (Rubenstein, 2006). The impact of OA and falls implies that prevention and intervention strategies are needed to prepare for the increasing number of chronic conditions and injuries in the ageing population. Thus, an essential step to achieve an effective intervention is through identifying condition-related symptoms and risk factors that can be modified.

Recommendations for exercise and physical activity are commonly known among middle to older adult population yet maintaining regular exercise can be a daunting task. Inadequate physical activity such as lack of exercise, is a pressing concern in this age group (Lim & Taylor, 2005). Various barriers often get in the way, such as lack of social support, the challenges of getting to treatment or exercise venues, competing priorities, and lack of motivation (Franco et al., 2015). Moreover, adherence to exercise is considered as one of the challenges in implementing exercise programs since beneficial effects decline if regular exercise is not maintained (Mazieres et al., 2008). Therefore, identifying enjoyable and engaging exercise is needed to sustain its beneficial impact (Pressman et al., 2009).

As technology becomes more accessible and affordable, some forms of technology can be integrated to address these barriers to exercise and alleviate the burden of chronic conditions such as knee OA. For example, exercise using video games has gained popularity as a tool for improving balance ability (van Diest, Lamothe, Stegenga, Verkerke, & Postema, 2013). However, limitations of this approach in healthcare delivery are being challenged to address the changing health status of the ageing population. Some of the issues include effectiveness, usability, and safety (Nawaz et al., 2015).

### 1.3 | Knee osteoarthritis

OA is the most common form of arthritis which mainly involves weight-bearing joints (Felson, 2013). The occurrence of OA is on the rise due to an ageing population (Blagojevic, Jinks, Jeffery, & Jordan, 2010) and increasing prevalence of obesity (Lementowski & Zelicof, 2008). OA is more common in women than in men and is steadily becoming the most common cause of disability for the middle-aged group (Thorstensson, Andersson, Jönsson, Saxne, & Petersson, 2009). The high prevalence and high rate of disability related to disease make it a leading cause of disability in the older adult population (Felson, 2013). In NZ, OA is ranked as the 16th highest contributor to disability (Cox, 2016).

Knee OA is more common than hip OA with the prevalence of 3.8% and 0.85%, respectively based on GBD study (Cross et al., 2014). In the 2014/2015 NZ Health Survey, 11% (401,000) of the population was estimated to have OA (New Zealand Health Statistics, 2015). Knee OA is one of major causes of disability among people aged 65 years old and above, and is characterized by joint instability, muscle weakness, pain, stiffness, functional impairment, and decreased QoL (Jadelis, Miller, Ettinger, & Messier, 2001; Johnson & Hunter, 2014). A recent study was conducted to develop and validate a new population-based simulation model to specifically look at the burden of knee OA in NZ (Abbott, Usiskin, Wilson, Hansen, & Losina, 2017). Using their model-based evaluation of QoL of individuals with knee OA, on the average, there is a 3.44 years' loss of healthy life, compared with those without knee OA.

OA is a failure of a joint (McAlindon et al., 2014). It is a disease in which all structures of the joint have undergone pathologic changes. These changes are characterised by thinning of the hyaline articular cartilage with loss of joint space, osteophyte formation, and deformity (Johnson & Hunter, 2014). The pathologic hallmark is cartilage loss, present in focal and, initially, non-uniform manner. This is accompanied by increasing thickness and sclerosis of subchondral bone, by outgrowth of osteophytes at the joint margin. (McAlindon et al., 2014).

Although OA is not classified as an inflammatory disease, OA is generally accepted to be an inflammatory and biomechanical whole-organ disease that is influenced by a number of factors including obesity (Bliddal, Leeds, & Christensen, 2014), synovitis and systemic inflammatory mediators (Berenbaum, 2013), and the low-grade inflammation

induced by metabolic syndrome (Courties et al., 2015). In patients with knee OA, the balance between breakdown, and repair processes is disturbed resulting in structural impairments (Hunter & Felson, 2006).

The abnormal intra-articular stress and failure of repair may arise as a result of biomechanical and biochemical factors. Biomechanical factors are essential in the pathogenesis of OA (Felson, 2013). Altered joint biomechanics are generated by joint incongruity, laxity, muscle weakness, and impaired proprioception in addition to trauma and heavy physical load (Hassan, Mockett, & Doherty, 2001). Each can contribute to the initiation and progress of the disease in the joint. Biochemical processes involving cartilage, bone, and synovium eventually intertwine and collectively damage knee joint compartments (Wieland, Michaelis, Kirschbaum & Rudolphi, 2005). This results in articular cartilage breakdown, osteophyte formation, subchondral bone sclerosis, bone marrow lesions, and changes in the synovium that manifest as episodic synovitis. Hence, this may suggest that inflammatory mediators also play an important role in the initiation and perpetuation of the OA process and would be critical in joint repair.

Knee OA can be defined broadly as a common complex disorder with multiple risk factors (Zhang et al., 2010). Risk factors can be categorized as intrinsic or extrinsic risk and as modifiable or non-modifiable risk factors (Blagojevic et al., 2010; Hunter, 2009). The main non-modifiable risk factors associated with the incidence of OA are age and female sex, while family history and developmental conditions that affect bone growth have also been identified (Zhang et al., 2010). Modifiable risk factors for OA include body mass index (BMI), lifestyle, physical activity, and diet (Silverwood et al., 2015).

Patients with knee OA mostly present with activity-related joint pain (Johnson & Hunter, 2014). With disease progression, pain is often present even at rest and may lead to significant functional impairment (Felson, 2013; Jordan et al., 2007). Stiffness, usually in the mornings and following periods of rest, is relieved by movement (Gustafson, Gorman, Fitzgerald, & Farrokhi, 2016). Limited of range of motion may be caused by irregular joint surface movement due to cartilage degeneration, muscle spasms due to pain, muscle weakness due to disuse and osteophyte formation. Crepitus may occur as the joint is moved. Knee joints can be enlarged due to synovitis, joint effusion, connective tissue, or osteophyte formation. Joint deformity may occur, as forces are inappropriately distributed between joint

structures (Hunter, 2009). In knee OA, buckling may occur, in part, due to weakness of the muscles crossing the joint (Nguyen et al., 2014).

In this thesis, the American College of Rheumatology (ACR) clinical criteria using history and physical examination for classification of knee OA (Altman et al., 1986) were used as the basis for inclusion. Diagnosis of knee OA can be made on the basis of clinical signs and symptoms (Felson, 2013). The clinical classification criteria developed by the ACR remains the most commonly employed method of classifying knee OA (Altman et al., 1986). It is recommended for clinical and epidemiological studies as well as in primary care (Altman et al., 1986). Radiographs are a useful adjunct but not necessary to make a diagnosis of knee OA (Zhang et al., 2010). The relationship between clinical symptoms and radiographic change has been disputed, with systematic review reporting variation in the extent of correlation or discordance reported in different studies (Bedson and Croft, 2008). Discordance maybe greater in milder cases of the disease, with radiographic changes being more common in those with severe symptoms (Duncan et al., 2007; Bedson and Croft, 2008).

There are many treatment options for OA. The ACR, the European League Against Rheumatism (EULAR), the Osteoarthritis Research International (OARSI), and the American Academy of Orthopaedic Surgeons (AAOS) have all published recommendation for management of OA (Zhang et al., 2010). An individualised, patient-centred approach is recommended. Evidence-based approaches to the treatment of knee OA include non-pharmacologic, pharmacologic, and surgical modalities targeted at relieving pain, improving joint function, and modifying risk factors for disease progression (Zhang et al., 2010).

Exercise is recommended in clinical guidelines for management of knee OA (Pisters et al., 2007). International guidelines recommend individuals with knee OA engage in physical activities and exercise programs to relieve the symptoms and improve muscle strength, joint range of motion, and aerobic fitness (Fransen et al., 2015; McAlindon et al., 2014). Exercise in a supervised group, practising Tai Chi, and participating in physical activities such as walking have been proven effective (Wang et al., 2009). The ACR has published recommendations for the treatment of hip and knee osteoarthritis based on a systematic review of the existing literature (Hochberg et al., 2012). In general, for patients with OA in weight-bearing joints, regular exercise and weight loss are strongly recommended. Strength training and aerobic exercise can improve joint control and decrease

pain (Fransen et al., 2015). Strategies aimed at reducing loads on joints include weight loss and foot orthoses (Hochberg et al., 2012).

Other evidence-based interventions for knee OA include manual therapy (Abbott et al., 2013) such as passive physiologic and accessory joint movements, manual muscle stretching, and soft-tissue mobilisation; the use of assistive devices such as a cane (Kemp, Crossley, Wrigley, Metcalf, & Hinman, 2008); and transcutaneous electric nerve stimulation (Osiri et al., 2000). Patient education on changes in lifestyle, exercise, weight loss, and ways to minimise joint loading should be considered (Fernandes et al., 2013). Adherence to non-pharmacological and pharmacological interventions should be emphasised. Finally, surgical strategies may be considered to correct anatomical abnormalities that may contribute to the development of knee OA (Vina et al., 2013).

As the most common form of arthritis and a leading cause of chronic disability, OA continues to be a challenge in the field of physiotherapy and rehabilitation. Acknowledging the anticipated increase of OA prevalence, the need to identify risk factors associated with physical functional decline is a priority for healthcare providers. Given the complex pathophysiology and clinical presentations of knee OA, there is a need to further investigate and explore other interventions that could contribute to holistic and effective management of knee OA.

## 1.4 | Falls

The WHO considers falls a pressing global health concern, since frequency of falls increases with age (World Health Organization, 2004). Management of falls is a health care priority because of its complex interacting causes and serious consequences (Feder, Cryer, Donovan, & Carter, 2000). Many sociodemographic, medical and physiological factors are strongly related to falls. As a result of age-related changes, such as sensorimotor and balance system may become impaired and predispose individuals to falls (Rubenstein, 2006). The addition of other conditions such as knee OA complicates the evaluation and intervention strategies (Ambrose, Paul, & Hausdorff, 2013).

Falls are a leading cause of morbidity and mortality in the older adult group (Rubenstein, 2006; Tinetti, 2003). Approximately 15-33% of the adults aged 65 year and older experience a fall every year (Doré et al., 2015). Fifty percent of those who fall once are two to three times more likely to fall again within the following year (Ambrose, Paul, & Hausdorff, 2013; Tinetti, 2003). Estimated number of falls in the community setting is largely dependent on self-reporting and the majority of falls do not come to the attention of any medical service (World Health Organization, 2004).

In the past, there was no widely agreed definition of falls. The Prevention of Falls Network European (ProFaNE), a multinational work group dedicated to reducing falls and injuries through implementation of evidence-based interventions, has, however, proposed the following as the most reliable and valid definition:

*“A fall is an unexpected event in which the participant comes to rest on the ground, floor or lower level.”* (Lamb, Jorstad-Stein, Hauer, & Becker, 2005).

This definition was used throughout this thesis. Although it provides some consistency for reporting, there are still areas of confusion. It is unclear if it is appropriate to include events associated with loss of consciousness or overwhelming external forces in this definition. There are problems with regard to reporting the history of falls that influence the frequency of falling which could result to under- or over-estimation (Ambrose, Paul, & Hausdorff, 2013; Lord, Sherrington, Menz, & Close, 2007). To address these issues, additional questions recommended by the National Institute for Health and Care Excellence (NICE) were included in this thesis. This includes the number of falls in the past year including the frequency, context, and characteristics of the falls (NICE, 2013).

Epidemiologic observational studies of older adults in community, acute, and chronic care institutions have identified risk factors for falls (Vieira, Palmer, & Chaves, 2016). Falls have a wide range of risk factors which include family history, female sex, obesity, ageing, joint trauma, prior occupational and recreational activities and muscle weakness (World Health Organization, 2004). Risk factors are often categorized as either person specific/ intrinsic, or environmental/extrinsic factors (Ambrose, Paul, & Hausdorff, 2013; Lord et al., 1992). Moreover, falls are not just restricted to older persons but can have severe consequences for other at-risk groups, such as those with arthritis. Table 1.1 shows further categories of risk factors for falls in older adult population.

**Table 1.1** Categories of falls risk factors

Intrinsic risk factors	Extrinsic risk factors	Exposure to risk
Demographics	Home / Environmental	Complex relationship between falls, activity and risk. The type and extent of environmental challenges that an older person chooses to embrace interact with the person's intrinsic risk factors.
<i>Age</i>	<i>Inadequate lighting</i>	
<i>Gender</i>	<i>Uneven surfaces</i>	
<i>Race</i>	Poor footwear	
<i>Ethnicity</i>	Inappropriate spectacles	
<i>Living Alone</i>	Medication	
Systems	<i>Psychoactive</i>	
<i>Gait and balance</i>	<i>Four or more medications</i>	
<i>Strength</i>		
<i>Vision</i>		
<i>Cognition</i>		
Symptoms/disease		
<i>Cardiovascular disease</i>		
<i>Chronic Pulmonary disease</i>		
<i>Depression</i>		
<i>Arthritis</i>		
<i>Dizziness/vertigo</i>		
<i>Dementia</i>		
<i>Nutritional deficiencies</i>		
<i>Neurologic</i>		

A range of tools for screening falls risk has been validated for use in older adults in community, hospital, and residential care settings (Scott, Votova, Scanlan, & Close, 2007). A simple, easy-to-administer screening method is to ask individuals about their history of falls in the past 12 months. As indicated above, a number of studies have identified previous falls as one of the strongest predictors for falling again in the following year (Nevitt et al., 2016). Assessment of their balance and mobility status is essential. Several balance assessment tools have been developed and validated for different population groups and setting. This includes the Timed Up and Go (TUG) Test which is usually used both for clinical and community settings (Podsiadlo & Richardson, 1991; Sackley et al., 2005). Assessing fall risk typically involves tools covering a wide range of falls risk factors that focus on physiologic and functional domains of postural stability including vision, strength, and balance. This can be assessed using Sensory Organisation Test (SOT) (Cohen, Heaton, Congdon, & Jenkins, 1996) and Physiologic Profile Assessment (PPA) (Lord et al., 1992).



There is strong evidence to support interventions for preventing falls in older individuals. Single and multifactorial fall prevention strategies have been shown to successfully reduce falls based on a Cochrane systematic review (Cameron et al., 2012). The review included 60 randomised controlled trials (RCT) involving 60,345 participants. Single intervention strategies shown to successfully prevent falls include exercise, physiotherapy and occupational therapy interventions, psychotropic medication withdrawal, cognitive behavioural therapy, provision of single lens glasses for regular multifocal glasses wearers, and vitamin D supplements for people with low levels of vitamin D (Goodwin et al., 2014; Sherrington & Tiedemann, 2015).

Tailored multifaceted interventions are the most effective interventions for preventing falls in high-risk populations including aged care facility residents (Sherrington & Tiedemann, 2015). Recently, several trials have examined exergaming performed on the Wii Fit™ balance board, step mats or using other form of VR for decreasing falls (Nitz, Kuys, Isles, & Fu, 2010). Preliminary evidence indicates exergaming can improve physical and cognitive factors associated with falls in older adults and are equivalent to traditional exercise interventions (Fu et al., 2015; Rendon et al., 2012).

#### 1.4.1 | Falls and balance

Balance is the ability to remain in a position without losing control or falling (Pollock, Durward, Rowe, & Paul, 2000). It is a generic term used to describe the dynamic process by which the body's position is maintained in equilibrium (Kisner, Colby, & Borstad, 2017). The complexity of controlling the body within a variety of positions and environmental situations can be appropriately conceptualised by the term postural control (Horik, 2006). Postural control is defined as, the mechanism of complex and collective interaction of the body in space for the dual purposes of stability and orientation (Shumway-Cook & Wollacott, 2001). Postural control helps maintain stability during daily activities and other exercises, and can be either static or dynamic (Sturnieks et al., 2004; Takacs, Garland, Carpenter, & Hunt, 2014). However, with increasing age, changes in the sensorimotor and cognitive systems may affect postural control, leading to difficulties producing an adequate response to loss of balance (Pollock et al., 2000; Sibley, Beauchamp, Van Ooteghem, Straus, & Jaglal, 2015).

In this thesis, the term dynamic balance, a component of postural control is used and measured. Dynamic balance is commonly described in the concepts of self-initiated movements, responses to external perturbation, and anticipatory postural adjustment (Horik, 2006). The ability to balance the centre of mass (COM) within the base of support is necessary for voluntary self-initiated movements. Dynamic balance is often referred to as functional balance.

Individuals with knee OA have been shown to have deficits in dynamic balance and mobility as compared to healthy controls (Takacs, Garland, Carpenter, & Hunt, 2014). Impaired dynamic balance is an important risk factor for falls (Campbell et al., 2012). The contributors to falls can be examined from the perspective of physiological systems. The sensory inputs for postural control are comprised of three systems: vision, vestibular sense, and the somatosensory system (Hassan et al., 2001). These systems provide input on the location and movement of the body, and when integrated with the motor system, control balance by maintaining the relationship between the base of support and the COM of the individual (Kisner, Colby, & Borstad, 2017). Vision is involved in planning movement and avoiding obstacles. The vestibular system senses linear and angular acceleration which has an influence on balance correcting reactions, while the somatosensory system provides input on the position and velocity of body segments in space. While there is redundancy among the systems, degeneration in one or more can result in difficulties maintaining balance (Sturnieks et al., 2004; Takacs, Garland, Carpenter, & Hunt, 2014).

#### 1.4.2 | Falls and knee OA

In one study, more than 50% of a knee OA population reported a fall during the previous year (Hoops, Rosenblatt, Hurt, Crenshaw, & Grabiner, 2012). When considering knee OA as a risk factor for falls, it may be the symptoms, and not the degree of structural change, that lead to an increased propensity to fall (Ng & Tan, 2013). Impaired strength, proprioception, balance, and increased levels of pain may be important underlying mechanisms for both falls and knee OA (Hassan et al., 2001; Johnson & Hunter, 2014). Individuals with knee OA commonly experience reduced levels of muscular strength (Alencar et al., 2007; van der Esch et al., 2014). Quadriceps strength deficits of between 20% and 70% have been reported for people with OA affecting the knees (Alencar et al., 2007; Sturnieks et al., 2004). Muscle weakness is associated with knee instability in about 60% of

patients with knee OA (van der Esch et al., 2014). Sensory deficits, particularly proprioception have been described in OA populations (Barrett, Cobb, & Bentley, 1991; Marks, Quinney, & Wessel, 1993). Altered sensory information of an affected joint may result in a balance problem that impacts upon daily function and may increase susceptibility to falling (Sharma & Pai, 1997).

Clinical symptoms of knee OA such as pain, weakness, and instability are identified as the intrinsic risk factors for falls as presented in Table 1.1. The increased risk of falling in people with knee OA may be due to disease-related symptoms but has not yet been investigated in detail. Understanding the impact of balance as a risk factor for falls may allow the possible mechanism to be elucidated in people with the condition such as knee OA. Studies undertaken over the past decades have shown balance exercises are the most important component of efficacious exercise programs for older adults to reduce falls (Rubenstein, 2006; A. Shumway-Cook, Brauer, & Woollacott, 2000; Tinetti, 2003). Thus, given the impact of falls and the high prevalence of knee OA in an ageing society, identification of risk factors for falls in this population is essential in creating effective prevention and intervention strategies.

## 1.5 | Exergaming

Over the past few decades there has been increasing published scientific evidence for the physical, cognitive and social health-related benefits of increased exercise, especially in older adults (Liu-Ambrose et al., 2010; Sherrington et al., 2008). This includes improvements in strength, balance, coordination and aerobic capacity, leading to reduced levels of disability, better mobility function, and reduced fall risk in older adults. However, exercise adherence is a significant hurdle. Recently a new approach has been proposed to motivate people to be physically active through VR (Lange et al., 2009; Rizzo, Lange, Suma, & Bolas, 2011).

VR can be defined as the interactive simulations created with computer hardware and software, to present users with opportunities to engage in environments that appear to be similar to real world (Weiss et al., 2004). The virtual environments can be grouped into three categories namely non-immersive, semi-immersive, and immersive (Rose, Nam, & Chen, 2018). Basic non-immersive virtual environments use desk top computers and TV screens that create a low sense of immersion. Semi-immersion attempts to increase the immersive experience by using panoramic screens. Immersive VR uses head-mounted displays and

multi-projected environments to create the perception of being physically present in a non-physical world.

Exergaming is a term coined for the combination of exercise and gaming (Sinclair et al., 2007; Staiano & Calvert, 2011). It uses non- to semi-immersive VR-based intervention that can be administered through any computer game or VR where the participant can interact with virtual objects through physical movement. Compared with other VR systems, exergaming focuses on balance, strength, cardiovascular or flexibility training (Oh & Yang 2010). These games, incorporating technology, play, and physical activity, are referred to as active-play videogames. For the context of this thesis, exergaming is the preferred term. Some of the better-known commercial exergames tool are the Nintendo Wii Fit™ games and Microsoft (Redmond) Kinect games™.

Initially, these video games have been viewed as a sedentary living room activity, used by children and adolescents (Vandewater, Shim, & Caplovitz, 2004). However, the release of the PlayStation-based Dance Dance Revolution™ video game in 2004, where players stand on a "dance platform" or mat while stepping on specific areas in sync with music and following instructing arrows on the screen (Bailey & McInnis, 2011; Vandewater et al., 2004), drew considerable media attention. Video games started to be sold for the purpose of exercising (Lu, Kharrazi, Gharghabi, & Thompson, 2013). After the introduction of Nintendo Wii™ in 2006, the use of body movements to control video games rapidly gained momentum and almost overnight became the new mode for a player to interact with a game system (Nitz, Kuys, Isles, & Fu, 2010).

In this thesis, the Nintendo Wii Fit™ exergaming system was used. A systematic review which included 126 studies explored scientific evidence from previously published studies related to the use of video games in physical rehabilitation (Bonnechere, Jansen, Omelina, & Van Sint Jan, 2016). Most studies used the Nintendo Wii Fit™ (79%), which was used more frequently than the Microsoft Xbox Kinect (13%) and Sony PlayStation (8%). Of the 126 studies reviewed, stroke (26 studies), cerebral palsy (16 studies), and Parkinson's disease (10 studies) were common conditions studied using exergaming.

Advances in technology have opened the doors for incorporating commercial or off-the-shelf virtual game consoles such as Nintendo Wii Fit™ in rehabilitation. Nintendo Wii Fit™ includes games such as yoga, strength training, aerobics, and various balance games that focus more on controlled movements. Studies about exergaming evaluated the feasibility

and effects on physical functions in healthy older adults in the context of balance and falls. These studies concluded that exergames could be an adjunct to traditional therapy and exergaming interventions could improve balance and reduce falls (Agmon, Phelan, & Nguyen, 2011; Heick, Flewelling, Blau, Geller, & Lynskey, 2012; Nitz, Kuys, Isles, & Fu, 2010). Exergaming has been used to motivate older adults to engage in physical activity, as therapy is design to be entertaining and motivational, and therefore to increase the amount of time spent in physical activity (Lange et al., 2009).

Exergaming has several advantages compared to conventional exercises. It can motivate people to practice through an attractive and interactive way and train both motor and cognitive skills when users performing dual tasks (Skjæret et al., 2016; van Diest et al., 2013). The players can also focus their attention on the outcome of the movements in the game, not on the movements itself (Proffitt et al., 2015). This can be supported by the types of feedback associated with motor control and learning namely knowledge of performance (KP) and knowledge of results (KR) (Schmidt, Lee, Winstein, Wulf, & Zelaznik, 2018). In KP, the feedback is related to the way a specific skill is performed. It gives feedback on the nature or quality of the performance of a motor task and may come from either intrinsic or extrinsic sources. In KR, it is how successfully a skill is performed or the outcome of a motor task. Lastly, the exergame can be undertaken at home, either alone or within a small group, which may make the activity more accessible to many older adults (Yardley et al., 2006).

Despite the fun component of the games, which simulate feedback and encourage individuals to perform exercises, parameters to target improvements in balance have not yet been established (Agmon et al., 2011; Fu, Gao, Tung, Tsang, & Kwan, 2015). A recent systematic review was conducted to determine the effect of Nintendo Wii Fit™ based exercise in enhancing balance training in healthy older adults; however, results from the included studies were incomparable to each other due to the variability of study protocols (Laufer, Dar, & Kodesh, 2014).

Although an increasing number of studies have investigated Wii Fit™ as a tool for balance improvement, evidence for prescribing exercise dosage (frequency, intensity, and duration) is lacking. Variability of gaming protocols, including intervention setting and game selection must be standardised to provide an effective balance exercise regimen in

exergaming. Preliminary evidence supports using exergaming as an intervention for older adults to maintain or improve physical function and reduce falls risk (Fu et al., 2015; Rendon et al., 2012). One pilot study demonstrated the safety and efficacy of using Nintendo Wii Fit™ in an assisted living facility with a recommendation to explore this mode of exercise delivery via individualised training, supervised group classes or unsupervised use at home (Nicholson et al., 2015).

Most published articles investigating the use of exergaming included healthy and patient population where the latter focused mainly on individuals with neurologic conditions such as Stroke, Parkinson's disease, and Multiple Sclerosis (Laufer et al., 2014; Laver et al., 2012). 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 the degree of effectiveness of these exergaming programmes is unknown in a knee OA group. Furthermore, few have studied the importance of the user's acceptance and perspectives on exergaming (Heinz et al., 2013). Thus, a feasibility study is an important step to evaluate trial protocols and procedures before determining its effectiveness.

## 1.6 | Research objectives

The focus of this research was to bring into perspective exergaming as an intervention to improve balance and reduce the risk of falling in a knee OA population. The primary aim of this thesis was:

- to determine the feasibility of implementing an exergaming balance intervention programme using Nintendo Wii Fit™ games in individuals with knee OA.

In this study, Nintendo Wii Fit™ system was used as an exergaming tool. Although an increasing number of studies have investigated Wii Fit™ as a tool for balance improvement, there remains a lack of evidence for prescribing exercise dosage (frequency, intensity, and duration). To inform the dosage of Wii Fit™ intervention of the feasibility study, nested in this thesis was a narrative synthesis review that aimed:

- To synthesise the literature and present Nintendo Wii Fit™ gaming system protocols, which include game preference, intervention setting, and exercise dosage used in improving balance.

Two supplementary studies (systematic review and cross-sectional) were integrated in this thesis to address the overlapping risk factors and issues related to knee OA and falls.

Thus, the following were the secondary aims:

- To systematically review the literature that identifies risk factors for falls in individuals with knee OA; and
- To explore the relationship between falls and clinical characteristics of knee OA such as balance, pain, instability, muscle strength and physical function.

The summary of the different supplementary studies with corresponding objectives and study design are presented in Table 1.2

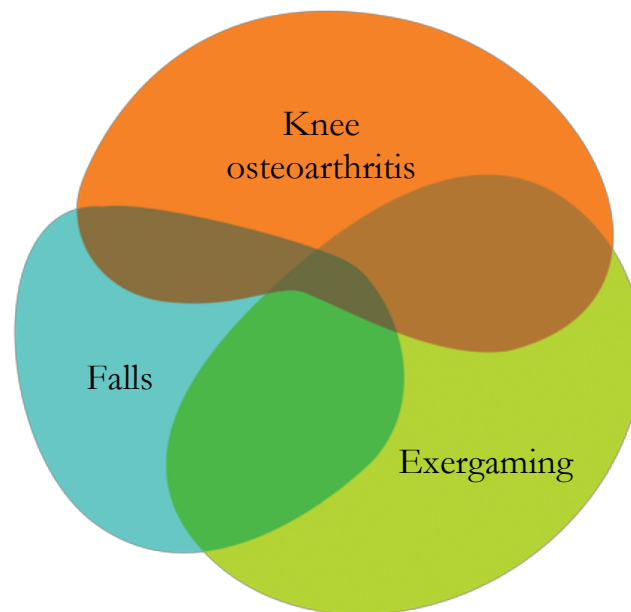
**Table 1.2** Summary of the supplementary studies and the main study

Study	Main objectives	Study Design
<b>Study 1</b> Risk factors for falls in adults with knee OA: a systematic review	This study aimed to explore the evidence of risk factors for falls in older adults with knee OA.	Systematic review of literature
<b>Study 2</b> Factors associated with risk of falling among older adults with knee OA	The study aimed to explore the relationship between falling in adults with knee OA and clinical characteristics of knee OA such as balance, pain, instability, muscle strength, and physical function.	Cross-sectional study
<b>Study 3</b> A narrative review on Wii-gaming protocols in addressing balance problem among older adults: what system works?	The aim of this review was to present and evaluate Nintendo Wii Fit™ gaming system protocols which include game preference, set-up, and dosage used in improving balance.	Narrative synthesis review
<b>Study 4</b> Effects of exergaming programme on balance and risk of falling in individuals with knee OA	The primary aim of the study was to investigate the feasibility and acceptability of exergaming in improving balance and decreasing the risk of falling in individuals with knee OA.	Feasibility study; mixed-methods design

*Note.* OA- osteoarthritis

## 1.7 | Thesis organisation

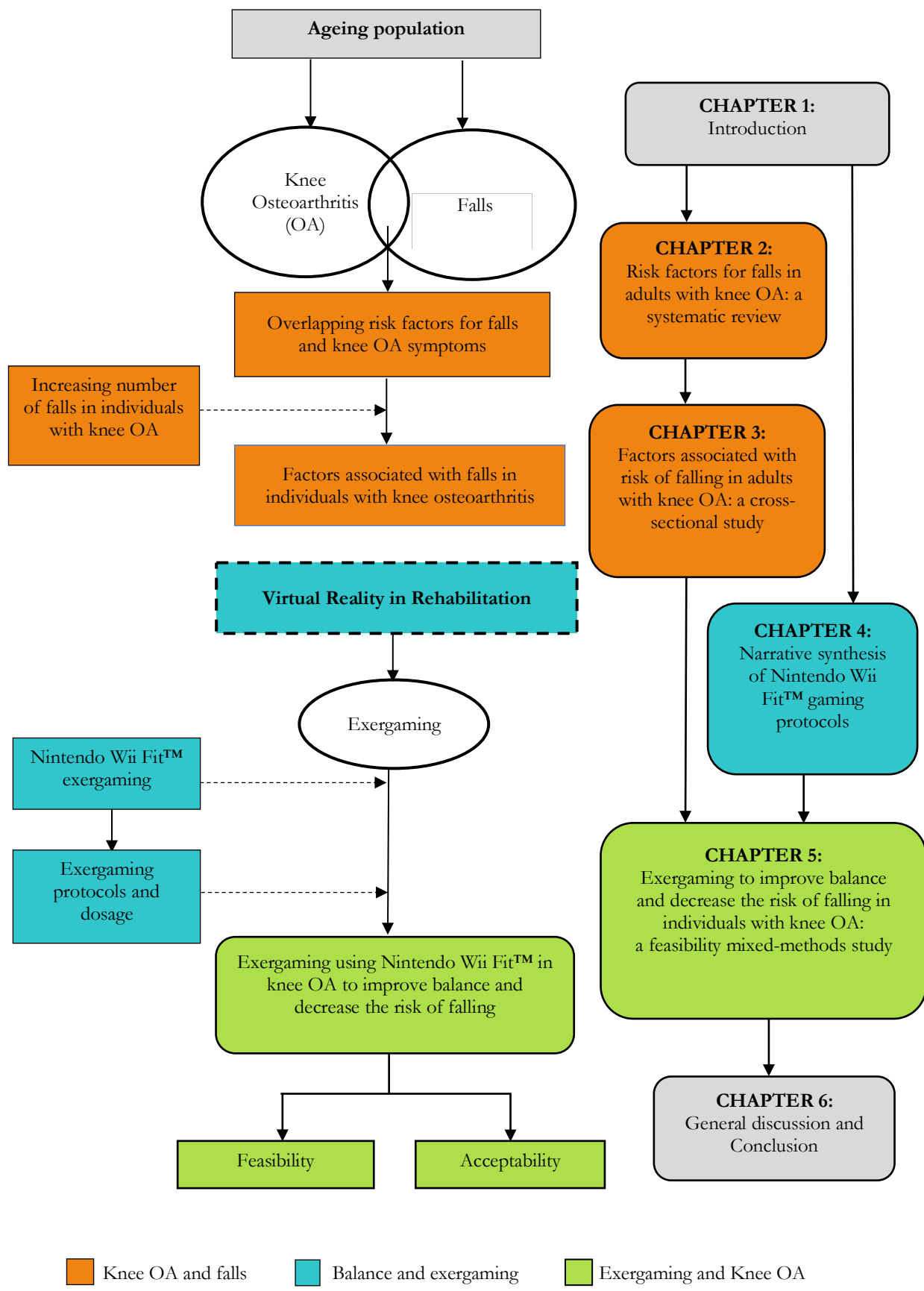
The presentation of this thesis is divided into three sections linked with the concepts of knee OA, falls, and exergaming. Section 1 (Chapters 2 and 3) identifies the risk factors for falls in individuals with knee OA and the relationship of falls to knee OA-related symptoms. Section 2 (Chapter 4) introduces the concept of exergaming and how it is used in rehabilitation particularly in improving balance and reducing the risk of falling. This section also focuses on the parameters and dosage that inform the methods of the main study. Finally, Section 3 presents the feasibility and acceptability study (Chapter 5), with two phases: quantitative and qualitative phase. This section concludes with the integration of the three core concepts through a discussion of the issues and challenges encountered in the thesis as a whole (Chapter 6). Figure 1.2 shows the linking visual of knee OA, falls, and exergaming.



**Figure 1.2** Linking visual guide for knee osteoarthritis, falls, and exergaming

This thesis is structured as a series of reports from each stage of the research progress. It comprises four interrelated studies: systematic review, narrative synthesis review, cross-sectional study, and mixed-methods feasibility study. The thesis was organised based on the research framework (Figure 1.3), emanating from the literature regarding knee OA, falls, and exergaming aligned with the corresponding chapters.





**Figure 1.3** Research framework showing the contributions of the supplementary studies

## 1.8 | Significance of the study

This research is expected to contribute to the body of knowledge in the multi-disciplinary areas of physiotherapy, falls prevention, gaming technology, and management of knee OA. Its contribution can be summarised in two ways: it offers an understanding of the mechanism underlying the occurrence of falls in knee OA and the potential of exergaming to improve balance and decrease the risk of falling in individuals with knee OA.

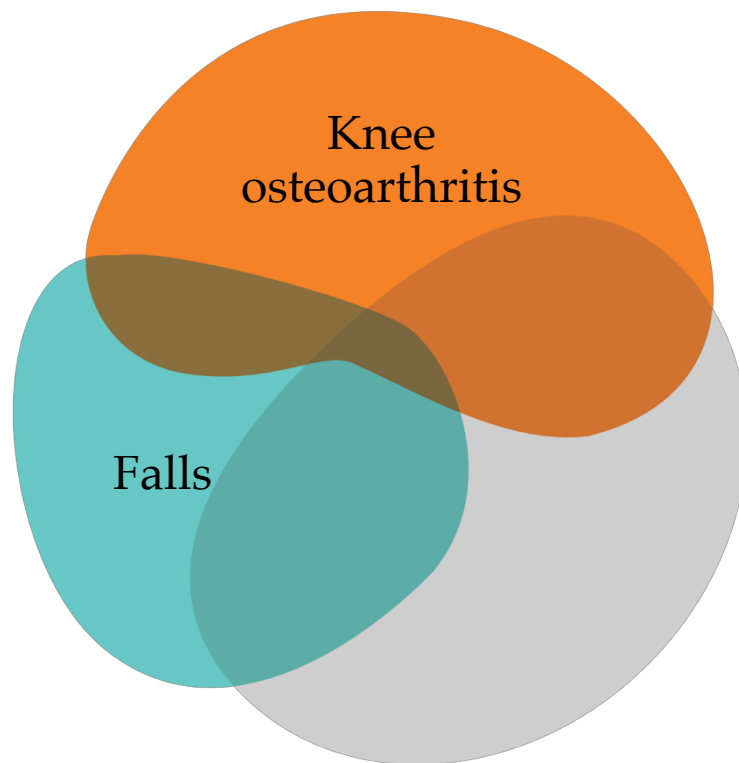
As mentioned above, the prevalence of falling and knee OA is expected to increase substantially in the future. Identifying risk factors for falls in the knee OA population and how falls and knee OA interact will play a central role in fall prevention. This study will contribute to both knee OA and falls literature by furthering the understanding of underlying relationships and mechanisms between clinical symptoms of knee OA and falls. The study will be clinically relevant since recognising risk factors for falls in a knee OA population will help physiotherapists and other healthcare providers identify individuals at risk of falling. It will assist in the creation of prevention strategies that focus on modifiable risk factors.

The proposed feasibility study is a preliminary step towards investigating exergaming as a balance intervention in a fully powered RCT. 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. It has been shown that exergames have multiple benefits in different domains of health outcomes. However, it is critical that new approaches are adopted to address the current issues of falling in knee OA. There is limited research to support such an approach; therefore, this thesis research will add some much-needed evidence on the benefit or otherwise of exergaming to address falls in knee OA.

This research hopes to contribute an alternative intervention and approach for better managing the disease including self-managing of the condition. Creating a novel intervention that is safe and effective is critical to the success of implementation of falls prevention to reduce the risk of falling in knee OA.

# SECTION 1

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*"The ability to simplify means to eliminate the unnecessary so that the necessary may speak."*

*– Hans Hofmann*

# CHAPTER 2

## **Risk factors for falls in adults with knee osteoarthritis: a systematic review**

### **2.1 | Chapter overview**

Knee OA has been widely accepted to be a risk factor for falls, yet the direct relationship between knee OA symptoms and incidence of falls remains uncertain (World Health Organization, 2008; Jadelis et al., 2001; Nevitt et al., 1991). This chapter provides an overview of the risk factors for falls in adults with knee OA. A systematic literature search was performed to examine the evidence of risk factors for falls in adults with knee OA. The content of this chapter was recently accepted for publication in *Physical Medicine & Rehabilitation (PM&R) Journal*.

### **2.2 | Background**

The etiology of falls is multifactorial and can result from a complex interaction of risk factors (Ambrose, Paul, & Hausdorff, 2013; Rubenstein, 2006). Risk factors for falls may be modifiable or non-modifiable and are frequently categorized as being person specific (intrinsic), or environmental (extrinsic) (Ambrose, Paul, & Hausdorff, 2013; Society Prevention & Panel, 2001). The risk factors for falls are similar to risk factors for developing knee OA, which include obesity, aging, female gender, muscle weakness and prior occupational and recreational activities (Hunter, 2009; Johnson & Hunter, 2014).

A systematic review and meta-analysis has been conducted to identify risk factors for the onset of knee OA (Blagojevic et al., 2010), but the implications for increased falls risk have not been considered. Knee OA is one of the principal causes of disability in older adults and is characterized by joint instability, muscle weakness, pain, stiffness, functional

impairment, and decreased quality of life (QoL) (World Health Organization, 2008; Hoops et al., 2012; Levinger et al., 2011). These condition-related symptoms of knee OA seem to overlap with risk factors of falls found in the older adult group (Gillespie et al., 2009; Hoops et al., 2012; Levinger et al., 2011; Williams, Brand, Hill, Hunt, & Moran, 2010). To address the increased risk of falls in individuals with knee OA, identification of risk factors for falls in this population is essential for creating effective prevention and intervention strategies. Therefore, the aim of this systematic review was to examine the evidence of risk factors for falls in adults with knee OA.

## 2.3 | Methods

### 2.3.1 | Protocol

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) applicable for observational studies (Liberati et al., 2009) (Appendix D). The study protocol is registered in PROSPERO: CRD42015027582 (<http://www.crd.york.ac.uk/prospero>) (Appendix E).

### 2.3.2 | Eligibility criteria

Observational study designs such as prospective cohort, cross-sectional, and case-control studies investigating risk factors relating to falls in individuals with knee OA were considered in this review. To be eligible for inclusion, studies had to satisfy the following criteria: (1) studies involving individuals with unilateral or bilateral knee OA in which the mean age of participants is greater than 18 years old; (2) confirmed knee OA according to American College of Rheumatology (ACR) criteria (Alencar et al., 2007), radiographic evidence, Kellgren-Lawrence classification, doctor-diagnosed or self-reported knee OA; and (3) knee OA study participants with history of falls.

A range of fall definitions was permitted in this review. One such definition is an event in which a person unintentionally comes to rest on the ground or other lower levels (NICE, 2013; Gibson, 1987). Prospective and retrospective studies with falls history as the primary or secondary outcome measure were included. Falls recorded during the past 12 months and/or prospective falls over a 12-month period or more were considered. Studies on participants with other types of inflammatory/autoimmune arthritis such as rheumatoid

arthritis were excluded. Comments, editorials and reviews, and conference proceedings where the data was inaccessible from the authors were also excluded.

### 2.3.3 | Literature search and study selection

Academic Search Complete, Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, PsychInfo, PubMed, Science Direct, Scopus, SPORTDiscus and Web of Knowledge were searched from their inception to December 2015, with an updated search on July 2016. The search strategy adapted for each database has been detailed in an online ([http://www.crd.york.ac.uk/PROSPEROFILES/27582\\_STRATEGY\\_20150927.pdf](http://www.crd.york.ac.uk/PROSPEROFILES/27582_STRATEGY_20150927.pdf)) data file (Appendix F). During the full-text screening, reference lists of included articles were reviewed to identify additional articles that did not appear in the electronic search. Two reviewers independently screened all relevant titles and abstracts. Full-text articles were then independently screened by the same reviewers according to the inclusion and exclusion criteria. To avoid duplication, only one version of a study was included when two articles were published from the same study. Duplication of data was determined by crosschecking the name of the authors, source of recruitment, and number of participants. If reviewers observed that included participants came from the same cohort study, included the most recent study for further analysis. Any discrepancies were resolved through discussion with the second reviewer, and a third reviewer was available if needed.

### 2.3.4 | Quality assessment

The quality of included studies was assessed using a modified Quality Index Tool developed by Downs and Black (Downs & Black, 1998). The original version of Downs and Black (27-item checklist) was developed to evaluate the quality of observational and non-randomized studies and was reported to have good test-retest and inter-reliability (Downs & Black, 1998). Sixteen out of 27 items of the Quality Index Tool (*items 1-3, 5-7, 10-12, 16, 18, 20-22, 25, 26*) were used. These items were used to represent four categories: reporting, external validity, internal validity and selection bias. In observational studies, representativeness of the population and minimizing selection bias (due to selection and retention of participants) are two important considerations (Mann, 2003). Also, items not relevant to the aim of the study or related to intervention and treatment were removed.

Literature reviews in both falls and OA have also used these items (Oliver et al., 2007; Richmond et al., 2013). All items (except item five) were scored yes=1, no/unable to determine=0. Age, gender, and body mass index (BMI) were considered as the most relevant confounders found both in falls and knee OA literature (Hoops et al., 2012; Hunter, 2009; Rubenstein, 2006). Thus, for item five, where the description of principal confounders was evaluated, a score of two was awarded if all the relevant confounders were considered, one point for partial consideration ( $\leq$ two relevant confounders), and no points if none of the relevant confounders was considered. Since the study also focused on falls, item 20, which evaluated the clarity of outcome measure, one point was given if fall definition and method of reporting falls were described. Two independent raters, Normala Mesbah (NM) and Mandeep Kaur (MK,) evaluated each included study using the modified Quality Index Tool, with a third rater Donald Manlapaz (DM) resolving any disagreements. To determine the agreement between the two raters, Cohen's kappa correctional coefficient was calculated.

### 2.3.5 | Data extraction and synthesis

An electronic form was developed to systematically extract the data from the included studies (Appendix G). To ensure relevant information was captured, the first reviewer (DM) piloted the electronic form on five studies, which were then independently cross-checked by a second reviewer (MK). Once accuracy and completeness of the process for data extraction were established, the first reviewer (DM) continued with the remaining records. The following data were extracted from the included studies: study objective/s, participant demographics, confirmation of OA diagnosis, study setting, study design, fall definition, method of recording falls, study variables, outcome measurement, and key findings. Results reported as odds ratios (OR), relative risk (RR), prevalence ratios (PR) or hazard ratios (HR) were also extracted to identify the potential risk factors for falls.

An option for the synthesis of the studies included meta-analysis for risk factors with a consistent definition of falls and where risk factors and results were reported similarly. However, a meta-analysis was not appropriate due to heterogeneity with differences in the description of risk factors, outcome measures used, or methodological heterogeneity due to differences in study design observed between studies. Therefore, the data were analysed using a qualitative synthesis and reported using a narrative approach according to PRISMA guidelines (Liberati et al., 2009).

To further investigate the heterogeneity and examine the risk factors for falls in knee OA, a secondary sub-group analysis was conducted. Included articles were grouped according to study design (cross-sectional/case-control and cohort) and articles with the same outcome measure were combined. The Review Manager version 5.3.5 developed by the Cochrane Collaboration was used to determine the pooled estimates and heterogeneity. Heterogeneity was measured using the  $I^2$  statistic and was interpreted such that a score of 25%, 50%, and 75% were considered low, moderate, and high heterogeneity, respectively (Higgins, Thompson, Deeks, & Altman, 2003). Combined studies resulted to  $I^2 \geq 50\%$  were considered to have substantial heterogeneity and were excluded from the quantitative analysis (Higgins, Thompson, Deeks, & Altman, 2003).

### 2.3.6 | Level of evidence

The level of evidence was determined using the criteria adapted from Lievense et al. (Lievense, Bierma-Zeinstra, Verhagen, Verhaar, & Koes, 2002). Included studies were ranked according to their design, with prospective cohort studies considered to be a higher level of evidence than cross-sectional studies. The ranking was defined as (1) ‘strong evidence’, when consistent findings were supported by multiple high-quality cohort studies; (2) ‘moderate evidence’, when consistent findings were supported by 1 high-quality cohort study, >2 high quality case-control studies, or >3 high quality case-control studies; (3) ‘limited evidence’, when consistent findings were supported by a single cohort study, 1 or 2 case-control studies, or multiple cross-sectional studies; (4) ‘conflicting evidence’, when study reported <75% consistency of findings; and (5) ‘no evidence’ if no studies could be found (Lievense, Bierma-Zeinstra, Verhagen, Verhaar, & Koes, 2002).

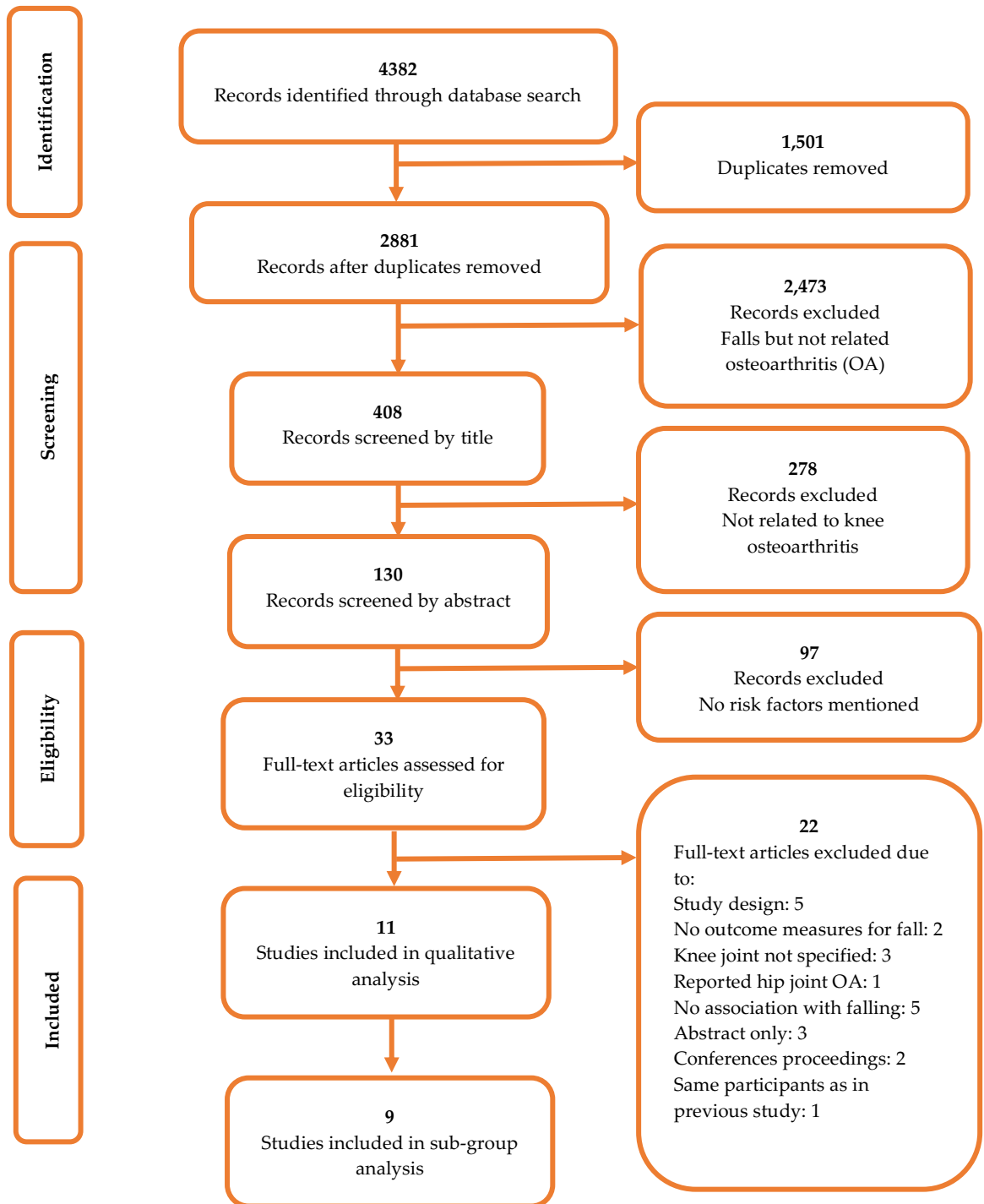
## 2.4 | Results

### 2.4.1 | Study selection

The electronic data search yielded 4382 references from nine databases. Full-text screening of 33 articles was conducted to assess for eligibility. During the full-text screening, one longitudinal study (Muraki et al., 2011), was excluded as results from the same population are reported in a later study. Thus, the more recent article was retained. A total of 11 articles met the inclusion criteria, nine records from the initial search (Alencar et al., 2007;



Arden et al., 2006; de Zwart et al., 2015; Dore et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Prieto-Alhambra et al., 2013; Sturnieks et al., 2004) and two from the updated search (Mat et al., 2015; Nevitt et al., 2016). Hand searching did not yield any additional records for inclusion. Figure 2.1 shows the details of the screening and selection process.



**Figure 2.1** Flow of the study selection

## 2.4.2 | Quality assessment

The summary of scores of the quality assessment using the Quality Index Tool is provided in Table 2.1. Ten (91%) of the included studies were classified as high quality with a score of at least 75% whereas the remaining study was classified as moderate quality with a score of 73.33%. For item five, 7/11 (64%) of the included studies scored ‘2’ for considering all the relevant confounders (Alencar et al., 2007; de Zwart et al., 2015; Dore et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Nevitt et al., 2016; Sturnieks et al., 2004) while for item 20, 8/11 (73%) of the included studies scored ‘1’ for stating the definition and method of collecting falls data (Alencar et al., 2007; de Zwart et al., 2015; Dore et al., 2015; Mat et al., 2015; Muraki et al., 2013; Nevitt et al., 2016; Petrella et al., 2012; Sturnieks et al., 2004). Only three studies collected history of falls but did not report definition of falls (Arden et al., 2006; Leveille et al., 2002; Prieto-Alhambra et al., 2013). Cohen’s Kappa correlation coefficient ( $\kappa$ ) between the two reviewers was 0.81 (SE = 0.029, 95% CI= 0.75-0.86) showing “substantial” agreement on the risk of bias assessment (Viera & Garrett, 2005).

**Table 2.1** Quality scores of the included studies

Included Study	Reporting						External validity			Internal validity (Bias)				Internal validity (Selection bias)		Score (%)	Quality	
	1	2	3	5*	6	7	10	11	12	16	18	20	21	22	25			26
Alencar et al. (2007)	1	1	1	2	1	1	1	1	0	0	1	1	1	NA	1	NA	13/15 (86.67)	High
Arden et al. (2006)	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	13/17 (76.47)	High
De Zwart et al. (2015)	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	NA	16/16 (100.00)	High
Dore et al. (2015)	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	17/17 (100.00)	High
Leveille (2002)	1	1	1	2	1	1	1	1	1	1	1	0	1	1	1	1	16/17 (94.12)	High
Mat et al. (2015)	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	NA	14/16 (87.50)	High
Muraki et al. (2013)	1	1	1	2	1	1	1	1	1	1	1	1	0	1	1	1	16/17 (94.12)	High
Nevitt et al. (2016)	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	17/17 (100.00)	High
Petrella et al. (2012)	1	1	1	1	1	1	0	0	1	1	1	1	0	NA	1	NA	11/15 (73.33)	Moderate
Prieto-Alhambra et al. (2013)	1	1	1	1	1	1	1	0	1	1	1	0	0	1	1	1	13/17 (76.47)	High
Sturnieks et al. (2004)	1	1	1	2	1	1	0	0	1	1	1	1	1	0	1	NA	13/16 (81.25)	High

*Note.* Yes =1 , No and undetermined – 0, NA- not applicable, \*2= considered set confounders (age, gender, body mass index), 1 = considered 2 out 3 confounders, 0 = none of the confounders: **1** clear aim/hypothesis, **2** outcome measures clearly described, **3** patient characteristics clearly described, **5** confounding variables described, **6** main findings clearly described, **7** measures of random variability provided, **10** actual probability values reported, **11** participants asked to participate are representative of entire population, **12** participants who were prepared to participate representative of entire population, **16** data degrading was made clear, **18** appropriate statistical test used, **20** valid and reliable outcome measures, **21** cases and controls recruited from same population, **22** cases and controls recruited from same population, **25** adjustment made for confounding variables, **26** follow-up taken into account

### 2.4.3 | Study characteristics

Table 2.2 shows the summary of characteristics of the 11 included studies, conducted across different countries. There were five cross-sectional (Alencar et al., 2007; de Zwart et al., 2015; Mat et al., 2015; Petrella et al., 2012; Sturnieks et al., 2004) and six prospective study designs included in this review (Arden et al., 2006; Dore et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Nevitt et al., 2016; Prieto-Alhambra et al., 2013). The number of participants in each study varied between 30 and 684 participants for the cross-sectional studies (Alencar et al., 2007; de Zwart et al., 2015; Mat et al., 2015; Petrella et al., 2012; Sturnieks et al., 2004), and between 940 and 20409 participants for the longitudinal cohort studies (Arden et al., 2006; Dore et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Nevitt et al., 2016; Prieto-Alhambra et al., 2013). The mean age of the participants in all the included studies ranged from 61 to 80 years old. Overall, studies included more female, n=25,840 (91.34%) than male, n=1,707 (8.66%) participants with four studies including only female participants (Alencar et al., 2007; Leveille et al., 2002; Petrella et al., 2012; Prieto-Alhambra et al., 2013). For diagnosis of knee OA, 54% of the included studies used ACR clinical criteria (Alencar et al., 2007; de Zwart et al., 2015; Leveille et al., 2002; Petrella et al., 2012), while others used self-reported OA (Arden et al., 2006; Prieto-Alhambra et al., 2013; Sturnieks et al., 2004) and radiographic changes (Dore et al., 2015; Mat et al., 2015; Muraki et al., 2013; Nevitt et al., 2016).

**Table 2.2** Summary of the characteristics of reviewed studies

Study		Participants					Methods			Main results and findings
Author Year	Study Setting	Objective	Sample size	Age (SD)	Gender	Diagnosis	Study Design	Fall Definition Fall Attainment	Factor of Interest	
Alencar et al. 2007	Brazil University Hospital (Outpatient clinic)	To compare muscle function and functional mobility between faller and non-faller elderly women with knee OA	30	Faller: 74.20 (4.46) Non-faller: 71.73 (4.73)	30 female	ACR	Cross-Sectional	<i>Definition:</i> defined as non-intentional event that results in the shift of individual's posture to a lower level  <i>Fall History:</i> occurrence in the past 6 months	Strength Balance Functional mobility Pain	Participants with history of falls: *↑ <i>TUG test performance time</i> ( $p = 0.038$ ) *↑ <i>STS time variable</i> ( $p = 0.049$ )  No significant difference between groups for isokinetic dynamometer variables and pain measurement.
Arden et al. 2006	United Kingdom Hampshire, Wiltshire, and Dorset (Wessex Primary Care Research Network)	To determine the association of knee OA and knee pain with fractures and falls in elderly men and women	6641	78.7	414 female 285 male	Clinically diagnosed OA and Self-reported	Prospective Cohort Study	<i>Definition:</i> no definition reported  <i>Fall History:</i> Prospective every 6 months	Fracture Knee Pain Walking Aids	Knee pain was associated with an increased risk of falls and hip fracture. ** <i>Knee pain: HR 1.26 CI (1.17-1.36)</i> ** <i>Fracture: HR 2.0 CI (1.18-3.37)</i>  Walking aids usage was associated with increase of all falls ** <i>Walking aids: HR 1.34 CI (1.25-1.44)</i>
De Zwart et al. 2015	Netherlands Amsterdam Community Setting	To evaluate the association between knee muscle strength, and fall among patients with knee OA reporting knee instability, proprioception, laxity and pain	301	Faller: 61.4 (9.7) Non-faller: 61.5 (8.5)	203 female 98 male	ACR	Cross-Sectional	<i>Definition:</i> defined as non-intentional event that results in the shift of individual's posture to a lower level  <i>Fall History:</i> occurrence of at least 1 in the past 3 months	Strength Proprioception Varus-valgus laxity Knee pain	High knee strength flexion and extension are associated with low risk of falls. ** <i>Knee Extension: OR 0.3 CI (0.1-0.8)</i> ** <i>Knee Flexion: OR 0.2 CI (0.0-1.0)</i>  Pain associated when included in the model ** <i>Pain: OR 0.5 CI (0.2-1.4)</i>  Confounding factors proprioception and laxity have no association.

**Table 2.2** Summary of the characteristics of reviewed studies (continued)

Study		Participants					Methods			Main results and findings
Author Year	Study Setting	Objective	Sample size	Age (SD)	Gender	Diagnosis	Study Design	Fall Definition Fall Attainment	Factor of Interest	
Dore et al. 2015	United States of America, North Carolina Community Setting	To explore the risk factors associated with falls in person with or without Lower Limb OA	1619	Faller: 64 Non-faller: 62	1090 female 529 male	Radio-graphic Evidence, Kellgren/Lawrence	Prospective Cohort Study	<i>Definition:</i> A participant was considered to have a fall if he or she answered yes to the following questions: fall in the 12 months and how many  <i>Fall History:</i> occurrence in the past 12 months	Symptomatic OA: Radiographic Evidence Non-Symptomatic OA: Kellgren /Lawrence	Risk for falls increases with additional symptomatic joint involvement. <b>**Symptomatic knee OA: Radiographic Evidence OR 1.39 CI (1.02-1.88)</b>  The odds of falling increased with an increasing number of joint involvement <i>1 joint: 53%</i> <i>2 joints: 74%</i> <i>3-4 joints: 85%</i>
Leveille et al. 2002	United States of America, Baltimore, Maryland Women and Health Aging Study	To determine whether musculoskeletal pain increase the risk for falls in older women with disabilities	940	>65 years old	940 Female	ACR	Prospective Cohort Study	<i>Definition:</i> No definition reported  <i>Fall History:</i> previous history for the past 12 months during baseline, 6 months (semi-annual) during the 3-year follow-up	Musculoskeletal pain	Widespread musculoskeletal pain is a substantial risk factors for falls in older women: <b>**OR 1.66 CI (1.25-2.21)</b>
Mat et al. 2015	Malaysia, Kuala Lumpur Malaysian Falls Assessment and Intervention Trial	To investigate the association between falls and OA and the role of impaired physical function as a potential mediator of this association	389	72.2 (6.1) Faller: 229 Non-faller: 160	263 female 26 male	Self-reported, Clinician and Radio-logical OA	Cross-sectional; Case-control	<i>Definition:</i> defined as unintentional coming to rest on the ground or other lower level not as a result of a major intrinsic event.  <i>Fall History:</i> occurrence in the past 12 months	TUG Functional Reach Diabetes Visual Impairment	OA with impaired physical function have about 3–5 fold increased risks of falls Functional reach test: <b>**Self-reported: OR 4.66 (1.52-14.31)</b> <b>**Clinical: OR 4.45 (1.80-11.04)</b> <b>** Radiographic: OR 3.43 (1.41-8.33)</b> TUG: <b>** Self-reported: OR 4.97 (2.33-10.62)</b> <b>** Clinical: OR 3.58 (1.76-7.27)</b> <b>** Radiographic: OR 4.00 (1.98-8.09)</b> Diabetes: <b>**OR 5.79 (2.09-16.03)</b> Visual Impairment: <b>**OR 3.08 (1.33-7.12)</b>

**Table 2.2** Summary of the characteristics of reviewed studies (continued)

Study		Participants					Methods			Main results and findings
Author Year	Study Setting	Objective	Sample size	Age (SD)	Gender	Diagnosis	Study Design	Fall Definition Fall Attainment	Factor of Interest	
Mukari et al. 2012	Japan, Tokyo ROAD Study	To clarify the associations of physical performance and bone and joint disease with incidence of single and multiple falls	1348	Male: 64.9 (11.7) Female: 63.3 (11.8)	896 female 452 male	Radio-graphic	Prospective Cohort Study	<i>Definition:</i> defined as non-intentional event that results in the shift of individual's posture to a lower level <i>Fall History:</i> previous history for the past 12 months during baseline then during 3-year follow-up	Joint pain Radiographic Bone mineral density Physical Performance Cognitive	*Knee OA and knee pain at baseline was significantly associated with incidence rate of falls after 3-year follow-up. ( $p = 0.0001$ )  Longer walking time for women and longer chair stand time were risk factors for falls.  Knee pain and mineral bone density were risk factors for women but not for men.
Nevitt et al. 2016	United States of America, Alabama, Birmingham, Iowa MOST study	To examine the association of knee buckling, sensation of knee instability, slipping with falls	1842	69.9 (7.8)	1093 female 749 male	Radio-graphic Evidence, Kellgren/Lawrence	Prospective Cohort Study	<i>Definition:</i> landed on the floor, ground or stairs. Do not include being knocked down by moving person, vehicle  <i>Fall History:</i> occurrence in the past 12 months	Knee Instability: Buckling and shifting/slipping	↑risk of falling for those who reported knee buckling and shifting/slipping in the past 3 months <i>Falls in the past 12 months</i> **OR 2.00 (1.42-2.82) – Buckling **OR 1.51 (1.12-2.03) – Shifting/slipping <i>Falls in the past 12 months at 2-year follow-up</i> **OR 1.98 (1.35-2.91) – Buckling OR 1.10 (0.78-1.55) – Shifting/slipping
Petrella et al. 2012	Brazil, Sao Paulo	To compare stabilometric parameters of elderly female fallers and non-fallers associated or not with knee osteoarthritis	56	Faller OA: 69.3 (5.74)  Non-Faller OA: 68.43 (5.84)	56 female	ACR	Cross-sectional; Case-control	<i>Definition:</i> non-accidental falls  <i>Fall History:</i> occurrence in the past 6 months	COP Balance displacement  Velocity of COP	Knee OA increases sway on Anterior-Posterior (AP) direction ↑ AP direction sway ( $p < 0.05$ )  Fallers showed greater sway on Medio-lateral (ML) direction ↑ ML direction sway ( $p < 0.05$ )  Knee OA per se increases AP direction, while history of falls, regardless of the presence of Knee OA hinders postural control in ML direction

**Table 2.2** Summary of the characteristics of reviewed studies (continued)

Study		Participants					Methods			Main results and findings
Author Year	Study Setting	Objective	Sample size	Age (SD)	Gender	Diagnosis	Study Design	Fall Definition Fall Attainment	Factor of Interest	
Prieto-Alhambra et al. 2013	Global Longitudinal Study of Osteoporosis	To determine the association between self-reported OA and incident of falls and fracture in postmenopausal women	20409	69.1(8.6)	20409 female	Self-reported	Prospective Cohort Study	<i>Definition:</i> No definition reported  <i>Fall History:</i> occurrence in the past 18 months	Fracture Falls	Postmenopausal women with self-reported OA: ↑ risk of fracture by 20% and 25% more falls compared with non-OA participants
Sturnieks et al. 2004	Australia, Sydney	To investigate physiological risk factors for falls in people with self-reported lower limb arthritis	684	80.0 (4.4) Faller: 64 Non-faller: 62	446 female 238 male	Self-reported	Cross-Sectional	<i>Definition:</i> defined as unintentional coming to rest on the ground or other lower level not as a result of a major intrinsic event.  <i>Fall History:</i> occurrence in the past 12 months	Physiologic falls risk Pain Balance Sensorimotor	*↑ number of falls in OA group **RR 1.22 CI (1.03-1.46)  Reduced knee extension strength and increased sway were identified as significant predictors of falls.

*Note.* CI, confidence interval; OR, odds ratio; HR, hazard ratio; RR, risk ratio; OA, osteoarthritis; ACR, American College of Rheumatology; TUG, Timed Up and Go test; STS, Sit to Stand test; QoL, Quality of Life, KOOS-QoL, Knee Osteoarthritis Outcome Survey- Quality of Life; SF-12, Short Form-12; COP, Centre of Pressure  
\*significant ( $p= 0.05$ ), \*\* 95% confidence interval



#### 2.4.4 | Fall definition and reporting

Eight (73%) studies reported a definition of a fall (Alencar et al., 2007; de Zwart et al., 2015; Dore et al., 2015; Mat et al., 2015; Muraki et al., 2013; Nevitt et al., 2016; Petrella et al., 2012; Sturnieks et al., 2004). However, the fall definition was inconsistent across the studies. Some used recommended guidelines or a broad definition of a fall (Dore et al., 2015; Nevitt et al., 2016; Prieto-Alhambra et al., 2013); others used a specific definition (Alencar et al., 2007; de Zwart et al., 2015; Mat et al., 2015; Muraki et al., 2013; Sturnieks et al., 2004). There was also a variation in methods of collecting falls history. A self-reported fall was the most commonly used method of collecting falls data (Alencar et al., 2007; de Zwart et al., 2015; Dore et al., 2015; Mat et al., 2015; Nevitt et al., 2016; Petrella et al., 2012; Sturnieks et al., 2004). Structured questionnaires (Alencar et al., 2007) and interviews (Dore et al., 2015; Muraki et al., 2013) were also utilized. History of self-reported falls recalled from the past 12 months was the most common timeframe (de Zwart et al., 2015; Nevitt et al., 2016; Prieto-Alhambra et al., 2013) although this ranged from three months to 18 months (Alencar et al., 2007; de Zwart et al., 2015). For prospective studies, falls data collection was recorded at every six-month follow-up, with a maximum follow-up of three years (Leveille et al., 2002; Muraki et al., 2013).

#### 2.4.5 | Identified risk factors

Eight risk factors were identified in this review with seven categorized as intrinsic and one as an extrinsic risk factor. The intrinsic risk factors can be sub-divided into biomechanical factors (balance, strength, proprioception, instability), knee OA symptoms (pain, number of symptomatic joints), and presence of comorbidities. The use of walking aids was the only extrinsic risk factor identified. Table 2.3 summarises the risk factors for falls with the reported outcome measures, associations, effect sizes, and p-values.

**Table 2.3** Summary of findings for risk factors for falls in individuals with knee OA

Risk factors	Author	Tool / Outcome measure	Was the factor associated?	Effect size (95% CI)	p value
<b>Intrinsic risk factors</b>					
<i>Balance</i>	Alencar et al.	Balance Master	Yes	Not reported	0.049
	Petrella M et al.	Force platform COP displacement			
		AP direction	Yes	Not reported	<0.05
		ML direction	Yes	Not reported	<0.05
	Sturnieks et al	Postural sway	Yes	Not reported	<0.05
<i>Strength</i>	Alencar et al.	Isokinetic dynamometer: Flexors and extensors	No	Not reported	Not reported
	De Zwart et al.	Isokinetic dynamometer: Flexors	Yes	OR 0.2 CI (0.1-1.0)	0.048
		Extensors	Yes	OR 0.3 CI (0.1-0.8)	0.022
	Sturnieks et al.	Physiologic fall profile- Strength: Flexors	Yes	Not reported	<0.01
		Strength: Extensors	Yes	Not reported	<0.01
	<i>Proprioception</i>	De Zwart et al.	Isokinetic dynamometer	No	OR 0.4 CI (0.1-1.0)
	Sturnieks et al.	Physiologic fall profile	Yes	Not reported	Not reported
<i>Knee instability</i>	De Zwart et al.	Varus-valgus laxity- knee joint motion detection	No	OR 0.5 CI (0.2-1.4)	0.202
	Nevitt et al.	Self-reported knee instability: buckling (baseline and 2-year follow-up)	Yes	OR 2.00 (1.42-2.82) OR 1.98 (1.35-2.91)	Not reported
		Self-reported knee instability: shifting/sliding (baseline)	Yes	OR 1.51 (1.12-2.03)	Not reported
<i>Pain</i>	Alencar et al.	Visual analogue scale	No	Not reported	Not reported
	Arden et al.	Pain Questionnaire	Yes	HR 1.51 CI (1.32-1.75)	Not reported
	De Zwart et al.	Numeric Rating Scale	No	OR 0.5 CI (0.2-1.4)	0.212
	Leveille et al.	Joint Pain Questionnaire	Yes	OR 1.66 CI (1.25-2.21)	Not reported
	Muraki et al.	Pain interview	Yes	Not reported	<0.0001
	Sturnieks et al.	Short Form-12	Yes	Not reported	<0.001
↑ number of symptomatic joint	Dore et al.	No. of symptomatic joint: 1 symptomatic OA joint 2 symptomatic OA joints 3-4 symptomatic OA joints	Yes	OR 1.53 CI (1.10-2.14) OR 1.74 CI (1.19-2.53) OR 1.85 CI (0.96-3.55)	Not reported
	Leveille et al.	No. of symptomatic joint	Yes	OR 1.66 CI (1.25-2.21)	Not reported
	<i>Comorbidities</i>	Arden et al.	Fracture Questionnaire	Yes	HR 2.0 CI (1.18-3.37)
	Mat et al.	Self-reported diabetes	No	OR 5.79 (2.09-16.03)	Not reported
		Self-reported visual impairment	No	OR 3.08 (1.33-7.12)	Not reported
	Prieto et al.	Fracture Questionnaire	No	HR 1.14 (1.12-1.16)	<0.0001
<b>Extrinsic risk factor</b>					
<i>Walking aids</i>	Arden et al.	Walking aid questionnaire	Yes	HR 1.34 CI (1.25-1.44)	Not reported

*Note.* CI, confidence interval; OR, odds ratio; HR, hazard ratio; PR, prevalence ratio; AP, anteroposterior; ML, mediolateral, TUG, Timed Up and Go test; STS, Sit to Stand test; FR, functional Reach Test; COP, Center of Pressure; QoL, Quality of Life, KOOS-QoL, Knee Osteoarthritis Outcome Survey- Quality of Life; SF-12, Short Form-12

#### 2.4.5.1 *Intrinsic risk factors*

In four studies, biomechanical factors, namely balance and strength, were consistently identified as risk factors for falls in individuals with knee OA (Alencar et al., 2007; de Zwart et al., 2015; Petrella et al., 2012; Sturnieks et al., 2004). Three cross-sectional studies reported a significant agreement that poor balance in a knee OA group increased the risk for falling ( $p=0.05$ ) (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004). Balance was measured using a force platform i.e. Balance Master in two studies (Alencar et al., 2007; Petrella et al., 2012) while one study used the Physiologic Fall Profile to evaluate the risk of falling (Sturnieks et al., 2004). The weakness of quadriceps muscles was highlighted to be an important contributing factor for falls (de Zwart et al., 2015; Sturnieks et al., 2004). Two studies suggested an increase in muscle strength to be protective for falls while a decrease in muscle strength increased the tendency of falling (de Zwart et al., 2015; Sturnieks et al., 2004). In one study, no significant difference was found between muscle strength of fallers and non-fallers although participants with a history of falls scored worse in muscle function using isokinetic dynamometer (Alencar et al., 2007). Included studies measured knee muscle strength with an isokinetic dynamometer (Alencar et al., 2007; de Zwart et al., 2015) and the muscle strength section of the Physiologic Fall Profile (Sturnieks et al., 2004).

Included studies also considered proprioception and knee instability as potential risk factors for falls. There was a positive association between the risk of falling and proprioception assessed by the Physiologic Fall Profile (Sturnieks et al., 2004), but not when assessed with an isokinetic dynamometer ( $p = 0.061$ ) (de Zwart et al., 2015). Regarding instability of the knee joint, there was an association found between those who have a history of falls and self-reported knee buckling and shifting/sliding (Nevitt et al., 2016). Previous experience of falls and knee-buckling increases the likelihood of future recurrent falls (Nevitt et al., 2016). However, one study did not reach significant association for knee instability assessed by varus-valgus laxity using knee joint motion detection (de Zwart et al., 2015).

Presence of comorbidities (Arden et al., 2006; Mat et al., 2015; Prieto-Alhambra et al., 2013) and knee OA symptoms such as pain (Alencar et al., 2007; Arden et al., 2006; de Zwart et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Sturnieks et al., 2004) and number of symptomatic joints (Dore et al., 2015; Leveille et al., 2002) were also identified as risk factors for falls. Fracture, diabetes, and visual impairment were comorbidities that were

investigated as potential risk factors for falls (Arden et al., 2006; Mat et al., 2015; Prieto-Alhambra et al., 2013). Two studies supported positive association with presence of fracture using a questionnaire (Arden et al., 2006; Prieto-Alhambra et al., 2013), while one study reported an increased risk of falling for participants with a self-reported diagnosis of diabetes and presence of visual impairment (Mat et al., 2015). Self-reported pain was measured using the numeric pain scale (Dore et al., 2015), visual analogue scale (Alencar et al., 2007), and pain questionnaires (Arden et al., 2006; Leveille et al., 2002; Muraki et al., 2013; Sturnieks et al., 2004). One study found that an increasing number of symptomatic joints has a positive association with the number of falls (Dore et al., 2015).

#### 2.4.5.2 Extrinsic risk factors

Only one extrinsic risk factor for falls was identified in this review. The use of a walking aid was associated with increased risks of falls assessed by the numbers of falls recorded (Arden et al., 2006). No other extrinsic or environmental falls risk factors have been reported in knee OA populations in this review.

#### 2.4.6 | Sub-group analysis

Sub-group analyses were possible for five risk factors for falls which showed insignificant results: balance (Alencar et al., 2007; Petrella et al., 2012), pooled OR=0.74, 95% CI = 0.35-1.59,  $p=0.45$ ; strength (Alencar et al., 2007; de Zwart et al., 2015), pooled OR=0.11, 95% CI = 0.00-8.17,  $p=0.32$ ; pain in cross-sectional studies (Alencar et al., 2007; de Zwart et al., 2015; Sturnieks et al., 2004), pooled OR=0.22, 95% CI = 0.01-4.74,  $p=0.34$ ; pain in prospective studies (Arden et al., 2006; Muraki et al., 2013), pooled OR=0.59, 95% CI = 0.20-16.43,  $p=0.76$ ; number of the symptomatic joint (Dore et al., 2015; Leveille et al., 2002), pooled OR=0.02, 95% CI = 0.00-81.40,  $p=0.35$ ; and presence of fracture as comorbidities (Arden et al., 2006; Mat et al., 2015) (pooled OR=1.33, 95% CI = 0.24-7.45,  $p=0.75$ ). Substantial heterogeneity ( $I^2$ ) was found for the risk factors, except for balance. Table 2.4 shows the summary of pooled estimates and heterogeneity of the sub-group analysis.

**Table 2.4** Summary of the sub-group analysis

Study type	Cross-sectional study			Prospective study		
	Balance	Strength	Pain	Pain	Symptomatic	Comorbidities
<b>Risk factors</b>						
<b>No. of studies</b>	2	2	3	2	2	2
<b>No. of participants</b>	54	331	614	1058	546	20842
<b>Pooled OR</b>	0.74	0.11	0.22	0.59	0.02	1.33
<b>95% CI</b>	0.35-1.59	0.00-8.17	0.01-4.74	0.02-16.43	0.00-81.40	0.24-7.45
<b>p-value</b>	0.45	0.32	0.34	0.76	0.35	0.75
<b>Heterogeneity (I<sup>2</sup>)</b>	0%	98%	99%	100%	97%	99%

*Note.* CI, confidence interval; OR, odds ratio

#### 2.4.7 | Level of evidence

The 11 studies were included in a synthesis of evidence (Table 2.5). The significance of findings was determined based on reported confidence intervals and p-values <0.05. Although 10 out of 11 of the studies were rated as ‘high’ quality, the grading of a strong and moderate level of evidence was hampered primarily by the low number of studies to be synthesized. Impaired balance (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004), decreased muscle strength (Alencar et al., 2007; de Zwart et al., 2015; Sturnieks et al., 2004), presence of comorbidities (Arden et al., 2006; Mat et al., 2015; Prieto-Alhambra et al., 2013), and number of symptomatic joint (Dore et al., 2015; Leveille et al., 2002) demonstrated ‘moderate’ level of evidence. The inconsistency of the results was found in pain (Alencar et al., 2007; Arden et al., 2006; de Zwart et al., 2015; Leveille et al., 2002; Muraki et al., 2013; Sturnieks et al., 2004) as a risk factor for falls which resulted in a ‘conflicting’ level of evidence. Knee instability (de Zwart et al., 2015; Nevitt et al., 2016), impaired proprioception (de Zwart et al., 2015; Sturnieks et al., 2004), and the use of walking aids (Arden et al., 2006) were also identified as risk factors for falls. However, the level of evidence was limited due to a low number of studies to support the findings.

**Table 2.5** Summary of the strength of evidence of the risk factors of falls in knee OA

Risk factors	No. of studies	Quality of the study	Number of studies with positive association	Strength of Evidence	Positive association with the risk of falling
<b>Intrinsic risk factors</b>					
<i>Balance</i>	3	2 High 1 Moderate	3/3	Moderate	↓ postural balance ( $p < 0.05$ ) ↑ sway time ( $p < 0.05$ )
<i>Strength</i>	3	3 High	2/3	Moderate	↓ <i>knee extensor muscle strength</i> OR 0.2, CI (0.1-1.0) OR 0.3, CI (0.1-0.8)
<i>Proprioception</i>	2	2 High	1/2	Limited	↓ proprioception OR 0.4, CI (0.1-1.0)
<i>Knee instability</i>	2	2 High	1/2	Limited	↓ instability has no association OR 0.5, CI (0.2-1.4) PR 1.4, CI (1.30-1.60)
<i>Pain</i>	6	6 High	4/6	Conflicting	↑ pain level HR 1.26 CI (1.17-1.36) OR 0.5, CI (0.2-1.4) OR 0.95, CI (0.60-1.49)
<i>Number of symptomatic joint</i>	2	2 High	2/2	Moderate	↑ number of symptomatic joint OR 1.66, CI (1.25-2.21)
<i>Comorbidities</i>	3	3 High	2/3	Moderate	↑ presence of fracture HR 2.0 CI (1.18-3.37) ↑ presence of diabetes OR 5.79 (2.09-16.03) ↑ presence visual impairment: OR 3.08 (1.33-7.12)
<b>Extrinsic risk factors</b>					
<i>Walking aids</i>	1	1 High	1/1	Limited	↑ Use of walking aids HR 1.34 CI (1.25-1.44)

Note. CI, confidence interval; OR, odds ratio; HR, hazard ratio; PR, prevalence ratio; QoL, Quality of Life

## 2.5 | Discussion

The aim of this systematic review was to explore the evidence of risk factors for falls in individuals with knee OA. Eleven observational studies met the inclusion criteria identifying moderate level of evidence that impaired balance, decreased knee muscle strength, increasing number of symptomatic joint, and presence of comorbidities were risk factors associated with falling in individuals with knee OA. Conflicting evidence was found for pain while impaired proprioception, knee instability, and use of walking aids had limited evidence for being significantly associated with risk for falls.

### 2.5.1 | Identified risk factors

Pain is recognized as the most common symptom affecting individuals with knee OA (Hunter, McDougall, & Keefe, 2009). However, conflicting evidence for pain was found in this study. While six studies identified an association between knee pain and risk of falling, two studies (Alencar et al., 2007; de Zwart et al., 2015) reported no association. This suggests that pain may partly explain the increased risk of falling. The increasing pain severity might be protective against falls (Alencar et al., 2007; de Zwart et al., 2015). Although it appears to be counterintuitive that increasing pain severity is associated with a decreased falls risk, it could be that presence of severe pain deters participants from doing too much activity, avoiding potential activities and environments with risk of increased pain and loss of balance, and thereby, decreasing the actual risk for falling. The interesting findings of the conflicting and protective role of pain are similar with the literature found in falls and older adults with lower limb OA (Ng & Tan, 2013; Stubbs et al., 2014). Thus, factors other than pain may account for risk of falling among individuals with knee OA.

Presence of knee pain may negatively influence muscle strength, postural sway, and proprioception. However, the mechanisms whereby knee OA symptoms may increase the risk of falling remain complex. Some of these mechanisms have been explored previously: knee pain may influence muscle activation (Leveille et al., 2002; Sturmeiers et al., 2004) and increase postural sway (Foley, Lord, Srikanth, Cooley, & Jones, 2006; Ng & Tan, 2013) that can contribute to further falls risk. Another possible mechanism may include the limitation of knee range of motion due to pain which hinders participants to perform an activity. Thus, the interaction of knee OA symptoms such as muscle weakness might be more relevant to increased falls risk.

This review found moderate level of evidence for an inverse relationship between knee muscle strength and risk of falling. Aside from knee extensor weakness, one study identified knee flexors to be associated with risk of falling (de Zwart et al., 2015). As previous, the debilitating effect of knee pain might be affecting the knee muscle function in two ways: loss of muscle strength due to decreasing physical activity, and/or a reflex inhibition of knee muscles generated by pain that has been suggested as one possible mechanism (de Zwart et al., 2015; Hassan et al., 2001; Sharma et al., 1999). While the importance of knee muscle strengthening in managing knee OA symptoms has been extensively studied (Alencar et al., 2007; Blagojevic et al., 2010; de Zwart et al., 2015; Jadelis et al., 2001; Lange, Vanwanseele, & Fiatarone singh, 2008; Sturnieks et al., 2004; Uthman et al., 2013), there is a paucity of information on its role as a risk factor for falls specifically in individuals with knee OA.

The decline in balance was suggested to be a result of both physiological changes due to the aging process, and an impaired integration of somatosensory and neuromuscular information due to the presence of knee OA symptoms (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004). Sturnieks et al. (2004) showed participants with lower limb OA performed worse in tests for postural sway compared with a non-arthritic group, identifying impaired postural balance as a risk factor for falls (Sturnieks et al., 2004). Furthermore, increased knee pain and decrease muscle strength might be associated with increased postural sway (Hassan et al., 2001). The underlying mechanism behind this may be the disturbance of joint mechanoreceptors which may impair proprioception, and thereby result in decreased somatosensory information (Hassan et al., 2001; Sharma et al., 1999). This may explain why poor balance was consistently being found to be a risk factor for falls in this review, albeit with moderate strength of evidence (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004).

Self-reported diabetes and visual impairment were comorbidities considered in this review (Mat et al., 2015). These comorbidities affect the somatosensory and visual components of postural balance. The ability of an individual to position and move in space requires a combination of visual and sensory inputs from peripheral receptors which are impaired in individuals with diabetes (Horak, 2006; Simoneau, Ulbrecht, Derr, Becker, & Cavanagh, 1994). Although these two components work as one to achieve postural balance, most individuals can compensate if one is impaired (Horak, 2006). The presence of



comorbidities makes it more likely that people are on medication. A recent study suggested that individuals with knee OA who used opioids and antidepressants may have increased risk of recurrent falls (Lo-Ciganic et al., 2017). Thus, the increased risk for falls for individuals with comorbidities may be due to disease-specific changes in somatosensation, and also due to side-effects of medication or both.

This review found limited associations with risk of falling regarding proprioception and knee instability. It has been suggested that proprioception in individuals with knee OA influences muscle and physical function (Hassan et al., 2001), thereby influencing falls. Possibly results were different since different methods were used in measuring proprioception, an instrumented (de Zwart et al., 2015) and assessor-dependent measurement (Nevitt et al., 2016). Individuals who reported experience of knee buckling and shifting/slipping demonstrated increased risk of falling and future falls (Nevitt et al., 2016). However, knee instability measured by joint laxity showed no association (de Zwart et al., 2015). It should be highlighted that stability of the joint relies not just on passive support provided by the ligaments but also by other structures such as muscles which are considered dynamic stabilizers. This might imply that future study associating falls and knee instability should consider both static and dynamic aspects as two independent factors.

Approximately 20% of falls were reported in the older adult group due to extrinsic factors: walking aids, footwear, and environmental hazards (Feder et al., 2000). This current review identified one extrinsic factor, the use of walking aid (Arden et al., 2006). Nevertheless, there are conflicting findings about the use of walking aids in older adults. Some studies found the use of walking aids as to be a risk factor for future falls (de Mettelinge & Cambier, 2015), while others found it to be protective against falls (Graafmans, Lips, Wijnhuizen, Pluijm, & Bouter, 2003). Walkers and canes are commonly prescribed for individuals with lower limb OA to decrease the load on the affected joint and decrease symptoms. However, such individuals may have been prescribed a walking aid as a consequence of a previous fall. In that case, the underlying risk factor for falling is a previous fall and not the use of the walking aid. Thus, necessary caution is needed in interpreting the role of walking aids in future falls in a knee OA group.

### 2.5.2 | Falls in knee OA

Different definitions for falls were used across the studies, which might affect the self-reporting of falls. This is a common limitation in falls research where in most cases defining a ‘fall’ is subject to the participants’ interpretation, rather than having objective evidence (Graafmans et al., 2003; Lord et al., 2007). The timeframe of fall recall might also influence the reported frequency of falling, which can result in under- or over-estimation. Also, the location of falls should be considered. Combining all falls regardless of location such as failure to separate indoor and outdoor falls can make it difficult to measure the magnitudes of associations of various risk factors with falls (Kelsey et al., 2010).

### 2.5.3 | Limitations

The findings of this review need to be considered in the context of the methodological limitations. A meta-analysis was precluded due to methodological heterogeneity across the studies. Also, the sub-group analyses showed high statistical heterogeneity for most risk factors, and insignificant results for pooled estimates. Thus, interpretation of the results of secondary results was hampered. Most of the significant risk factors for falls were explored in cross-sectional studies where causality cannot be inferred. However, this was moderated by the longitudinal studies where the relationship between variables can be followed over time. Variability among the studies in terms of outcome measures used to evaluate risk factors makes it difficult to compare or pool findings. Finally, the low number of studies for some risk factors means that future well-designed, fully-powered studies may change those findings.

The review excluded unpublished papers and studies not written in English, so it is possible valuable evidence was missed. Given the lack of studies that identified known risk factors for falls such as medication, polypharmacy, use of alcohol, and depression, it may be that the search terms/strategy was not precise enough to identify such studies and must be addressed in future reviews. We suggest that future studies could explore other potentially clinically relevant factors not included in this review, such as the presence of knee joint stiffness, gait problems, and the experience of fatigue which could contribute to the risk of falling in a knee OA group (Ambrose, Paul, & Hausdorff, 2013; Lord et al., 2007). Finally, consensus on fall definition and reporting should be implemented.

## 2.6 | Conclusion

This systematic review identified the strength of evidence for risk factors for falls for individuals with knee OA. Impaired balance, decreased knee muscle strength, increasing number of symptomatic joint, and the presence of comorbidities were risk factors with ‘moderate’ evidence. Clinicians can be confident these are important risk factors that contribute to the risk of falling in individuals with knee OA. Although the interaction of knee OA related symptoms influences falls, limited evidence was found for proprioception, knee instability, and use of walking aids. Assessment of knee OA symptoms that are critical to increasing falls risk can provide valuable information for both clinicians and fall prevention program developers. Thus, additional studies investigating modifiable risk factors are warranted. The low number of existing studies of these factors means future studies may change review findings.

## 2.7 | Relationship of the study to thesis

This systematic review is conducted to identify published evidence regarding the risk factors for falls in individuals with knee OA. Given the overlapping risk factors for falls in knee OA and in the older adult population, the known risk factors found in this review provided the context of the next chapter. The results of this review justify why there is a need to further investigate risk factors for falls particularly in a knee OA population. Some of the identified risk factors such as knee muscle weakness and balance are considered modifiable risk factors which can be amendable to an intervention such as exercise.

# CHAPTER 3

## Factors associated with risk of falling in knee osteoarthritis: a cross-sectional study

### 3.1 | Chapter overview

Building on the evidence found in the systematic review, this chapter reports the association of the risk factors for falls in adults with knee OA. It was highlighted in Chapter 1 that risk factors for falls overlap with other risk factors for common musculoskeletal conditions such as knee OA, one of the issues that this thesis wanted to investigate. To provide a better understanding of risk factors for falls in knee OA, the current study examined the strength of relationship between falling and clinical characteristics such as dynamic balance, pain, instability, muscle strength, and physical function in adults with knee OA.

### 3.2 | Background

There is evidence of increasing number of falls in adults with knee OA (Hinman, Bennell, Metcalf, & Crossley, 2002; Hoops et al., 2012). However, the contributing factors for falling in adults with knee OA remain uncertain. The risk factors included in this study were selected on the basis of evidence from the systematic review (Chapter 2) that were common to both knee OA and falls. As previously highlighted in Chapter 2, the presence of knee pain (Leveille et al., 2002; Muraki et al., 2013), muscle weakness (Alencar et al., 2007; de Zwart et al., 2015), and instability (Nguyen et al., 2014) are important underlying risk factors for both knee OA and falls. Consequently, altered sensory information from the affected knee joint may result in compromised balance performance that may impact daily function (Sturnieks et al., 2004). These selected variables are clinical risk factors that could potentially explain falling in knee OA. The variables are routinely used in clinical practice thus, having good utility. Also, these risk factors are considered to be modifiable risk factors and thus, can be mitigated.

Given the complex interaction of knee OA-related symptoms and the impact of falls in this population, it is essential to investigate the relationship between falling and clinical characteristics of adults with knee OA. Thus, the primary aim of this study is to examine the strength of association between dynamic balance, physical function, pain, instability, and muscle strength of individuals with knee OA and falls history. The following research questions were addressed in this current study:

- (1) What are the differences in the dynamic balance, physical function, pain, instability, and muscle strength of individuals with knee OA with history of falling compared to individuals with knee OA and no history of falling?
- (2) Are the dynamic balance, physical function and clinical characteristics of knee OA such as pain, instability, and muscle strength associated with individuals with knee OA and history of falling?

### **3.3 | Methods**

#### **3.3.1 | Study design**

This cross-sectional study was reported in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement. The study protocol has been prospectively registered with the Australian New Zealand Clinical Trial Registry reference: ACTRN12617000154303 (Appendix H).

An observational cross-sectional design was adopted to explore falls history and clinical characteristics of individuals with knee OA. This design enables the researcher to observe and examine factors that are associated with a particular variable of interest using multiple outcome measures at one point in time (Mann, 2003; Portney, 2015). Comparative measures can also be used such as comparing the characteristics of two or more population subgroups (Portney, 2015). The study design is relatively quick to conduct and best to determine prevalence in a given population of interest, such as prevalence of falls and risk factors in a knee OA population (Mann, 2003; Portney, 2015).

### 3.3.2 | Sample size

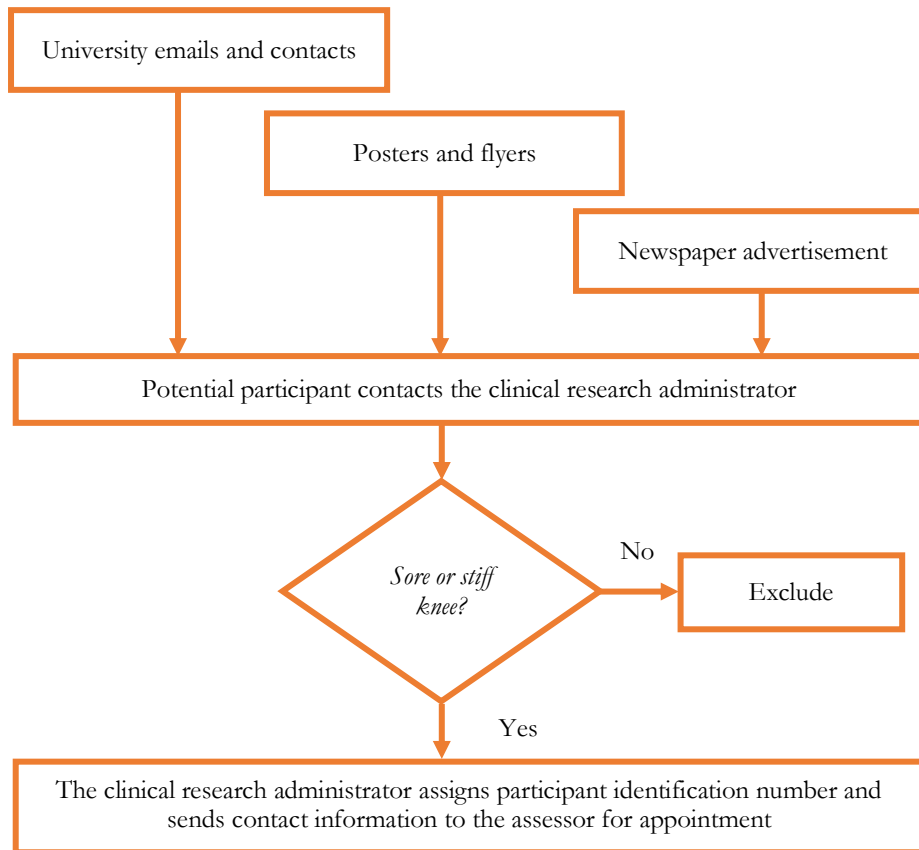
Sample size calculation was based on previous studies that reported the prevalence rate of falls in individuals with knee OA (Brand, Aw, Lowe, & Morton, 2005; Hoops et al., 2012; Williams, Brand, Hill, Hunt, & Moran, 2010). Notably, two studies reported that more than 50% of people with knee OA reported a fall during the previous year (Hoops et al., 2012; Williams, Brand, Hill, Hunt, & Moran, 2010). Williams et al. (2010) reported that more than 64% of people with knee OA have had a fall in the previous year (Williams, Brand, Hill, Hunt, & Moran, 2010). A conservative estimate of the proportion of fallers and non-fallers in knee OA is set at 50%. Estimated sample size was computed using G\*Power 3.1.9.2 software with statistical test of logistic regression. Given the five independent variables (postural control, knee pain, instability, muscle strength, and physical function) included in the study, the sample size needed for an error margin of 5% is 81 using significance level of  $p=0.05$  and power of 0.80.

### 3.3.3 | Ethical approval

Ethical approval was obtained from the University of Otago Human Ethics Committee for Health reference number: H16/12 (Appendix I). Māori consultation was also undertaken with the University of Otago Ngāi Tahu Research Consultation Committee (Appendix I).

### 3.3.4 | Recruitment and screening of participants

Participants were recruited between April and December 2017 from the Dunedin community through the strategies detailed in Figure 3.1. This included email and community advertisement through posters and local newspaper (Appendix J). The implemented recruitment strategies sought a wide cross-section of the community since the study also included those who were active and still working.



**Figure 3.1** Schematic diagram of recruitment of participants from the community

### 3.3.5 | Study setting

All data collection and screening were completed at the School of Physiotherapy Balance Clinic, University of Otago.

### 3.3.6 | Eligibility of participants

The primary inclusion criteria were meeting the ACR clinical criteria using history and physical examination for classification of knee OA (Altman et al., 1986). The ACR clinical criteria is the highly recommended method of classifying knee OA for clinical and epidemiological studies (Brooks, Hochberg, Ilar, & Omeract, 2001). The criteria have been demonstrated to have 95% sensitivity and 69% specificity in classifying knee OA (Altman et al., 1986) (Table 3.1).

**Table 3.1** Inclusion and exclusion criteria used in the study

Inclusion criteria	Exclusion criteria
<i>American College of Rheumatology clinical criteria for the diagnosis of knee OA*</i>	
OA of the knee: Clinical <input type="checkbox"/> Knee pain  At least 3 of 6: <input type="checkbox"/> Age > 50 years <input type="checkbox"/> Stiffness < 30 mins <input type="checkbox"/> Crepitus <input type="checkbox"/> Bony tenderness <input type="checkbox"/> Bony enlargement <input type="checkbox"/> No palpable warmth	<input type="checkbox"/> Previous lower limb injury/surgery in previous in 12 months <input type="checkbox"/> Consultation with orthopaedic specialist for knee OA <input type="checkbox"/> Commencement of new medication for OA (previous one month) <input type="checkbox"/> Presence of other forms of arthritis, particularly inflammatory disease <input type="checkbox"/> Undergoing any treatment/physiotherapy management of the knee

*Note.* OA, osteoarthritis \*Adapted from Altman et al., 1986

Participants with any other concomitant lower extremity musculoskeletal condition such as an inflammatory arthritis, previous history of lower limb joint replacement, presence of neurological diseases, presence of cognitive deficits, and those with a vestibular problem were excluded from the study. Participants who had sought a consultation with orthopaedic specialist were excluded to ensure that they were not undergoing treatment that could have influenced the results of the assessment or testing. Similarly, potential participants who were also undergoing any treatment/physiotherapy management of the knee were excluded since this could have affect the baseline results.

### 3.4 | Materials and procedures

#### 3.4.1 | Dependent variable

The history of falling in the previous 12 months was the dependent variable (outcome variable) in this study. A fall was operationally defined as an event in which the person unintentionally comes to rest on the ground or other lower level (Gibson, 1987; Lamb, Jorstad-Stein, Hauer, & Becker, 2005). This dichotomous dependent variable was used in analysis of data and to categorised participants into faller and non-faller group.



However, several questions related to falls were asked to collect a established a definite history of falls. The participants were asked the questions shown in Table 3.2 (NICE, 2013). These questions were adapted from “Ask, Assess, Act” of Health Quality and Safety Commission NZ to deduce and identify fall/s and fall characteristics. The questions also included details pertaining to falls in the past year namely the frequency, context, and characteristics of the falls in the assessment (NICE, 2013). If needed, the terms slip (sliding of the support leg) and trip (impact of the swinging leg with an external object or a body part) were also explained and demonstrated to the participants.

**Table 3.2** Questions to collect falls characteristics of the participants.

Questions	Response
a. Have you slipped, tripped, or fallen in the last year?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
<i>Definition: A fall is defined as an event in which person unintentionally comes to rest on the ground or other lower levels.</i>	
If yes, how many fall/s in the last year?	No of fall/s: _____
What activity are you doing?	Activity: _____
Where did it happen?	Place: _____
b. Can you get out of a chair without using your hands?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
c. Have you avoided some activities because you are afraid you might lose your balance?	<input type="checkbox"/> YES
	Activity: _____
	<input type="checkbox"/> NO

### 3.4.2 | Independent variables

The independent variables in the study included dynamic balance, physical function, knee OA symptoms, knee instability, and knee muscle strength. The list of independent variables with the corresponding outcome measures are presented in Table 3.3.

**Table 3.3** Independent variables and outcome measures of the study

Independent variables	Outcome measures
Dynamic balance	Sensory Organisation Test using NeuroCom SMART Equitest® system, version 8.6.0 ( <i>Equilibrium Score and Composite score</i> ) Timed Up and Go Test
Physical function	Knee injury and Osteoarthritis Outcome Score (KOOS) ( <i>KOOS- function in daily living subscale</i> ) Timed Up and Go Test
Knee OA symptoms	Knee injury and Osteoarthritis Outcome Score (KOOS) ( <i>KOOS- Pain, KOOS-Symptoms, KOOS-knee related Quality of Life, KOOS-Sports and recreation subscales</i> )
Knee instability	Knee Outcome Survey – Activities of Daily Living Scale ( <i>Item 6</i> )
Knee muscle strength	Hand-held dynamometer using Nicholas MMT, Model 01160 <i>Knee extensors and flexors at 0° and 90°</i>

### 3.4.3 | Outcome measures for the independent variables

Outcome measures for each of the independent variable are described below. These outcome measures included self-reported measures, laboratory-based measures and a physical performance measure. A justification for the selection of each independent variable is provided. Questionnaires, equipment, and physical performance tests are also discussed together with their psychometric properties, followed by the procedure conducted during the assessment session.

#### 3.4.3.1 Knee injury and Osteoarthritis Outcome Score (KOOS)

Symptoms of knee OA in the past seven days were measured by the disease-specific outcome measure, Knee injury and Osteoarthritis Outcome Score (KOOS). It is a 42-item questionnaire divided into five separate subscales addressing symptoms, pain, function in ADL, function in sport and recreation, and knee-related QoL. It has a five-point Likert scale scoring system ranging from 0 (least severe) to 4 (most severe) with a maximum score of 100 (Roos, Lohmander, Ekdahl, & Beynnon, 1998).

KOOS has been developed from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and contains same subscales, thus facilitating calculation of the WOMAC scores, if required. Also, a significant innovation and advantage of KOOS over the WOMAC is the inclusion of two different subscales of physical function relating to daily life, and sport and recreation (Roos & Lohmander, 2003). This improves the questionnaire's validity for individuals with a wider range of present or anticipated level of physical activity (Roos & Lohmander, 2003; Roos, Lohmander, Ekdahl, & Beynnon, 1998). KOOS is freely available to download (<http://www.koos.nu>) and takes only minimal time to administer. Other advantages are it is free to use, and does not require a license (Collins, Misra, Felson, Crossley, & Roos, 2011; Roos, Lohmander, Ekdahl, & Beynnon, 1998).

The KOOS has been well studied worldwide, and is reliable, valid, and sensitive to change (Collins et al., 2011; Goncalves, Cabri, Pinheiro, & Ferreira, 2009; Ornetti et al., 2008; Roos & Lohmander, 2003; Steinhoff & Bugbee, 2016). The KOOS is considered reliable for assessing baseline function and change over time in individuals with knee OA (Roos & Lohmander, 2003; Steinhoff & Bugbee, 2016). All subscales of KOOS have demonstrated adequate test-retest reliability with intraclass correlation (ICC) range of 0.85 to 0.90 (Collins et al., 2011; Roos & Lohmander, 2003). Several studies also reported that the KOOS demonstrates construct validity, with the KOOS more strongly correlated with subscales of the Short Form 36 (SF-36) that measure similar constructs of QoL (Goncalves et al., 2009; Roos & Lohmander, 2003). The KOOS appears to be responsive to change for physiotherapy treatment with large effect sizes of 0.88 seen at four weeks on the pain, symptoms, and ADL subscales; while the sport/recreation and QOL subscales have shown moderate effect sizes 0.05 (Collins et al., 2011; Goncalves et al., 2009; Ornetti et al., 2008).

#### *3.4.3.2 Knee Outcome Survey-Activities of Daily Living Scale for knee instability (KOS-ADL)*

A single question (Item 6) from a self-reported questionnaire from the KOS-ADL was used to measure knee instability (Irrgang, Snyder-Mackler, Wainner, Fu, & Harner, 1998). Instability is defined as a sensation of “shifting, buckling or giving way of the knee” (Fitzgerald et al., 2011; Irrgang et al., 1998). The KOS-ADL 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 OA (Irrgang et al., 1998). An ordinal scoring system was used to assign a value to the responses, with a

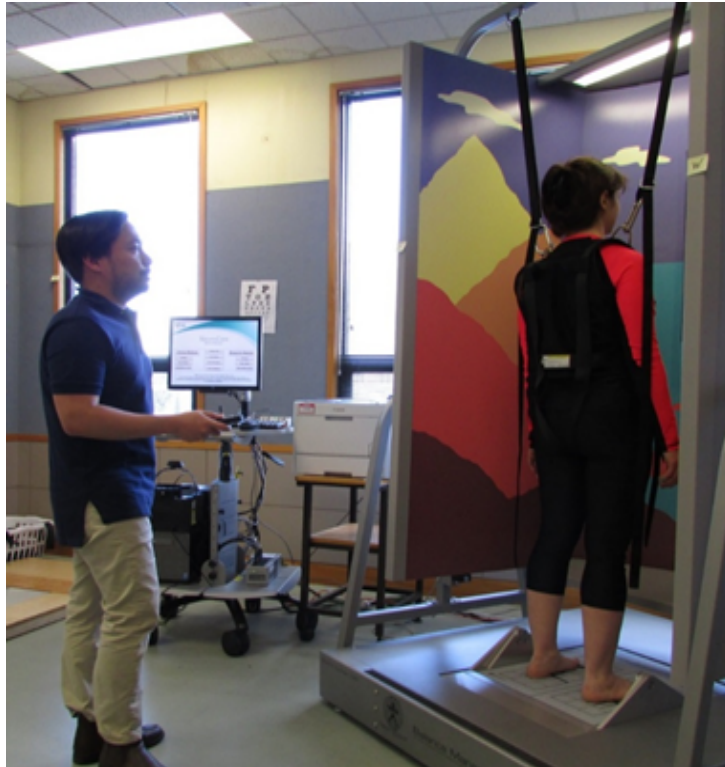
lower level of function resulting in a lower score (Irrgang et al., 1998). Selection of the single item 6 is commonly used in studies of knee instability (Mizner et al., 2011; Yoshida, Mizner, Ramsey, & Snyder-Mackler, 2008).

The KOS-ADL scale is a reliable and valid instrument that is responsive to change in patients with a variety of knee conditions such as knee OA who are undergoing physiotherapy or orthopaedic procedures (Collins et al., 2011; Irrgang et al., 1998). The test-retest reliability ICC coefficient of KOS-ADL was 0.97 and validity has been demonstrated by moderately strong correlations with concurrent measures of function ( $r=0.66$  to  $0.75$ ), including the global assessment of function as measured on a scale ranging from 0 to 100 points in individuals with knee OA (Irrgang et al., 1998).

#### *3.4.3.3 Sensory Organization test (SOT)*

Individual with knee OA have been shown to have deficits in dynamic balance and mobility as compared to healthy controls (Takacs, Garland, Carpenter, & Hunt, 2014). In this thesis, dynamic balance was measured using the standardised Sensory Organization Test (SOT). The SOT was administered using the NeuroCom SMART EquiTest® Balance system version 8.6.0, a commercially available Computerised Dynamic Posturography (CDP) system (NeuroCom International Inc., Clackamas, Oregon, USA).

The NeuroCom SMART EquiTest® Balance system comprises a force platform and is supported by software on Microsoft Windows® XP. The force platform contains two movable force plates measuring 23 x 46 cm (9 x 18 inches) each, which are mounted on four force transducers to measure movement in two planes (X and Z directions). Another transducer is located under the connecting pin joint for the two platforms which measures shear forces in the Y direction (Monsell, 1997). The EquiTest® system also included a visual surround which is movable (Figure 3.2).



**Figure 3.2** NeuroCom Equitest® Balance Manager System (*with signed agreement for talent release-Appendix K*)

The SOT is the currently available gold standard test for investigating sensory information and organisation for balance (Cohen et al., 1996; Shumway-Cook, 2001). SOT assesses the ability of an individual to effectively use the three sensory inputs (vision, somatosensory, and vestibular), under six different testing conditions (Monsell, 1997; Nashner & Peters, 1990). It challenges postural control via sway referencing by altering the availability and accuracy of sensory information from these three systems (Nashner & Peters, 1990).

The six conditions of the SOT test are performed by standing on the force platform either with eyes open or eyes closed. The sway of the platform and the visual surround were referenced to the participant's sway, at a ratio of 1:1 (Ford-Smith, Wyman, Elswick, Fernandez, & Newton, 1995; F. B. Horak, Shupert, & Mirka, 1989; Nashner & Peters, 1990). Table 3.4 shows the six different conditions.

**Table 3.4** Sensory organisation test six conditions and sensory cues in NeuroCom Equitest® Balance Manager System

Condition	Situation	Available cues	Unavailable / Altered sensory cues
<b>Condition 1</b>	Eyes open, fixed support	Visual, vestibular, somatosensory	Nil
<b>Condition 2</b>	Eyes closed, fixed support	Vestibular, somatosensory	No vision
<b>Condition 3</b>	Sway referenced surround, fixed support	Vestibular, somatosensory	Altered vision
<b>Condition 4</b>	Eyes open, sway referenced support	Vision, vestibular	Altered somatosensory input
<b>Condition 5</b>	Eyes closed, sway referenced support	Vestibular	No vision, somatosensory altered
<b>Condition 6</b>	Sway referenced surround, sway referenced support	Vestibular	Vision altered, somatosensory altered

Two measures were obtained and retained for further analysis namely the Equilibrium Score (ES) and the Composite Score (CS). ES, expressed as percentage balance, is reflective of how a participant can stay within a certain sway envelope or limit of stability during the SOT trials (Monsell, 1997; Venema & Karst, 2012). An ES score of 100% represents no sway, while 0 indicates completely loss of balance. The ES is the difference between the participant’s greatest anterior/posterior centre of gravity (COG) sway angle ( $\theta_{max}$ ) and the lowest anterior/posterior COG sway angle ( $\theta_{min}$ ) relative to the defined stability limits. Estimated by the accompanying software, ES is computed for each trial using the following equation:

$$ES = \frac{12.5 - (\theta_{max} - \theta_{min})}{12.5} \times 100$$

The Composite Score (CS) represents participant's overall level of performance on SOT, and it was used to represent the dynamic balance in this study. It is the weighted average of 18 ES across the six conditions with more weighting to conditions 3, 4, 5 and 6. It is calculated by adding the average scores of conditions 1 and 2, and average scores of condition 3, 4, 5, and 6 divided by the sum of number of trials. (Nashner & Peters, 1990). Similar with ES scores, the CS scores range from 0-100. A score of near 100 signifies minimal sway.

Ford-Smith et al., (1995) determined the test-retest reliability of the SOT, using computer-generated scores and loss of balance episodes 40 older adults in a non-institutionalized setting (Ford-Smith et al., 1995). Analysis revealed fair to good test-retest reliability for computer-generated scores and good reliability for loss of balance across some conditions of the SOT. CDP has also been used among individuals with knee OA (Baert et al., 2013; Bressel, Wing, Miller, & Dolny, 2014; Lim & Lee, 2012; Venema & Karst, 2012; Visser, Carpenter, van der Kooij, & Bloem, 2008; Wegener, 1997). For instance, SOT was conducted using the Equitest® balance system to assess anticipatory postural adjustment during a standing reaching task in adults with knee OA during pre- and post- total knee replacement and compare to healthy age- and sex-matched control group (Venema & Karst, 2012). CDP using Equitest® balance system was also used to compare the balance of individuals with knee OA and healthy adults and to determine the effect of knee OA on dynamic balance by matching gender, age, mass, height, and body mass index (BMI) (Park, 2018).

#### *3.4.3.4 Hand-held dynamometer (HHD)*

The isometric muscle strength was measured using a hand-held dynamometer (HHD) (Nicholas MMT, Model 01160, Lafayette Instruments, Lafayette, Indiana). This device is valid and highly reliable for testing between trials and days (Trudelle-Jackson, Jackson, Frankowski, Long, & Meske, 1994). It also provides a reliable, quantitative method as compared to manual muscle testing in patients with knee OA (Hayes & Falconer, 1992). In community dwellers of older adults, the test retest strength reliability (ICCs) of HHD were high ranging from 0.95 to 0.99 (Wang, Olson, & Protas 2002). It was also investigated that knee extensor and flexor muscle strength recorded with a HHD is reproducible and significantly correlated with the isokinetic values, indicating that this method may in some cases be a useful replacement for isokinetic strength measurement (Muff et al.,

2016). However, there are conflicting results with respect to limits of agreement (LOA). In a systematic review and meta-analysis of psychometric properties using HHDs, knee extension had a high LOA (33.59%, 95% C.I. 23.91 to 43.26) which indicates error in measurement and lower reliability (Chamorro et al., 2017). The HDD was selected as the method for assessing muscle strength in this study since it is inexpensive, portable and provides an objective measure of muscle strength (Ford-Smith, Wyman, Elswick, & Fernandez; Roy & Doherty, 2004). HHD as used in the current study provided measures of muscle strength in kilograms (kg).

#### 3.4.3.5 *Timed-Up and Go Test (TUG)*

The Osteoarthritis Research Society International (OARSI) recommends a set of performance-based tests of physical function for use in clinical trials that are best suited for individuals diagnosed with hip and knee OA (Fitzgerald et al., 2015). One of the recommended tests is the Timed Up and Go Test (TUG) (Shumway-Cook et al., 2000) This simple test can easily assess functional mobility. The test measures the time (seconds) taken to rise from a standard chair with armrests (seat height approximately 44 cm), walk 3 metres as fast as they can without losing balance, turn 180°, walk back to the chair, and then sit down (Podsiadlo & Richardson, 1991; Sackley et al., 2005). Use of usual walking aid is allowed and recorded. TUG has an inter-rater reliability of ICC = 0.98 -0.99 and an intra-rater reliability of ICC = 0.97-0.98 in older adults (Sackley et al., 2005; Shumway-Cook et al., 2000) and in patients diagnosed with knee OA (Alencar et al., 2007; Mat et al., 2015). TUG was selected among the set of physical performance measures since it can target both dynamic balance and physical function. Also, this is to limit participants burden.

#### 3.4.4 | Procedures

All the assessments were performed by the principle investigator (PI). PI underwent specialist training in the use of the EquiTest® Balance system. During the baseline assessment, the PI explained the purpose and procedure of the assessment to the participants, before obtaining written informed consent. Demographic data including age, gender, ethnicity, weight, height, and BMI were collected. Falls characteristic and history of falling in the past 12 months were also collected. Participants completed self-administered



questionnaires (KOOS, KOS-ADL), then performed balance, strength, and physical function testing (Assessment Form – Appendix L).

A safety harness was provided to ensure the safety of the participants while performing the SOT on the EquiTest® Balance system (Figure 3.3). The harness straps were placed tight enough to prevent injury should the participant fall, but loose enough (allowing one or two fingers between harness and body) to prevent the participant’s movement from being restricted. All participants performed the SOT with bare feet. Participant’s positioning on the force plate was standardised according to manufacturer’s recommendations. After positioning, the participants were advised to adopt a relaxed upright standing posture (Figure 3.3). All participants completed three trials each, of the six sensory testing conditions, with each trial lasting for a duration of 20 seconds.



**Figure 3.3** Set-up and position of the participant on the EquiTest® balance system machine- the safety harness (left) and foot placement (right) on the force plate (*with signed agreement for talent release-Appendix K*).

The muscle testing using HHD was done in two positions – in prone for knee flexors (hamstrings) and in sitting for knee extensors (quadriceps). These were performed on the involved and then the uninvolved side. For both group of muscles, strength was measured first at 90° allowing movement not exceeding the position of 70 – 90° of flexion. The knee was extended as close to full extension as possible. A 0 – 20° of flexion was also permitted. If the participant could not assume the prone position, the participant was tested in sitting.

The participants were instructed to hold maximally and match the pressure exerted through the HHD for 3 seconds without moving the limb, thus producing an isometric contraction (Figure 3.4a and 3.4b).

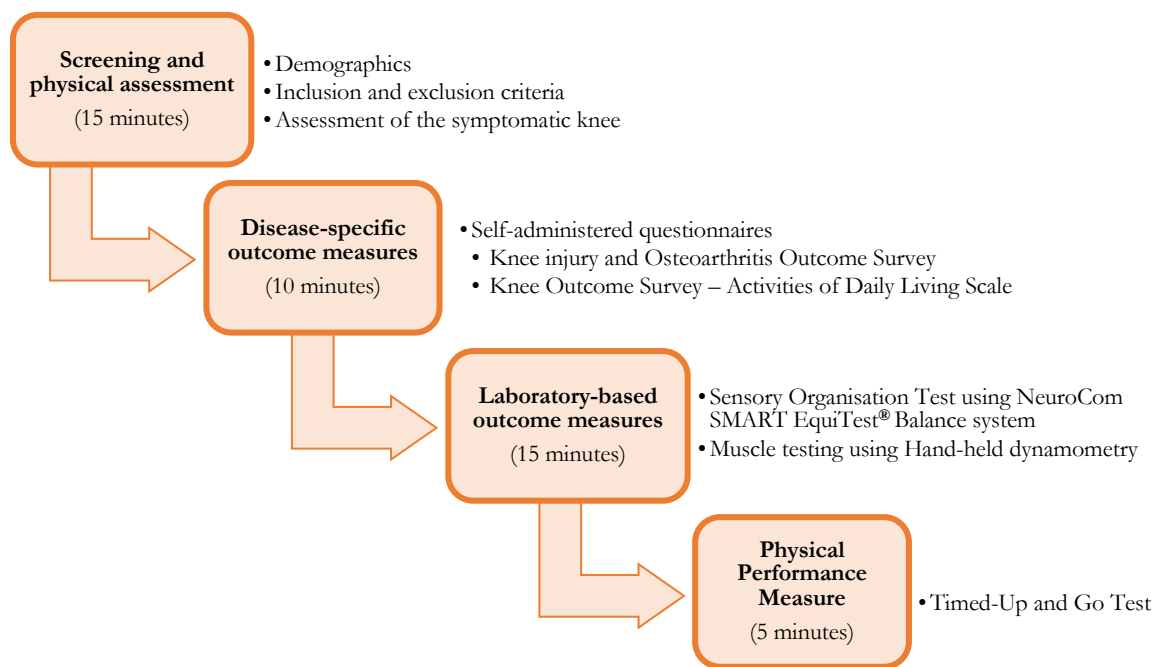


**3.4a** Measuring quadriceps muscle in sitting position at 90 degrees and at 0 degrees (with *signed agreement for talent release- Appendix K*).



**3.4b** Measuring hamstrings muscle in prone position at 90 degrees and at 0 degrees (with *signed agreement for talent release -Appendix K*).

The TUG was the final assessment performed. Figure 3.5 summarises the order of testing and duration of tests. To ensure standardisation of the testing procedure, the order was the same for all participants.



**Figure 3.5** Summary of the tests and measures conducted during the assessment of participant.

### 3.5 | Data management and analysis

#### 3.5.1 | Data management

The data were entered into a Microsoft Excel™ sheet manually by the PI, then examined for correctness and completeness by a second investigator. After the data in the Excel spreadsheet was verified, the data SPSS software was used for statistical analysis (SPSS, version 25, IBM Inc., Chicago, IL).

The KOOS scores were calculated using the scoring guide and Microsoft Excel files that are freely available online ([www.koos.nu](http://www.koos.nu)). The subscale scores were calculated independently using the following formula:

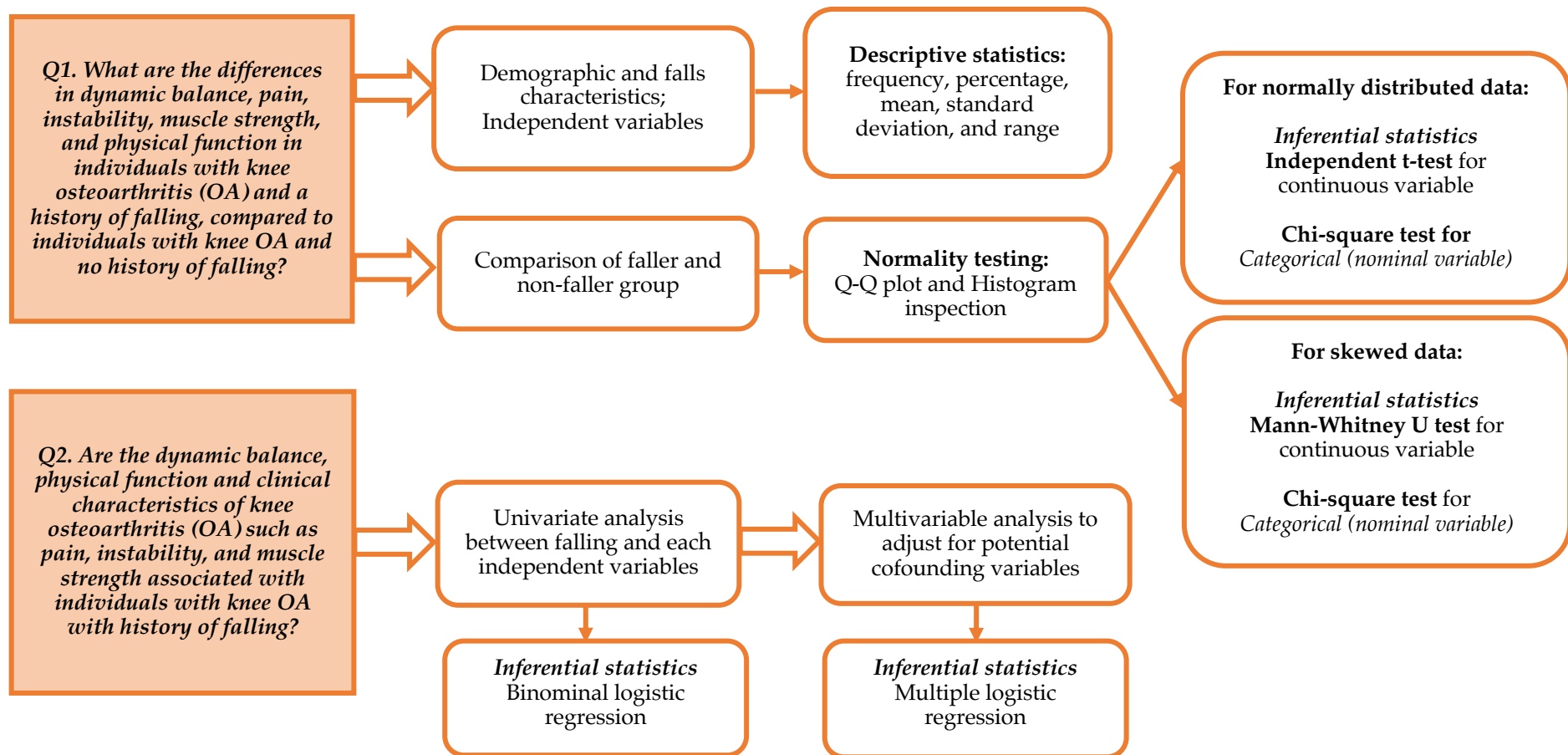
$$\text{Pain subscale} = 100 - \frac{\text{Mean score (P1 - P9)}}{4} \times 100 = \text{KOOS Pain}$$

For missing data, if a mark was placed outside a box, the closest box was chosen. If two boxes were marked, the one that indicated the more severe problem was chosen. As recommended in the KOOS guideline, as long as at least 50% of the subscale items for each subscale were answered, a mean score can be calculated (Roos & Lohmander, 2003). However, in this study, no missing data was found since all items in the questionnaire were inspected by the PI before proceeding to the next part of the assessment.

All SOT data obtained from the Equitest® balance system were extracted and transferred to Microsoft Excel. A sample output of the results was provided in this thesis (Appendix M).

### 3.5.2 | Data analysis

Descriptive statistics were used to characterise the participants in the study, distinguishing between those with and without a history of falls. Participants were grouped as ‘faller’ and ‘non-faller’ based on the 12-month history of falling. The mean and standard deviation were calculated for continuous data such as KOOS-subscores, ES and CS scores, TUG test scores, and knee muscle strength. Frequencies and proportions were used for knee instability as measured by the KOS-ADL (Item 6). Figure 3.6 shows the summary of statistical tests used in this study to answer the two research questions.



**Figure 3.6** Schematic diagram showing the different statistical analysis to answer the research questions of the study

The distribution of all variables included in the analysis was checked for normality using Q-Q plot and histogram visual inspection. Comparison between groups were computed using the independent t-test for normally distributed continuous variables. If the variable was skewed, comparison was done using the Mann-Whitney U test. Normality testing showed normal distribution of the population for all variables. The chi-square test was used for categorical variables namely sex, ethnicity, and symptomatic knee. A p-value of 0.05 or less in two-sided testing was used as criteria for statistically significant difference.

Univariate analysis using simple logistic regression was conducted to determine the association of each independent variable with the dependent variable. To address the second research question regarding the association, the independent variables examined were dynamic balance using ES, CS, and TUG scores, pain using KOOS-Pain subscale, instability using KOS-ADL for knee instability, muscle strength using the scores obtained from the HHD, and physical function using the TUG scores. The dependent variable was history of falling in last year (Yes/No). The OR and its 95% confidence interval (CI) were reported to identify the magnitude and direction of the association.

Variables with a p-value  $\leq 0.20$  from the univariate analysis were used to determine which variables would be included in the multivariable analysis. This p-value was selected based on the recommendation that using of higher level or the traditional level of significance ( $p < 0.05$ ) fails to identify variables known to be important during the preliminary screening (Greenland, 1989; Hosmer, 2013). Multivariable logistic regression analyses were conducted using the variables obtained from univariable analysis and adjusted analysis for the known confounders in knee OA which include age, gender, and BMI.

## **3.6 | Results**

### **3.6.1 | Participants characteristics**

Initially, 83 participants responded to the call for recruitment. Fourteen participants discontinued further participation due to either no follow-up/response ( $n=7$ ) or by not meeting the specified inclusion criteria ( $n=7$ ). Another six participants did not turn up for the assessment ( $n=6$ ). The study included a total of 63 participants.

A total of 63 participants with mean age ( $\pm$ SD) of 53.78 ( $\pm$ 16.17) were recruited in the study. Thirty females and 33 male participated in the study with the mean age of 54.02 and 53.78 years old, respectively. Most participants were of NZ European ethnicity (n=42), and five participants were Māori. Other participants were from the Philippines (n=6), Iran (n=3), Papua New Guinea (n=2) and one each (n=1) from Japan, Mexico, Ireland, Germany, and Sri Lanka. Of the 63 participants with knee OA, 31 (49%) reported one or more falls in the preceding 12 months. Of those with a history of fall, 12 (19%) reported to have had a fall in the past 12 months (single-fallers), and 19 (30%) have had more than one falls incident (multiple-fallers). In those with multiple histories of falling, the number of falls ranged from two to six times. Table 3.5 shows the summary of the falls characteristics of the included participants.

**Table 3.5** Participants' falls characteristics

Falls characteristics, n (%)	
Non-faller	32 (50.79)
Faller	31 (49.21)
Frequency of fall	
Single fall	12 (38.71)
Multiple falls	19 (61.29)
Activity during fall incident	
Walking	18 (28.57)
Sports/recreational activities	6 (9.52)
Stair negotiation	3 (4.76)
Household chores/gardening	3 (4.76)
Work-related activities	1 (1.59)
Location of fall	
Indoor	11 (17.46)
Outdoor	20 (31.74)

### 3.6.2 | Comparison between faller and non-faller group with knee OA

Normality testing using Q-Q plot and histogram visual inspection showed normal distribution of the population for all variables. Table 3.6 shows the comparison of the demographic characteristics of fallers and non-fallers. The results showed that the faller group were older and with higher BMI as compared to the non-faller group. Most of the participants with history of falling were of female gender and with bilateral symptomatic

knees. However, no significant difference ( $p < 0.05$ ) was found for all the remaining demographic characteristics.

**Table 3.6** Comparison of demographic characteristics of fallers and non-fallers with knee OA

Characteristics	Total (n=63)	Non-Faller (n=32)	Faller (n=31)	p-value
Age, mean $\pm$ SD	53.78 $\pm$ 16.17	52.06 $\pm$ 16.96	55.55 $\pm$ 15.40	0.397
Sex, n (%)				
Male	33 (52.38)	19 (59.38)	14 (45.16)	0.259
Female	30 (47.62)	13 (40.62)	17 (54.84)	
Ethnicity, n (%)				
NZ European	42 (66.67)	19 (59.38)	23 (74.19)	0.299
Maori	5 (7.93)	4 (1.25)	1 (3.23)	
Others	16 (25.40)	9 (28.12)	7 (22.58)	
Anthropometric Measurements, mean $\pm$ SD				
Height (cm)	169.3 $\pm$ 9.01	170.44 $\pm$ 10.07	168.03 $\pm$ 7.73	0.293
Weight (kg)	76.05 $\pm$ 22.26	74.16 $\pm$ 15.97	78.00 $\pm$ 15.68	0.339
BMI (kg/m <sup>2</sup> )	26.54 $\pm$ 7.03	25.46 $\pm$ 4.85	27.65 $\pm$ 5.62	0.102
Symptomatic knee, n (%)				
Right knee	24 (38.10)	14 (43.76)	10 (32.26)	0.253
Left knee	15 (23.80)	9 (28.12)	6 (19.35)	
Bilateral	24 (38.10)	9 (28.12)	15 (48.39)	

*Note.* NZ, New Zealand; SD, Standard deviation; cm, centimetre, kg- kilograms, sec- seconds; m<sup>2</sup>- meter squared

Table 3.7 shows the comparison of the independent variables between fallers and non-fallers with knee OA. The independent t-test suggested that the mean dynamic balance of the SOT Composite Score in the faller group was significantly reduced (mean  $\pm$ SD: faller=72.16 $\pm$ 3.26, non-faller=74.84 $\pm$ 4.77;  $p=0.012$ ), and the TUG test was significantly longer (mean  $\pm$ SD: faller=7.64 $\pm$ 1.29, non-faller=6.74 $\pm$ 0.78;  $p=0.001$ ) when compared with the non-faller group. Also, lower muscle strength of knee flexors and extensors were significantly less in the faller group in the two testing positions ( $p < 0.05$ ). No significant



difference was found between groups ( $p < 0.05$ ) for KOOS scores and presence knee instability.

**Table 3.7** Comparison of independent variables between fallers and non-fallers with knee OA

Independent variables Outcome measures	Total (n=63)	Non-Faller (n=32)	Faller (n=31)	95% C.I.	p-value
<b>Dynamic balance</b>					
Composite Score	73.52 ± 4.28	74.84 ± 4.77	72.16 ± 3.26	0.84-0.97	0.012*
Equilibrium Score-Condition 1	93.78 ± 5.04	90.53 ± 6.73	89.04 ± 2.22	0.89-1.24	0.547
Equilibrium Score-Condition 2	89.97 ± 7.43	89.28 ± 9.84	88.67 ± 3.36	0.93-1.28	0.215
Equilibrium Score-Condition 3	88.61 ± 5.62	86.83 ± 5.10	85.30 ± 6.09	0.87-1.10	0.620
Equilibrium Score-Condition 4	77.89 ± 12.28	77.21 ± 13.91	76.59 ± 10.30	0.97-1.08	0.541
Equilibrium Score-Condition 5	61.59 ± 14.44	61.10 ± 14.57	60.09 ± 14.29	0.96-1.06	0.717
Equilibrium Score-Condition 6	60.21 ± 16.14	62.54 ± 14.56	57.80 ± 17.30	0.21-0.91	0.072*
<b>Knee symptoms and related problems</b>					
KOOS-Pain	69.89 ± 16.58	73.09 ± 16.93	66.58 ± 15.80	0.95-2.00	0.120
KOOS-Symptoms	53.29 ± 11.57	53.24 ± 11.16	53.34 ± 12.16	0.35-1.56	0.972
KOOS-Activity, daily function	76.46 ± 16.87	79.37 ± 16.29	73.45 ± 17.19	0.58-1.97	0.166
KOOS-Sports-related Activity	46.59 ± 24.09	51.88 ± 23.89	41.13 ± 23.44	0.85-2.20	0.077
KOOS-QoL	54.17 ± 17.21	55.47 ± 16.71	52.82 ± 17.89	0.55-2.01	0.546
<b>Knee instability, n (%)<sup>a</sup></b>					
No instability (no buckling)	6 (9.50)	5 (15.63)	1 (3.23)	0.31-1.64	0.094
Presence of instability (buckling)	57 (90.48)	27 (84.37)	30 (96.77)	0.02-1.71	0.161
<b>Knee muscle strength, kg</b>					
Knee flexors 0°	7.93 ± 2.00	8.52 ± 1.79	7.34 ± 2.06	0.58-0.97	0.018*
Knee flexors 90°	8.26 ± 2.26	9.02 ± 2.11	7.47 ± 2.16	0.42-0.85	0.006*
Knee extensors 0°	9.32 ± 2.31	9.99 ± 2.32	8.65 ± 2.13	0.66-0.82	0.020*
Knee extensors 90°	9.73 ± 2.42	10.58 ± 2.33	8.86 ± 2.22	0.55-0.91	0.008*
<b>Physical function</b>					
Timed-Up and Go Test (sec)	7.18 ± 1.14	6.74 ± 0.78	7.64 ± 1.29	1.32-5.31	0.001*

*Note.* mean±SD reported \*significant at  $p < 0.05$ , <sup>a</sup> Chi-square test; QoL- Quality of life, KOOS- Knee injury and Osteoarthritis Outcome score, kg- kilograms, sec- seconds, CI – confidence interval

### 3.6.3 | Associations between clinical characteristics of individuals with knee OA and history of falling

Binominal logistic regression was used to analyse associations between the independent variables and history of falling in the preceding 12-month period. These univariate associations are presented in Table 3.8. Variables qualified with the set p-value of  $p \leq 0.20$  were considered for multivariable analysis except for knee flexor muscle strength at 0 and 90 degrees. Falling in the previous 12 months was associated with Composite Score (OR 0.85, 95% CI 0.74–0.97,  $p=0.017$ ), Equilibrium Score 6 (OR 0.96, 95% CI 0.91–1.01,  $p=0.120$ ), knee extensors strength [0 degrees (OR 0.76, 95% CI 0.66–0.82,  $p=0.025$ ) and 90 degrees (OR 0.71, 95% CI 0.55–0.91,  $p=0.008$ )], and TUG test (OR 2.65, 95% CI 1.32–5.31,  $p=0.006$ ) using univariate logistic regression analysis.

**Table 3.8** Results of univariate analysis for initial selection of variables

Independent variables	Outcome measures	OR	95% C.I.	p-value
Dynamic balance	Composite score	0.85	0.74-0.97	0.017*
	Equilibrium Score- Condition 1	1.05	0.89-1.24	0.551
	Equilibrium Score- Condition 2	1.10	0.94-1.28	0.246
	Equilibrium Score- Condition 3	0.97	0.86-1.10	0.614
	Equilibrium Score- Condition 4	1.02	0.96-1.08	0.535
	Equilibrium Score- Condition 5	1.01	0.96-1.06	0.712
Pain	Equilibrium Score- Condition 6	0.96	0.91-1.01	0.076*
	KOOS-Pain	0.98	0.95-1.00	0.120*
Instability	Presence of instability- buckling	0.18	0.02-1.64	0.128*
Knee muscle strength (kg)	Knee flexors at 0°	0.99	0.58-1.67	0.950
	Knee flexors at 90°	0.72	0.42-1.25	0.253
	Knee extensors at 0°	0.76	0.66-0.82	0.025*
	Knee extensors at 90°	0.71	0.55-0.91	0.008*
Physical function	Timed-Up and Go Test (sec)	2.65	1.32-5.31	0.006*

*Note.* OR= Odds Ratio, kg- kilograms, sec- seconds, SE- Standard Error, CI- confidence interval  
\*p-value  $\leq 0.20$

Multivariable logistic regression analysis identified associations between potential fall risk factors and falls in the preceding 12-months. Five variables obtained from the univariate analysis were entered into the model which included dynamic balance (CS and ES 6), pain (KOOS-Pain), muscle strength of knee extensors at 0° and 90°, and physical function (TUG). Composite Score (OR 0.86, 95% CI 0.73–0.98, p=0.049), knee extensors strength at 90° (OR 0.70, 95% CI 0.44–0.91, p=0.028), and TUG test (OR 1.65, 95% CI 1.85–4.21, p=0.006) showed significant association with the risk of falling (p<0.05).

To adjust for the confounding variables, age, gender, and BMI were entered into the model with five variables to obtain the adjusted OR (aOR). Composite Score (aOR 0.80, 95% CI 0.75–0.99, p=0.035), knee extensors strength at 90° (aOR 0.74, 95% CI 0.61–1.01, p=0.057), and TUG test (aOR 1.89, 95% CI 1.85–4.00, p=0.014) showed significant association with the risk of falling (p<0.05). Table 3.9 shows the results of the unadjusted and adjusted analysis.

**Table 3.9** Results of multivariate analysis for unadjusted and adjusted analysis

Independent variable		Unadjusted OR			Adjusted OR <sup>a</sup>		
		OR	95% C.I.	p-value	OR	95% C.I.	p-value
Dynamic balance	Composite score	0.86	0.73-0.98	0.049*	0.80	0.75-0.99	0.035*
	Equilibrium Score-Condition 6	0.95	0.89-1.02	0.124	0.94	0.89-1.02	0.124
Pain	KOOS-Pain	0.99	0.95-1.03	0.581	1.00	0.97-1.04	0.894
Instability	Presence of instability- buckling	0.40	0.30-5.26	0.128	0.21	0.02-2.05	0.180
Knee muscle strength	Knee extensors (kg) at 0°	0.28	0.77-0.82	0.025*	0.78	0.61-1.01	0.057
	Knee extensors (kg) at 90°	0.70	0.44-0.91	0.028*	0.74	0.34-0.81	0.030*
Physical function	Timed-Up and Go Test (sec)	1.65	1.85-4.21	0.006*	1.89	1.85-4.00	0.014*

*Note.* \* significant at p<0.05, <sup>a</sup>adjusted for age, gender, and BMI; BMI- Body Mass Index, OR- Odds Ratio, kg- kilograms, sec- second, CI- confidence interval, KOOS- Knee injury and Osteoarthritis Outcome Score

### 3.7 | Discussion

This study examines the strength of relationship between falling and clinical characteristics of individuals knee OA such as pain, instability, strength, dynamic balance, and physical function. The study demonstrated that 49% (31/63) of the participants with knee OA reported at least a fall during the 12 months preceding the assessment. Comparison of the faller and non-faller groups showed that participants with knee OA and history of falling had lower dynamic balance, weaker knee muscle strength, and poorer physical function ( $p < 0.05$ ). Lower dynamic balance demonstrated by CS, weaker quadriceps muscle measured by HHD showed association with increasing risk of falling. The decrease in physical function as measured by TUG test showed increased risk of falling by almost two-fold (OR=1.65,  $p=0.006$ , adjusted OR=1.89,  $p=0.014$ ).

#### 3.7.1 | Characteristics of falls in individuals with knee OA

The number of falls found in this study is considerably higher compared to the number of falls in older adult populations, which is approximately 15-33% (Rubenstein, 2006; Tinetti, 2003). However, findings in the current study are consistent with the previously reported prevalence of falls in individuals with knee OA: 48% (Levinger et al., 2011) and 64% (Williams, Brand, Hill, Hunt, & Moran, 2010), compared with a with healthy and age-matched sample in the preceding 12 months.

Interestingly, the majority of falls reported by the participants occurred outdoors (64.52%) as opposed to reports from the falls literature (Ambrose, Paul, & Hausdorff, 2013; Tinetti, 2003). Arguably, the location of falls may differ from age group and current activities. For instance, the MOBILIZE Boston study reported that indoor falls were associated with disability, indicators of poor health, and an inactive lifestyle, while outdoor falls were associated with an active lifestyle and with a good-to-average health condition (Kelsey et al., 2010). The latter description is comparable to the current study with mean age of 53.78 years, many of them were still working and engaged in recreational activities. This suggests that most of the participants recruited in this study can be considered relatively active despite the presence of knee symptoms such as muscle weakness and balance problems.

### 3.7.2 | Differences in the characteristics of fallers and non-faller with knee OA

The current study demonstrated that individuals with knee OA and history of falling had significant differences in terms of muscle strength and balance compared with those participants who did not fall. Lower limb muscle weakness is an important risk factor for falls in the ageing population (Moreland, Richardson, Goldsmith, & Clase, 2004) and a known predictor for onset of OA (Bennell, Wrigley, Hunt, Lim, & Hinman, 2013; Roos, Herzog, Block, & Bennell, 2011). A study by Sturnieks et al. (2004) identified knee extensors strength as an independent predictor of falls in older adults with lower extremity arthritis including knee OA (Sturnieks et al., 2004). However, their results were based on comparing patients with arthritis to a healthy sample of older adults with age range of 75 – 90 years old. It can be inferred that participants in their study might have been developing or already have weakness, which increases the likelihood of falling (Foley et al., 2006). Also, when comparing the knee muscle strengths of participants with and without history of falling, the current study showed not only significant difference in knee extensors but also in knee flexors strength as compared by previous studies demonstrating only knee extensors (Alencar et al., 2007; de Zwart et al., 2015).

The significant difference between the dynamic balance of fallers and non-fallers group in this current study concurred with a previous study that reported individuals with knee OA had deficits in dynamic balance and mobility as compared to healthy controls (Takacs, Garland, Carpenter, & Hunt, 2014). Sturnieks et al. (2004) showed participants with lower limb OA performed worse in tests for postural sway compared with a non-arthritic group (Sturnieks et al., 2004). Furthermore, increased knee pain and decreased muscle strength might be associated with increased postural sway (Hassan et al., 2001). The underlying mechanism behind this may be the disturbance of joint mechanoreceptors which may impair proprioception, and thereby result in decreased somatosensory information (Hassan et al., 2001; Leena Sharma et al., 1999). It was also suggested that balance is 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 (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004).

### 3.7.3 | Associations between clinical characteristics of individuals with knee OA and history of falling

This current study found dynamic balance to be associated with increased risk of falling. Impaired integration of somatosensory and neuromuscular information due to the presence of knee OA symptoms is proposed as a reason for the decline in balance performance (Alencar et al., 2007; Petrella et al., 2012; Sturnieks et al., 2004). However, a recent study challenged previous assumptions that the lower limb OA is linked with falls via reduced balance (Mat, Ng, & Tan, 2017). In the study of 102 participants with mean age of 73 years old, the authors postulated that falls do not necessarily occur because of knee symptoms such as pain or stiffness, due to effective compensatory strategies such as taking more time and avoiding positions that can compromise stability (Mat, Ng, & Tan, 2017). Authors argued that falls can be accounted for age-related deterioration of balance (Mat, Ng, & Tan et al., 2017). Thus, it should be acknowledged that both ageing process and presence of knee OA contribute in the decline of balance.

The use of SOT was an appropriate outcome measure to understand dynamic balance in a sensory-motor context. Dynamic balance as component of postural control can be examined from the perspective of physiological system. The sensory inputs for postural control are comprised of three systems: vision, vestibular, and somatosensory system (Hassan et al., 2001) and as highlighted above, these can be affected due to physiological changes as part of the ageing process. It should be noted that other studies used different variables in CDP to assess balance in knee OA such as such as limit of stability (Mat, Ng, & Tan, 2017), COG displacements (Petrella et al., 2012), and speed of movement (Alencar et al., 2007). Thus, a comprehensive balance assessment among individual with knee OA is required particularly tasks which are related to the dynamic balance (Hinman et al., 2002).

The current study demonstrated that weaker quadriceps muscle is associated with increasing likelihood of falling in individuals with knee OA. This is supported by previous studies reporting the inverse relationship between knee muscle strength and risk of falling (Alencar et al., 2007; Blagojevic et al., 2010; de Zwart et al., 2015). As previous, the debilitating effect of knee pain might be affecting the knee muscle function in two ways: loss of muscle strength due to decreasing physical activity, and/or a reflex inhibition of knee muscles generated by pain that has been suggested as one possible mechanism. The findings

in this current study partly corroborates with previous study were both knee extensor and flexor strengths were associated with increased number of falls (de Zwart et al., 2015). Regardless of the muscle groups affected, this important inverse relationship between knee muscle strength and risk of falling must be taken into consideration during assessment and management of knee OA.

It is not surprising that decrease in physical function, as defined by longer time to perform TUG test, was associated with almost two-fold increased risk of falling in this current study. A previous study compared the functional mobility between subjects with knee OA with and without history of falls found that fallers had significantly higher TUG scores (Alencar et al., 2007), which agreed with the results of this study. Moreover, the association of impaired balance and weakness of knee extensor muscles in this study might also compound the decrease in physical function, which in turn increase the risk of falling.

Pain is also recognized as the most common symptom affecting individuals with knee OA (Hunter et al., 2009) but was not established in this study. The findings might be in agreement with the suggestion that knee pain just partly explains the increased risk of falling (Hoops et al., 2012) and the increasing pain severity might be protective against falls (Alencar et al., 2007; de Zwart et al., 2015). Also, the study used only one outcome measure (KOOS-Pain subscale) which limits the assessment of knee pain. Thus, additional outcome measures for pain must be used and must include other domains such as psychosocial component due to its multidimensional aspect (Edwards, Dworkin, Sullivan, Turk, & Wasan, 2016).

Interestingly, no association was found between presence of knee instability and increasing risk of falling in this study despite of knee instability as a known contributor for falling in knee OA (Nevitt et al., 2016; Nguyen et al., 2014). Although self-reported knee instability is a common complaint of patients with knee OA (Fitzgerald et al., 2004; Knoop et al., 2012; van der Esch et al., 2012), it might be other factors such poor balance confidence and fear of falling, which were not measured in this cross-sectional study can fully explain the association (Nevitt et al., 2016).

### 3.7.4 | Strengths and limitations

This study collected main characteristics of falls such as history, frequency, and location. Congruent with published studies about falls in knee OA (de Zwart et al., 2015; Nevitt et al., 2016; Prieto-Alhambra et al., 2013), this study utilised a retrospective recall over a 12-month period to determine falls. Potential recall bias is a recognised limitation of this method. Retrospective recall has been shown to underestimate falls compared to prospective data collection, and actual fall rate might be even higher than reported (Hill et al., 2013). In this current study, of the participants who reported falling (n=31), 61.29% (n=19) reported multiple falls, which is similar with literature suggesting that a previous history of falling is a risk factor for future falls (Deandrea et al., 2010; Lord et al., 2007).

This study extends previous research by examining modifiable intrinsic risk factors for falls that are focused on a sample group of knee OA. The prevalence of falls and knee OA is expected to increase substantially in the future and examining the relationships between the risk factors for falls in the knee OA population could help identify a target for therapeutic interventions, and thus play a central role in fall prevention. The findings in this study contribute both to knee OA and fall literature by understanding the contribution and mechanisms between clinical symptoms of knee OA and falling.

The findings of this study must also be interpreted in light of several limitations. The use of HHD in measuring the strength of knee muscles may have introduced some measurement error during assessment. Also, difficulties in recalling information relating to the circumstances of the fall may have resulted in misclassification bias. To minimise such bias, a standardised questionnaire was used. While we aimed to examine important modifiable risk factors, other potential determinants of falls in knee OA such as range of motion, gait analysis, proprioception were not assessed. Lastly, the sample size was not met, and most of the participants were from NZ which limits the generalisability of current findings.

Cognizant of the fact that both ageing process and presence of knee OA symptoms have implications in the reduction of function, other factors such as psychological aspects related to falls such fear of falling (Nguyen et al., 2014), severity and duration of the condition (Dore et al., 2015), and extrinsic factors like influence of weather and uneven surfaces (Campbell, 2012) should also be investigated.



### **3.8 | Conclusion**

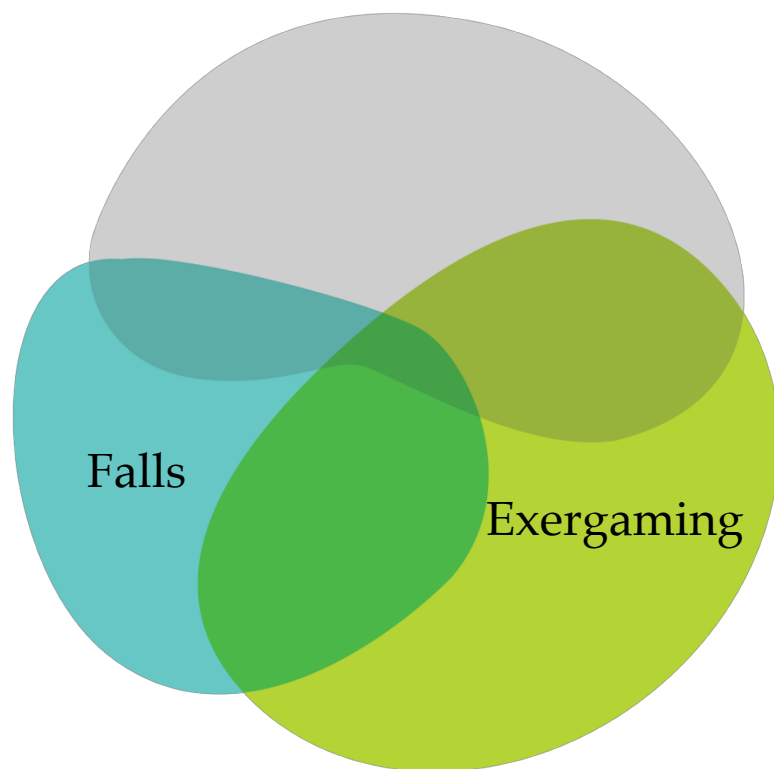
This study demonstrated that dynamic balance, knee muscle strength, and performance of physical function of participants with knee OA and history of falling were significantly reduced when compared with knee OA without history of falling. Lower dynamic balance, weaker quadriceps muscle, and poorer physical function showed association with the increasing risk of falling. Attention must be given to the assessment of functional activities to implement an appropriate intervention to reduce falls in this patient population. Other risk factors that contribute to falling in knee OA warrant further investigation. Furthermore, this present study suggests that falls assessment should be part of the routine in clinical practice and in the community. Monitoring the modifiable risk factors for falls in people with knee OA may assist in the creation of effective prevention strategies.

### **3.9 | Relationship of the study to thesis**

The results of this study corroborate with the identified risk factors for falls in knee OA found in the systematic review. The findings in this observational study strengthen that impairments such as decrease dynamic balance, weak knee muscle strength, and poor physical function are essential modifiable risk factors for falls in knee OA. This justifies that an intervention to target these impairments are worth of an investigation. The next sections propose for possible emerging intervention to address the risk factors for falls particularly balance.

# SECTION 2

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*"The best way to create value in the 21<sup>st</sup> century is to connect creativity and technology."*

*– Steve Jobs*

# CHAPTER 4

## A narrative synthesis of Nintendo Wii Fit™ gaming protocol in addressing balance among healthy older adults: what system works?

### 4.1 | Chapter overview

The optimal dose of exercise is an important component of exercise prescription. A tailored programme is also needed to maximise the beneficial effects of exercise. The contribution of this chapter is to address the lack of standard protocols and parameters such as frequency and duration utilised in exergaming. Importantly for the thesis investigation, it was necessary to undertake this review to inform the intervention protocol of the feasibility study (Chapter 5). The content of this chapter is published in *Games for Health Journal* (Manlapaz, Sole, Jayakaran, & Chapple, 2017).

### 4.2 | Background

Advances in technology could influence health care providers to create alternative and novel treatment options. With the use of popular video game-based exercises or ‘exergaming’ (Millington, 2015), systems such as Nintendo Wii Fit™ have evolved to become therapeutic tools for rehabilitation. As technology becomes more accessible, equipment such as the Wii Fit™ balance board could be an alternative way of assessing and training balance (Burns, Andeway, Eppenstein, & Ruroede, 2014; Clark et al., 2010). Preliminary evidence supports using exergaming as an intervention for older adults to maintain or improve physical function and reduce falls risk (Fu et al., 2015; Rendon et al., 2012). One pilot study demonstrated the safety and efficacy of using Wii Fit™ in an assisted living facility with a recommendation to explore this mode of exercise delivery via individualized training, supervised group classes or unsupervised use at home (Chao, Scherer, Wu, Lucke, & Montgomery, 2013).

A recent systematic review was conducted to determine the effect of Wii Fit™ based exercise in enhancing balance training in healthy older adults; however, results from the included studies were incomparable due to variability of study protocols (Laufer et al., 2014). Another systematic review was conducted that considered all available commercial video games including Wii Fit™ but investigated in a clinical population in terms of balance and motor function improvement (Bonnechere, Jansen, Omelina, & Van Sint Jan, 2016). Despite increasing number of studies investigating Wii Fit™ as a tool for balance, there is still lack of evidence for describing exercise dosage (frequency, intensity, and duration). Variability of gaming protocols, including intervention setting and game selection must be standardized to provide an effective balance exercise regimen in exergaming thus facilitating synthesis or comparison of results. To our knowledge, there is no in-depth review specific to balance intervention protocols focused to healthy older adults playing exergames using the Nintendo Wii Fit™ system.

The aim of this review was to synthesize the literature and present Nintendo Wii Fit™ gaming system protocols, which include game preference, intervention setting, and exercise dosage used in improving balance in healthy older adults. Also, this review identified safety and technical issues of the Wii system, and the outcome measures used in the Nintendo Wii Fit™ balance board intervention.

### **4.3 | Methods**

#### **4.3.1 | Data sources**

A literature search was performed in the following electronic databases from their inception to 2 May 2016: MEDLINE, PubMed, EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Scopus, Science Direct and Web of Science. Search terms such as (“older adult” OR “aging” OR “aged” AND “Nintendo Wii Fit” OR “Wii Fit” OR “exergaming” AND “balance” OR “postural balance”) were applied as keywords and subject headings.

#### 4.3.2 | Study selection

All peer-reviewed published papers with pre- and post-test study design and written in English were considered for inclusion. Inclusion criteria were set following a PICOS (Population, Intervention, Comparator, Outcome and Study design) approach.

<i>Population:</i>	Healthy adults with average age 65 years or older, with or without perceived balance problem, in any setting
<i>Intervention:</i>	Nintendo Wii Fit™ game-based exercise system
<i>Comparator:</i>	None or any
<i>Outcome:</i>	Self-reported questionnaires, functional assessment tools that measures that measure balance, postural sway and falls, Centre of Pressure (COP)
<i>Study design:</i>	Experimental study with random or non-randomized allocation, single group, intervention, prospective cohort study, single-subject design

Non-experimental or observational studies that focused on specific condition (neurologic, musculoskeletal, and vestibular) were excluded. Additionally, commentaries, conference proceedings, editorials, reviews, and theses were excluded. Reference lists of relevant articles during full-text screening were reviewed to identify additional articles that did not appear in the electronic search.

#### 4.3.3 | Data extraction

From the selected studies various data were extracted: study objectives, participants' demographics, study setting, study design, interventions, outcome measures and statistical test results. Further data extraction was done to identify the Wii Fit™ gaming system protocol including games that were used, the intervention setting that was implemented, and the dosage and progression that were prescribed. Technical and safety issues of Nintendo Wii Fit™ system were also extracted.

#### 4.3.4 | Data analysis

Descriptive statistics were used to describe the overall characteristics of the participants of the included studies. In terms of Wii Fit™ dosing data, range (minimum and maximum value), mean and standard deviation, and median were used to present the summary of the parameters in terms of frequency, number of sessions, and program duration. All data were analyzed using IBM Statistical Package for Social Sciences (SPSS) Statistics 23.

### 4.4. | Results

#### 4.4.1 | Study selection

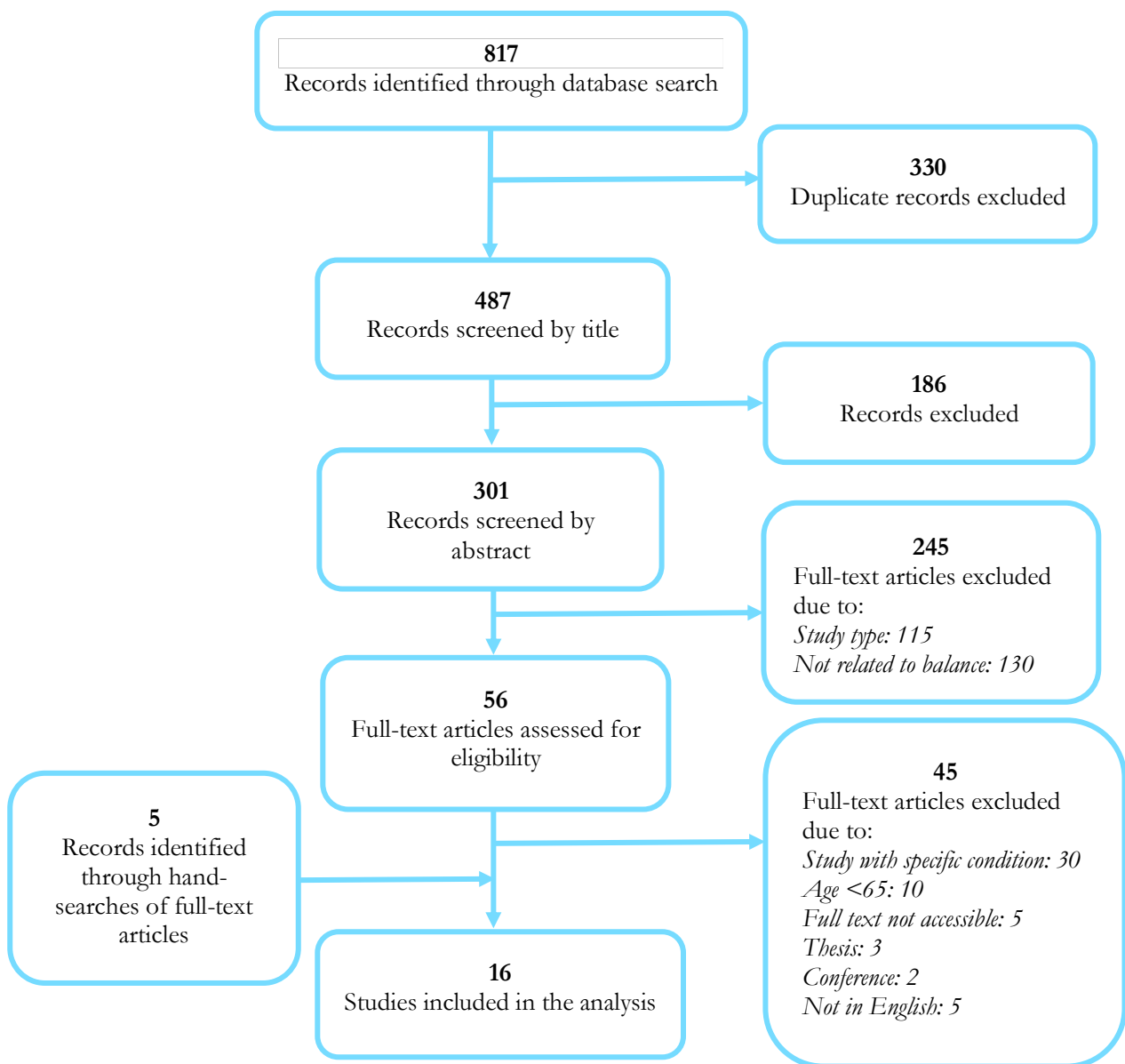
The electronic search identified 817 studies related to balance and Nintendo Wii Fit™ and 11 of those articles met the inclusion criteria (Agmon et al., 2011; Bainbridge, Bevans, Keeley, & Oriel, 2011; Bateni, 2012; Bieryla & Dold, 2013; Franco, Jacobs, Inzerillo, & Kluzik, 2012; Fu et al., 2015; Janssen, Tange, & Arends, 2013; Orsega-Smith, Davis, Slavish, & Gimbutas, 2012; Pluchino, Lee, Asfour, Roos, & Signorile, 2012; Rendon et al., 2012; Williams, Doherty, Bender, Mattox, & Tibbs, 2011). A further five articles were identified through hand searching giving a total of 16 studies included in the review (Chao et al., 2013; Cho, Hwangbo, & Shin, 2014; Jorgensen, Laessoe, Hendriksen, Nielsen, & Aagaard, 2013; Nicholson et al., 2015; Toulotte, Toursel, & Olivier, 2012). Figure 4.1 shows the results and the flow of the study selection.

#### 4.4.2 | Study participants and characteristics

The number of participants in each study varied between 7 and 60 participants, while mean age of the participants ranged between 71 and 85 years old. Overall, studies included more female (69%) than male (31%) participants. Participants came from the community (44%), nursing facility (31%), senior or retirement facility (15%) and clinic-based facility (10%).

Included studies determined the potential effect of Nintendo Wii Fit™ system on balance in a single cohort, or compared with passive control groups, or in combination with standard physiotherapy, balance exercises, Tai Chi, or physical activities. Different study

designs were utilized: seven experimental studies with random allocation (Cho et al., 2014; Franco et al., 2012; Fu et al., 2015; Jorgensen et al., 2013; Pluchino et al., 2012; Rendon et al., 2012; Toulotte et al., 2012), six experimental studies with non-randomized allocation (Bateni, 2012; Bieryla & Dold, 2013; Chao et al., 2013; Janssen et al., 2013; Nicholson et al., 2015; Orsega-Smith et al., 2012), and three single group intervention with pre-post-test design (Agmon et al., 2011; Bainbridge et al., 2011; Williams et al., 2011).



**Figure 4.1** Results and flow of the study selection

A variety of outcome measures were used to measure potential effects of Wii Fit gaming. The most commonly used tests employed were clinical and functional measures of balance, specifically Berg Balance Scale (BBS) (Agmon et al., 2011; Bainbridge et al., 2011; Bateni, 2012; Bieryla & Dold, 2013; Chao et al., 2013; Franco et al., 2012; Janssen et al., 2013; Orsega-Smith et al., 2012; Williams et al., 2011), Timed Up and Go Test (TUG) (Bieryla & Dold, 2013; Chao et al., 2013; Jorgensen et al., 2013; Nicholson et al., 2015; Orsega-Smith et al., 2012; Pluchino et al., 2012), and COP (Bainbridge et al., 2011; Chao, 2014; Cho et al., 2014; Jorgensen et al., 2013; Pluchino et al., 2012). Other measures used that include balance as part of the assessment were Physiologic Profile Assessment (Fu et al., 2015), Chair Stand test (Jorgensen et al., 2013; Orsega-Smith et al., 2012), Activities-Specific Balance test (ABC) (Bainbridge et al., 2011; Orsega-Smith et al., 2012; Pluchino et al., 2012; Rendon et al., 2012), Tinetti test (Franco et al., 2012; Pluchino et al., 2012; Toulotte et al., 2012), and Unipedal test (Toulotte et al., 2012).

Significant improvement in balance measures using BBS and TUG were reported in six studies that investigated within group changes for participants undertaking Wii Fit™ (Wii) (Agmon et al., 2011; Bainbridge et al., 2011; Chao et al., 2013; Nicholson et al., 2015; Orsega-Smith et al., 2012; Williams et al., 2011), and three studies between groups changes when the Wii Fit™ groups were compared to a control group (Nicholson et al., 2015; Orsega-Smith et al., 2012; Williams et al., 2011).

The included studies used inferential statistics to compare the pre-and post-test data, within and between groups. Parametric statistics were used in experimental studies with random allocation using paired and independent t-test for within and between groups, respectively (Chao et al., 2013; Cho et al., 2014; Fu et al., 2015; Jorgensen et al., 2013; Orsega-Smith et al., 2012; Williams et al., 2011). Mean and median difference, Wilcoxon ranked signed test and Mann-Whitney U test were used for those study that do not satisfy the condition of parametric measurement (Agmon et al., 2011; Bainbridge et al., 2011; Bateni, 2012; Bieryla & Dold, 2013; Janssen et al., 2013; Jorgensen et al., 2013; Rendon et al., 2012). One-way and repeated ANOVA were used for studies with more than three means or groups to compare (Franco et al., 2012; Pluchino et al., 2012; Toulotte et al., 2012).



**Table 4.1** Summary of included studies

Author (year)	Study Objective	Participants			Study Design	Methods		Findings Statistical Treatment Significant Results
		Sample Size	Age (SD)	Gender		Intervention	Outcome Measures	
Agmon et al., 2011	To determine the safety and feasibility of using Nintendo Wii Fit exergames to improve balance in older adults	7	84 (5)	Female 4 Male 3	Quasi-experimental single-group, pre-post-test design	<i>Wii group:</i> Three sets of balance games out of 4 possible games. Training sessions were provided to the participants.	BBS, Timed 4-meter test, PACES, Wii Game Scores	<i>Wilcoxon signed ranked test</i> BBS increased (p=0.017) Walking speed increased (p=0.018).
Bainbridge et al., 2011	To determine if 6-week intervention program using Nintendo Wii Fit balance board would lead to improvements in balance	8	75 (9.7)	Female 7 Male 1	Prospective, cross-sectional pilot, pre-post-test design	Session began and ended with 5 min warm-up and cool down. Games were played for 5 mins and progressed every 2 weeks. Two 1-min breaks were given.	BBS, ABC, Multi-Directional Reach Test, COP	<i>Wilcoxon signed ranked test</i> Improvement in BBS (p=0.066), ABC (p=0.753), COP (p=0.075) scores but not significant.
Batani et al., 2012	To determine the effectiveness of Wii Fit training on balance control in older adults compared with PT training	17	73 (13.7)	Female 9 Male 8	Quasi-experimental, repeated measure	<i>Three groups: PT + Wii group, PT Group and Wii Group.</i>  Wii intervention was repeated 3x in each training session. PT intervention was standard PT exercises to improved strength, posture and balance	BBS (all groups), Bubble Test scores (Wii and PT + Wii)	<i>Median differences, 95% CI</i> PT and PT + Wii showed greater improvement in BBS and Bubbles test than Wii only group.
Bieryla and Dold, 2013	To investigate the feasibility of using Nintendo's Wii Fit for training to improve clinical measures of balance and to retain the improvements after period of time.	12	81.5 (5.5)	Female 10 Male 2	Pilot experimental randomized controlled trial, pre-post-test design	<i>Wii Group:</i> consisted of yoga, aerobics, balance Wii game modes.  <i>Control Group:</i> normal daily activities.	BBS, Fullerton Advanced Balance Scale, Functional Reach, TUG	<i>Mann-Whitney U-tests and Friedman two-way ANOVA</i> Significant changed on BSS within Wii group (p = 0.037). No significant changed between groups for all outcome measures.

**Table 4.1** Summary of included studies (continued)

Author (year)	Study Objective	Participants			Study Design	Methods		Outcome Measures	Findings
		Sample size	Age (SD)	Gender		Intervention	Statistical Treatment Significant Results		
Chao et al., 2015	To investigate the physical and psychological effects of the Wii Fit exergames incorporating self-efficacy theory on assisted living residents	32	85.19 (6.47)	Female 24 Male 8	Quasi-experimental pre-post-test design	<i>Wii Group:</i> performed Wii games on their own pace and level with 4 types of exercise-yoga, balance, aerobics and strengthening.  <i>Education Group:</i> health education once a week for 1 month.	BBS-14, TUG, Depression GDS-15, Health-related QOL, Falls Efficacy Scale, Self-efficacy for exercise	<i>Paired t-test</i> Significant changed on BSS and TUG ( $p < 0.01$ ) within Wii Group  <i>Independent t-test</i> No significant changed between groups for all outcome measures.	
Cho et al., 2014	To determine the effects of virtual reality-based balance training on balance of the elderly	32	VR:73.1 (1.1) Control :71.7 (1.2)	Not reported	Two groups, pre-post-test design	<i>VR Group:</i> Wii fit balance board  <i>Control Group:</i> no intervention	COP	<i>Paired and unpaired t-test</i> Significant improvement for Eyes open and eyes closed ( $p < 0.05$ ) for virtual group. No improvement within control group or between two groups.	
Franco et al., 2012	To compare the effect of Nintendo Wii Fit to the Master Balance program on improving balance and well-being to decrease the risk of falls	32	78.27 (6)	Female 24 Male 8	Randomized group intervention study using a mixed design	<i>Wii group:</i> Wii games plus supplemental home exercise program  <i>Master balance group:</i> master balance program  <i>Control group:</i> no intervention	BBS, Tinetti Gait and Balance Assessment, SF -36, Wii Fit Enjoyment Questionnaire,	<i>Repeated measures ANOVA</i> Balance scores improved in all 3 groups but not statistically significant. BBS ( $p=0.837$ ), Tinetti ( $p=0.913$ ), SF-36 ( $p=0.256$ ).	
Fu et al., 2015	To use Nintendo's Wii Fit balance board to determine the effectiveness of exergaming training in reducing risk of falls	60	Wii group: 82.3 (4.3) Control :82.4 (3.8)	Female 39 Male 21	Randomized controlled clinical trial	<i>Wii Group:</i> Wii game exercises  <i>Control Group:</i> balance exercises	PPA, Falls incidence	<i>Independent t-test</i> Significant difference on post-test between groups.  <i>Negative Binomial Regression</i> Improved fall incidence rate ratio (IRR=0.31, 95% CI 0.17-0.57, $p<0.001$ ).	

**Table 4.1** Summary of included studies (continued)

Author (year)	Study Objective	Participants			Study Design	Methods		Outcome Measures	Findings
		Sample size	Age (SD)	Gender		Intervention	Statistical Treatment Significant Results		
Janssen et al., 2013	Investigate the effect of playing Nintendo "Wii Fit Plus" on body balance and physical activity of nursing home residents	29	G1: 84.5 G2: 81.5 G3: 80.0	Female 20 Male 9	Experimental with non-randomized allocation	G1: with Wii experience G2: without Wii experience G3: control	BBS, LASA Physical Activity Questionnaire	<i>Kruskal-Wallis test</i> Balance improvement for all groups but not statistically significant. No effect of playing Wii Fit Plus (p=0.89).	
Jorgensen et al., 2012	To determine if Wii training could lead to improvements in strength, balance, and functional performance, and motivational effect	58	75 (6)	Female 40 Male 18	Randomized controlled clinical trial	<i>Wii Group:</i> Wii game exercises <i>Control Group:</i> daily use of ethylene vinyl acetate copolymer shoe insole	Maximal muscle strength, COP velocity, TUG, Fall Efficacy Scale, Rapid force capacity, 30-second repeated chair test	<i>Unpaired t-test</i> Significant difference between groups in all outcome measures in favour of Wii group except for COP velocity.	
Nicholson et al., 2015	To determine the effectiveness of Nintendo Wii Fit balance training in older adults	41	75.4 (5.4)	Female 27 Male 14	Experimental, two groups	<i>Wii Group:</i> Wii game exercises <i>Control Group:</i> continue with usual activities	TUG, Physical Activity Enjoyment Scale, Single leg balance, Gait speed	<i>Mean Difference</i> Significant improvements between groups in TUG, left single leg balance, lateral reach and gait speed (p<0.05).	
Orsega-Smith et al., 2012	To investigate the impact of Nintendo Wii Fit on functional and perceived balance measures in older adult population over 4 to 8 week program	25	71.60 (7.79)	Female 20 Male 2	Experimental pre-post-test design	<i>4 weeks Wii Group</i> and <i>8 weeks Wii Group:</i> Wii fit balance board <i>Control Group:</i> no intervention	BBS, Chair stands, TUG, ABC, Falls Efficacy Scale	<i>Paired t-test</i> Significant changes in the scores of chair stands, BBS, and ADL Scale for the 4-week group (p<0.05), and BBS, ABC for the 8-week group (p<0.05).	

**Table 4.1** Summary of included studies (continued)

Author (year)	Study Objective	Participants			Study Design	Methods		Findings	
		Sample size	Age (SD)	Gender		Intervention	Outcome Measures	Statistical Treatment Significant Results	
Pluchino, et al., 2012	To compare the impact of Tai Chi, standard balance exercise and Wii board on postural control and perceived fall risks	40	72.5 (8.40)	Female 25 Male 15	Randomized controlled clinical trial	<p><i>Tai Chi Group</i>: exercise based on Sun-style program twice a week</p> <p><i>Balance Group</i>: standard balance exercise consisted of 14 functional activities</p> <p><i>Wii Group</i>: Wii fit games divided in categories: yoga, aerobics, balance, and strength training</p>	TUG, One-leg stance Functional reach, Tinetti Performance Oriented Mobility Assessment, COP, Dynamic Posturography, Falls risk and Falls Efficacy Scale	<i>Repeated-measures ANOVA</i> No significant difference seen between groups for all outcome measures except for significant time difference seen for total COP.	
Rendon et al., 2012	To determine the feasibility and outcome using WBB for improvement of dynamic balance in older adults classified as fall risk individuals.	40	VR: 85.7 (4.3) Control : 83.3 (6.2)	Female 26 Male 14	Experimental pre-post-test design	<p><i>VR Group</i>: Wii fit balance board with warm-up and cool-down on a stationary bicycle</p> <p><i>Control Group</i>: no intervention</p>	8-foot Up and Go, ABC Geriatric Depression Scale	<i>Mann-Whitney U-test</i> Significant improvement on 8-foot Up and Go and ABC for VR group ( $p=0.038$ ).	
Toulotte et al., 2012	To compare the effectiveness of three protocols (Adapted PA, Wii Fit and Adapted PA + Wii Fit) on the balance of independent senior subjects	36	75.09 (10.26)	Female 22 Male 14	Case comparison study	<p>G1: Adapted Physical Activities training program</p> <p>G2: Wii Fit training</p> <p>G3: : Adapted Physical Activities and Wii Fit training program</p> <p>G4: No training</p>	Tinetti Test, Unipedal Test, Wii Fit Test	<i>One-way and Two-way ANOVA</i> Significant decrease ( $p<0.05$ ): Tinetti Test for static (G1, G2, G3) and dynamic (G1, G3), and Unipedal test (G1 and G3).	

**Table 4.1** Summary of included studies (continued)

Author (year)	Study Objective	Participants			Study Design	Methods		Outcome Measures	Findings	
		Sample size	Age (SD)	Gender		Intervention	Statistical Treatment		Significant Results	
Williams et al, 2011	To explore the benefits of Nintendo's Wii Fit activities on the balance of 22 community living older adults	22	83.86 (5.47)	Female 18 Male 4	Quasi-experimental, pilot, pre-post-test design	Wii Fit intervention includes balance and aerobic exercises	BBS	<i>Paired t-test</i>	Significant improvement on BBS score ( $p < 0.01$ ).	

*Note.* BBS- Berg Balance Scale, ABC-Activities –specific Balance Confidence Scale, TUG- Timed Up and Go Test, ADL- Activities of Daily Living, COP- Centre of Pressure, PACES- Physical Activity Enjoyment Scale, PPA- Physiologic Profile Assessment, VR- Virtual reality, GDS- Geriatric Depression Scale, QOL: Quality of Life, SF-36: Short form-36, LASA- Longitudinal Aging Study Amsterdam, ANOVA- Analysis of variance, CI- Confidence Interval USA- United States of America, G1: Group 1, G2: Group 2, G3: Group 3 G4: Group 4.

#### 4.4.3 | Nintendo Wii Fit™ protocol

All included studies reported playing time, frequency or number of sessions per week, and program duration (Table 4.2). Most of the balance games were already pre-selected, and were combined with other exercises such as yoga, strengthening and aerobic exercises as part of the program. Only one study did not specify the Nintendo Wii Fit™ games used (Williams et al., 2011). Regarding game selection, Table tilt, Soccer heading, Ski slalom and Ski jump were the most commonly played games. Warm up and cool down exercises were also given. Variability of gaming protocols were reflected in the wide range of dosage given for Wii Fit™ intervention: playing duration varied between 15 and 80 minutes, frequency between once a week and 3 times a week, and program duration between 3 weeks and 20 weeks. Table 4.3 summarizes the range, mean and mean of the Wii gaming parameters. The most common frequency of Wii exergaming was playing the Wii game 3 times per week, with a duration of 30 minutes per session for 6 weeks. While the extracted data revealed variability and inconsistency in terms of dosing and outcome measures used, a further analysis was conducted. The study was grouped based on the most common playing time (30 minutes) and outcome measures used (BBS and TUG). Improvement on balance was reported in four studies that had 30 minutes (Bieryla & Dold, 2013; Nicholson et al., 2015; Orsega-Smith et al., 2012) and three studies with over 30 minutes of playing Wii Fit™ games (Chao et al., 2013; Pluchino et al., 2012; Toulotte et al., 2012). Three studies which utilized <30 minutes of playing Wii Fit™ games reported no significant changed (Batani, 2012; Franco et al., 2012; Janssen et al., 2013).

In all studies, potential safety issues were addressed by providing supervision and orientation of participants. In addition, researchers were trained on how to use and implement the Wii Fit™ system and program. Equipment such as chairs and walkers were placed in front and at the side of the participants for support to ensure their safety (Bieryla & Dold, 2013; Chao et al., 2013; Janssen et al., 2013; Rendon et al., 2012; Toulotte et al., 2012). Rest periods between intervals were also given. Three studies did not explicitly mention any supervision while playing Wii (Cho et al., 2014; Orsega-Smith et al., 2012; Pluchino et al., 2012). Technical issues, such as setting up the Wii Fit™ system and troubleshooting were not reported. However, technical assistance was provided in the form of monitoring in the form of telephone call and follow-up visits (Agmon et al., 2011; Bainbridge et al., 2011; Rendon et al., 2012). No calibration was reported in any included study.

**Table 4.2.** Extracted Wii Fit™ gaming protocol

Study	Intervention details						Intervention issues	
	Wii Gaming		Wii Dosage				Wii Safety Issues	Wii Technical Issues
	Setting, Supervision	Balance Game	Exercise Duration	Frequency	Program Duration	Wii Progression		
<b>Agmon et al., 2011</b>	Individual, Supervised to un-supervised	Basic step Soccer heading Ski slalom Table tilt	≥ 30 minutes per session	≥ 3 times per week	12 weeks	Monitored weekly progression	Monitoring and training sessions were provided.	Monitored through telephone call and visit.
<b>Bainbridge et al., 2011</b>	Individual, Supervised	Soccer heading Ski jump Ski slalom Tightrope walk Table tilt Penguin slide	30 minutes per session	3 times per week	6 weeks	Progression of games every 2 weeks	Two 1-min seated breaks were given in each interval	Active training time was measured using a stop-watch to avoid inaccuracy of the Wii timekeeping system.
<b>Batani et al., 2012</b>	Individual Supervised	Ski jump Ski slalom Table tilt	<30 minutes per session	3 times per week	4 weeks	No progression reported	Supervised exercise	No reported technical issues
<b>Bieryla and Dold, 2013</b>	Individual Supervised	Soccer heading Ski jump	30 minutes per session	3 times per week	4 weeks	Scores as basis of progression	Supervised exercise. Chairs were placed in front of and to the left and right of the balance board	No reported technical issues
<b>Chao et al., 2015</b>	Paired, Supervised	Basic turn Lunge Penguin slide Table tilt Chair Deep Breathing	60 minutes per session	2 times per week	4 weeks	Increased repetition of game during the 3 <sup>rd</sup> week	Trained researched assistance. Walker was placed on around the board	No reported technical issues

**Table 4.2** Extracted Wii Fit™ gaming protocol (continued)

Study	Intervention details						Intervention issues	
	Wii Gaming			Wii Dosage			Wii Safety Issues	Wii Technical Issues
	Setting, Supervision	Balance Game	Exercise Duration	Frequency	Program Duration	Wii Progression		
<b>Cho et al., 2014</b>	Individual Supervised	Ski slalom Table tilt Bubble balance	30 minutes per session	3 times per week	8 weeks	No progression reported	No reported safety issue	No reported technical issues
<b>Franco et al., 2012</b>	Individual Supervised	Soccer heading Ski jump Ski slalom Tightrope walk Table tilt Balance bubble	10-15 minutes per session	2 times per week	3 weeks	Progression of the game during the 3 <sup>rd</sup> week	Self-reported fatigue and motivation were documented	Used Wii Fit Bank for average time per game
<b>Fu et al., 2015</b>	Individual Supervised	Soccer heading Table tilt Balance bubble	60 minutes per session	3 times per week	6 weeks	No progression reported	Supervision of trained rehabilitation assistant	No reported technical issues
<b>Janssen et al., 2013</b>	Paired Supervised	Table tilt, additional games not reported	10-15 minutes per session	2 times per week	12 weeks	Progression by adding new games	Chair was placed in front	No reported technical issues
<b>Jorgensen et al., 2012</b>	Individual Supervised	Table tilt Ski slalom Perfect 10 Tightrope walk Penguin slide	60-80 minutes per session	2 times per week	10 weeks	No progression reported	Monitoring of adverse events during intervention	No reported technical issues



**Table 4.2** Extracted Wii Fit™ gaming protocol (continued)

Study	Intervention details						Intervention issues	
	Wii Gaming			Wii Dosage			Wii Safety Issues	Wii Technical Issues
	Setting, Supervision	Balance Game	Exercise Duration	Frequency	Program Duration	Wii Progression		
<b>Nicholson et al., 2015</b>	Paired, Un-supervised	Soccer heading Penguin slide Ski slalom Ski jump Table tilt Snowball fight Perfect 10 Tightrope walk	30 minutes per session	3 times per week	6 weeks	No progression reported	Familiarization, orientation, and monitoring	No reported technical issues
<b>Orsega-Smith et al., 2012</b>	Individual Supervised	Ski jump Ski slalom Balance bubble Table tilt Penguin slide	30 minutes per session	2 times per week	4 or 8 weeks	No progression reported	No reported safety issue	No reported technical issues
<b>Pluchino, et al., 2012</b>	Individual Supervised	Soccer heading Ski slalom Ski jump Table tilt Tightrope walk River bubble Penguin slide Snow slalom Lotus focus	60 minutes per session	2 times per week	8 weeks	Progression by increasing the number of games and duration of play	No reported safety issue	No reported technical issues

**Table 4.2** Extracted Wii gaming protocol (continued)

Study	Intervention details						Intervention issues	
	Wii Gaming			Wii Dosage			Wii Safety Issues	Wii Technical Issues
	Setting, Supervision	Balance Game	Exercise Duration	Frequency	Program Duration	Wii Progression		
<b>Rendon et al., 2012</b>	Individual Supervised	Lunges Single leg extension Twist	35-45 minutes per session	3 times per week	6 weeks	No reported progression	Gait belt Chair in front Assistive devices	Assistance in operating the system
<b>Toulotte et al., 2012</b>	Individual Supervised	Soccer heading Ski jumping Yoga Downhill skiing Game balls Tightrope	60 minutes per session	once per week	20 weeks	Encouraged to increased level of performance	Chair in front	No reported technical issues
<b>Williams et al. 2011</b>	Group, Supervised	Not reported	40 minutes per session	3 times per week	4 weeks	No reported progression	Experienced researcher using Wii Fit training	No reported technical issues

**Table 4.3** Dosing of Nintendo Wii Fit™ exergames from included articles

Parameters	Minimum value	Maximum value	Mean (SD)	Median
<b>Playing time (minutes)</b>	15	70	37.81 (16.53)	30
<b>Number of sessions</b>	6	36	17.38 (7.11)	18
<b>Program duration (weeks)</b>	3	20	7.56 (4.34)	6

*Note.* SD, standard deviation

## 4.5 | Discussion

The review aimed to synthesise Nintendo Wii Fit™ exergaming protocols in terms of gaming, intervention setting, exercise dosing, and intervention issues. Balance outcome measures used in the studies were also identified and summarised in this review. Sixteen studies used a Wii Fit™ system to improve balance of healthy older adults above the age of 65 years.

Included studies had a wide range in number of participants, frequency of intervention session and interaction time with each game. Different outcome measures and study designs were used in the included studies, making it difficult to make recommendations based on the accumulated evidence available. It should also be highlighted that most of the included studies reported small sample size which limits generalisability of the results. Only two of the studies reported *a priori* sample size and power of the study (Janssen et al., 2013; Jorgensen et al., 2013).

### 4.5.1 | Gaming selection and setting

Games were pre-selected based on the judgement of the researchers in 12 out of 16 studies. Some studies rationalised reasons for choosing the games based on description of movements and the objectives of the game (Agmon et al., 2011; Fu et al., 2015; Nicholson et al., 2015; Pluchino et al., 2012) while other studies allowed participants to select their own games (Chao et al., 2013; Jorgensen et al., 2013; Nicholson et al., 2015; Williams et al., 2011). One of the limitation of available games, or so called “off-the-shelf” gaming, is lack of modification and customization. Interestingly, only two studies highlighted the importance of using the same Wii games uniformly for all participants (Bainbridge et al., 2011; Bateni, 2012). Uniform use of games would lessen the bias and the threats in internal validity of the experiment (McMahan, Ragan, Leal, Beaton, & Bowman, 2011). Three included studies maximised the Wii Fit™ gaming features instead (Agmon et al., 2011; Bainbridge et al., 2011; Bieryla & Dold, 2013).

The exercise programmes were performed differently: as individuals (Agmon et al., 2011; Bainbridge et al., 2011; Bateni, 2012; Bieryla & Dold, 2013; Cho et al., 2014; Franco et al., 2012; Fu et al., 2015; Jorgensen et al., 2013; Orsega-Smith et al., 2012; Pluchino et al.,

2012; Rendon et al., 2012; Toulotte et al., 2012), together with a partner (Chao et al., 2013; Janssen et al., 2013; Nicholson et al., 2015) or in groups (Williams et al., 2011). Supervision while playing the game was seen in all except for two studies, which gave positive results: one study used a progression of supervised to unsupervised Wii Fit™ training (Agmon et al., 2011), and a second study investigated 6 weeks of unsupervised Wii Fit™ gaming (Nicholson et al., 2015). Group participation in exercise has been suggested to be beneficial in older adults (Millington, 2015; Sherrington et al., 2008). However, only one included study in this review used group exercise as the type of interaction, compared to the majority of the studies wherein participants played the game individually (Williams et al., 2011). One possible reason maybe technical difficulties to set-up a group exergaming using Wii Fit™.

#### 4.5.2 | Dosing and progression of exercise

There was a lack of information about optimal dosing, or any guidelines on the specific games, frequency and duration to be used for the Wii Fit™ system. There was large variability of protocols in the included studies. One study determined the game duration based on participants' comfort and confidence (Agmon et al., 2011) while another study used two sessions per week based on a typical physiotherapy plan of care (Bainbridge et al., 2011). In general, these aspects of study protocols were poorly reported with 12 out of 16 failing to justify exercise dose. Arguably, dosage of exergaming should consider modification of gaming components to match the changing health needs of ageing individuals.

It is recommended that for balance exercise programmes to have an effect they must be of sufficient duration (Sherrington et al., 2008). One study investigated if Wii Fit™ exergaming would have an effect after 4 weeks or after 8 weeks of training and results suggested that changes in balance outcome measures were seen at the beginning of the fourth week (Orsega-Smith et al., 2012). These findings were replicated in another study where improvement in BBS scores were seen in the fourth week (Bieryla & Dold, 2013). A recent systematic review and meta-analysis was done on dose-response relationship of usual balance training for older adults aged 65 and above (Lesinski, Hortobágyi, Muehlbauer, Gollhofer, & Granacher, 2015). The review concluded that a training period of 11-12 weeks, a frequency of 3 sessions per week and a duration of 31-45 minutes for each training session is needed to improve balance performance of healthy older adults (Lesinski, Hortobágyi, Muehlbauer, Gollhofer, & Granacher, 2015). The median values presented in Table 4.3 are a good representation of typical exercise parameters. The median values of playing Wii Fit™

for 30 minutes, 3 times a week in this review appears to be in agreement with the systematic review recommendation (Lesinski, Hortobágyi, Muehlbauer, Gollhofer, & Granacher, 2015). Furthermore, comparing the durations of the included studies, playing Wii Fit™ games ≥30 minutes showed significant improvement in terms of balance measure BBS and TUG. However, intervention duration of 6 weeks is far from the recommended 11-12 weeks of training period. The Wii Fit™ gaming interventions previously used may not be long enough to detect significant balance improvement.

Defining the intensity of exercise and guidelines for progression of Wii Fit™ exergaming were described inconsistently. Progression of the exercise regimen of playing Wii Fit™ system was based on increasing the number of games, challenging the participants to move on the next level and increasing the playing time. As part of progression, one study included Wii Fit™ exergaming as home exercise program (Franco et al., 2012).

#### 4.5.3 | Safety and technical issues

Safety and technical difficulties were mostly monitored with phone calls and written logs (Agmon et al., 2011; Bainbridge et al., 2011; Franco et al., 2012; Rendon et al., 2012). As presented, supervision was the most commonly reported way to address safety of the participants. However, findings of Nicholson et al. suggest that unsupervised gaming is also safe and effective (Nicholson et al., 2015). Regarding adverse responses, only two studies mentioned episodes of neck pain and back pain during the initial attempt of playing Wii but this subsided with further use (Agmon et al., 2011; Bainbridge et al., 2011). There were no incidents of falls reported in any included studies. Surprisingly, no equipment calibration was reported in any of the selected studies. Although Wii Fit™ was used as an intervention and not as an outcome measure, calibration is still needed to ensure that the data and features of Wii Fit™ system are accurate (Leach, Mancini, Peterka, Hayes, & Horak, 2014) to ensure the dose is as prescribed and consistent. The ability to detect precise measurement can be affected by deformation due to frequent loading since the material properties of Wii Fit™ balance board is one of its limitation as compared to laboratory-grade force plate (Leach, Mancini, Peterka, Hayes, & Horak, 2014).

#### 4.5.4 | Outcome measures

Variability of outcome measures affected the findings of our review. Included studies used outcome measures ranging from commonly utilized clinical balance tests such as BBS and TUG, which were easy to administer, to a more complex equipment such as systems that can detect balance changes in postural sway and centre of pressure. Studies using standard outcome measures were reported problems with the use of BBS and TUG due to ceiling effects (Agmon et al., 2011; Bainbridge et al., 2011; Bateni, 2012; Bieryla & Dold, 2013). Meanwhile, three studies used Wii as an outcome measure by using Wii Bubble and Wii Score features (Agmon et al., 2011; Bateni, 2012; Toulotte et al., 2012). Future research should investigate how Wii Fit™ features compare to clinical balance outcome measures.

#### 4.5.5 | Limitations

While the results of the included studies highlight potential use of Wii Fit™ for improving balance, there are limitations to this review. The review excluded unpublished studies and papers not written in English which may contain pertinent data related to dosing. Variability among the studies in terms of Wii intervention protocols and outcome measures used make it difficult to compare or pool findings from different studies. Although the focus of this review was to identify key features of a Wii Fit™ protocol for training balance, the lack of evaluation of methodological quality of each included study is a limitation. As the objective of the study was to identify Nintendo Wii Fit™ protocols, all study types were included. Given this heterogeneity, the overall strength of evidence on effectiveness of the Wii Fit intervention for balance was not possible.

#### 4.5.6 | Recommendations

To further improve research on exergaming, a fully-powered randomised controlled study should be conducted to identify the optimal dosage of exercise and other parameters of exercise programmes. No study has provided a detailed rationale for possible mechanisms of action, or the physiological basis for the reported significant changes in balance. Future exergaming research protocols should include a scientific rationale for decisions such as intervention duration. In the absence of mechanism-based justification of dose parameters, the findings of this review are based on the frequency and median. Further studies should also address methodological issues, include longer follow-up periods and examine gaming adherence. Careful consideration of the outcome measures to be used is also recommended

to standardise the testing protocol and ensure findings are comparable with other studies. The number of outcome measures selected should also be considered to lessen the burden of assessment for the participants. Although falling outside the scope of our study, perspectives of the user and the influence of psychological and social aspect in exergaming must also be part of future studies.

#### **4.5 | Conclusion**

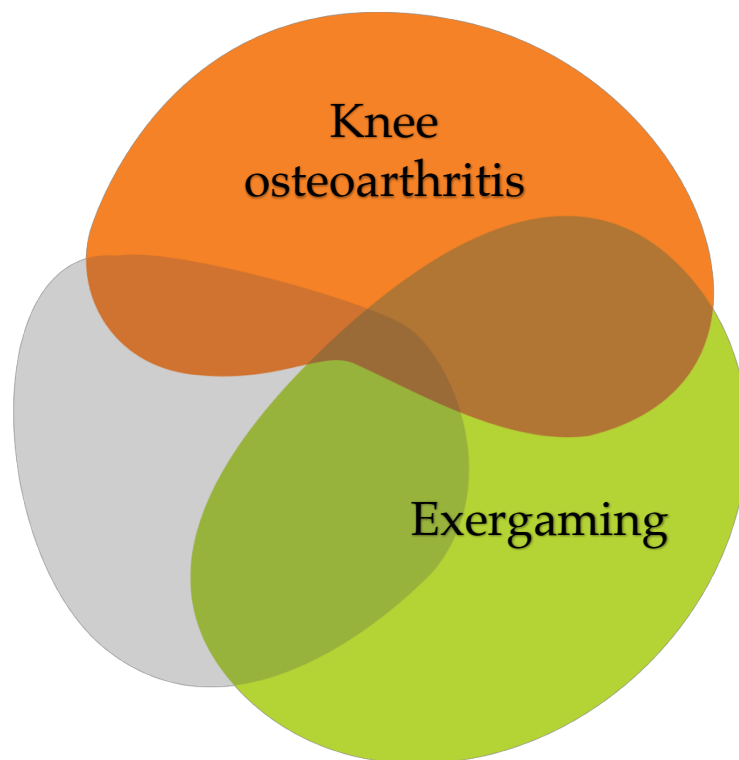
This narrative synthesis reviewed four aspects of exergaming research protocols using Wii Fit™ balance for healthy older adult: game preference, intervention setting, and exercise dosage . Game selection for balance training showed a preference for Wii games Table tilt, Soccer heading, Ski slalom and Ski jump. The interventions were delivered in a clinical setting. The most frequent dosage was three times per week, with a duration of 30 minutes per session for 6 weeks. BBS, TUG, and COP were the most commonly used outcome measures. Wii Fit™ exergaming is an alternative to improve balance if safety and technical procedures are provided. With the conflicting evidence on optimal dosage presented, exergaming parameters require further research before firm recommendations can be made. Clinically, effective dosage is an important component in any type of intervention and exergaming should not be an exception. To date, the search for the best exergaming regimen for addressing balance among older adult continues.

#### **4.6 | Relationship of the study to thesis**

This chapter serves as a bridge between exergaming and falls as part of the issues being investigated in this thesis. The first section has established the risk factors that contribute to falling in individuals with knee OA. Dynamic balance and strength are two of the risk factors for falls identified in Section 1 and being targeted by exergaming. This chapter presents the use of the Nintendo Wii Fit™ as an exergaming tool to inform the feasibility study and justify the dosage and parameters used in the next section.

# SECTION 3

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*"A journey of a thousand miles begins with a single step"*  
– Lao Tzu



# CHAPTER 5

## **Exergaming to improve balance and decrease the risk of falling in adults with knee osteoarthritis: a feasibility study**

### **5.1 | Chapter overview**

This chapter describes the final study of the thesis that investigated the use of exergaming in individuals with knee OA and history of falling. It begins with the description of the type of mixed methods approach and the common methods used. This is followed by a separate description of the methods, results, and discussion of the two parts (Part 1: Quantitative phase and Part 2: Qualitative phase). Lastly, an integrated discussion is presented by merging the interpretation of the quantitative and qualitative findings including the strengths and limitations of the study.

Components of this feasibility study were conceptualised and informed by the results of the previous chapters. Chapters 2 and 3 have presented research focusing on the risk factors for falls in individuals with knee OA. The increased number of falls in a knee OA group and intrinsic modifiable risk factors that contributed to falling were identified. These risk factors included dynamic balance, knee muscle strength, and performance of physical function. Chapter 4 showed that parameters to target improvements in balance have not yet been established (Batani, 2012; Fu, Gao, Tung, Tsang, & Kwan, 2015). A narrative review reported in Chapter 4 was conducted to synthesise published evidence on Nintendo Wii Fit™ exergaming. The results of the review suggested that the most commonly used protocols in playing Wii Fit™ game was 30 minutes, three times weekly for six weeks (Manlapaz, Sole, Jayakaran, & Chapple, 2017). However, strong recommendations could not be developed due to conflicting evidence on optimal dosage. The synthesis of findings from review studies was used to inform the design of the final study.

## 5.2 | Background

Exercise is recommended as one of the key interventions in clinical guidelines for managing knee OA (Fransen et al., 2015; McAlindon et al., 2014; Pisters et al., 2007). Likewise, international groups such as American College of Rheumatology (ACR), Osteoarthritis Research Society International (OARSI), and European League Against Rheumatism (EULAR) advocate that individuals with knee OA engage in physical activities and exercise programmes, to relieve symptoms and to improve muscle strength, joint range of motion, and aerobic endurance (Fransen et al., 2015; McAlindon et al., 2014; Pisters et al., 2007). Video-game technologies such as exergaming are among novel interventions demonstrating clinical effectiveness for a range of health conditions seen in rehabilitation (Bonnechere, Jansen, Omelina, & Van Sint Jan, 2016; Skjæret et al., 2016).

The majority of published articles investigating the use of exergaming included healthy and patient populations where the latter mostly had neurologic conditions such as Stroke, Parkinson's disease, and Multiple Sclerosis (Laufer, Dar, & Kodesh, 2014; Laver et al., 2012). The use of exergaming in individuals with knee OA is limited. Furthermore, the use of exergaming for balance in this population has not been investigated. Several games have been developed to increase physical fitness and balance, yet it is unclear to what degree exergaming programmes are useable, safe and acceptable for individuals with knee OA (Skjæret et al., 2016). Thus, a feasibility study is an initial step to evaluate trial protocols and procedures and should be conducted before determining effectiveness of the intervention.

Feasibility studies are important step in conducting a fully powered definitive trial (Whitehead, Sully, & Campbell, 2014). They can address elements of the planned trial and ensure it will be conducted in a manner that reduces threats to study validity (Tickle-Degnen, 2013). A feasibility study explores intervention-specific issues, such as protocols, and effectiveness (Bowen et al., 2009; Craig et al., 2012). Feasibility studies are also used to test the methods proposed for use in the main study such as recruitment process, retention rate, intervention acceptance, compliance and safety (Arain, Campbell, Cooper, & Lancaster, 2010). Lastly, a feasibility study is not expected to have the large sample sizes that are needed to adequately power statistical hypothesis testing since this study just aims to identify and assess practicality issues in conducting future RCT of a particular intervention in a particular setting (Arain, Campbell, Cooper, & Lancaster, 2010).

The primary aim of the current study was to investigate the feasibility and acceptability of exergaming in improving balance and decreasing the risk of falling in individuals with knee OA. The specific objectives were as follows:

- Determine the success of the recruitment strategy of individuals with knee OA and history of falling;
- Determine the retention rate of the participants over a 16-week period study programme;
- Determine the compliance of the participants in an eight-week exergaming balance intervention;
- Report adverse effects and safety;
- Calculate clinical outcome scores of knee OA symptoms, instability, balance, physical function, falls risk and fear of falling to provide preliminary estimates of treatment effect;
- Explore participants' acceptability and experiences of exergaming using the Nintendo Wii Fit™.

### 5.3 | Methods

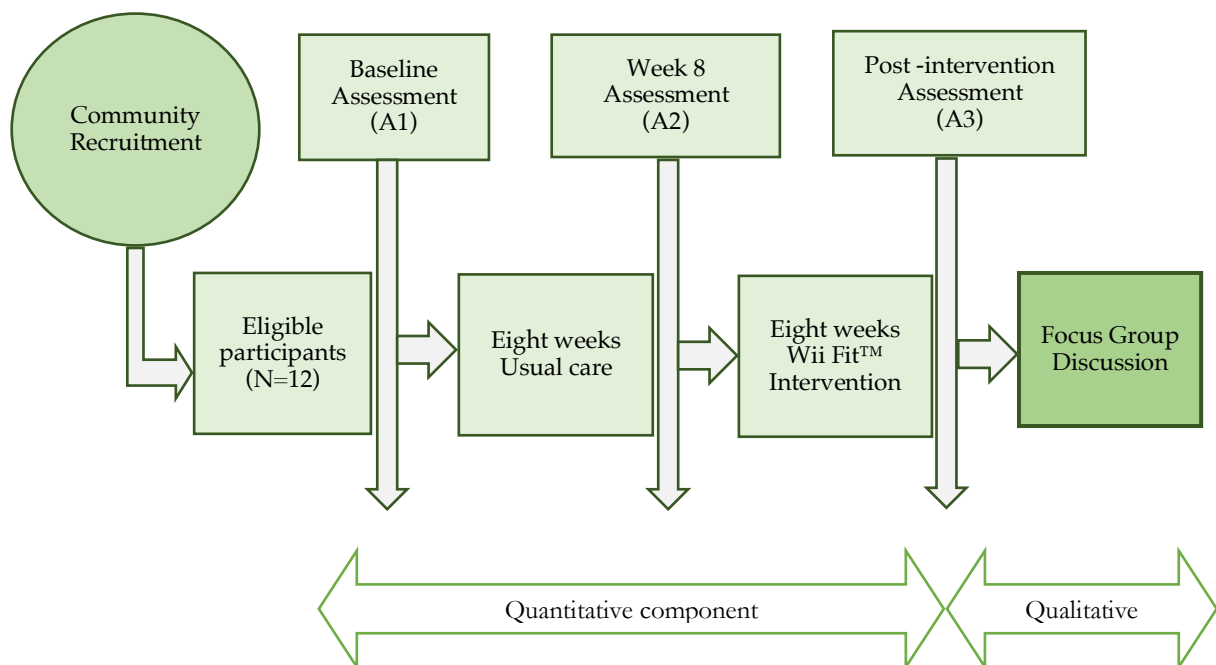
This study is reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) statement extension for pilot and feasibility study (Eldridge et al., 2016). The reporting of the qualitative phase was guided by Consolidated Criteria for Reporting Qualitative Studies (COREQ) (Tong, Sainsbury, & Craig, 2007). The study protocol is registered prospectively with Australian New Zealand Clinical Trial Registry (ANZCTR) reference: ACTRN12617000154303 (Appendix N).

#### 5.3.1 | Study design

To address the objectives of this study, a mixed methods, explanatory sequential study design was conducted consisting of two-distinct phases: a quantitative phase followed by a qualitative phase (Creswell, 2011). The first phase (quantitative component) was a single-group pre-post experimental study design. Participants in first phase participated over a 16-week period with three assessment time points: baseline (A1), after eight weeks (A2), and post-intervention assessment (A3) after 16 weeks as part of the quantitative phase.

During the first eight weeks, eligible participants continued with their usual activities and did not use the Nintendo Wii Fit™. After the eighth-week assessment (A2), participants commenced with the Wii Fit™ exergaming programme for eight weeks.

The qualitative phase followed after completing the post-intervention assessment. Participants were invited for a focus group discussion. Semi-structured focus groups were conducted to explore patient perceptions about the feasibility of the study and their experiences while using the Nintendo Wii Fit™ as an exergaming tool. Figure 5.1 shows the schematic diagram of the two components of the study.



**Figure 5.1** Schematic diagram of the quantitative and qualitative component of the study

Rationale for choosing mixed-method design was to further explain the results of quantitative component of the study. The qualitative data was used to elaborate on the quantitative findings of the first phase, providing deeper understanding of the research question. (Creswell, 2011). To ensure the rigour of this mixed-method design, important elements and factors were considered. These included timing of the components of study (sequential approach) and integration of the qualitative and quantitative components

(Creswell, 2011). The sequential timing was chosen due to the explanatory nature of this feasibility study and the distinct implementation of the two phases of the study. By comparison, an exploratory sequential design wherein qualitative data is collected first, followed by collection and analysis of quantitative data is use the purpose of developing an instrument such as survey, and classifying or identifying variables for testing (Creswell, 2011).

### 5.3.2 | Ethical approval

Ethical approval was obtained from the Health Disability and Ethic Committees (HDEC), reference: 17/STH/183 (Appendix O). Māori consultation was undertaken with the University of Otago Ngāi Tahu Research Consultation Committee prior to submitting the ethics application.

### 5.3.3 | Recruitment

Participants were recruited from Dunedin through community advertising. Recruitment took place from October to December 2017. The recruitment strategies that were used in the cross-sectional study were also utilised in this feasibility study (Chapter 3, Figure 3.1). To facilitate recruitment and the selection process, all participants from the cross-sectional study with history of falling were also invited to participate in the feasibility study.

### 5.3.4 | Eligibility of participants

A two-stage screening procedure was conducted: the first stage by the primary researcher (DM) and the second stage by one of the two assessors (RH or AA). First, potential participants underwent preliminary screening through telephone interview and email exchange by DM before attending the research centre at the School of Physiotherapy. Participants were asked if they had pain or soreness of the knee in the last seven days and a history of falling in the previous 12 months. If the participants answered yes for these two questions, the information sheet and informed consent were sent to the participants. Participants were given seven days to decide and an opportunity to ask questions regarding the study before agreeing to join. Interested participants were scheduled for assessment. The

second screening was done by one of the blinded assessors by applying the set inclusion and exclusion criteria.

This study applied the same inclusion and exclusion criteria as for the cross-sectional study (Chapter 3) and shown in Table 3.1. The main criteria for including participants were based on the ACR clinical criteria using history and physical examination for classification of knee OA (Altman et al., 1986), and history of falling. Since the participants were going to have the exergaming intervention, additional criteria were included in order to ensure safety. This included comorbidities that would preclude safe participation in mild to moderate exercise: uncontrolled or severe hypertension, cardiac arrhythmia, uncontrolled cardiovascular disease, unstable diabetes. The American Heart Association/American College of Sports Medicine screening questionnaire (Assessment form - Appendix P) was used to determine participant's risk in relation to any history of cardiovascular conditions and the level of assistance needed by the participants during the exergaming session (Medicine, 2013). Aside from safety, other considerations for inclusion in the study were access to television, willingness to set up the Wii Fit™ component at home, and ability to attend assessments and treatment over a four-month period. Lastly, participants with prior experience of using Wii Fit™ gaming were excluded to ensure that all participants who joined the study would have the same baseline experience. Table 5.1 shows the summary of inclusion and exclusion criteria for this feasibility study.

**Table 5.1** Inclusion and exclusion criteria used in the study

Inclusion criteria	Exclusion criteria
<p>OA of the knee: Clinical</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Knee pain (past 7 days for a month)</li> </ul> <p>At least 3 of 6:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Age &gt; 50 years</li> <li><input type="checkbox"/> Stiffness &lt; 30 mins</li> <li><input type="checkbox"/> Crepitus</li> <li><input type="checkbox"/> Bony tenderness</li> <li><input type="checkbox"/> Bony enlargement</li> <li><input type="checkbox"/> No palpable warmth</li> </ul> <p>Other considerations</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Access to television</li> <li><input type="checkbox"/> Willing for Wii Fit to be set up in home</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Previous lower limb injury / surgery in previous 12 months</li> <li><input type="checkbox"/> Consultation with orthopedic specialist for knee OA, or commencement of new medication for OA (previous 1 month)</li> <li><input type="checkbox"/> Presence of other forms of arthritis particularly inflammatory disease</li> <li><input type="checkbox"/> Having any treatment / physiotherapy management of the knee</li> <li><input type="checkbox"/> Inability to understand and comply with trial information or instruction</li> <li><input type="checkbox"/> Failed AHA/ACSM screening</li> <li><input type="checkbox"/> Unable to attend treatment sessions/assessments for 4-month period</li> <li><input type="checkbox"/> Previous use of Nintendo Wii Fit™</li> </ul>

*Note.* OA, osteoarthritis; AHA/ACSM, American Heart Association/American College of Sports Medicine

### 5.3.5 | Study setting

The study was conducted at the School of Physiotherapy, University of Otago. The assessments were done at Balance Clinic while the exergaming sessions were held in a designated room that contained the Wii Fit™ system set-up.

## Part 1: Quantitative Phase

The quantitative component of this feasibility study is discussed in the following sections. Methods utilised in the quantitative phase are presented first followed by the results of the primary outcome measures: feasibility of the intervention, and secondary outcome measures: clinical outcomes. This quantitative phase section is concluded with a discussion of the findings.

### 5.4 | Quantitative phase: methods

#### 5.4.1 | Interventions

##### *5.4.1.1 Usual care*

During the first eight weeks, participants continued with their usual daily activities and physical activities. Usual care is recognised as an appropriate and informative choice of the control arm in feasibility studies (Campbell et al., 2000). The inclusion of usual care allows for monitoring of expected variability of musculoskeletal condition such as OA, including symptoms' frequency and fluctuation (Campbell, Cooper, & Lancaster, 2010).

Participants were contacted during the eighth-week period to schedule the second assessment before commencing with the exergaming intervention. Contact information and residential addresses were also collected to set up the Wii Fit™ system in their home. The Risk Management Implementation Plan form (RAM) was completed prior to the visits to ensure that all possible risk in conducting the study were identified and actions to mitigate the risk were likewise addressed. The RAM form was approved by the School of Physiotherapy Health and Safety committee.

##### *5.4.1.2 Exergaming intervention*

The weekly sessions in the School were supervised by DM, who is registered with Physiotherapy Board of NZ and has experience in management of knee OA. The Nintendo Wii Fit™ consoles and accessories underwent systems check-up. The assistant technician of the School of Physiotherapy inspected the power of the consoles, syncing of sensor bars and remotes, and checked the batteries and rechargeable battery packs. A Wii Fit™ set was packed and readily available for home use.



In the narrative synthesis (Chapter 4), no equipment calibration was reported in any of the selected studies. In this study, the Wii balance boards were calibrated prior to use. This was to ensure that the data and features of Wii Fit™ system are accurate (Leach, Mancini, Peterka, Hayes, & Horak, 2014). The Wii Fit™ manual was also consulted for further instructions in calibrating the Wii Fit™ board.

During the first supervised session, a quick screening of the participants was conducted prior to exergaming. The screening included taking a relevant history and physical examination of the symptomatic/reference knee to determine the extent of participant's knee problem and any pertinent changes from the initial assessment at entry into the study. This was to ensure the safety of the participants prior to exergaming and to minimise risk of exacerbating potential current symptoms. Before the start of exergaming, the participants were registered in the Wii Fit™ system by creating a *Mii* avatar, a special character that was used for each session. This *Mii* avatar served as a profile to monitor the date of the session, time spent in playing Wii Fit™ games, and the progression of games. Participants were also asked to complete a recoding sheet for their home programme. Each participant received an exergaming kit folder which contained the games, instructions, diary calendar, and recording sheets. (Appendix Q).

Each training session was designed to include up to seven different Wii Fit™ games. The session began with a five-minute warm-up activity using the games from Aerobic exercises menu. This was followed by playing five Wii Fit™ games that focused on challenging the participant's balance. The first four Wii Fit™ games were pre-selected from the Balance Games menu. These pre-selected balance games were Soccer Heading, Table Tilt, Penguin Slide and Ski Slalom. Pre-selecting the game ensured that all participants were undertaking the same balance games exercise at baseline. It also served as the basis of exergaming progression. The fifth and last balance game was freely chosen by the participants from the Training Plus menu to enhance their gaming experience and to provide them a personal choice. The session ended with a cool-down exercise and Yoga. Table 5.2 shows the description of the main balance Wii Fit™ games selected in the study.

**Table 5.2** Description and movement requirements of the main balance games used in the study.

Game	Description	Movement requirements
<p data-bbox="347 315 523 342"><b>Soccer Heading</b></p> 	<p data-bbox="639 315 1059 696">Participants shifted weight from the left or right sides in order to head soccer balls on screen. Participants mimicked soccer players and took turns kicking soccer balls, cleats, or panda heads at each other. Participants scored a point if their head butted a soccer ball but lost a point if a cleat hit them, and three points if they were hit by a panda head.</p>	<p data-bbox="1091 315 1347 383">Weight shifting in mediolateral directions.</p>
<p data-bbox="384 757 485 784"><b>Table tilt</b></p> 	<p data-bbox="639 757 1038 1016">Participants tilted a board to roll marbles into holes by shifting their body weight. They had to carefully manipulate the board to roll the balls (visualised on the TV screen) into the holes without dropping a ball off the table</p>	<p data-bbox="1091 757 1374 1055">Weight shifting in mediolateral directions lead to a left–right tilting movement, and in anteroposterior directions to front–back movements of the virtually displayed platform or table.</p>
<p data-bbox="357 1077 512 1104"><b>Penguin Slide</b></p> 	<p data-bbox="639 1077 1066 1301">Participants shifted their weight right or left to tilt an iceberg and to 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. Game ends when time runs out.</p>	<p data-bbox="1091 1077 1347 1144">Weight shifting in mediolateral directions.</p>
<p data-bbox="373 1375 496 1402"><b>Ski Slalom</b></p> 	<p data-bbox="639 1375 1034 1525">Participants has to solve a ski slalom course from first-person perspective. Participants has to pass between two markers while controlling the speed.</p>	<p data-bbox="1091 1375 1369 1603">Player has to move on mediolateral direction to ski around the slalom poles and anteroposterior direction to control velocity</p>

Table 5.3 shows the different games of the Nintendo Wii Fit™ menu. The participants each performed for around five minutes or playing a game for two to three times with the summary of the Wii Fit™ protocol.

**Table 5.3** Summary of Wii Fit™ protocol and games used in the study.

Aerobic Exercises	Balance Games	Training Plus**	Yoga
Step Basics	Soccer heading*	Perfect 10	Deep breathing
Jogging	Table Tilt*	Obstacle Course	Half-moon
Hula Hoop	Penguin Slide*	Snowball Fight	Warrior
Step Plus	Ski Slalom*	Tilt City	Chair
Rhythm Boxing	Tightrope Tension	Table Tilt Plus	
	Balance Bubble	Balance Bubble Plus	
	Ski Jump	Basic Run Plus	
	Snowboard Slalom		

**Protocol of the Wii Fit™**

- Duration: 45 to 60 minutes per session
- Frequency: Three times a week (1- school session, 2- home sessions)
- Programme duration: Eight weeks

\* pre-selected balance games, \*\*optional games selected by the participants

During the supervised training, a stand-by assist (neither direct physical contact nor assistance given instead close enough for safety during the task being performed) was provided for participants. If needed, chairs were placed in front and to the left and right of the Wii Fit™ balance board for safety in case a participant lost balance. Participants were allowed to rest within the exercise time period as necessary. Borg’s Rating of Perceived Exertion Scale (RPE) was utilized to monitor the level intensity of the activity to keep the exercise at a comfortable level (Borg, 1962). Participants were advised to play at a RPE level between 11 (fairly light) and 15 (hard) for every game (Borg, 1962). Exergaming with the presence of other participants was allowed and participants were informed about this set-up. Figure 5.2 shows the set-up of Wii Fit™ room and participants who are playing Wii Fit™ games.



**Figure 5.2** Participants playing Nintendo Wii Fit™ during their school exergaming session.

During the succeeding sessions, the participants were asked to report current knee symptoms, any incidents of falls, changes in medication, and other pertinent information that might influence the study. The supervised sessions were also an opportunity to address any questions and for the physiotherapist (DM) to progress the exergaming programme. Wii Fit™ games were progressed every two weeks to maintain a challenging level of performance for the participants. Table 5.4 shows the list of different games progressed every two weeks. Participants were instructed to select from the list of games with the inclusion of the pre-selected balance games. If a participant did not want to change the game, progression was done by moving to the advanced stage of the game.

**Table 5.4** Selection of Wii Fit™ game as part of progressing the exergaming programme.

Wii Fit™ games	Week 1-2	Week 3-4	Week 5-6	Week 7-8
<b>Aerobic Exercises</b>				
Step Basics	✓	✓		
Jogging	✓	✓	✓	
Hula Hoop	✓	✓	✓	✓
Step Plus		✓	✓	✓
Rhythm Boxing				✓
<b>Balance Games</b>				
Soccer heading	✓	✓	✓	✓
Table Tilt	✓	✓	✓	✓
Penguin Slide	✓	✓	✓	✓
Ski Slalom	✓	✓	✓	✓
Tightrope Tension			✓	✓
Balance Bubble			✓	✓
Ski Jump				✓
Snowboard Slalom				✓
<b>Training Plus</b>				
Perfect 10	✓	✓	✓	✓
Obstacle Course	✓	✓	✓	✓
Snowball Fight		✓	✓	✓
Tilt City		✓	✓	✓
Table Tilt Plus				✓
Balance Bubble Plus				✓
Basic Run Plus				✓
<b>Yoga</b>				
Deep breathing	✓	✓	✓	✓
Half-moon		✓	✓	✓
Warrior			✓	✓
Chair				✓

The *Mii* avatar was also created for the respective Wii Fit™ systems provided for each participant for home-use within the eight-week exercise programme. They used the same *Mii* avatar at home as during the supervised sessions and played the same games. To monitor the home session, participants were asked to accomplish the exergaming recording sheet given them which included instructions, list of recommended games, and an exercise diary. The diary included a log of the games undertaken, time taken for the session and RPE levels at which the exercises were performed. Participants brought the exercise diary to each supervised session to monitor their performance and address any issues. Reusable batteries

and chargers were supplied and any difficulties with the use of Wii Fit™ system at home were discussed in person or via phone.

#### 5.4.2 | Assessors

Assessments were conducted by the two blinded assessors who screened the participants. They were trained in the administration of the questionnaires, balance measurement using the NeuroCom EquiTest® Balance system, conducting Physical Performance Measures (PPM) and Physiologic Profile Assessment (PPA). The assessors had a background in physiotherapy and had prior clinical experience in assessing patients with knee OA for at least three years. Prior to being involved in the study, the assessors underwent three training sessions provided by DM and two sessions with supervisors for the use of the NeuroCom EquiTest® Balance system.

#### 5.4.3 | Primary outcome measure: feasibility outcomes

The feasibility was evaluated based on recruitment, retention, compliance, and safety. Recruitment was measured by the number of participants recruited in three months. A formal sample size calculation was not performed given the feasibility nature of the study. A minimum of 12 participants based on the recommended sample size for preliminary studies was used to measure the success of recruitment (Julious, 2005). The rate of recruitment and the number of participants from the two sources (database of participants from cross-sectional and community advertisement) were also described. Retention was defined as the number of participants that completed all weeks of training and the post-intervention assessment. Compliance of the participant with the study programme was defined as the number of sessions attended and completed by the participants per week. The total compliance rate for the exergaming intervention was also obtained by dividing the number of sessions attended by the participants over the total number of sessions (24 sessions). Compliance rate for the supervised sessions at the School (8 sessions) and the unsupervised home sessions (16 sessions) were also determined. The exergaming folder with instructions, diary calendar, and recording sheets was used to monitor the compliance. Participants were also asked to complete a recording sheet for their home programme. Safety was also one of the considerations of this feasibility study. Adverse events were defined as untoward events

directly caused by the intervention. These events were recorded whether related or unrelated to the study.

A pragmatic criterion per feasibility outcome was set to determine if this study is feasibility, feasible with modification or not feasible. Table 5.5 shows the specific definitions and the set of *a priori* criteria that were applied. All criteria of the feasibility outcome measures should be met to consider the feasibility of the study. If two feasibility outcomes are not met, then the study is considered feasible with modification. In an event that all outcomes related to feasibility is not met, then the study is not feasible.

**Table 5.5** Feasibility outcomes definition and criteria for the success of the study.

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	6-11 participants	<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

#### 5.4.4 | Secondary outcome measure: clinical outcomes

Five of the seven clinical outcome measures used in this feasibility study were also utilised in the cross-sectional study. The description of these five outcome measures and their respective psychometric properties were detailed in Chapter 3. These outcome measures comprised of the five subscales of KOOS (pain, symptoms, functional activity, sports and recreation, QoL), SOT using NeuroCom Equitest™ balance system, muscle

strength using HHD, and physical performance measure using TUG. Since the study was also interested in the risk of falling, two additional outcome measures were included: Short form of the Physiologic Profile Assessment (PPA) and Short form of the Fall Efficacy Scale-International (FES-I). These two outcome measures are described in detail below. Tables 5.6 shows the summary of all the clinical outcome measures and their respective measurements.

**Table 5.6** List of clinical domains and corresponding outcome measures

Clinical Domain	Outcome Measure/Instrument
Dynamic balance	Sensory Organization Test using NeuroCom SMART Equitest® system, version 8.6.0 (Composite score)
Falls risk	Physiological Profile Assessment (PPA)
Knee OA symptoms	Knee injury and Osteoarthritis Outcome Score (KOOS) (KOOS- Pain, KOOS-Symptoms, KOOS-knee related Quality of Life, KOOS-Sports and recreation subscales)
Knee instability	Knee Outcome Survey – Activities of Daily Living Scale ( <i>Item 6</i> )
Knee muscle strength	Hand-held dynamometer using Nicholas MMT, Model 01160 Knee extensors and flexors at 0-20° and 70-90°
Physical function	Knee injury and Osteoarthritis Outcome Score (KOOS) (KOOS- function in daily living subscale) Timed Up and Go Test (TUG)
Fear of Falling	Short Fall Efficacy Score – International (FES-I)

#### 5.4.4.1 Physiologic Profile Assessment

Falls risk was determined using the PPA approach, NeuRA FallScreen®. The PPA was developed by a research team from the Prince of Wales Medical Research Institute, Randwick, Sydney, New South Wales, Australia (Lord, Menz, & Tiedemann, 2003). The NeuRA FallScreen® is an evidenced-based falls risk assessment that can accurately identify an individual at risk of falls by integrating visual, sensation, strength, coordination and balance impairments (Lord et al., 2003). When compared to other systems related to falls and balance, the PPA was chosen because of its practicality of use in clinical settings, the tests were quick and easy to administer, and adaptive for individuals with various levels of conditions (Lord, Delbaere, & Gandevia, 2016) such as individuals with knee OA (Sturnieks et al., 2004).



There are two versions of the PPA: a comprehensive long version that requires 45 minutes to assess all domains, and a short version useful for screening when time is constrained. The short version, requiring 15 minutes to administer, was used in this study. This was to limit participants' burden and to be time-effective since participants were already attending a battery of tests. The short version comprised of a set of five tests to measure visual contrast sensitivity, proprioception, quadriceps muscle strength, hand reaction time and postural stability under four sensory conditions (eyes open and eyes closed on a firm surface or a foam surface) to evaluate falling risk. Based on the performance of five physiological domains, the PPA computes a falls risk score (standardised score) for each individual. The PPA composite score comprises weighted contributions from the above five test measures derived from discriminant function analysis (Lord, Menz, & Tiedemann, 2003). The individual PPA tests are described below.

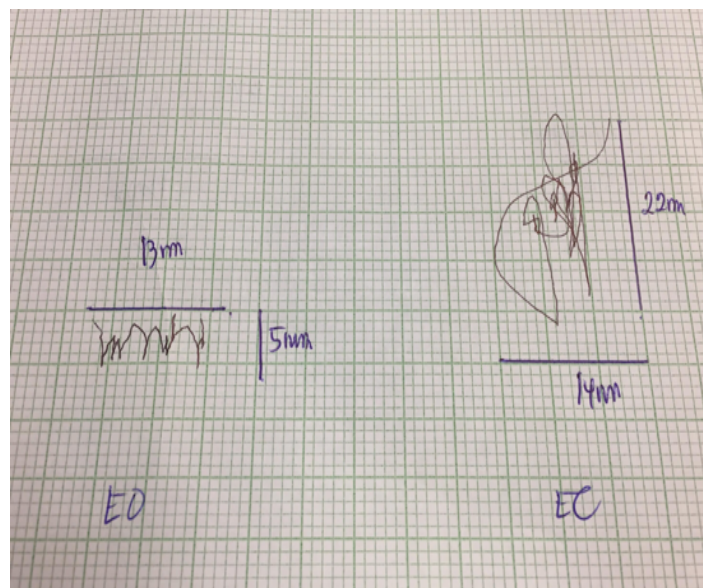
Visual contrast sensitivity was assessed using the Melbourne Edge Test (Verbaken & Johnston, 1986). The chart had 20 circular 25-mm-diameter patches containing edges with reducing contrast with variable orientation as the identifying feature. Lowest contrast patch correctly identified was recorded as the participant's contrast sensitivity in decibel units, where  $1 \text{ dB} = 10 \log_{10} \text{ contrast}$ . A higher score indicated better contrast sensitivity (Lord et al., 2003).

Proprioception and quadriceps muscle strength were assessed in a sitting position using a high chair (66 cm). Proprioception was measured using a lower limb-matching task. Participants were instructed to lift their legs simultaneously and stop at specified angles (30 to 50 degrees). The assessor inspected the symmetry of the feet. Errors were recorded in degrees using a protractor inscribed on a vertical clear acrylic sheet ( $60 \times 60 \times 1 \text{ cm}$ ) placed between the legs. Using the same high chair, quadriceps strength was measured by pulling isometrically at  $90^\circ$  against padded straps attached to strain gauges. Participants were instructed to hold it for three seconds. The same procedure was done for every participant. Three trials were recorded, and the average score was used for the analysis (Lord et al., 2003).

Reaction time for the PPA was assessed in milliseconds using a hand-held electronic timer and a modified computer mouse with a light. This electronic timer had a built-in variable (random) delay of one to five seconds to remove any form of cues. The coloured

red light is located adjacent to the response switch (click). This red light was bright enough to ensure that the tests were not influenced by the subject's visual contrast sensitivity. The light served as the stimulus and clicking of switch as the response. Initially five attempts were undertaken as a practice trial, followed by 10 attempts which were recorded. The best time record was used for analysis.

Postural sway was measured using a sway meter that recorded the sway of the body in the mediolateral and anteroposterior directions while standing on a medium-density foam rubber mat ( $70 \times 60 \times 15$  cm thickness) placed on the floor, with the eyes open and closed. This device consisted of a 40 cm long rod with a vertically mounted pen at its end was attached to participant's waist with a belt. The pen recorded the sway while participants attempted to stand as still as possible. Total excursion of the sway was measured in millimetres with the use of graphing (grid) paper (Figure 5.3). The total sway (number of square millimetre squares traversed by the pen) in the 30 seconds was recorded for the four tests.



**Figure 5.3** Sample postural sway trace on a graphing paper with corresponding measurements in millimetres with eyes open (EO) and eyes closed (EC).

A license was obtained to access a web-based computer software programme to calculate the risk of falling (<https://www.neura.edu.au/fbrg>). The web based programme generates falling risk evaluation reports: an overall falls risk score for each participants presented in a graph, the test performances in relation to age-matched norms presented in a table and a report that briefly describes the meaning of the results of assessing the falls risk (Lord et al., 2003). A normative range of falls risk was developed based on data acquired from a random selection of 550 community-dwelling in Australia (Lord et al., 2003). The PPA composite z-scores of 0, 1, 2 and 3 and above were used to indicate mild, moderate, marked, and very marked risk of falling, respectively (Lord et al., 2003).

The falls risk scores is a single index score derived from discriminant function analysis using the data from large-scale studies (Lord, 2013). The discriminant function is made up of weighted scores of independent risk factors such as visual contrast sensitivity, lower-extremity proprioception, knee extension force, reaction time, and sway. The graph presents the falls risk score in relation to individual of the same age and falls risk criteria ranging from very low to marked. A sample report is shown in Figure 5.4.

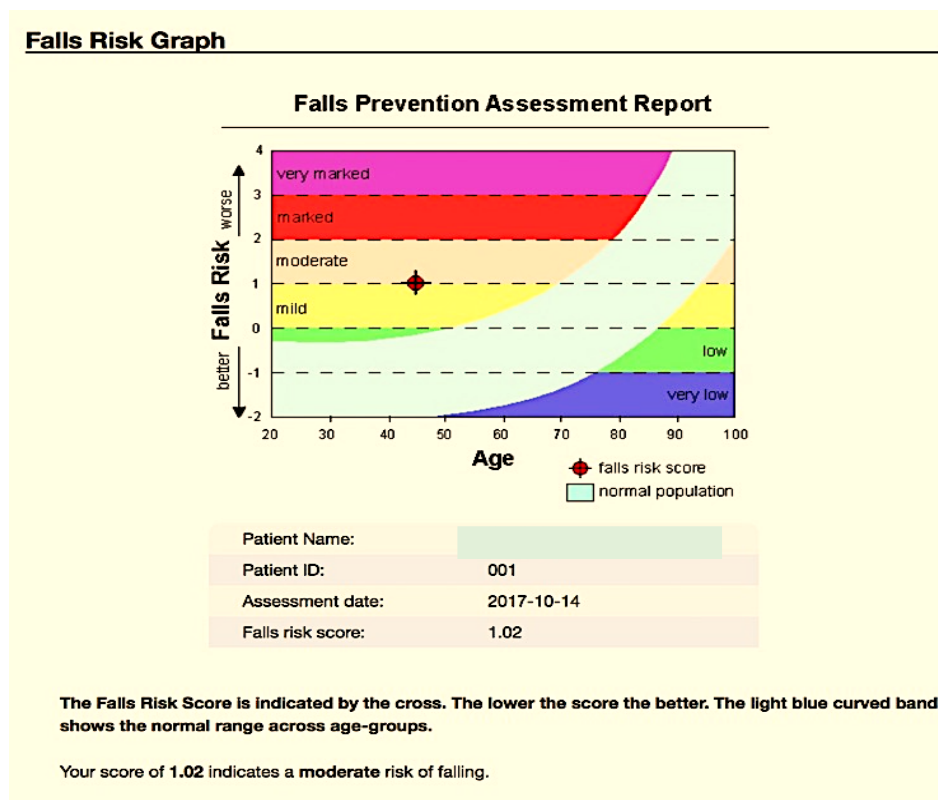


Figure 5.4 Sample of falls risk graph generated from NeuRA FallScreen®.

A number of studies have evaluated validity of the PPA with community-dwelling older adult and it was found to be valid in assessing previous falls (Lord et al., 1991; Lord et al., 2003). The PPA also has good predictive ability of falls in community-dwelling populations. For instance, the discriminative validity of PPA measurements correctly classified participants into a multiple falls group (two or more falls) or a non-multiple falls group (no falls or one fall) with an accuracy of 79% (Lord et al. 1992). The PPA has been used in clinical groups with balance disorders and subsequent increased risk of falling, including lower limb OA (Sturnieks et al., 2004). It was also used as an outcome measure for individuals with knee OA in several studies (Foley, Lord, Srikanth, Cooley, & Jones, 2006; Sturnieks et al., 2004).

#### *5.4.4.2 Short form Falls Efficacy Scale-I*

The Fall Efficacy Scale - International (FES-I) is a questionnaire that assesses patients' fear of falling (Yardley et al., 2005). In order to minimise the assessment burden, a seven-item shortened version of the FES-I (short FES-I) was used (Kempen et al., 2008). It was also developed, validated and recommended for the community-dwelling older population. (Li, Fisher, Harmer, McAuley, & Wilson, 2003; Tinetti, Richman, & Powell, 1990; Yardley et al., 2005). There are four responses which are: 'not at all concerned' (score=1), 'somewhat concerned' (score=2), 'fairly concerned' (score=3) and 'severe concerned' (score=4). The total score ranges from 7 (no concern about falling) to 28 (severe concern about falling across a range of seven common activities of everyday life, including dressing, bathing, getting in or out the chair, stair climbing, reaching, walking on a slope, and attending social events (Kempen et al., 2008). The tool was administered through participant's self-reported experience (Li et al., 2003; Tinetti et al., 1990; Yardley et al., 2005). Total short FES-I score was calculated by adding the score of each item: the total ranges from a minimum of seven (no concern about falling) to a maximum of 28 (severe concern about falling). Delbaere and colleagues established cut-off points for low (7-8), moderate (9-13) and high (14-28) concern about falling (Delbaere et al., 2010).

Psychometric properties of the Short FES-I were as good as the original FES-I with excellent Cronbach's alpha 0.92, intra-class coefficient 0.83 (Li et al., 2003; Tinetti et al., 1990; Yardley et al., 2005). The correlation between the Short FES-I and the FES-I was 0.97 (Kempen et al., 2008). Additionally, after a one-year follow-up study, the predictive validity

of the FES-I and short FES-I revealed that both questionnaires accurately predicted future falls, physiological falls risk, muscle weakness, overall disability, and depressive symptoms (Delbaere et al., 2010). Both forms of FES-I have shown adequate to good sensitivity to change in older adults with or without cognitive impairment (Hauer et al., 2011). FES-I has been used as an outcome measure for fear of falling in knee OA subjects (Bhedi, Sheth, & Vyas, 2015; Mat, Ng, Fadzil, Rozalli, & Tan, 2017).

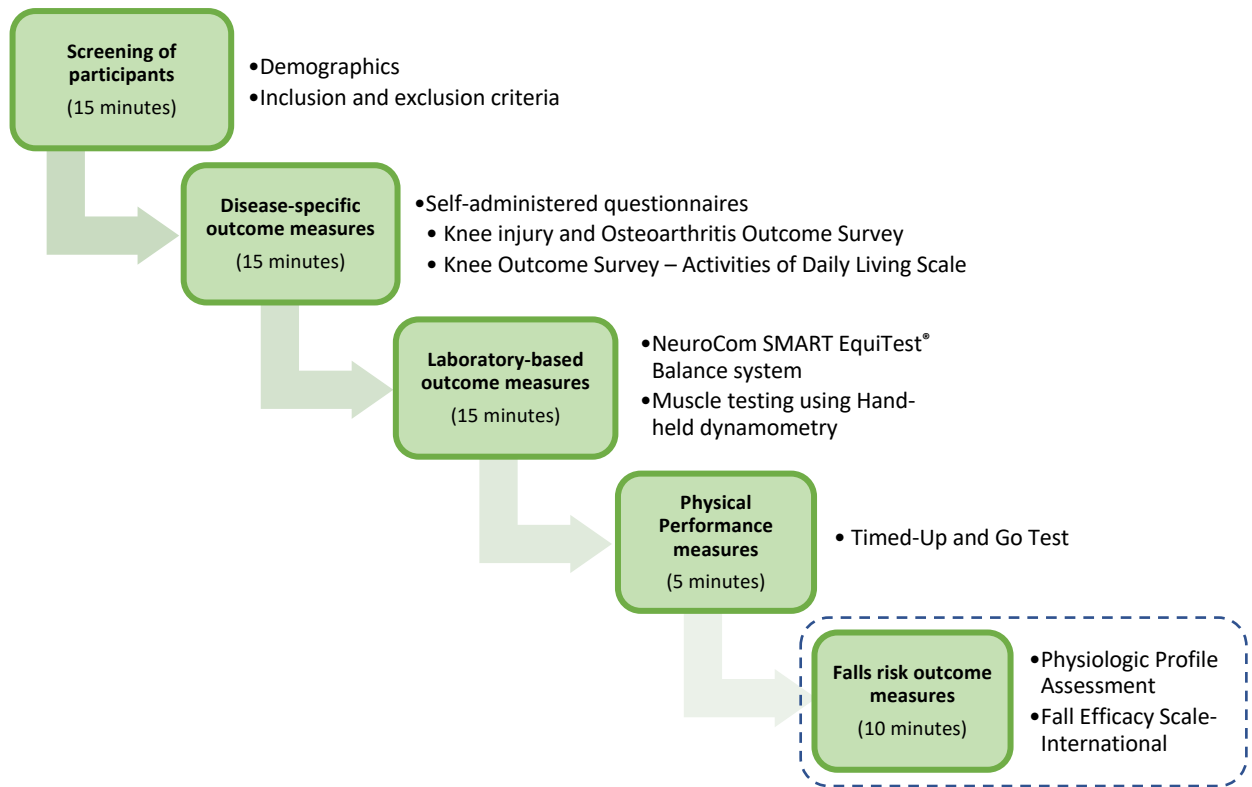
#### 5.4.5 | Assessment procedure

Blinded assessments were conducted at three time-points: baseline (A1), after eight weeks (A2), and post-intervention assessment (A3). During the first visit, the assessor explained the purpose and procedure of the assessment to the participant. The assessor answered any queries the participants may have had, after which the assessor collected the obtained informed consent. Participants were informed prior to the sessions that they were welcome to bring a support person. Each participant was given a corresponding number through a computer-generated number provided by the research clinical administrator. Demographic data including age, gender, ethnicity, weight, height and BMI were collected. The participant's weight and height were measured using an electronic digital scale and a wall mounted scale, respectively. Participants were also asked to report use of pain medication, other maintenance medications, and co-morbid conditions. Table 5.7 summarises the application of primary and secondary outcome measures from recruitment to the last assessment session.

**Table 5.7** Application of outcome measures across the different time points of the study.

Procedure and outcome measure	Time-points						
	Recruitment	Screening	Baseline assessment (A1)	Usual care	Week 8 assessment (A2)	Exergaming intervention	Post-assessment (A3)
Eligibility screening		✓					
Informed consent	✓						
Baseline demographics			✓				
<b>Primary outcome measures</b>							
Recruitment	✓	✓	✓				✓
Retention			✓		✓		✓
Compliance						✓	✓
Safety						✓	✓
<b>Secondary outcome measures</b>							
Dynamic balance			✓		✓		✓
Falls risk			✓		✓		✓
Knee osteoarthritis symptoms			✓		✓		✓
Knee instability			✓		✓		✓
Knee muscle strength			✓		✓		✓
Physical function			✓		✓		✓
Fear of Falling			✓		✓		✓

The initial assessment session formally began with a history taking followed by physical examination. This included application of the set inclusion and exclusion criteria (Table 5.1). A similar screening of the characteristic and history of falling in the past 12 months in the cross-sectional study was also conducted. Participants then answered disease-specific outcome measure KOOS (Roos & Lohmander, 2003; Roos, Lohmander, Ekdahl, & Beynnon, 1998) and KOS-ADL (Irrgang, Snyder-Mackler, Wainner, Fu, & Harner, 1998) to collect data regarding knee symptoms and instability, respectively. Similar protocol and procedure as described in the cross-sectional study (Figure 3.5) were used in conducting the SOT, muscle strength testing, and physical performance measure. The short forms of PPA and FES-I were the additional outcome measures in this study to evaluate falls risk and fear of falling, respectively. Figure 5.5 summarises the duration and all tests that were conducted in this feasibility study.



**Figure 5.5** Summary of the assessment procedure conducted in this feasibility study. The highlighted part shows additional outcome measures used.

#### 5.4.6 | Data management and recording

Assessment data from each time point were manually entered into a Microsoft Excel sheet by the blinded assessors. A data code was prepared to assist in entry and cross-checking of the data. The data were then examined for correctness and completeness by the assessors before exporting into SPSS statistics computer programme (SPSS, version 25, IBM Inc., Chicago, IL), and Microsoft Excel Data Analysis package for statistical analysis.

KOOS scores were calculated and treated in similar with the cross-sectional study (Chapter 3). For missing data, if a mark was placed outside a box, the closest box was chosen. If two boxes were marked, the one that indicated the more severe problem was chosen (Roos & Lohmander, 2003).

All SOT data from the Equitest® balance system was collected by printing the results of the test. A pdf file with visual and numeric output of SOT was obtained from the system. For falls risk, a web-based computer software programme was used to calculate the risk of falling. The web-based programme generates four falling risk evaluation reports in a form of z-scores (<https://www.neura.edu.au/fbrg>) as presented previously in Figure 5.4.

Attrition of participants is inevitable in this type of study and will result in missing data. Missing data due to drop-out or withdrawal from the trial were replaced using multiple imputations. There are no universally applicable approaches for dealing with missing data (Shih, 2002; Tickle-Degnen, 2013; Yeatts & Martin, 2015). Other options considered for dealing with missing data in this study included replacing mean value and last observation carried forward. The current study considered LOCF inappropriate, as this method assumes stability of a health condition (Shih, 2002). Replacing the missing data with mean value can add bias on the estimates of the results.

#### 5.4.7 | Data analysis

The analysis of feasibility outcome measures was descriptive in nature. Demographic data and primary outcomes were classified as continuous (age, height, weight, and BMI) or categorical (sex, ethnicity, laterality of affected knee, and knee instability). Appropriate descriptive statistics were calculated such as mean, range, frequency and percentage. Feasibility of the recruitment strategy was measured by summarizing the number of participants recruited. The retention was assessed by number of participants who remained in the study from baseline to post-intervention assessment. The overall compliance rate was computed as the proportion of the number attended sessions out of the total number of sessions (24 sessions).

Clinical outcome measures were reported as mean, median, and standard deviation. The normal distribution of these outcome measures were checked using Q-Q plot and histogram visual inspection. Difference between the three time-points of assessment were calculated and descriptively compared. Although this study focused on the feasibility of the study process (primary), comparisons of clinical outcome measures between assessment time points were performed to examine changes in outcome measures.



Inferential analyses were performed within-condition comparison to identify changes in clinical outcome scores, and provide an indication of potential future findings, but were not used to interpret effectiveness of the intervention. Nonparametric statistical analyses were conducted due to the small sample size. Wilcoxon rank-signed test was conducted to compare two assessment time points: A1-A2 (usual care) and A2-A3 (exergaming). Effect size was computed to determine the magnitude of changed in score. The effect size for Wilcoxon rank-signed test was computed using the suggested formula (Rosenthal, 1994; Tomczak & Abarés-Seisdedos, 2014):

$$r = \frac{Z}{\sqrt{N}}$$

where, Z= test statistics and N= number of observations.

## 5.5 | Quantitative phase: results

### 5.5.1 | Demographics

A total of 18 participants responded to study advertising. Three participants withdrew after they were given a time to decide if they wanted to join the study. Upon application of the set inclusion and exclusion criteria, a total of 12 participants proceeded in the study. The participants' demographic and fall characteristics are presented in Table 5.8. Seven female and five male participants with the total mean age of  $55.25 \pm 10.00$  years old were included in the study. Participants were primarily of NZ European ethnicity (58.33%). Of the 12 participants with knee OA and history of falling, six (50%) participants fell once (single-fallers) and the other half fell more than once (multiple-fallers) in the preceding 12 months. Ten out 12 (83.33%) of the participants fell while walking and the location of falls regardless of the activity happened outdoors (100%).

**Table 5.8** Characteristics of participants at entry to trial

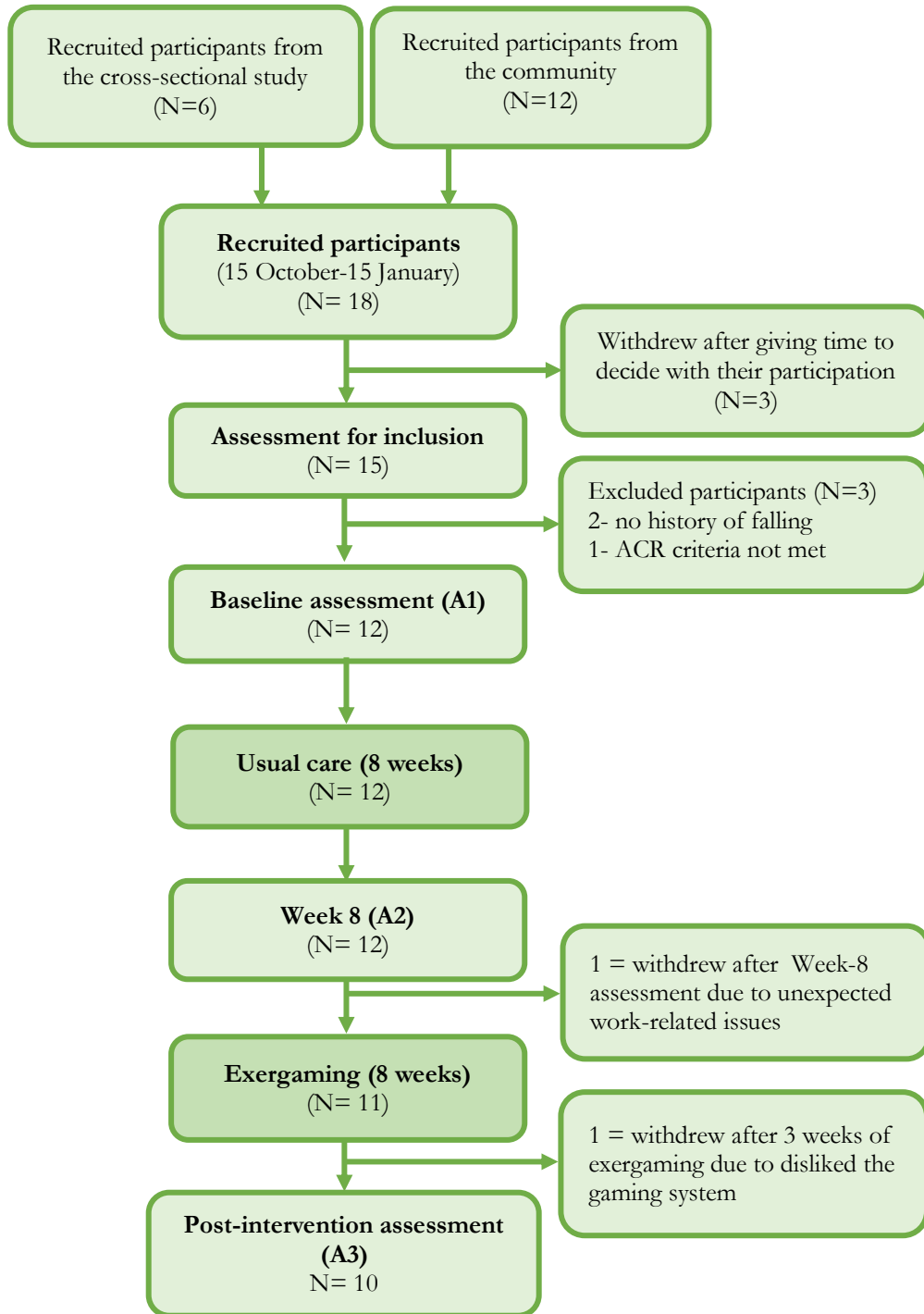
Age (years)	55.25 ± 10.00
Sex, n (%)	
Male	5 (41.67)
Female	7 (58.33)
Ethnicity, n (%)	
New Zealand European	7 (58.33)
Maori	1 (8.33)
Asian	4 (33.33)
Anthropometric Measurements	
Height (cm)	164.3 ± 0.12
Weight (kg)	79.40 ± 16.15
BMI (kg/m <sup>2</sup> )	29.50 ± 6.02
Most symptomatic Knee, n (%)	
Right knee	5 (41.67)
Left knee	4 (33.33)
Bilateral knee	3 (25.00)
Falls characteristics, n (%)	
Frequency of fall	
Single fall	6 (50.00)
Multiple falls	6 (50.00)
Activity during fall incident	
Walking	10 (83.33)
Stair negotiation	1 (8.33)
Household chores/gardening	1 (8.33)
Location of fall	
Outdoor	12 (100.00)

*Note.* cm, centimetre; kg, kilogram; m<sup>2</sup>, meter squared

## 5.5.2 | Primary outcome measure: feasibility outcomes

### 5.5.2.1 Recruitment

The flowchart of recruitment, retention, and study procedure is summarised in Figure 5.6. Thirty-one out of 63 potential participants were invited from the cross-sectional who were identified to have knee OA and history of falling. The recruitment was done through an email from 15 October to 30 November 2018. Following an email invitation, six participants expressed their interest to participate. The second stage of recruitment was done through community advertisement which resulted with 12 participants willing to join in the study.



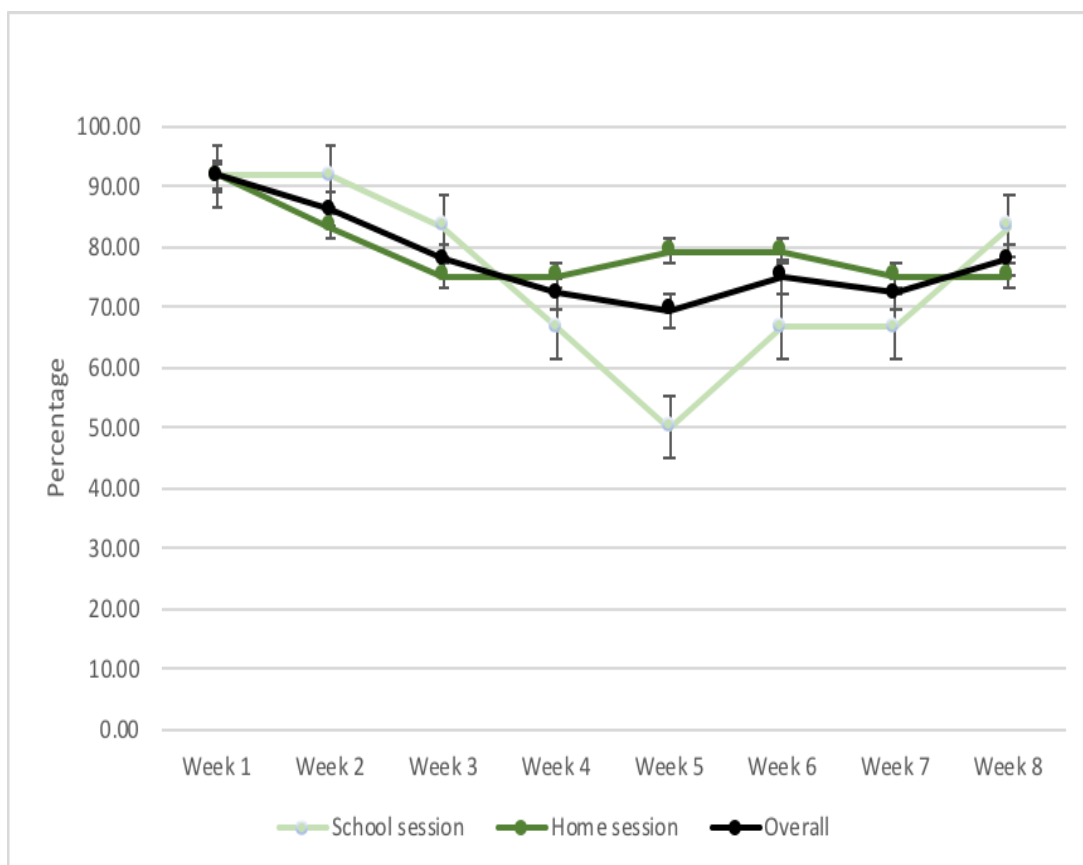
**Figure 5.6** Flowchart of recruitment, retention, and study procedure.

### 5.5.2.2 Retention

Participant retention exceeded the *a priori* criteria of 75% at the end of the quantitative phase (post-intervention assessment). A total of 10/12 (83%) of the participants retained and completed the post-intervention assessment. Fifteen participants completed the screening process. However, three participants did not meet the set criteria. One participant withdrew from the study after the Week-8 assessment (A2) and another one after three weeks of exergaming.

### 5.5.2.3 Compliance

Compliance was measured by the attendance of the participants in the exergaming sessions (supervised and unsupervised sessions). In total, there were 24 exergaming sessions: eight sessions supervised at the school and 16 sessions unsupervised at home. To determine the accuracy of exergaming at home, the *Mii* avatar were cross-checked side-by side with exercise kit and diary provided. An overall compliance rate of 78% was observed for the exergaming programme of three times a week for eight weeks (Figure 5.7). The compliance rate of the supervised sessions and home sessions were 75% and 79%, respectively. Compliance was high during Week 1 (92%). However, a declining trend in the next four weeks was observed which was noticeable during the third to fifth week. This was due to withdrawal of one participant from the programme at this stage. However, the compliance rate increased during the succeeding weeks and ended with 77% total compliance rate at eight-week sessions.



**Figure 5.7** The overall compliance rate of exergaming sessions three times a week for eight weeks

#### 5.5.2.4 Safety

No safety issues or adverse events directly related to the study or intervention were reported. However, there were several issues unrelated to the study that were reported. Prior to commencement of exergaming, two participants reported low back pain and one participant reported shoulder pain. During the supervised sessions, three participants reported falls unrelated to performance at home of the Nintendo Wii Fit™ exergaming sessions. The fall incidents and descriptions were recorded.

#### 5.5.3 | Secondary outcome measure: clinical outcomes

From this section onwards, baseline, week 8, post-intervention assessment are referred to A1, A2, and A3 time points respectively. Missing data at A3 from the two participants who withdrew were replaced using multiple imputation. Descriptive and inferential statistics for all secondary outcomes are reported in Table 5.9. The results of the

differences between time-points A1-A2 and A2-A3 are also presented. This is followed by the results of each secondary clinical outcome measures.

Significant changes in clinical outcome scores between A1-A2 (usual care) were seen in Composite scores ( $p=0.035$ ,  $r=0.431$ ). Between A2 and A3 (exergaming intervention) significant changes in clinical outcome scores were seen in KOOS-Activity ( $p=0.033$ ,  $r=0.436$ ), KOOS-Sports and recreation ( $p=0.020$ ,  $r=0.474$ ), KOOS-QoL ( $p=0.016$ ,  $r=0.492$ ), TUG ( $p=0.028$ ,  $r=0.492$ ) and short form-FES-I ( $p=0.018$ ,  $r=0.286$ ).

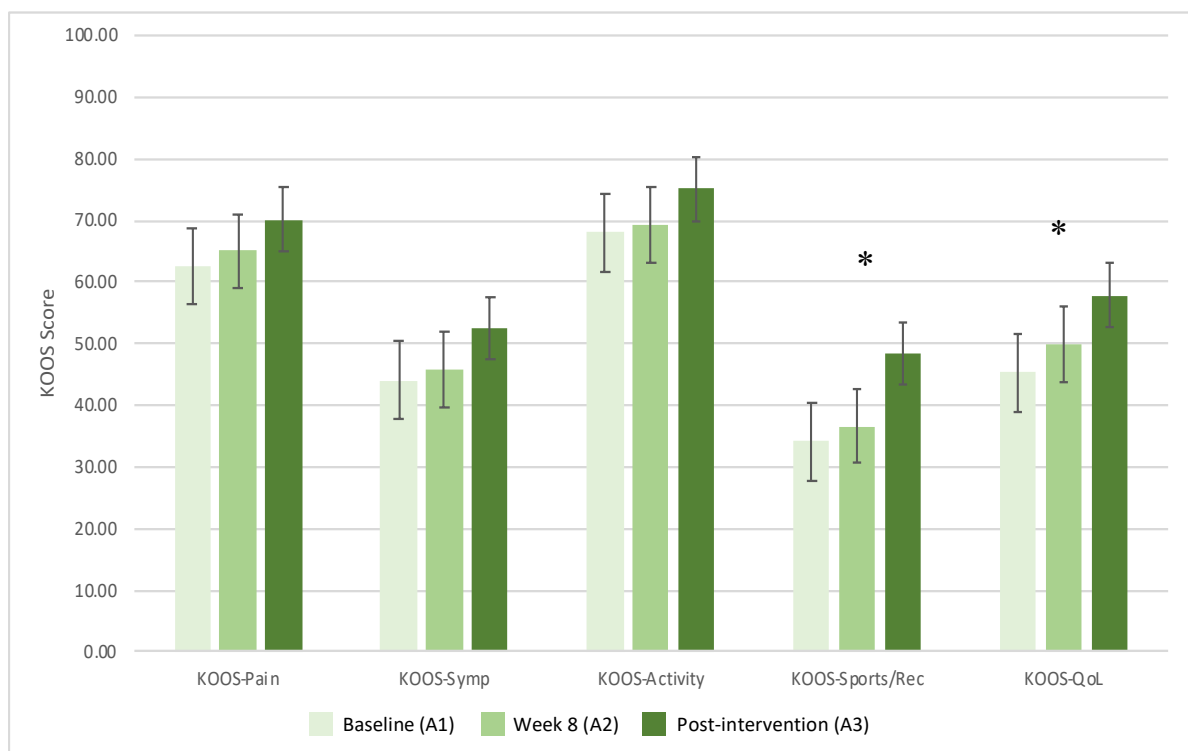
**Table 5.9** Descriptive summary of the clinical outcome scores and results of comparing baseline (A1), Week 8 (A2), and post-intervention (A3) assessments

Clinical outcome measures	Baseline Assessment (A1) (Mean±SD)	Week 8 Assessment (A2) (Mean±SD)	Post-intervention assessment (A3) (Mean±SD)	Usual care (A1-A2) <sup>a</sup>			Exergaming (A2-A3) <sup>a</sup>		
				Z	p-value	Effect size (r)	Z	p-value	Effect size (r)
KOOS-Pain	62.04±15.31	62.96±13.19	70.48±11.44	-0.357	0.721	0.073	-1.601	0.109	0.327
KOOS-Symptoms	44.64±5.55	46.43±9.56	51.69±10.47	-0.551	0.582	0.112	-1.847	0.065	0.377
KOOS-Activity	67.40±13.48	67.65±9.08	75.79±10.48	-0.089	0.929	0.018	<b>-2.137</b>	<b>0.033*</b>	<b>0.436</b>
KOOS Sports/Recreation	33.75-24.78	34.17±15.79	48.23±18.38	-0.277	0.782	0.057	<b>-2.320</b>	<b>0.020*</b>	<b>0.474</b>
KOOS-Quality of life	43.23±13.85	45.83±9.99	57.39±9.91	-0.553	0.580	0.113	<b>-2.409</b>	<b>0.016*</b>	<b>0.492</b>
Knee Instability	5.00±0.92	4.00±0.80	4.00±0.80	-0.447	0.655	0.091	-0.333	0.739	0.068
Composite Score	69.33±3.25	72.67±3.70	73.92±4.23	<b>-2.113</b>	<b>0.035*</b>	<b>0.431</b>	-0.140	0.889	0.286
Knee flexors – 0°	8.42±2.60	9.15±2.51	10.03±2.86	-0.652	0.514	0.073	-0.561	0.575	0.327
Knee flexors – 90°	9.18±3.90	9.22±2.46	10.23±2.50	-0.059	0.953	0.953	-0.968	0.333	0.377
Knee extensors – 0°	9.53±3.31	10.53±2.82	11.41±3.70	-0.533	0.594	0.018	-0.533	0.594	0.436
Knee extensors – 90°	10.21±3.56	11.18±2.67	12.28±3.23	-0.432	0.578	0.057	-0.764	0.445	0.474
Timed-Up and Go Test	9.64±3.25	7.93±1.38	7.18±1.52	-1.255	0.209	0.113	<b>-2.191</b>	<b>0.028*</b>	<b>0.492</b>
PPA (Short-form)	-0.41±0.67	-0.01±0.51	-0.29±0.57	-1.883	0.060	0.091	-1.804	0.071	0.068
Falls Efficacy Scale-I	13.25±3.72	11.75±2.49	10.25±2.30	-1.635	0.102	0.431	<b>-2.375</b>	<b>0.018*</b>	<b>0.286</b>

Note. <sup>a</sup>Wilcoxon rank-signed test; \*p-value significant at 0.05; KOOS, Knee Osteoarthritis Outcome Score, SD, standard deviation PPA, Physiologic Profile Assessment.

### 5.5.3.1 KOOS

Figure 5.8 shows the increasing KOOS scores in all subscales from A1 to A3 assessments. Maximum possible score for KOOS is 100, with higher scores indicating improvement. The mean score of KOOS- Sports/Recreation showed the greatest change by 14.21 ( $\pm 15.65$ ) followed by KOOS-QoL by 11.98 ( $\pm 13.18$ ) between A2-A3. There were no significant changes between A1 and A2 mean scores for all the KOOS subscales. However, significant differences were seen after doing exergaming (A2 and A3). These were observed for the KOOS Symptoms, Activity, Sports and recreation, and QoL subscales ( $p < 0.05$ ).



**Figure 5.8** The changes of each KOOS subscale scores during the three-assessment time-points with standard errors, \*significant difference ( $p < 0.05$ ).

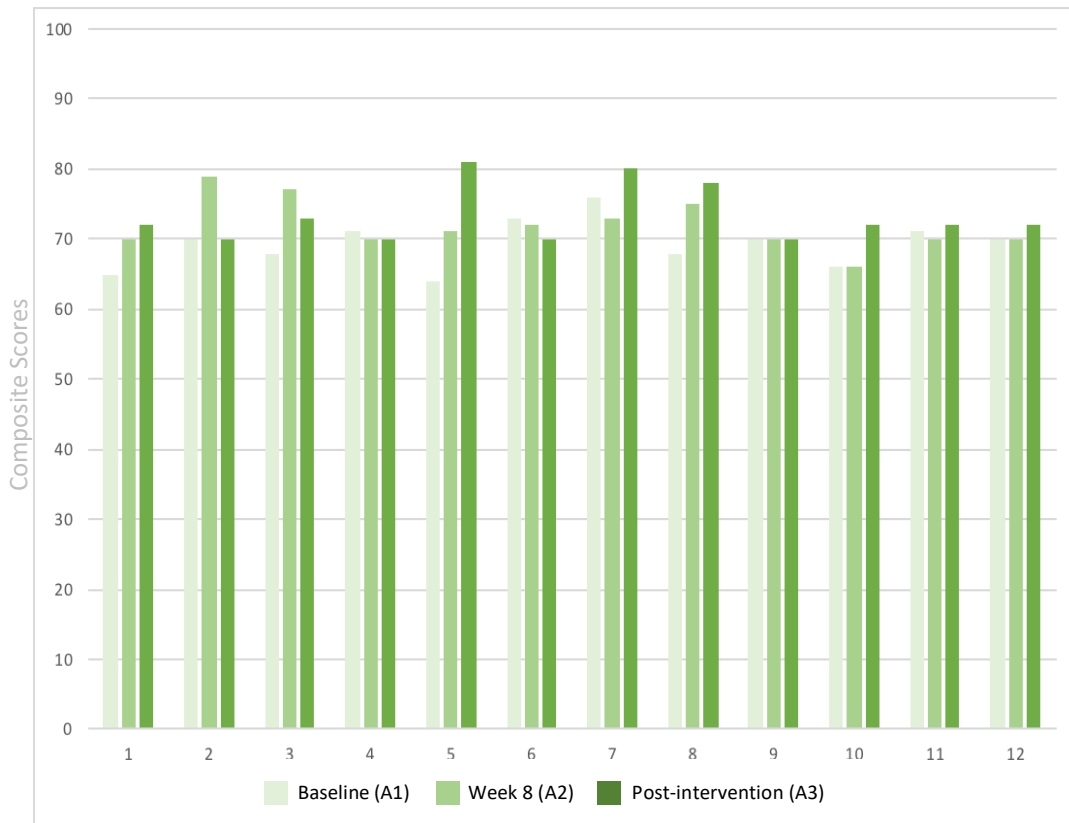
### 5.5.3.2 KOS-ADL for knee instability

Reports of buckling as an indication of knee instability ranged from three (buckling slightly affects my activity) to five (I never had bucking of my knee). The group median score was four which signifies that knee buckling did not affect ADL of the participants. No significant changed in KOS-ADL were observed at any time points.



### 5.5.3.3 Balance Composite Scores

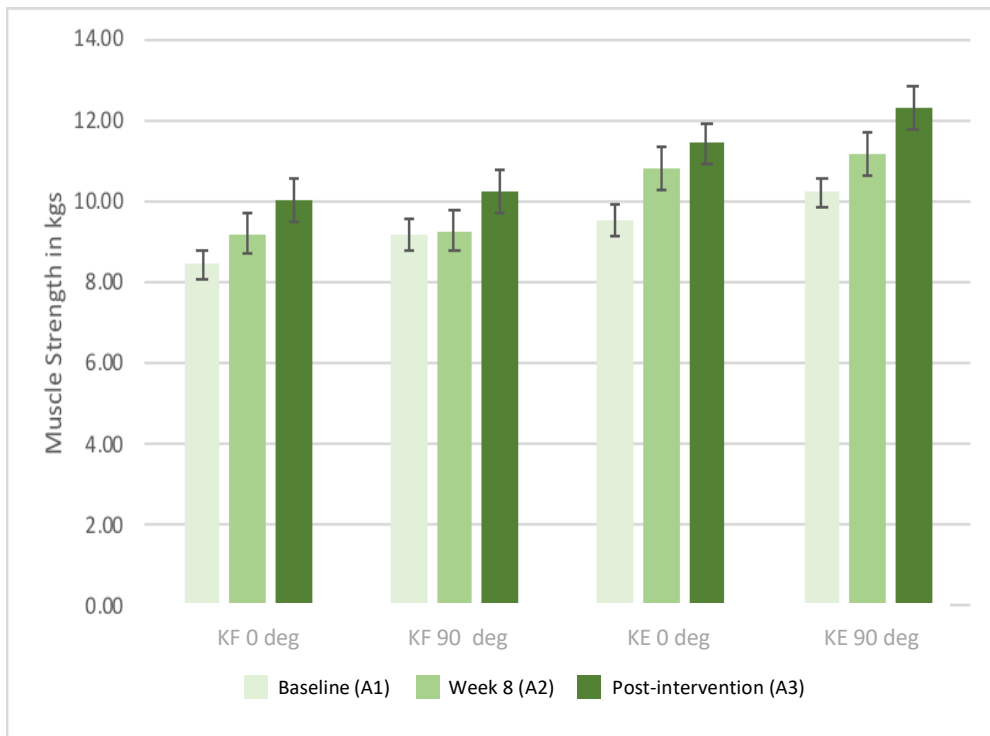
Figure 5.9 shows the increasing CS scores obtained from the EquiTest® NeuroCom balance system of the 12 participants. The mean Composite Scores from A1 (69.33), A2 (71.92), to A3 (73.33) assessment, with higher scores indicating improvement showed significant change between A1 and A2 with a mean difference of  $3.33 \pm 4.38$  ( $p=0.035$ ). However, no significant difference was seen after exergaming (A2 to A3) ( $p=0.286$ ).



**Figure 5.9** Composite Scores of participants from baseline to post intervention assessment

### 5.5.3.4 Knee muscle strength

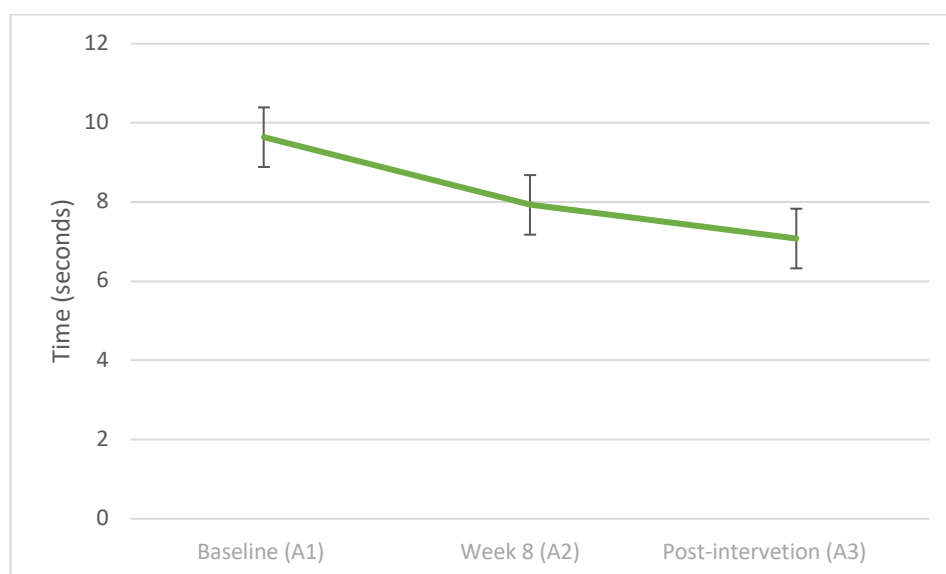
Changes in the mean knee extensors and flexors strengths measured at 0 and 90 degrees are presented in Figure 5.10. The graph shows consistent increased in muscle strength. However, no significant difference is seen for all the measured strength between A1-A2 and A2-A3 ( $p>0.05$ ).



**Figure 5.10** Changes of each muscle strength scores during the assessment time-points with standard errors.

#### 5.5.3.5 TUG test

The TUG test showed significant decrease in the duration of performance between A2 and A3 ( $p=0.028$ ). However, no significant difference found in TUG scores between A1 and A2. Figure 5.11 shows the decreasing score of TUG test.



**Figure 5.11** The mean TUG scores from baseline to post intervention assessment with standard errors.

### 5.5.3.6 PPA

Falls risk scores were obtained from the NeuRA FallScreen® fall risk graph and which were analysed. The falls risk scores showed no significant changes when compared to A1-A2 and A2-A3 ( $p>0.05$ ). Although there were changes in the falls risk scores, there were five participants who had the same falls risk description from A1 to A3. Table 5.10 shows the individual falls risk scores and corresponding descriptions.

**Table 5.10** Physiologic Profile Assessment falls risk scores obtained from the NeuRA FallScreen®

Participants	Baseline		Week 8		Post-intervention	
	Falls risk score	Falls risk description	Falls risk score	Falls risk description	Falls risk score	Falls risk description
1	1.02	Moderate	0.76	Mild	0.22	Mild
2	1.21	Moderate	0.71	Mild	-1.31	Very low
3	0.48	Mild	0.7	Mild	0.24	Mild
4	0.1	Mild	-0.19	Low	-0.56	Low
5	-0.58	Low	-0.13	Low	-0.88	Low
6	1.29	Moderate	-0.38	Low	-0.56	Low
7	0.19	Mild	0.04	Mild	-0.83	Low
8	1.15	Moderate	0.15	Mild	0.11	Mild
9	-0.14	Low	-0.06	Low	-0.39	Low
10	0.05	Mild	-0.15	Low	-0.43	Low
11	-0.71	Low	-0.94	Low	-0.56	Low
12	0.61	Mild	0.38	Mild	0.26	Mild

### 5.5.3.7 FES-I

The FES-I mean scores decreased significantly between A2 and A3 with a mean difference of  $1.50 \pm 1.75$  ( $p=0.018$ ). However, no significant difference was found between A1 and A2. The mean of each participants KOS-ADL score compared to group mean was 11.75 and median scores of 11.5. Based on the cut-off points by Delbaere et.al, (2010), the mean and median group scores fall into the moderate level of concern performing ADLs (Delbaere et al., 2010).

## 5.6 | Quantitative phase: discussion

The quantitative component of this mixed-method suggests that it is feasible and safe for individuals with knee OA and history of falling to participate in a 16-week exergaming intervention using an active gaming console, Nintendo Wii Fit™. Interesting changes in the selected clinical outcome measures are observed after undergoing exergaming programme. This discussion section focuses on the quantitative findings. This includes the interpretation of the results of the primary (feasibility) and secondary (clinical outcomes) outcome measures.

### 5.6.1 | Feasibility of exergaming

The study achieved the minimum of 12 participants set within the period of three months. The justifications for this sample size was based on rationale of conducting a feasibility study with at least 12-15 participants as a recommendation (Julious, 2005). Also, the number of recruited participants in this study was within the range (10-15 participants) of the sample sizes of previous feasibility studies using the Nintendo Wii Fit™ in improving balance of adults and older adults (Agmon, Perry, Phelan, Demiris, & Nguyen, 2011; Bainbridge, Bevans, Keeley, & Oriel, 2011; Bateni, 2012; Bieryla & Dold, 2013; Nicholson et al., 2015). One of the challenges encountered in recruiting participants in the study was the criterion on history of falling. Most of the participants who responded in this study were clinically diagnosed with knee OA but did not have an established history of falling. This is a common limitation in falls research where in most cases defining a “fall” is subject to the participants’ interpretation, rather than having objective evidence (Graafmans, Lips, Wijnhuizen, Pluijm, & Bouter, 2003; Lord, Sherrington, Menz, & Close, 2007). Nevertheless, recruitment was facilitated because of the established criteria used to identify falls, the strategies used in the recruitment process, and the interest of the participants in this new way of exercising.

The current study had 77% compliance rate and 88% retention rate which exceeded the set criterion of greater than 60% and 75%, respectively. This is similar to the study of Williams et al. (2011) where participants demonstrated willingness and compliance in balance training using the Wii Fit™ (Williams et al., 2011). However, an obvious trend of declining compliance rate was observed after one month. This might be due to the two participants

who dropped out from the study and the repetitiveness or familiarisation of the participants with the games. This is one of the disadvantages of using commercial video games where modifications to software are essentially restricted (McMahan, Ragan, Leal, Beaton, & Bowman, 2011), limiting the features of the games in terms of having alternative challenges and level of difficulties (van Diest, Lamothe, Stegenga, Verkerke, & Postema, 2013). In order to address this issue in this study, participants were given further instructions during the supervised sessions on how to progress and maximise the advantages and entertainment components of exergaming. The high retention rate in this study is comparable with other exergaming studies that utilised Nintendo Wii Fit™ (Bainbridge et al., 2011; Bieryla & Dold, 2013; Fu et al., 2015).

Compared to other exergaming tools, the Nintendo Wii Fit™ has a balance board to step on which gave an additional challenge to participants' balance. In this study, no adverse events were reported by the participants when using the Wii Fit™ balance board. This was achieved by compliance with the safety procedure, and presence of support to the participants during each supervised session. Also, none of the participants felt unsafe although at the beginning of the training most of them reported being cautious on their steps or moves. A study conducted by Agmon et al. (2011) reported that individuals who played exergaming using Wii Fit™ had difficulty adjusting on how to play the game but mastered the game later (Agmon et al., 2011). Lastly, no safety issues were reported while playing at home which corroborate with the findings of Nicholson et al. (2015) where unsupervised gaming at home using Wii Fit™ for older adults was also safe (Nicholson et al., 2015). Thus, exergaming using the Wii Fit™ platform seemed to be safe both for supervised and unsupervised sessions.

#### 5.6.2 | Preliminary changes in clinical outcome measures

The results demonstrated a trend toward improvements in clinical outcome scores from A1 to A3. There were interesting and encouraging changes in several outcome measures which included KOOS Sports/Recreation, KOOS ADL, and KOOS QoL, TUG, and the short form FES-I. However, caution with the results should be taken due to the nature of the study and low sample size albeit some positive findings.

The changes in the mean scores of KOOS Sports/Recreation, KOOS ADL and KOOS QoL after eight weeks of exergaming in this present study showed score difference

ranging from 14 to 16. Previous study using KOOS as an outcome measure showed that initial changes are seen in these same KOOS subscales (Collins & Roos 2012). The score differences in this study were also comparable with the minimal detectable change (MDC) in the study of Collins et al (2011) which included individuals with knee OA: 7-8 for KOOS ADL, 5.8-12 for KOOS Sport/Rec and 7-7.2 for KOOS QOL (Collins et al., 2011). The changes in KOOS QoL score in this study was an important finding since this component is essential in assessing falls risk and previous history of falling (Sherrington & Tiedemann, 2015). Moreover, previous history of falling correlates with the quality of the performance of ADL which in turn affects the QoL (Smee, Anson, Waddington, & Berry, 2012).

The improvements seen in KOOS scores were reflected with the changes in the physical function of the participants in this study. Physical function as measured by the TUG showed overall improvement after 16 weeks. It was highlighted in the systematic review (Chapter 2) that impaired physical function was associated with increased risk of falling in knee OA (Alencar et al., 2007). This was also supported by the cross-sectional study (Chapter 3) where poor physical function increased the likelihood of falling in individuals with knee OA. This is to acknowledge the important role of assessing physical function and prescribing balance exercises to address this issue on falls in individuals with knee OA. Also, it should be noted that other factors related to physical function might affect falls in individuals with knee OA. Contributing factors that may affect physical function include severity and duration of the condition (Mat et al., 2015). Thus, this call for further research on the interaction of other related factors that affect the physical function of individuals with knee OA and history of falling. This is to develop a holistic and tailored intervention and prevention management.

Fear of falling has been linked to functional decline, decreased QoL, and decreased self-efficacy (Scheffer, Schuurmans, Van Dijk, Van Der Hoof, & De Rooij, 2008). In this study, there was a decrease in FES-I scores, and it can be speculated that exergaming caused this improvement. In fact, exercise intervention is one of the most promising single intervention strategies in falls literature as there is an evidence that it can reduce falls and improve balance. (Büla, Monod, Hoskovec, & Rochat, 2011; Gillespie et al., 2009; Sherrington & Tiedemann, 2015). The increased confidence of the participants may be due to the challenges on the Wii Fit games as well as manoeuvring with the Wii Fit™ balance board. Through these mechanisms, exercise may reduce fear of falling and enable to perform

ADLs without falling, leading to a more positive appraisal of their ability to maintain balance (Howe, Rochester, Neil, Skelton, & Ballinger, 2011).

Despite most of the games being geared toward challenging the balance of the participants, the overall Composite scores obtained from NeuroCom Equitest® system and falls risk scores from PPA did not improved significantly. There are several reasons why less improvements were obtained from these scores. Aside from the sample size, it could be the dosage or parameters of the balance games. Even though the parameters were informed by the narrative synthesis (Chapter 4), the games itself may not be challenging for the participants. Thus, exergaming needs to be personalized to goals and performance levels of each individual participant (McMahan et al., 2011). Also, some of the studies that utilised Wii Fit™ showed improvement when it is used as an adjunct to other balance exercise programmes or physiotherapy (Bateni, 2012; Franco et al., 2012; Williams, Doherty, Bender, Mattox, & Tibbs, 2011). It was also observed that when PPA falls risk scores of the different assessment timepoints were compared, there was a greater increase between A1-A2 than A2-A3. This might be due to performance bias since participants were aware what to do and perform better during the succeeding assessment sessions. This was also seen with the use of NeuroCom Equitest® system where a possible learning effect between the trials were observed (Wrisley, Stephens, Mosley, Wojnowski, Duffy, & Burkard, 2007).

Knee muscle strength and stability are both needed to maintain balance. However, changes in knee muscle strength and instability did not reach significant change. It was anticipated that knee muscle strength and instability will not achieved significant improvement since most of the games are geared toward improvement of balance. Although strength might potentially improve with balance exercises, the intensity of the games may not be enough to challenge the muscles. This can be explained by the overload principle, a guiding principle of exercise prescription that has been one of the foundations on which the use of resistance exercise to improve muscle performance is based (Baar, 2006; Lange, Vanwanseele, & Fiatarone, 2008; Kisner, Colby, & Borstad, 2017). This principle focuses on the progressive loading of a muscle group where the amount of resistance should provide a greater stress on the muscle than it is normally accustomed to in order to increase strength. Also, the length of the programme may not be enough to improve muscle strength and instability of the knee joint. It may require a longer time (12 or more contacts or sessions) to see improvements in these outcome measures (Fernandes et al., 2013). Thus, calling for

further investigation if Wii Fit™ could increase muscle strength of the knee joint while taking advantage of its motivational effects.

The trend of increasing changes in balance scores and knee muscle strength, although did not reach significant difference when A2 and A3 were compared can be attributed in the significant difference in TUG, short form-FES-I, and KOOS subscales: Activity, Sports and recreation, and QoL. This interesting finding showed how important muscle strength and balance contribute to the increasing function, confidence of performing ADLs, and recreations of individuals with knee OA. A recent study observed a statistically significant association between increased knee extensor strength and improved self-reported physical function in people with knee OA who underwent exercise therapy (Hall et al., 2017). A previous study also supports associations of knee extensor strength and balance with physical function in knee OA (Pua, et al., 2011). Thus, it can be inferred that these impairments control how an individual can perform functions of daily life particularly in people with knee OA. The quantitative data suggest that balance performance and knee muscle strength may play important roles for function and that these clinical outcomes require attention.



## Part 2: Qualitative Phase

A qualitative study design was chosen as the next component of this study to investigate the acceptability of the study programme to the participants and explore their experiences of exergaming. Rationale for this approach is to elaborate on the quantitative findings of the first phase and provide a deeper understanding of the research questions. (Creswell, 2011). The following sections present the methods of the qualitative phase of the study. This is followed by the results of the focus group interviews and discussion of the qualitative findings.

### 5.7 | Qualitative phase: methods

#### 5.7.1 | Data Source

A purposive sampling technique was utilised in this study. All participants from the quantitative phase were invited to join the focus group irrespective of whether they withdrew at any point of the study or did not complete all the Wii Fit™ exergaming sessions. This was to ensure that the study captured a wide range of experiences, including potentially positive and negative feedback, and to reduce bias in the interpretation of the results.

#### 5.7.2 | Interview guide development

A focus group discussion template was developed within the research team, using questions that explored the acceptability of the participants and experiences of the study. (Appendix R). This template was used to map the questions and to allow the research team members to provide feedback through a brainstorming process. The template contained essential components following the suggestions of Kruger and Casey (2002) for developing questions for focus group discussion. These included topic/content guide, time allocation, and categories of question (Krueger & Casey, 2002). The latter included introduction, key, transitions and ending questions combined with follow-up and probing questions. Estimated time allocation for each question was provided to keep track of the duration of the focus group discussion (Krueger & Casey, 2014).

A three-step approach was utilised for the interview guide and questions, following the recommendations by King and Horrocks (2010) and Kruger and Casey (2002). First, the topic guide and questioning route were utilised to structure the group interview, making sure that the interview was in a conversational tone, spontaneous, and consistent. Second, the interview questions were reviewed and discussed by the research supervisory team. Feedback was also sought by peer review from a colleague (MB) who has previous experience of interviewing participants with OA. The third step entailed piloting the questions. Final key and probing questions for the focus groups are presented in Table 5.11.

**Table 5.11** Focus group guide key questions and probing questions.

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Key questions:
1. How did you find the testing or assessment sessions?
2. How did you find playing Wii Fit™ sessions at the clinic and at home?
3. Think back to an instance where you felt playing Wii Fit games was particularly good. Briefly, tell us what made it good?
4. What did you find not so good about playing Wii Fit games?
5. Was there an instance, while playing Wii Fit™ games, you felt uncomfortable or unsafe?
Probing questions:
1. That's interesting, will you explain further?
2. Can you provide us an example?
3. Could you tell us a little more?
4. Is there anything else?

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### 5.7.3 | Setting

The setting of the focus group plays a major role in a focus group discussion (King & Horrocks, 2010; Krueger & Casey, 2014). Three main aspects that might lead to a successful interview are comfort, privacy and quiet (King & Horrocks, 2010; Krueger & Casey, 2014). All the focus group discussions were conducted in the Boardroom at the School of Physiotherapy that comfortably accommodates up to ten participants. The room also had a small kitchen area which allowed for light refreshments provided at the end of the sessions.

#### 5.7.4 | Focus group discussion

A focus group method was employed as it facilitates an interactive discussion (Krueger & Casey, 2002; Morgan, 1996). Such interactive discussions are reported to provide in-depth understanding of participants' opinions and experiences with the study (Krueger & Casey, 2014). DM was present and acted as a note-taker. Although DM was not allowed to interfere or influence the discussion at any point, the presence of DM (primary investigator) might have influenced participants, particularly as he had supervised the intervention phase.

The sessions were arranged at the most convenient time for the participants and lasted between 30 to 60 minutes. All sessions were audio-recorded using a Dictaphone (Sony ICD- UX523F). The interview consisted of open-ended questions and also allowed the interviewer to diverge to clarify and probe the answers (Krueger & Casey, 2014). The flexibility of this approach, particularly compared to structured interviews, also allowed discovery or elaboration of information that was important to participants (Gill, Stewart, Treasure, & Chadwick, 2008).

According to Kruger and Casey (2014), the true pilot test is the first focus group discussion with participants (Krueger & Casey, 2014). Pilot testing was conducted with the first group of participants. It is suggested that if the first session provides data substantial enough to contribute to the analysis, then it may be considered as the first focus group (Krueger & Casey, 2002). After the first session, a debriefing was conducted between DM and MB to check what had transpired. The debriefing allowed reflection on the completed interview, an opportunity to decide whether to change some questions, and to consider if the first session (pilot) met requirements to be included in the qualitative study as the first focus group. As the first focus group appeared to provide substantial answers relevant to the research aim, it was decided to include it in the interpretation of the results.

Once all the interviews were completed, they were professionally transcribed verbatim. Before being analysed, transcripts were checked by listening to the audio-recorded interview. Any identifying personal information was removed. Following checking of the transcription, a content summary of the focus group that the participant had attended was sent to them through email for participant validation. Participants were asked to check factual errors, and to verify or comment on the summary to ensure that it reflected their

descriptions and answers. All participants responded with no disagreement in the summary of transcript given.

#### 5.7.5 | Data analysis

Two methods of thematic analyses were used in this qualitative study. Firstly, the template analysis approach was used to analyse data relating to the feasibility of the study. Secondly, a general inductive approach was used to explore participants' experiences of using exergaming.

Template analysis is a form of deductive thematic analysis that involves the development of a coding 'template', which summarises themes identified by the researcher (King, 2012). In this study, the key questions on feasibility and safety were structured to collect qualitative data about participant's insights about study procedures. The analysis was focused on the important data set and organised in a meaningful and useful manner (Brooks, McCluskey, Turley, & King, 2015; King, 2012). The technique also relies upon the coding of text in a thematic way to produce a given structure, or template (Brooks et al., 2015). Specific themes that the researchers aimed to explore with reference to feasibility of the study included the participants' perspectives of the acceptability of frequency and duration of the assessments and training sessions. Thus, this template analysis technique was useful to analyse and structure qualitative data with regard to the feasibility of the study, specifically with regard to acceptability.

The general inductive approach was used to analyse participants' experiences while playing the Wii Fit™ at the School and at home. This approach allowed the research findings to emerge inductively from the data through coding and theme generation which did not need to be attached to a set theoretical concept (Braun & Clarke, 2006). The emergent themes in this study helped in the overall interpretation of the results of the quantitative results.

Five steps were followed for these thematic analyses: the preparation of the data, 'immersion' by the researcher in the data, creating code for the data, searching for overlaps, and refining and revising the categorical system (Miles, Huberman, & Saldana, 2013; Thomas, 2006). First, the transcripts were checked against the recordings of the data to ensure accuracy. After checking the transcripts against the recordings, the transcripts were

read and re-read by DM to immerse himself in the data (Miles et al., 2013). Notes were taken during reading to record items of potential interest, similarities or disparities with other participants or potential codes. Notes taken by DM during the focus groups were also cross-checked with the transcripts by CR.

Coding was subsequently undertaken by DM. The NVivo software tool (v8, QSR International) was used to facilitate analysis through computerised coding, organisation, and classifying of data. Two steps of coding were used. The first, descriptive coding, is a method of taking a segment of textual data of interest and inserting a code to a template or prepared code or nodes based on the key questions. The second coding method used was written coding, which are codes of textual data more explanatory in nature (Miles et al., 2013; Saldaña, 2015). Codes were tabulated based on the two topic questions: feasibility and acceptability. The tabulated codes were used for discussion with the supervisory team in order to identify possible themes.

Thematic analysis was then performed whereby codes were read and re-read to look for certain repetitive and overlapping categories which were labelled as themes. Themes were then named and defined to bring meaning to the data, and presented in a matrix table (Miles et al., 2013; Saldaña, 2015). Both methods of presentation of the themes also included appropriate raw data, called quotes, to give meaning to the information that was generated. After identifying the themes, these themes were reviewed by the research team members.

The last step involved refining the themes using thematic analysis and constant comparative methods for creating categories and looking for overlaps (Miles et al., 2013). The research team worked together on this process until the final themes and subthemes were identified. Development of the codes and themes are seen in Appendix S.

#### 5.7.6 | Ensuring rigour

In qualitative study, rigour is the means of demonstrating credibility and integrity of the study (Ryan, 2005). Rigor is necessary to ensure that a study is of sound quality. Several strategies were used in this study to ensure rigour, including transparency, trustworthiness, validation, code-recode strategies and reflexivity (Miles et al., 2013; Ryan, 2005; Saldaña, 2015).

Recording and transcribing of the interviews by a professional third-party transcriber contributes towards transparency and trustworthiness of the data. Trustworthiness is also assured by discussing emerging themes within the research team, and by respondent validation. In this study, the moderator who was not part of the study facilitated the discussion. Rationale behind this was that DM conducted the intervention component of the study, thus may have biased the discussion. Accuracy of the data, as well as scientific and ethical integrity, was also maintained at all times by ensuring that their identities would not be revealed in any form such as publication. During the focus group interview, participants were allowed to have the opportunity to speak and to have their answers heard, irrespective of their views.

Validity and reflexivity are important issues in qualitative studies (Miller et al., 2013). Respondent validation was done to ensure validity of the focus group. Transcripts were returned to the participants who were asked to validate their answers. For this study, a subset of transcripts was double checked by CR to ensure consistency of coding decisions and any differences in opinion were discussed and resolved by consensus. This process also ensured credibility (Ryan, 2005). Reflexivity refers to recognition of the influence a researcher brings to the research process (Miles et al., 2013). The moderator in this study (MB) is a physiotherapist specialising in OA, but she did not participate in any other part of the studies included in this thesis. Also, none of the participants declared that they were known to the moderator prior to the focus group to minimise any form of bias. DM was also present during the focus group sessions which may have influenced the participants' answers and insights regarding the study. Data were analysed by DM who has degree in physiotherapy and was involved in delivering the intervention.

## **5.8 | Qualitative phase: results**

### **5.8.1 | Participants' description**

A total of six participants expressed interest in joining the focus group discussion. Initially, two focus group sessions with three participants were planned. However, due to time constraints, three focus groups were held with two participants each. The duration of focus group discussions ranged from 30 to 60 minutes. Four women and two men aged

between 45 and 66 (mean age of 54 years old) were interviewed. A summary of the participant demographics is summarized in Table 5.12.

**Table 5.12** Participants demographics and falls characteristics.

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
<b>Focus group</b>	Session 1		Session 2		Session 3	
<b>Age</b>	57	66	66	45	45	45
<b>Gender</b>	Female	Male	Female	Male	Female	Female
<b>BMI</b>	22.1	29.4	22.6	26	42.7	31.2
<b>Falls Characteristics</b>						
Number of falls	2	6	2	1	2	2
Location of falls	Outdoor	Outdoor	Outdoor	Outdoor	Outdoor	Outdoor
Activity during fall	Walking	Walking	Walking	Walking	Stairs	Walking
<b>Short FES-I (7-28)<sup>a</sup></b>	12	16	20	8	15	16
<b>KOOS Scores (0-100)<sup>b</sup></b>						
KOOS-Pain	63.89	58.33	50.00	87.22	88.89	63.89
KOOS-Symptoms	39.29	50.00	42.86	53.57	50.00	46.43
KOOS-ADL	77.94	69.12	51.47	95.59	85.29	61.76
KOOS-Sport/Rec	25.00	25.00	20.00	75.00	20.00	75.00
KOOS-QoL	37.50	37.50	43.75	62.50	62.50	43.75

*Note.* KOOS, Knee Osteoarthritis Outcome Score; ADL, Activities of Daily Living

<sup>a</sup>Short FES-I, lower scores indicate lower balance confidence, <sup>b</sup>KOOS scores, 100 indicating no symptoms and 0 indicating extreme symptoms)

### 5.8.2 | Qualitative findings – feasibility

Feasibility of the assessment and intervention in terms of frequency, duration, and safety was analysed deductively using template analysis. The key questions on feasibility and safety were structured to collect qualitative data about participants' insights regarding procedural aspect of the study such as frequency and duration of the assessment and intervention. With template analysis, the use of *a priori* codes and categories allowed to define themes in advance. A summary of the themes and other examples of direct quotes to support the themes are presented in Table 5.13.

### 5.8.2.1 Theme 1: Feasibility from participant's perspective

This theme was pre-determined as part of the feasibility study, thus was analysed deductively. The feasibility of the study was categorised into two: assessment and intervention sessions. All participants viewed that the study is feasible from their perspectives as shown in their affirmation with the study. Participants found that the assessment sessions were worth participating and did not burden them unnecessarily. The frequency of assessments (baseline, after eight and 16 weeks) for them was evenly distributed. The duration of the assessment approximately an hour to complete the questionnaires, and to perform the physical performance, muscle, and balance testing was enough. The instructions and objectives for each outcome measures were clear and intuitive. These perceptions are exemplified in the following quotes:

*“Very clear and not too complicated and not too demanding and I could understand how it related to the old knee issue. The timing was fine. The input was ok, it wasn't onus. Nicely spaced out, I guess.” [Participant 2]*

*“I think I found it just right. It was not too short and not too long.” [Participant 4]*

Aside from the duration and frequency of the assessment, one participant commented about the questionnaire (KOOS). Participant 3 found the self-reported questionnaire (KOOS) was a bit confusing and difficult to answer particularly when quantifying the symptoms of the knee in the past seven days:

*“Sometimes it [questionnaire] seems quite tricky. Like you know, answering the questions: mild, moderate, always [Participant 3]*

In terms of the intervention, all participants felt comfortable using the exergaming system Nintendo Wii Fit™. Participants who were interviewed were first time users and most of them found exergaming very interesting. Only one participant [Participant 5] mentioned that it was a little bit boring comparing the exergaming to the aqua-jogging she was doing before. Frequency and duration of the exergaming intervention were also acceptable.

*“I think it was a good decision to have a session here [school] because I was kind of a bit forcing myself to do the other sessions... I'm not a regular exerciser. It was good to have this session*



*otherwise I would probably skip some sessions. But if you said you know, four sessions, I imagine I wouldn't be able to do that.” [Participant 4]*

Similarly, supervised sessions were found to be helpful in confirming whether they were exercising correctly, feedback if they were improving and progressing the games.

*“I was eager to move into the exercise which could help me, and I did, most of them it was like one hour but of course, in between, I'm not familiar with the TV or connecting. The session here [school] helped me understand the games, movements, and going to the next level.” [Participant 3]*

Participants initially had difficulty navigating the layered menu on the Wii Fit™. However, the intervention kit given to the participants and the assigned Mii avatar were helpful to improve system navigation. A more common difficulty was allocating the training sessions. It was a problem at the beginning of the study fitting the time for exergaming at the School and at home:

*“The frequency I sometimes found hard if I had things in the evenings during the week. Because I work every day, I don't get home till about six o'clock, so sometimes it was harder to do it on a week day but I would just try and, I would do it sometimes twice on the weekend instead.” [Participant 5]*

*“It was a bit difficult just to allocate time in the evenings and occasionally in the mornings I'd, just organising a space in the day to do it...and suddenly oh, five or six days had gone past and I haven't done anything but the routine once you set it up was yep, not too difficult.” [Participant 2]*

#### 5.8.2.2 Theme 2: Safety while doing exergaming

No adverse events were reported. Two participants reported falls, but the fall did not happen during the sessions. Most of the participants who were interviewed reported feeling safe at any part of the exergaming session. However, some participants reported feeling unsafe and anxious while playing at the beginning of the study. This theme is exemplified by the following quotes:

*“I was a bit anxious then that I might miss the board or fall off or go over the edge but over time, oh it didn't take very long actually, I just got used to the space how far I needed to step to be on it or off it.” [Participant 5]*

*“No, I didn't feel unsafe, tired sometimes, I mean I didn't.” [Participant 2]*

**Table 5.13** Summary of the themes and sub-themes with other direct quotes from the participants to support the emergent themes using template analysis

Themes	Sub-themes	Participants quotes
Feasibility	Assessment	<p><i>“From the start to end, the instructions were very clear” [Participant 5]</i></p> <p><i>“I think it was quite straight forward, I didn’t have any difficulty with understanding the instructions.” [Participant 6]</i></p> <p><i>“Yeab very clear and not too complicated and not too demanding and I could understand how it related to the old knee issue.” [Participant 2]</i></p> <p><i>“I think I found it; it was like just right. It was not too short and not too long” [Participant 4]</i></p>
	Intervention	<p><i>“I found, at home sessions, yeab like it was up to you what you put into it so you could you know, adjust your times. Some days I may have only had half an hour that I had spare and I would you know, work out the exercises and do them to fit that timing. But when we came into here, we had a set you know, one hour say so that timing was you know, you made allowances for that timing anyway.” [Participant 2]</i></p> <p><i>“Each session was kind of taking half an hour for me which I think alright.” [Participant 4]</i></p> <p><i>“I might’ve, half an hour seemed to be the optimum length of time.” [Participant 3]</i></p>
Safety	Being safe	<p><i>“Yes, in the beginning, I felt a bit unsafe until I got used to the concept of stepping on and off the board, especially for the step, step plus, those things where you’re having to look at the screen but you’re stepping on and off the board.” [Participant 6]</i></p> <p><i>[P1] I nearly lost my balance, but no I...no I never felt unsafe at all [Participant 1]</i></p>

### 5.8.3 | Results of the general inductive approach

Acceptability of exergaming was assessed by asking participant’s experiences regarding the use of Nintendo Wii Fit™. Most participants expressed high expectations that Wii Fit would be fun to play, would help their knees and balance, and increase their overall physical activity level because of the additional fitness and exercise combined with gaming. Three major themes emerged from their experiences: (1) exergaming boots motivation, (2) interactions with exergaming, and (3) barriers in using exergaming. An in-depth explanation of the themes is outlined in this section and summary of the themes and other examples of direct quotes to support the themes are presented in Table 5.14.

### 5.8.3.1 Theme 1: Exergaming boosts motivation

Motivation appeared to be one of the critical aspects of their exergaming experiences using Nintendo Wii Fit™. The motivation to participate in this form of exercise was supported by the sub-themes of enjoyment, competitiveness, and sense of achievement. Codes such as “fun” and “interesting to play” explained the enjoyment experience of the participants while playing Wii Fit™. At the beginning of the study, most participants expected Wii Fit™ would be a fun way to engage in exercise. However, their expectations were exceeded in terms of engagement and time devoted in playing. During the interview, participants often described that these expectations were met later in the programme. For example:

*“Yes! Once that got into the feel of it, yeah it was enjoyable. You forgot the time” [Participant 2]*

*“One here [school] and two at home, yeah. Oh, I enjoyed it, I enjoyed the [laughs] games”  
[Participant 4]*

*“I enjoyed the games. It was very interesting. Participant 3]*

Participants described the Wii Fit™ as a novel and convenient approach to engage and bring out not just enjoyment but also competitiveness. The competitive nature of games motivated the participants to play with the exergaming system. It provided a sense of control and fun to compete against themselves due to the scores they have seen while playing:

*“I enjoyed them, like probably competitively as well so competing against yourself every time and so I liked ones that were quite challenging, and I’d always try and beat my next or beat my last score and yeah, I was very competitive” [Participant 1]*

*“I guess I chose games that were different, used slightly different parts of my brain or my body and balance; challenging for those aspects I guess, that’s why I chose them. I felt challenged about that to ok, I’m gonna do a bit better next time” [Participant 5]*

The games presented a series of challenges in increasing difficulty. This provided participants opportunities to acquire and practise new skills, and then demonstrate their mastery on playing the games. Some of the participants were frustrated at the beginning but they recognised that they needed to play or practice often. The combination of fun

contributed by the games and the competitiveness nature of the participants allowed to enhance the feeling of achieving something which in turn enhanced their commitment to continual practice of exergaming:

*“It’s kind of positive reinforcement I think, is giving you some sort of a feeling that you achieve something” [Participant 4]*

*“It took time but then I mastered it till then I ran for the other one, then I failed it... but I said never mind, as long as I’ve mastered it, it’s alright” [Participant 3]*

*“I wanted to beat that one that was on the screen and be the best you know, so it was always a, you know, great achievement” [Participant 1]*

#### 5.8.3.2 Theme 2: Interactions in exergaming

There were two types of interactions provided by exergaming. The interaction with technology as exemplified by the ability to use and navigate the system without prior experience of using the Wii Fit™ system, and the interaction with family members while playing Wii Fit™ games. This theme was supported by these two sub-themes: technology interaction and socialisation. These were exemplified by the following verbatim responses from the recorded data:

*“Even though I don’t play those games and, we don’t have any of those and we don’t watch TV quite often, you know it was easy to navigate” [Participant 4]*

*“You always felt relaxed and yeah, and I used to actually find it quite good, there were a couple of times when there might have been somebody else there [school session] and you could kind of encourage” [Participant 2]*

*“When I finished, I’d spend you know, more time, playing some other games as with the kids, they enjoyed it as well” [Participant 4]*

### 5.8.3.3 Theme 3: Barriers of exergaming

Initial impressions of Wii Fit™ were mostly positive at the beginning of the study. However, participants reported common barriers that people report when trying to engage with this type of technology, particularly the repetition of display or interface, and feedback of the virtual trainer. Although none of the participants expressed concerns in learning to use the Wii Fit™, some participants observed some delay in terms of the system sensing the movement and syncing with the system. For example:

*“Watching the same screen over and over is yeah, so down the track if I sort of, if I was going to use it and I’m thinking about maybe getting hold of one but I think I’d probably find that the repetitive screen thing a bit off putting after six months of doing the penguin thing” [Participant 2]*

*“I sometimes used to get annoyed with the people speaking back at you, that would be the only thing that I found rather annoying” [Participant 1]*

*“Well perhaps the accuracy of the software was a bit lacking but (chuckles), well there’s a certain amount of familiarity to gaming in that as well” [Participant 2]*

**Table 5.14** Summary of the themes and sub-themes with corresponding quotes from the participants to support the emergent themes.

Themes	Sub-themes	Participants quotes
Exergaming boosts motivation	Enjoyment	<p>“Yes, one here and two at home, yeah. Oh I enjoyed it, I enjoyed the [laughs] games” [Participant 4]</p> <p>“I do enjoy, after my exercise I’m good as gold, I haven’t got a problem. I’m happy exercising” [Participant 3]</p>
	Competitiveness	<p>“I don’t especially like doing exercise, that’s why I’m overweight so the ones that allowed me to exercise as a sort of secondary thing while I was working on the mental thing, that’s what I liked ‘cause it didn’t seem so much like exercise to me” [Participant 5]</p> <p>“I’m quite competitive and so that was what was driving me...and making me want to you know, oh I’m gonna do it one more time and oh I’m gonna do it another time” [Participant 1]</p>
	Sense of accomplishment	<p>“It’s interesting, it’s challenging, I kept wanting to improve because you have to... those games, or all of those games actually you need to have got through all levels to be able to feel that you’ve completed that game, so I enjoyed it” [Participant 6]</p> <p>“It’s kind of positive reinforcement I think, is giving you some sort of a feeling that you achieve something” [Participant 4]</p>
Interactions in exergaming	Technology interaction	<p>“Even though I don’t play those games and, we don’t have any of those and we don’t watch TV quite often, you know it was easy to navigate” [Participant 4]</p> <p>“It was definitely something new. I would never buy a Wii Fit you know...but then having this presented and looking, I thought oh that’s actually quite good, it could be something to look into” [Participant 3]</p>
	Socialisation	<p>“It was enjoyable, especially with other people playing as well” [Participant 6]</p> <p>“When I finished, I’d spend you know, more time, you know playing some other games as with the kids, they enjoyed it as well” [Participant 4]</p>
Barriers to use exergaming	Repetition	<p>“I think I might want a different screen to look at” [Participant 4]</p> <p>“I think if you just stayed on the same stage all the time, you would then find, oh you wouldn’t play anymore because you were always achieving so” [Participant 1]</p>
	Accuracy	<p>“Well perhaps the accuracy of the software was a bit lacking but (chuckles), well there’s a certain amount of familiarity to gaming in that as well” [Participant 2]</p>

## 5.9 | Qualitative phase: discussion

Positive experiences were mostly reported by the participants after playing Wii Fit™ for eight weeks. The main themes emerged in this study such as motivation and interaction facilitated the experiences of the participants which can be linked to the acceptability of exergaming. Several studies in exergaming using Wii Fit™ have used a qualitative approach to validate and complement the results of their quantitative findings (Chan et al., 2012; Chiang, 2011; Nawaz et al., 2015). However, these were mostly conducted with healthy older adults and neurologic conditions. Thus, the findings in this study are novel because they are conducted on a people with knee OA. At the same time, participants shared similar experiences with the previous qualitative studies as reflected in the overarching themes that emerged in this study (Chan et al., 2012; Chiang, 2011; Nawaz et al., 2015)

Exergaming heightened the motivation of the participants in this study. This can be explained by the attributes of enjoyment, competitiveness, and self-accomplishment that supported the theme on motivation. Exergaming has been shown to be an enjoyable activity for adults and older adults (Sween et al., 2014), thereby having a potential for sustained activity participation. The concept of time flying is said to be positively correlated with enjoyment, with time seeming to pass more rapidly with enjoyable activities (McMahan et al., 2011). This distortion in the perception of time can be associated with the concept of the flow theory (Eccles & Wigfield, 2002). Flow theory is defined as an intrinsically motivated behaviour in terms of the immediate subjective experience that occurs when an individual is engaged in an activity (Csikszentmihalyi, 2014). It is an optimal experience and high level of enjoyment that is said to occur when immersed in a goal-directed task (Csikszentmihalyi, 2014; Eccles & Wigfield, 2002). Although Wii Fit™ is considered as non-immersive VR tools use in rehabilitation (Rizzo, Lange, Suma, & Bolas, 2011), it seems that potential flow experience can also be experienced when playing exergaming using Wii Fit™. A recent review of immersion in VR in rehabilitation found that there was no distinct correlation between increased immersion and improved users' performance (Rose et al. 2018). This means that further investigation should be done in terms of the relationship between the level of immersion (fully-, semi-, or none-immersed) and the results of the targeted performance using exergaming.

The sub-themes we identified on competitiveness and self-accomplishment also supported the theme on motivation. Participants in the study retained their interest because of their competitive nature that can be observed during playing as they beat their own scores or scores of other participants. This competitive nature can be explained by the Self-determination theory. This theory argued that individuals seek out optimal stimulation and challenging activities (Deci & Ryan, 2008). Individuals find activities that are intrinsically motivating because they have a basic need for competence (Eccles & Wigfield, 2002). In addition, intrinsic motivation is maintained only when a person feels competent and self-determined (Deci & Ryan, 2008).

Participants in this study challenged themselves to stay focused to achieve something and continue playing the game to get a higher score. It should be acknowledged that extrinsic motivation may also influenced the participant to continue playing the Wii Fit™ games. The fact that they agreed to join the study affects their motivation in accomplishing the task. Interestingly, five out six participants reported multiple falls. This could have impacted the results of the study since those with multiple falls might have some difficulties in playing the games. This might also affect their perceptions in terms of using the Nintendo Wii Fit™ as an exergaming tool.

Given the nature and mechanics of exergaming, the focus of attention is not on the movements itself, but on the outcome of the movements in the game (Lamoth, Alingh, & Caljouw, 2012). This gave participants the feeling of accomplishing a specific task. One of the advantages of exergaming compared to conventional exercises is that it can motivate individuals to practice and by performing dual tasks, users can train both cognitive and motor skills (Fitzgerald, Trakarnratanakul, Smyth, & Caulfield, 2010). When individuals are intrinsically motivated, they are interested in and enjoy the activity. They are eager to do more since they have achieved something (Standage, Sebire, & Loney, 2008). Thus, these components can be an important determinant influencing the time an individual allocates to an activity that can be used to sustain compliance or adherence with exercising.

The second theme of interaction with exergaming was related to the motivational component of exergaming. This can be seen with the interaction of participants with the Wii Fit™ system and with other individuals. A scoping review examined the usability of exergaming and found that smooth interaction with the gaming system enhanced the



acceptability and engagement of participants (Nawaz et al., 2015). Thus, interaction of participants with the technology is essential to sustain an individual performing a specific task. Moreover, the interaction is not only seen with the technology but also extended to the social interaction. One of the benefits of exergaming is to engage and play with others (participants) and family members (kids and grandchildren) (Khoo, Merritt, & Cheok, 2008). Although the intervention was designed to play alone (one player), leveraging older adults' social network and encouraging intergenerational play could further increase engagement and motivation (Koeman & Sheehan, 2014). Lastly, there is a strong evidence that group exercise is beneficial particularly in this age group (Millington, 2015; Sherrington et al., 2008; Williams et al., 2011).

The last theme emerged from the focus group discussion was the barriers of exergaming. Participants highlighted some problem with the accuracy of the Wii Fit™ system and repetitiveness of the game scenes (background) and settings (e.g. beginner and advance stage). Even though participants did not have prior use of the system, they have confidence in using the technology due to the simplicity of the system. However, participants expressed that they were annoyed when the system was not in-sync particularly when they are moving or pointing the Wii remote to the screen. These were also similar problems reported in previous studies where technical issues with the use of the system were reported (Bainbridge et al., 2011; Rendon et al., 2012). The barriers presented in the study were also rooted from the repetition of the same game setting. (McMahan et al., 2011). Although different game levels and modes are available, the felt the redundancy of the game which can lead to boredom. Thereby, if exergaming holds the potential to increase adherence to exercise by creating a medium to entertain and challenge individuals with knee OA, then then this accuracy problem and repetition must be addressed in future studies.

## 5.10 | Integrated discussion

This mixed methods study found that it is feasible and acceptable to use Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling in adults with knee OA. The pre-defined feasibility criteria such as recruitment, retention, and compliance were successfully met. This was affirmed by the participants' views on the procedures of the study in terms of frequency and duration of the assessment and intervention sessions. The study also demonstrated that it is safe to use Nintendo Wii Fit™

as an exergaming tool as there were no adverse events reported throughout the study period. Moreover, preliminary indication of changes in clinical outcome measure scores were observed in KOOS Sports/Recreation, KOOS ADL, KOOS QoL, TUG, and short form FES-I. Participants also expressed positive experiences with the exergaming programme. They have enjoyed playing Wii Fit™ games and found it motivating and interactive in spite of some barriers with the use of technology.

The results of template analysis regarding feasibility of the Nintendo Wii Fit™ system confirmed the quantitative finding about retention in the study. There was an agreement between retention rate and the participants' responses during the focus groups in terms of the study timeframe (duration and frequency). The participants mentioned that the study was doable and no burden from their part. In terms of the intervention frequency and duration, participants expressed that the exergaming sessions per week were manageable given the frequency and length of the programme. Although there were difficulties in arranging the schedule and in navigating the system at the beginning of the exergaming programme, there was a recognition that these were part of the training and learning curve using the Wii Fit™ system. Overall, they felt to be intuitive and could operate the Wii Fit™ system without the need for extensive instructions.

Other factors contributing to good compliance and retention rate of the participants were highlighted in the findings of the qualitative component of this study. The supervised sessions were valued by the participants since they wanted to receive feedback and use the session as a regular time to exercise. All participants were able to use the system independently but with some difficulty at the start. The intervention kit, instructional materials, and feedback given to the participants helped to facilitate the flow of the programme. Additionally, there were no difficulties in terms of using and setting up the Wii Fit™ system which also facilitated good participants' compliance in the study. Lastly, the perceived benefits and existing knowledge about exercise and the added fun of gaming facilitated their attendance in the study.

There was an agreement between qualitative and quantitative findings regarding the safety of using Nintendo Wii Fit™. The safety of the participants in this current study was monitored with written logs and supervision similar to other exergaming studies (Agmon et al., 2011; Bainbridge et al., 2011; Franco, Jacobs, Inzerillo, & Kluzik, 2012; Rendon et al.,

2012). The implication of these findings support that exergaming can be used as an intervention or exercise programme at home for as long as proper instructions are given to the participants.

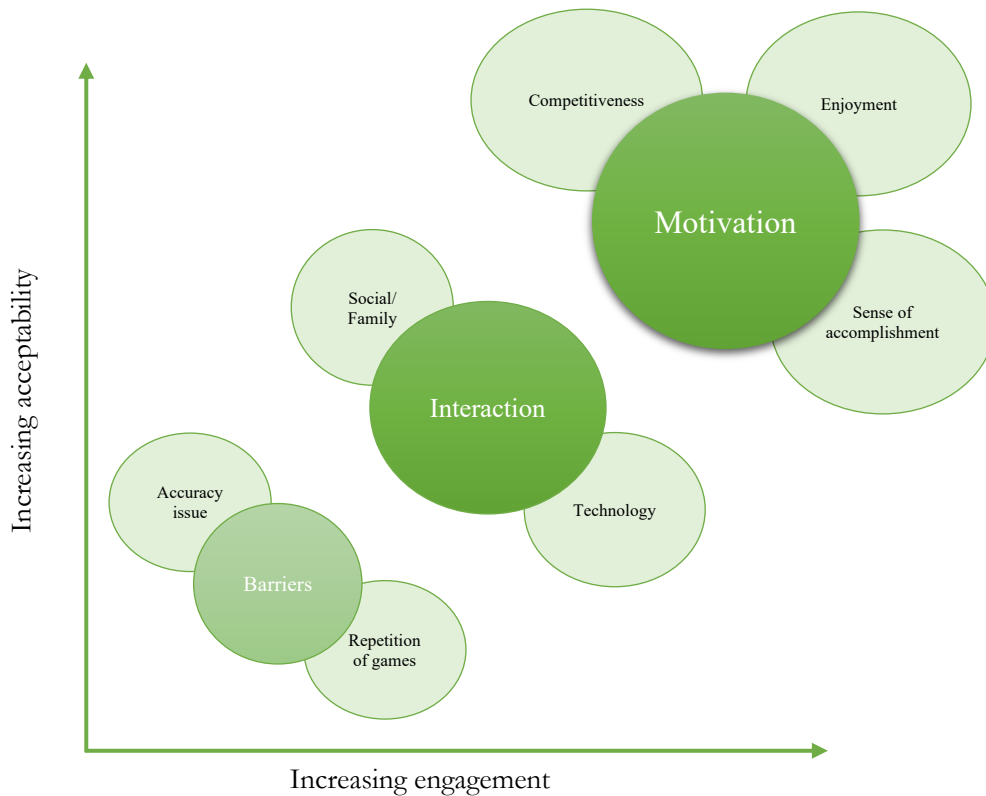
Chao et al. (2014) used the experiences of the participants to examine the acceptability of exergaming using Nintendo Wii Fit™ (Chao et al., 2014). There was a link between participants experiences and acceptability of exergaming in this current study. Both quantitative and qualitative findings contributed with the acceptance of the Nintendo Wii Fit™ as balance exergaming tool for individuals with knee OA. Quantitatively, it appears that the study was acceptable as shown by compliance and retention of the participants. Qualitatively, the study design was acceptable for them particularly the timeframe (duration, frequency), and procedures of the assessment and intervention. The responses from the focus group also identified strong emerging themes associated with attitudes toward the use of this technology as seen with the engagement of the participants.

The effect of increasing engagement in this study was mainly due to motivation and interaction provided by exergaming. On the one hand, barriers such as problem with system and repetition of the games can lead to decrease engagement which in turn decreases the acceptability. Indication of engagement with this form of exercise is also supported by voluntary participation, retention, and compliance in this study.

Acceptability can be supported by the most commonly use model when it comes with acceptability of technology, the Technology Acceptance Model (TAM) (Venkatesh & Davis, 2000). This theory models how users come to accept and use a technology. The model suggests that when users are presented with a new technology, a number of factors influence their decision namely perceived usefulness and perceived ease-to-use. Several studies had used TAM for acceptability and utilization in exergaming balance literature (Nawaz et al., 2015). These components were seen in this current study as participants believed that exercise plus gaming can help them and the use of Nintendo Wii Fit™ was relatively easy.

The relationship between the themes coming from general inductive approach, and the contributing engagement and acceptance is illustrated in Figure 5.12. It shows how the themes of motivation, interaction, and barriers contributed to increasing acceptability and

engagement with exergaming. The themes with their supporting sub-themes were arranged to show the relationship of engagement and acceptability. For example, presence of technological barriers will result to less engagement and thus, less acceptable for the user. If the exergaming programme includes a good technology system in terms of navigation and ease-of-use, coupled with a facility that promotes social interaction, then it can facilitate engagement and acceptability in this kind of technology. Finally, the major contribution of enjoyment, competitiveness, and sense of accomplishment were able to maximise the use and benefits of exergaming and eventually be accepted as on the tool in rehabilitation for knee OA population.



**Figure 5.12** Framework of increasing engagement and acceptance of this study

### 5.10.1 | Strengths and limitations

Based on the researcher's knowledge, this is the first mixed methods feasibility conducted to investigate the use of Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling specific for knee OA. One of the strengths of this study was the use of mixed methods design where integration of quantitative and qualitative findings provided greater insight in addressing the issues of using exergaming in a knee OA population. The use of the two methods also allowed the strengths of both types of study to off-set the methodological weaknesses inherent in the other. In the quantitative component, the intervention protocol was informed by the synthesis of available literature with regards to parameters to improve balance and decrease the risk of falling. Calibration was also conducted to ensure that the data and features of Wii Fit™ system are accurate and consistent (Leach, Mancini, Peterka, Hayes, & Horik, 2014). Calibration was not reported in most of the Wii Fit™ studies (Manlapaz et al., 2017). Furthermore, most of the assessment used in this study are routinely used in clinical practice such as muscle strength testing and TUG. Lastly, there were also some steps to decrease some of the biases in the study. The primary researcher was blinded with the assessment to avoid conscious and unconscious bias in the design and results of the study. In the qualitative phase, the use of an interviewer unknown to the participants decrease also the bias. To help address other biases in qualitative study, focus discussion notes and engagement with the research team were undertaken to avoid inadvertent bias in development of themes. The steps mentioned to ensure rigour of the study was observed throughout the qualitative phase.

The study was primarily designed to examine issues of feasibility and acceptability and was not specifically designed to look at effectiveness. This also reflects the purpose of a feasibility study, which is to test the rationale and method proposed for use in the future study (Arain et al., 2010). The limitation of the present research also relates to the lack of a passive control group being a single group intervention with pre-post-test study design. As the study was underpowered without a control group, it is impossible to determine if changes in clinical outcome scores were due to the intervention or other factors such as familiarity with tests over time. However, the use of one-way repeated measures study design in this study has several advantages. It can be very beneficial since it can control for factors that cause variability between subjects. Repeated measures designs can track an effect overtime, such as the learning curve for a specific task (Crowder, 2017). In this

situation, it is often better to measure the same subject at multiple times rather than different subjects at one point in time for each. A repeated measures design can also use fewer subjects to detect a desired effect size (Portney, 2015).

Limitations in the qualitative study included the number of participants per focus group discussion. Some of the reasons stated for non- participation were difficulty in taking time off work and being unable to travel which were beyond the control of the primary investigator. Nevertheless, the small sample of participants from the focus groups provided an in-depth and participative discussion. Past experiences and prior assumptions can influence the research process and it is important within qualitative research that these biases are considered and acknowledged to help promote trustworthiness (Miles et al., 2013). The idea for this research arose from the experiences of the primary investigator as a clinician and researcher having worked with previous exergaming projects, therefore it was not possible for him to come to this research without having a priori ideas about their experiences. However, this was mitigated by assigning a different facilitator during the focus group discussion and consultation with the research team during the data analysis. Lastly, the primary investigator included willingness to set-up the Wii Fit component at home as part of the inclusion criteria. This may have introduced bias in relation to acceptability of exergaming and may have reduced external validity of the findings.

#### 5.10.2 | Recommendations

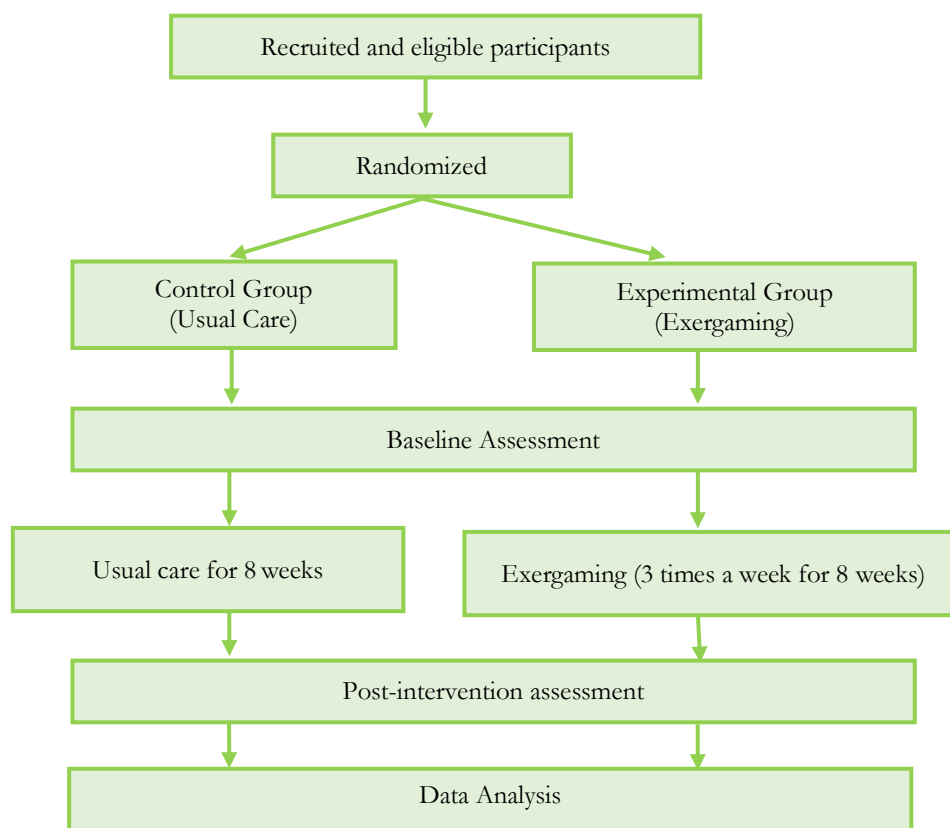
This study appears to be feasible however there are several recommendations that need to be considered in this study before conducting a full RCT. Some aspects of feasibility were not measured quantitatively such as feasibility of the measurement tools (time taken to complete questionnaires, difficulty of completing the questions). This must be considered on the next phase of the study. The most efficient approach for recruiting participants was with the use of database (emails) which highlights the importance of incorporating communication technologies into recruitment in the future trial (Gupta et al., 2015; Martinez et al., 2014). Additionally, the best physical places to recruit a definitive trial were community centres (e.g. noticeboards at supermarkets and cafes). This strategy of recruitment also supports further use of low-cost recruitment method in future research.

The current literature has reported that enjoyment in rehabilitation has been shown to increase adherence to rehabilitation programming (Agmon et al., 2011; Bainbridge et al.,

2011; Bateni, 2012; Bieryla & Dold, 2013; Nicholson et al., 2015). In order to elucidate the potential of exergaming to improve compliance/adherence, the following are the suggestions for the future trial. First, the scores can be routinely monitored and recorded to further challenge the participants and reinforce competitiveness and enjoyment. Future research needs to consider other factors such as socio-economic factors (educational background, civil status) and identify the types of individuals who would engage with this technology before using in their own home. Game software should incorporate progression where there is an automatic way adapting with the level of challenge (difficulty and load) to the current performance level, making games more challenging when the user achieves consistently good performance and less challenging when performance drops. This might overcome the barriers on repetition mentioned in this study. Furthermore, if information about how the players moved during the gaming session can be obtained then this can give insight into the quality of exercise performed. Thus, addressing the issue on the level or intensity of balance games. Even though exergaming is largely purported to be fun and motivating, there is still little evidence of whether exergames achieve higher adherence than conventional forms of exercise. Future studies should include outcomes on adherence for exergaming interventions. This also calls for prospective longitudinal studies to be conducted.

### 5.10.3 | Design of the future exergaming study

The objective of the future study is to determine the effectiveness of exergaming in improving balance and decreasing the risk of falls in older adults with knee OA. Given the positive results of the feasibility study, the future study will be an eight-week prospective, assessor blinded randomised controlled parallel-group trial. The same inclusion and exclusion criteria will be used to recruit participants. The included participants will be randomised using a computer-generated random sequence with block allocation. Participants in the control group will continue their usual activities and will not use Nintendo Wii Fit™. Participants who will be assigned in the experimental group will undergo the Wii Fit™ exergaming programme three times a week for eight weeks following the protocol set in the feasibility study. Figure 5.13 shows the flow of the future study.



**Figure 5.13** Flow of the future study

The primary outcome measures will include SOT using NeuroCom Equitest™ system to measure balance and the Short form PPA since the study was also interested in the reducing the risk of falling. Secondary outcome measures for balance will be comprised of the five subscales of KOOS (pain, symptoms, functional activity, sports and recreation, QoL), Biodex System 3 Isokinetic Dynamometer (Biodex Medical Systems, Shirley, NY) instead of HHD to measure quadriceps and hamstrings muscle strength, and physical performance measure using TUG. Fall Efficacy Scale-International (FES-I) will be the secondary outcome measure for the risk of falling.



## 5.11 | Conclusion

This mixed methods study highlights the feasibility and acceptability of using Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling in adults with knee OA. The study appears to be feasible and safe with some modifications that need to be considered in future study. The interesting changes in clinical outcome measures can be used to further examine the effect of exergaming in individuals with knee OA and history of falling. Given the nature of this study, future interventions should employ rigorous designs and aim to develop protocols with exergaming technology that will enable better frameworks for evaluating their efficacy. The potential of this technology for helping to motivate and challenge participants can serve to increase adherence in rehabilitation, and ultimately result in better outcomes and self-management of the condition. Together, these enhanced their commitment to continual practice of the exercises and integration of the exercises into their daily routine. Overall, these findings coming from both quantitative and qualitative components are encouraging, and support the need to conduct a full-scale RCT.

# CHAPTER 6

## General discussion and Conclusion

### 6.1 | Chapter overview

This chapter provides an overview of the findings for the feasibility study that investigated the use of exergaming as an intervention to improve balance and reduce the risk of falling in individuals with knee OA. It integrates the findings from the feasibility study with those from the literature reviews and cross-sectional study to answer the overall research question of this thesis. Gaps that arise as a result of the thesis are discussed together with the challenges in the context of risk factors for falls and the use of Nintendo Wii Fit™ as an exergaming tool for individuals with knee OA. This chapter concludes with the overall strengths and limitations, the clinical and research implications, and the conclusion of this thesis.

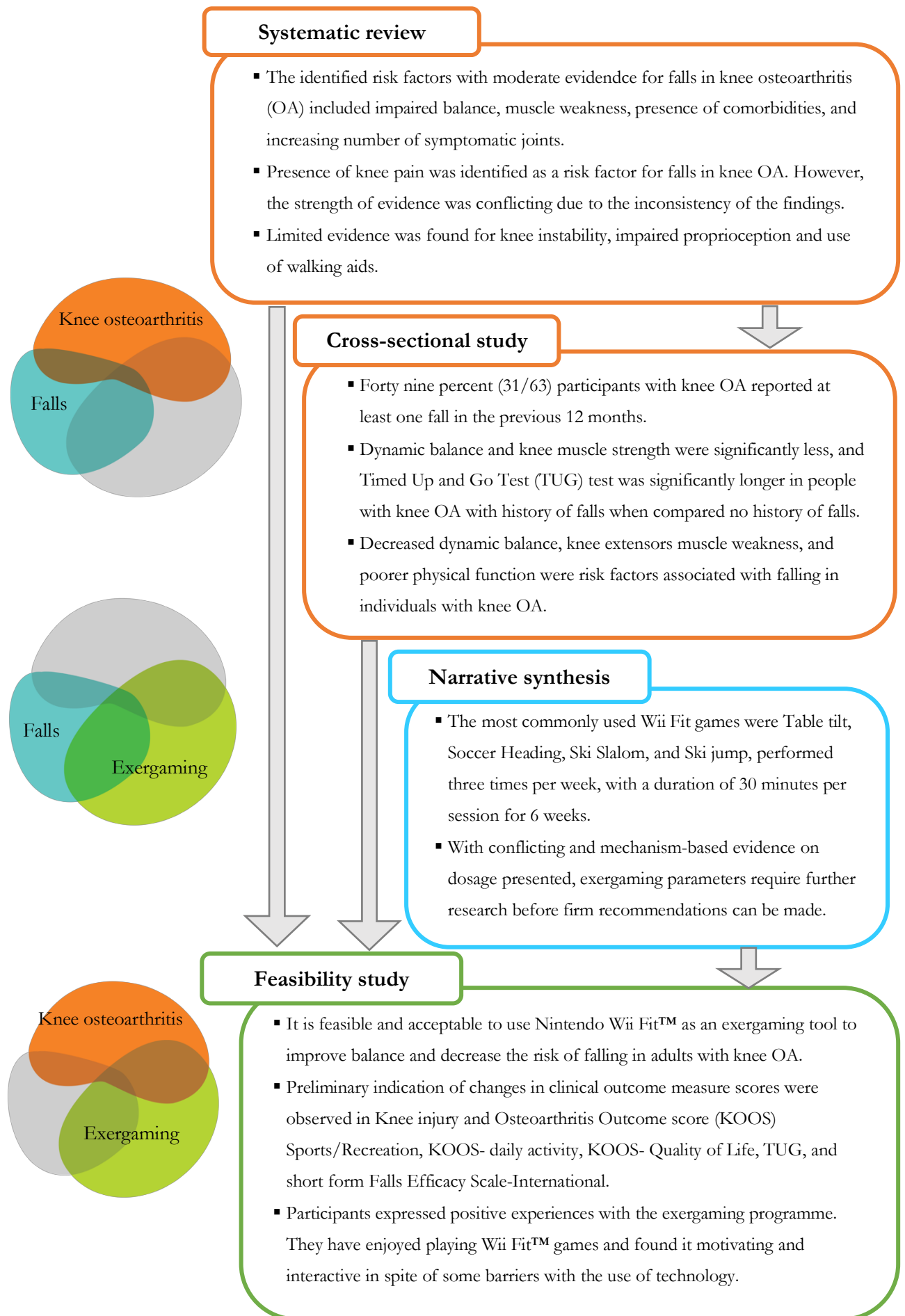
### 6.2 | Summary of the thesis findings

The last decade has seen a growing interest among researchers and health professionals in the role of exergaming in rehabilitation (Pirovano, Surer, Mainetti, Lanzi, & Borghese, 2016; Skjæret et al., 2016). Despite the recent adaptation of exergaming as an exercise tool, the current research environment is characterised by a paucity of empirical data, a lack of protocols on dosage and parameters, and inadequate clinical trials, particularly to investigate the use of exergaming in musculoskeletal conditions such as knee OA. This thesis set out to address these gaps by investigating whether exergaming is a feasible and acceptable intervention for improving balance and decreasing the risk of falling in individuals with knee OA.

Issues arising from the ageing population helped conceptualise the research framework of this thesis. Chapter 1 highlighted the increasing number of older adults and the challenges this posed to the healthcare system due to underlying physiological changes in this population. Increased prevalence is not surprising because the risk of developing most diseases increases progressively with age (World Health Organization, 2015). Also, this thesis is based on the examination of the risk factors for fall in individuals with knee OA, which has received little attention in the literature. This population warrants further investigation of risk factors as several impairments frequently seen in people with knee OA suggest a higher risk of falls due to muscle weakness, functional decline, and other knee OA-related symptoms.

Chapters 2 identified risk factors for falls in adults with knee OA. The systematic review provided evidence of an increasing number of falls in individuals with knee OA. The review also identified risk factors for falls seen in an older adult population that overlap with clinical characteristics of individuals with knee OA. This provided the context for the cross-sectional study in Chapter 3. Building on the results of the systematic review, the question arose: What are the risk factors that contribute to this higher frequency of falls in people with knee OA? The cross-sectional study attempted to answer this question by examining the strength of relationship of dynamic balance, clinical characteristics of knee OA such pain, instability, muscle strength, and physical function, with history of falling in individuals with knee OA.

The potential of exergaming to improve balance led to the next question explored in main study of this thesis: Is exergaming feasible and acceptable in improving balance and decreasing the risk of falling in individuals with knee OA? In Chapter 4, a narrative review synthesised evidence published on Nintendo Wii Fit™ as an exergaming tool. The findings of the narrative synthesis review informed the design of the feasibility study. In Chapter 5, a mixed-methods feasibility study was undertaken to address the primary research question. Figure 6.1 shows the main research findings of each component of this thesis.



**Figure 6.1** Summary of the significant findings of the studies included in the thesis

## 6.2.1 | What are the risk factors that contribute to falls in individuals with knee OA?

Despite the increasing number of falls in the knee OA population, little attention is paid to assessing and treating balance impairment and reducing falls. This thesis addressed two important aspects of falling in individuals with knee OA: the identification of risk factors for falls and the strength of association between falling and knee OA-related symptoms.

This thesis provides evidence of risk factors for falls in individuals with knee OA through a systematic review. Established risk factors for falls in older population included balance deficits, muscle weakness, pain, and obesity. These overlap with fall risk factors for people with knee OA (Ng & Tan, 2013). The systematic review found a moderate level of evidence that impaired balance, decreased knee muscle strength, increasing number of symptomatic joint, and the presence of comorbidities were risk factors associated with falling in individuals with knee OA. Conflicting evidence was found for pain, while there was limited evidence that impaired proprioception, knee instability, and the use of walking aids was significantly associated with risk for falls.

Different definitions for falls were used in the studies included in the systematic review, which might affect the self-reporting of falls. This variation is likely to be a major factor explaining differences in fall rates across the studies. This is a common limitation in falls research, where in most cases a fall is defined by the participants' interpretation, rather than having objective criteria (Graafmans et al., 2003; Lord et al., 2007). The timeframe of fall recall might influence the reported frequency of falling, which can result in under- or over-estimation. In this thesis, the use of standardised falls recall was used as part of the inclusion criteria. Additional questions aside from frequency of falling were asked to establish a definite history of falling. Several recommendations have been made regarding falls ascertainment (Lamb, Jorstad-Stein, Hauer, & Becker, 2005), the challenge is to tailor these to a specific patient population such as people with knee OA. Uniform collection of falls histories will help future researchers compare or pool findings for better reporting of falls data.

Chapter 3 explored the relationship between history of falling and clinical characteristics of individuals with knee OA such as pain, instability, muscle strength, and physical function. Sixty-three participants with knee OA (30 females, 33 male), with a mean

age ( $\pm$ SD) of 53.78 ( $\pm$ 16.17) years were included in the study. Thirty-one (49%) participants reported at least one fall in the previous 12-months. For participants with knee OA and a history of falling, dynamic balance, knee muscle strength, and performance of physical function were significantly reduced when compared to participants with knee OA and no history of falling ( $p < 0.05$ ). Lower dynamic balance measured by the Composite Score (OR 0.86, 95% CI 0.73–0.98,  $p = 0.049$ ) and weaker quadriceps muscles strength (OR 0.70, 95% CI 0.44–0.91,  $p = 0.028$ ) showed association with an increased risk of falling. Whereas, poorer physical function measured with the Timed Up and Go (TUG) test, showed increased risk of falling by almost two-fold (OR=1.65, 95% CI 1.85–4.21,  $p = 0.006$ ).

The systematic review and cross-sectional study highlighted known and modifiable risk factors for falls in knee OA. However, it is important to acknowledge that both ageing and the presence of knee OA can increase the risk of falling. For instance, decline in balance is suggested to be a result of both physiological changes due to the aging process, and an impaired integration of somatosensory and neuromuscular information due to the presence of knee OA symptoms (Alencar et al., 2007; Petrella et al., 2012; Sturmeiks et al., 2004).

The underlying mechanisms for increased risk of falls in people with knee OA are not clear due to complex interactions of intrinsic and extrinsic risk factors. First, knee OA is already a complex disorder with multiple risk factors (Zhang et al., 2010). Knee OA has a complex pathophysiology as exemplified by the imbalance between breakdown and repair processes, resulting in structural impairments (Hunter & Felson, 2006). Another challenge faced when attempting to elucidate the mechanism of falls in the knee OA population is the severity and the duration of the condition. For example, the presence and severity of knee pain may negatively influence muscle strength and postural control (Alencar et al., 2007; de Zwart et al., 2015). While pain was identified in Chapter 2 as a risk factor for falls, the evidence of pain increasing the likelihood of falls was not sufficiently consistent. The increasing pain severity might be protective against falls (Alencar et al., 2007; de Zwart et al., 2015). Although it appears to be counterintuitive that increasing pain severity is associated with a decreased falls risk, it could be that presence of severe pain deters participants from doing too much activity, avoiding activities and environments that pose the risk of increased pain and loss of balance, thereby decreasing the actual risk for falling.

This thesis identified factors contributing to falls in adults with knee OA that are potentially modifiable with physiotherapy, namely impaired balance, and decreased knee muscle strength. While improving muscle strength is a common therapeutic target, this thesis highlights that physiotherapists should also consider assessing and managing balance deficits in order to reduce falls risk for adults with knee OA. This also justifies that an intervention to target balance impairment is worth of an investigation. Emerging interventions such as commercially available exergames provide potential improvement to address the risk factors for falls particularly balance (Laver et al., 2011; Klompstra et al., 2014; Skjaeret et al., 2016).

#### 6.2.2 | Is exergaming feasible and acceptable in improving balance and decreasing the risk of falling in individuals with knee OA?

Exergaming has gained popularity among adults. However, the suitability of most of the exergames for people with OA of the knee has not been investigated. To decide the parameters and dosage of exergaming, literature on the use of Nintendo Wii Fit™ was reviewed. The aim of the review was to synthesize and present published evidence for Nintendo Wii Fit™ gaming system protocols. These included game preferences, intervention settings, and exercise dosage for improving balance in healthy older adults. Commonly used outcome measures were identified. The most commonly used Wii Fit™ games were Table tilt, Soccer Heading, Ski Slalom, and Ski jump. They were played for 30 minutes three times a week for six weeks. The Berg Balance Scale, TUG test, and Centre of Pressure were the most commonly used outcome measures.

Using information from the narrative synthesis, a mixed-method study was conducted. This showed that it is feasible and acceptable to use Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling in adults with knee OA. The pre-defined feasibility criteria such as recruitment, retention, and compliance were successfully met. This was affirmed by the participants' views on the procedures of the study in terms of frequency and duration of the assessment and intervention sessions. The study demonstrated that it is safe to use Nintendo Wii Fit™ as there were no adverse events reported throughout the study period. There were also encouraging results for change in key outcomes such as increasing muscle strength, balance, and performance of physical function sufficient to support the conduct of a future RCT. Participants were positive about the

exergaming programme. They have enjoyed playing on Wii Fit™ games and found it motivating and interactive in spite of some barriers with the use of technology.

To fully use the Nintendo Wii Fit™ exergaming platform to improve balance, games have to be designed for older adults. They have a low confidence in technology and games, therefore it is of utmost importance to design user-friendly interfaces that are clear and easy to understand such as reducing complexity by limiting the number of buttons or steps required for playing. Age-related changes affect the visual system as mentioned in Chapter 2, hence games with fast moving objects and small interfaces can cause uneasiness or panic. The game should have big icons and characters and tasks that are clear and easy to understand. Games require a variety of body movements and actions to control the game or interact with the settings, thus players should be allowed to practise movements in tutorials to get acquainted with the technology and feel comfortable with this new platform of exercising.

As enjoyment of exercise is an important factor to encourage people to perform the activity, the ability to adjust the speed of the game and cope with improving ability has to be built into the games. This will also avoid frustration and keep involvement in games at a high level. Furthermore, the options in exercise progression and game speed control are limited. In this study, the progression of the Wii Fit™ exercise regimen was based on increasing the number of games, challenging participants to move on to the next level and increasing the playing time. Incorporating varying levels in the game will permit progression, which is a key component of a good therapeutic exercise intervention. This enables the exergames to function as an exercise modality targeting balance improvement.

Safety is important to address before employing exergaming on a large scale. The Wii Fit board is quite narrow (50cm×25cm×5cm) and may pose a fall risk by itself, especially for an older adult with a balance problem and slower reaction times. The development of a low balance pad or mat is recommended to minimize adverse events.



### 6.3 | Strengths and limitations

The studies included in this thesis followed specific guidelines in conducting and reporting of the study. The cross-sectional and feasibility study as well as the systematic review were registered and published online to increase the transparency of the results. Most of the assessments used in this thesis, such as muscle strength testing and TUG test, are routinely used in clinical practice. Some steps were taken to decrease bias in the study. Recruitment via community advertisements may have introduced selection bias. However, this was mitigated by recruiting individuals with knee OA regardless of having history of falling or not. The primary researcher was blinded during the assessments to avoid conscious and unconscious bias in the design and results of the study. In the qualitative phase, the use of an interviewer unknown to the participants decreased the bias. Steps were taken to ensure the rigour of the study were observed throughout the qualitative phase.

Based on the researcher's knowledge, this is the first mixed-methods feasibility study of Nintendo Wii Fit™ as an exergaming tool to improve balance and decrease the risk of falling specific for knee OA. Moreover, by contrast with other studies that explored falling, the current thesis focused on comparing subgroups of faller and non-faller in a knee OA group to better represent the characteristics of this patient population. There is no focussed study that directly collected and compared falls history in individuals with knee OA in NZ. Thus, this current thesis showed preliminary findings to support the increasing number of falls in individuals with knee OA in NZ.

Using the ACR clinical criteria in this thesis increased the likelihood of including participants in the early stage of disease before structural changes occur, as well as those with a well-established diagnosis, resulting in a sample representing the full spectrum of disease. The intention was to recruit a wide cross-section of the community, which indeed happened, including those who are still working, providing a good sense of the demographics and the target population of the study.

This thesis needs to be considered in the context of the methodological limitations. In the systematic review, a meta-analysis was precluded due to methodological heterogeneity across the studies. Sub-group analyses showed high statistical heterogeneity for most risk factors, and insignificant results for pooled estimates, hampering secondary analysis. Most of the significant risk factors for falls were explored in cross-sectional studies where

causality cannot be inferred. However, this was moderated by the longitudinal studies, where the relationship between variables can be followed over time. The narrative review excluded unpublished studies and papers not written in English, which may contain pertinent data related to dosing in exergaming. Variability among the studies in terms of Wii intervention protocols and outcome measures used make it difficult to compare or pool findings. Given this heterogeneity, the overall strength of evidence on effectiveness of the Wii Fit™ intervention for balance was not possible. In this study, no adverse events were reported by the participants when using the Wii Fit™ balance board. However, it should be highlighted that this was a preliminary result regarding safety. The safety use of Nintendo Wii Fit™ as an exergaming tool should be based on a larger sample size and longer timeframe before confirmatory safety can be concluded.

This research focuses on one particular gaming system - Nintendo Wii Fit™ - but information and entertainment technology changes rapidly. It is possible the Wii Fit™ franchise might be discontinued, which would affect further investigation of this exergaming platform. However, it should be highlighted that the Nintendo Wii Fit™ system is just one of the many exergaming tools. At present, exergaming research on Nintendo Wii Fit™ continues to be explored in different clinical domains and patient populations (Kim & Timmerman, 2018). Another reason for using the Wii Fit™ system is that the existing preliminary results can be replicated or tested in other patient populations.

To critically appraise the Nintendo Wii Fit™ as a therapeutic tool, challenges can be viewed in the context of available literature. While the narrative review provided useful information for designing interventions for the feasibility study, the RCT studies that were reviewed had only small sample sizes and were not powerful enough to detect changes in the balance outcome scores. The lack of qualitative dimension posed a challenge as to whether this platform was really acceptable to patients, particularly with those with knee OA. This was addressed by incorporating a qualitative components to further explain the feasibility and acceptability of using exergaming in people with knee OA.

## **6.4 | Research implications**

The design of Wii Fit™ gaming system encompasses most of the components of exergaming such as game mechanics, content, and interface (Weiss et al., 2004). However,

the lack of reported mechanism of exergaming in the literature may be one of the reason why it is still underused. Thus, exergaming should be supported by the foundational concepts and principles of therapeutic exercises. There is still a need of guidelines and sound mechanism-based evidence despite that most balance exergaming mimics movement of traditional balance exercises.

One of the main challenges are likely to be technological barriers. A review of exergaming studies showed participants found the training more appealing than traditional exercises (Lamonth et al., 2011). The qualitative component of the current feasibility study agrees with these results. Technological barriers will reduce engagement and acceptability. If the exergaming programme has good navigation and ease-of-use, and promotes social interaction, it can facilitate engagement and acceptability.

It is necessary to continue exploring the potential benefits of this exergaming programme to improve the quality of health outcomes in individuals with knee OA. Increasing the number of participants, extending the duration of the program and extending the focus to include not only balance but also enjoyment and the functional activities for future studies are all areas recommended for future studies.

## **6.5 | Clinical Implications**

The systematic review highlighted overlapping risk factors for falls in older adults and knee OA-related symptoms. Clinicians should include a thorough assessment of the knee to identify symptoms of OA, and deficits of strength or balance that may contribute to an increased falls risk. The interpretation of the findings during evaluation, and attending to positive findings for risk factors for falls are important considerations that can be used in goal-setting and managing patient with knee OA and history of falling. Asking the patient whether they have fallen not only enables the clinicians to assess potential fall risk but also provides an opportunity for fall risk education.

Education is widely acknowledged as effective in preventing falls in older adults (Chang, Huang, & Jung, 2011). Likewise, education is an important aspect of OA management. Organisations such as Arthritis NZ provide excellent educational material for people with this form of arthritis. This includes brochures, videos, seminars, newsletters, support groups and links through social media. These resources and communication

pathways could be used to educate people with OA about falls risks. Future work, in collaboration with arthritis support organisations and other key stakeholders, is warranted to investigate the opportunities for falls education targeted to people with OA.

Several implications of this feasibility study will be relevant clinically and in future research. Since the thesis showed that it is feasible to use exergaming in individuals with knee OA, study should be continued, with three suggested improvements: (1) recruitment of knee OA participants be enhanced through collaboration with support and advocacy organisation; (2) the intervention period be extended with emphasis on monitoring participants or follow-up; (3) barriers and supports to Wii Fit™ exercise programmes should be identified, such as participants' overall level of physical activity, lifestyle, and QoL.

Wii Fit™ has the potential to overcome common barriers to exercise: cost, transportation, boredom/discomfort, and preference for home-based interventions. If proven effective in a larger trial, exergaming may offer an exercise intervention for older adults who find it challenging to access and participate in real world or group falls intervention activities. It would allow isolated older adults to enjoy the benefits of socially engaging exercise such as playing together with family members. Although ideally an exercise leader would be available to supervise exercise, isolated individuals could gradually learn to exercise at home with only periodic supervision and thus become more independent (Nicholson et al., 2015).

## **6.6 | Conclusion**

This thesis highlights the risk factors for falls and the potential of exergaming to improve balance and reduce the risk of falling in individuals with knee OA. It is essential to understand the mechanism underlying the occurrence of falls in knee OA by identifying modifiable risk factors which can be mitigated. Further studies should focus on determining the mechanism by which these complex risk factors influence falls in individuals with knee OA. Exergaming using the Nintendo Wii Fit™ appears to be feasible and safe, with some suggestions that need to be considered in future study. Interesting changes in clinical outcome measures can be used to further examine the effect of exergaming in individuals with knee OA and history of falling. Given the nature of this thesis, future interventions

should employ rigorous designs and aim to develop protocols with exergaming technology that will enable better way of evaluating their efficacy. Overall, findings coming from both quantitative and qualitative components of the feasibility study are encouraging, and support the need to conduct a full-scale RCT.

The potential use of exergaming as a balance tool and the assessment of knee OA symptoms that are critical to increasing falls risk can provide valuable information for both clinicians and fall prevention program developers. This exergaming technology can motivate and challenge individuals with knee OA which can result in better outcomes and self-management of the condition. In the future, this exergaming platform may enhance the commitment of individuals with knee OA to integrate exercise into their daily routine to maximise the beneficial effect of exercising.

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## Appendix A: Publication

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**Review**

# A Narrative Synthesis of Nintendo Wii Fit Gaming Protocol in Addressing Balance Among Healthy Older Adults: What System Works?

Donald G. Manlapaz, MSPT, Gisela Sole, PhD, Prasath Jayakaran, PhD, and Cathy M. Chapple, PhD

### Abstract

**Background:** Balance is crucial in performing functional tasks particularly among older adults. Exergaming is gaining attention as a novel approach to enhance balance in a number of clinical populations.

**Objectives:** The aim of this review was to synthesize and present published evidence for Nintendo Wii Fit™ gaming system protocols. These include game preference, intervention setting, and exercise dosage for improving balance in healthy older adults. Commonly used outcome measures were also identified.

**Methods:** A literature search was developed using the PICOS strategy using keywords such as “older adult,” “Nintendo Wii Fit,” “exergaming,” and “balance” in the databases: MEDLINE, PubMed, EMBASE, CINAHL, Scopus, Science Direct, and Web of Science.

**Results:** Sixteen articles were included with participants ( $n=491$ ) mostly female (69%), and mean age ranged between 71 and 85 years old. Participants were recruited mainly from the community. The most commonly used Wii Fit games were *Table tilt*, *Soccer Heading*, *Ski Slalom*, and *Ski jump*, performed three times per week, with a duration of 30 minutes per session for 6 weeks. Berg Balance Scale, Timed Up and Go Test, and Centre of Pressure were the most commonly used outcome measures.

**Conclusion:** Wii Fit exergames can be a potential alternative to improve balance if safety and technical procedures are provided. With conflicting and mechanism-based evidence on dosage presented, exergaming parameters require further research before firm recommendations can be made. Clinically, effective dosage is an important component in any type of interventions, and exergaming should not be an exception.

**Keywords:** Nintendo Wii Fit, Gaming protocol, Balance, Older adults, Exergaming

### Introduction

**B**ALANCE IMPAIRMENT IN older adults is a well-known problem worldwide, and injuries associated with loss of balance continue to be a serious health concern.<sup>1,2</sup> Falls are also a leading cause of morbidity and mortality in this population.<sup>1</sup> Approximately 30%–40% of adults aged 65 or older experience a fall every year.<sup>1,3</sup> The World Health Organization (WHO) reported that fall prevention has become a pressing global health concern as frequency of falls rise with age.<sup>4</sup>

Different forms of exercise, including strength training, Tai Chi, and aerobic exercises, all improved balance and reduced incidence of falls in older individuals.<sup>5–7</sup> Implementation of these exercises was based on tested protocols or exercise regimens, which were adapted to target the desired treatment effect. A multisensory approach is required for the rehabilitation of balance deficits in older adults, since postural stability

is a coordinated function of sensory (somatosensory, visual, and vestibular) and motor systems.<sup>8</sup> Therefore, a tailored program must be designed to improve balance and decrease the risk of falls.

Balance impairment can contribute to decreased independence coupled with increased frequency of falls in older adults.<sup>9</sup> Balance exercises have been found to be beneficial for healthy older adult.<sup>6,7</sup> However, adherence to exercise reduces over time. Adherence is considered as one of the challenges in implementing exercise programs since beneficial effects decline if regular exercise is not maintained.<sup>10</sup> Therefore, identification of an enjoyable and engaging balance exercise and fall prevention program is needed to sustain its beneficial impact.

Advances in technology could influence healthcare providers to create alternative and novel treatment options. The use of popular videogame-based exercises or “exergaming,”<sup>11</sup>

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1



## Appendix B: Conference proceedings

### 1. New Zealand Manipulative Physiotherapy Association Conference 2017

#### **Dr Cathy Chappie - Same time next week? What is the optimal frequency of manual therapy for people with knee osteoarthritis?**

**Objectives:** To identify factors physiotherapists consider important in making decisions about frequency of manual therapy (MT) treatment for individuals with knee osteoarthritis (OA).  
**Background:** Knee OA is a global health burden and MT is an effective physiotherapy intervention. However, parameters of MT such as frequency of treatment sessions, remain unclear. The current practice of physiotherapists when making decisions about frequency of MT treatments must be established. Findings may inform subsequent study design and facilitate translation of research findings back into the clinical environment.

**Methods:** This study used a qualitative method called the nominal group technique (NGT). One NGT session was conducted with 8 practising physiotherapists from public and private health sectors, to determine factors they consider most important when deciding on the frequency of MT. The question posed for the NGT session was "What factors do you consider when deciding on frequency of MT treatment for patients with knee OA?"

**Results & Findings:** Eighty-two individual ideas were generated and grouped into 23 themes. The top five most important themes identified were: 1) Between session responses to treatment, 2) Costs to patient, 3) Irritability in response to treatment, 4) Effects of other physiotherapy treatments, 5) Ability to self-manage.

**Conclusions:** Physiotherapists consider a wide range of factors when making decisions about the frequency of MT for people with knee OA. Participants in this study prioritised treatment-related factors they believed were likely to result in effective management. They also considered patient-centred factors such as costs and ability to self-management, both relevant to successful management of a long-term condition such as knee OA. Research evidence was not identified as a factor influencing decisions about treatment frequency, possibly a challenge for translating research into practice.

#### **Prof Gwen Jull - The management of neck pain – are we on the mark?**

The drawbacks of the dominance of the biological model in patient management of much of the last century are well recognised. Recent decades have witnessed the advents of, for example, the biopsychosocial model, patient centred management, evidence based practice, advances in pain sciences. This presentation will reflect on how these events have influenced practice and whether we are on the mark to meet the challenges of management of neck pain disorders.

#### **Prof Duncan Reid - Cervical Spine Screen – where are we heading?**

**Objectives:** The aim of this presentation is twofold; firstly, to provide a historical overview of the guidelines for cervical screening in Australasia and secondly to update the current best practice guidelines and key issues related to these.

**Background:** Cervical thrust manipulation has been a topic of considerable controversy for decades with a definitive conclusion regarding risk of cerebrovascular accident following cervical manual therapy not yet determined. As a primary contact health profession, physical therapists are charged with the responsibility to evaluate risk and benefit for each intervention with the maxim of 'do no harm' as a key tenet guiding their decision making. Importantly, 'do no harm' must be viewed as a coin with two sides: avoiding inappropriate or excessive treatment causing injury or worsening of symptoms, while also avoiding under-treatment that may result in perceived failure of conservative care and subsequent use of more invasive interventions that carry a higher level of risk.

#### **Hui Lin - Frequency of manual therapy for patients with knee osteoarthritis: what do physiotherapists think?**

**Objectives:** To identify factors physiotherapists consider important in making decisions about frequency of manual therapy (MT) treatment for individuals with knee osteoarthritis (OA).  
**Background:** Knee OA is a global health burden and MT is an effective physiotherapy intervention. However, parameters of MT such as frequency of treatment sessions, remain unclear. The current practice of physiotherapists when making decisions about frequency of MT treatments must be established.

**Methods:** This study used a qualitative method called the nominal group technique (NGT). One NGT session was conducted with 8 practising physiotherapists from public and private health sectors, to determine factors they consider most important when deciding on the frequency of MT. The question posed for the NGT session was "What factors do you consider when deciding on frequency of MT treatment for patients with knee OA?"

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**Conclusions:** Physiotherapists consider a wide range of factors when making decisions about the frequency of MT for people with knee OA. Participants in this study prioritised treatment-related factors they believed were likely to result in effective management. They also considered patient-centred factors such as costs and ability to self-management, both relevant to successful management of a long-term condition such as knee OA. Research evidence was not identified as a factor influencing decisions about treatment frequency, possibly a challenge for translating research into practice.

#### **Donald Manlapaz - Risk factors for falls in older adult with knee osteoarthritis: a systematic review**

**Background:** Falls are often reported by adults with knee osteoarthritis (OA). Despite this increased number of falls, the mechanisms and contributors underlying the occurrence of falls in individuals with knee OA are poorly understood.

**Objective:** To identify the evidence of risk factors for falls in older adults with knee osteoarthritis (OA).  
**Methods:** A systematic literature search was performed in nine electronic databases from inception to July 2016. Two reviewers screened articles using set inclusion and exclusion criteria. Observational study designs that included participants with knee OA and history of falls were considered. Results reported as odds ratios, relative risks, prevalence ratios or hazard ratios were extracted to identify the potential risk factors for falls. Included articles were assessed for methodological quality and level of evidence.

**Results:** The electronic data search yielded 4382 studies related to falls and knee OA. A total of 11 studies were identified to be relevant in this review. Pain showed strong evidence as a risk factor for falls, while muscle weakness, impaired balance, presence of comorbidities and increasing number of symptomatic joint had moderate evidence. Knee instability and decrease in proprioception were identified as risk factors for falls; however, the strength of evidence was conflicting due to the inconsistency of the findings.

**Conclusion:** Identification of modifiable risk factors for falls in individuals with knee OA can be valuable information for clinicians and fall prevention program developers. Although high to moderate quality studies are included in this review, further studies are warranted to examine risk factors of falls in a knee OA population.

21

22

1830 Saturday, 16 June 2018

Health Professionals in Rheumatology Abstracts

chronic diseases. Most often PA is self-reported while measures of the aerobic capacity are more seldom measured in subjects with chronic pain.

**Objectives:** To describe physical activity levels (self-reported and aerobic capacity) in people with chronic pain classified as regional or widespread and to compare the findings with a group that report no pain.

**Methods:** From the 2016 follow-up of the Swedish population based Epipain cohort (n 1321), 146 subjects were invited to a clinical assessment where the aerobic capacity was assessed by using a submaximal bicycle test, the Ekblom-Bak test, together with assessment of the Borg scale for perceived exertion (RPE). Aerobic capacity was also classified as low, average or high according to data from the general population. Self-reported physical activity was coded as MVPA<sub>rec</sub> if recommended levels of PA was reported (physically active on a moderate level  $\geq 150$  min/week (MPA) or on a vigorous level  $\geq 75$  min/week (VPA) or not). The Fear Avoidance Beliefs Questionnaire for PA (FABQ-PA, 0–24 best to worst) and for work (FABQ-W, 0–48 best to worst) were also assessed. The participants were classified as having chronic widespread pain (CWP), chronic regional pain (CRP) or no chronic pain (NCP) based on a pain mannequin presenting 0–18 pain regions and if pain had lasted for 3 months or more. Chi2 and Kruskal-Wallis tests were performed to study differences between the three pain groups.

**Results:** 141/146 (97%) subjects (mean (SD) age 59.4 (8.2) years) whereof 61% were women, could be classified into pain groups; 43 as CWP (94% women), 43 as CRP (42% women) and 55 as NCP (58% women). The group with CWP was slightly older than those with CRP (mean (SD) age 57.0 (7.6) years vs. 61.9 (6.9) years,  $p=0.02$ ). The CWP group also had lower aerobic capacity (mean (SD) 2.2 (0.5) l/min vs. 2.6 (0.6) l/min,  $p=0.03$ ), and a larger proportion was classified as having low aerobic capacity (CWP 21%, CRP 7% and NCP 10%,  $p=0.04$ ). The proportion of MVPA<sub>rec</sub> did not differ between the groups; CWP 70%, CRP 81% and NCP 74% ( $p=0.5$ ). There was neither a difference between the groups in BMI, RPE or in sitting hours/week ( $p>0.6$ ). However, differences were found in the FABQ where in the PA scale those with CRP had worse scores compared with NCP (mean (SD) 11.2 (7.3) vs. 6.0 (6.0),  $p<0.001$ ), the difference between CWP (mean (SD) 8.9 (6.7)) and NCP was  $p=0.06$ . In the work subscale of FABQ, CWP had worse scores compared with CRP (mean (SD) 18.9 (15.7) vs. 10.0 (12.5),  $p=0.002$ ) and CRP had worse scores compared to those with NCP (mean (SD) 10.0 (12.5) vs. 6.5 (9.1),  $p<0.001$ ).

**Conclusions:** In this sample of subjects with chronic pain or no pain, having widespread pain tended to affect the aerobic capacity negatively while self-reports of reaching recommended levels of physical activity did not differ between groups. Fear avoidance in relation to physical activity and especially in relation to work was more noticeable in subjects with chronic pain compared to those with no pain. Measures of aerobic capacity and information of fear avoidance beliefs might help health professionals to better tailor the non-pharmacological treatment for subjects with chronic pain.

**Disclosure of Interest:** None declared

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#### [SAT0738-HPR] FACTORS ASSOCIATED WITH RISK OF FALLING IN ADULTS WITH KNEE OSTEOARTHRITIS: A CROSS-SECTIONAL STUDY

D.G. Manjapaz, P. Jayakaran, G. Sole, C.M. Chapple. *Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy, University of Otago, Dunedin, New Zealand*

**Background:** There is evidence of increasing number of falls in adults with knee osteoarthritis (OA). However, the contributing factors for falling in adults with knee OA has not been substantially investigated.

**Objectives:** This cross-sectional study aimed to explore the relationship between falling in adults with knee OA and clinical characteristics of knee OA such as balance, pain, instability, muscle strength, and physical function.

**Methods:** Participants with knee OA were recruited from the community (Dunedin, New Zealand). The protocol of the study was registered in Australia New Zealand Clinical Trial Registry (ACTRN 12617000154303). Falls characteristics in the preceding year were collected to distinguish between those with and without history of falling. All participants completed the following measures: Sensory Organization Test (SOT) using NeuroCom SMART Equitest system, version 8.4.0 which produced Composite Score; Knee injury and Osteoarthritis Outcome Score for knee OA related symptoms; Knee outcome survey for self-reported knee instability (buckling); Nicholas MMT hand-held dynamometer for quadriceps and hamstrings isometric muscle strength measured at 20 and 70 degrees; and Timed-Up and Go (TUG) test for physical function.

**Results:** Sixty-three participants with knee OA (30 female, 33 male), with a mean age (SD) of 53.78 (16.17) years were included in the study. Thirty-one (49%) participants reported at least one fall in the previous 12 months. The independent t-test suggested that the SOT Composite Score in fallers was significantly less (mean  $\pm$ SD: faller=72.16 $\pm$ 3.26, non-faller=74.84 $\pm$ 4.77;  $p=0.012$ ) and the TUG test was significantly longer (mean  $\pm$ SD: faller=7.64 $\pm$ 1.29, non-faller=6.74 $\pm$ 0.78;

$p=0.001$ ) when compared with the non-faller group. Also, lower muscle strength of knee flexors and extensors were significantly less in the faller group ( $p<0.05$ ). Falling in the previous 12 months was associated with Composite Score (OR 0.85, 95% CI 0.74–0.97,  $p=0.017$ ), knee extensors strength [20 degrees (OR 0.76, 95% CI 0.66–0.82,  $p=0.025$ ) and 70 degrees (OR 0.71, 95% CI 0.55–0.91,  $p=0.008$ ), and TUG test (OR 2.65, 95% CI 1.32–5.31,  $p=0.006$ ) using univariate logistic regression analysis. There were no changes in these results with multivariate analyses adjusting for age, gender, and body mass index.

**Conclusions:** The study demonstrated that balance, knee muscle strength, and performance of physical function significantly differed between those with and without the history of falling. An understanding of these risk factors may help in implementing an appropriate evaluation and intervention strategy to reduce falls in this patient population. Given the prevalence of falls in knee OA, this study suggests that falls assessment should be part of the clinical practice routine when evaluating patients with knee OA.

**Acknowledgements:** This study was funded by Mark Steptoe Grant-in-Aid, University of Otago School of Physiotherapy

**Disclosure of Interest:** None declared

DOI: 10.1136/annrheumdis-2018-eular.4388

#### [SAT0739-HPR] OCCUPATIONAL EXPOSURE TO PESTICIDES INCREASES THE RISK OF RHEUMATOID ARTHRITIS: RESULTS FROM THE MALAYSIAN POPULATION-BASED CASE-CONTROL STUDY

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**Background:** Several studies have suggested farming occupation with exposure to pesticides as risk factor for rheumatoid arthritis (RA).

**Objectives:** We investigated the association between pesticides exposure and risk of RA subsets in the Malaysian population.

**Methods:** Data from the Malaysian Epidemiological Investigation of Rheumatoid Arthritis (MyEIRA) population-based case-control study involving 1055 early RA cases and 1057 age, sex and residential area matched controls were analysed. All study subjects answered a structured questionnaire on a broad range of issues including occupational exposures to pesticides. The self-reported information on ever/never occupationally exposed to pesticides was used to estimate the risk of developing ACPA-positive and ACPA-negative RA. Association between pesticides exposure and the HLA-DRB1 shared epitope (SE) was evaluated.

**Results:** The proportion of ACPA positivity in the RA patients was 64.4% and 1.9% in the normal controls. The presence of HLA-DRB1 SE alleles in RA patients was 40.2% and 15.8% in the normal controls. Our data demonstrated that occupational exposure to pesticides was significantly associated with an increased risk of developing RA in the Malaysian population (OR 2.31, 95% CI 1.12–4.73,  $p=0.03$ ). The association between occupational exposure to pesticides and risk of RA was observed with ACPA-positive RA (OR 3.10 95% CI 1.49–6.47,  $p=0.003$ ), but not with ACPA-negative RA. A dramatically increased risk for ACPA-positive RA was seen in individuals who both exposed to pesticides occupationally and carried SE alleles (OR 28.06, 95% CI 3.58–220.09,  $p<0.0001$ ).

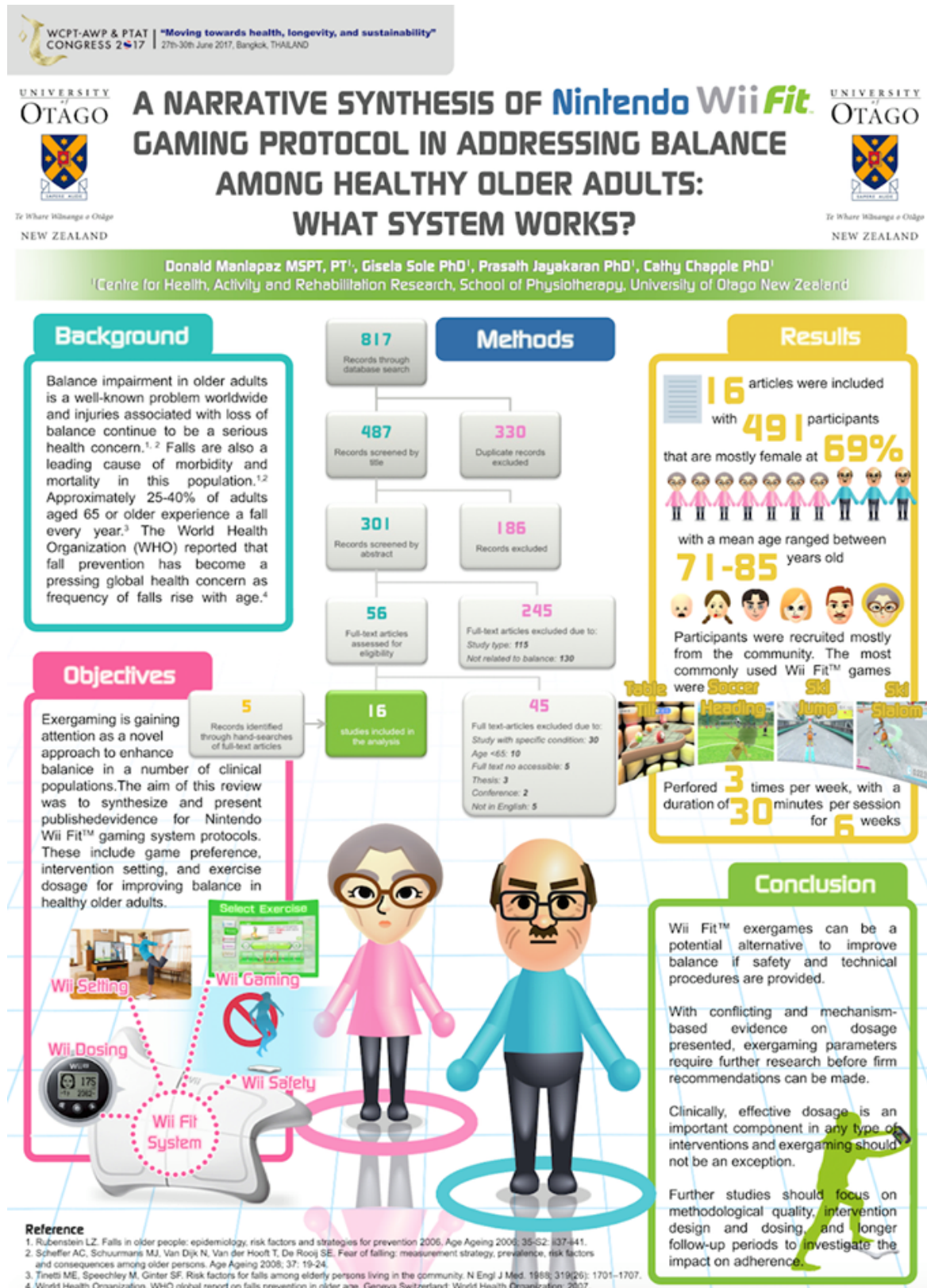
**Conclusions:** This study demonstrates that occupational exposure to pesticides is associated with an increased risk of ACPA-positive RA in Malaysian population.

#### REFERENCES:

- [1] Svendrup B, Källberg H, Bengtsson C, Lundberg I, Padyukov L, Alfredsson L, Klareskog L and the Epidemiological Investigation of Rheumatoid Arthritis study group. Association between occupational exposure to mineral oil and rheumatoid arthritis: results from the Swedish EIRA case-control study- Arthritis Research & Therapy 2005;7:R1296-R1303.

## Appendix C: Poster presentations

1. World Confederation of Physical Therapy-Asian Western Pacific Region (WCPT-AWPR) Congress 2017



SAT0738-HPR

Centre for Health, Activity,  
and Rehabilitation Research  
School of Physiotherapy

# FACTORS ASSOCIATED WITH RISK OF FALLING IN ADULTS WITH KNEE OSTEOARTHRITIS: A CROSS-SECTIONAL STUDY

Donald Manlapaz MSPT, Prasath Jayakaran PhD, Gisela Sole PhD, Cathy Chapple PhD  
Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy, University of Otago, New Zealand



## INTRODUCTION

There is evidence of increasing number of falls in adults with knee osteoarthritis (OA).<sup>1,2</sup> However, the contributing factors for falling in adults with knee OA remain uncertain. This cross-sectional study aims to examine the contribution of the clinical characteristics of knee OA such as balance, pain, instability, muscle strength, and physical function to the increasing number of falls in adults with knee OA.

## METHODS

Adults with knee OA were recruited in Dunedin, New Zealand through community advertising. Falls characteristics in the preceding year were collected to distinguish between those with and without history of falling. The knee OA clinical characteristics (independent variables) were measured and analysed to determine difference between 'faller' and 'non-faller' and association with increasing falls.

**Funding:**  
School of Physiotherapy, Munk Steacie Memorial Trust Research grant-in-aid, Health Science Discretionary fund University of Otago and Maurice and Phyllis Paykel Trust

**References:**  
1. Hirman, P., Bennell, K., McCall, B., & Crossley, K. (2002). Balance impairments in individuals with symptomatic knee osteoarthritis: a comparison with matched controls using clinical tests. *Rheumatology*, 41(12), 1388-1394.  
2. Hoopes, M. L., Rosenblatt, N. J., Hurt, C. P., Cvetkovic, J., & Gruber, M. D. (2012). Does lower extremity osteoarthritis exacerbate risk factors for falls in older adults? *Women's Health (Lond)*, 8(6), 665-696  
3. Weitt, M. C., Telych, I., Shaokor, N., Nguyen, U. S. D., Sgall, N. A., Lewis, C., & Felson, D. T. (2016). Symptoms of knee instability as risk factors for recurrent falls, arthritis care & research, 6(8), 1089-1097.  
4. Adkins, N. K., Crozer, S., Smith, H., Anderson, F., Edwards, C., Rejnart, H., & Cooper, C. (2009). Knee pain, knee osteoarthritis, and the risk of fracture. *Arthritis Rheum*, 55(4), 610-615.

Table 1. Independent variables and outcome measures used in the study

Independent Variables	Outcome Measures
Knee Pain	Knee Injury and Osteoarthritis Outcome Score
Knee Instability	Knee Outcome Survey – Activities of Daily Living Scale
Dynamic Balance	Sensory Organisation Test (SOT) using NeuroCom SMART Equitest® system, version 8.6.0
Knee Muscle Strength	Hand-held dynamometer using Nicholas MMT, Model 01160
Physical Function	Timed Up and Go Test

Composite Score was obtained from the Sensory Organisation Test (SOT) using NeuroCom Smart Equitest® system. The score represents participant's overall level of performance on SOT. A score near 100 means minimal sway while a decreasing score means that the sway is near the limit of stability which increases the risk of falling.

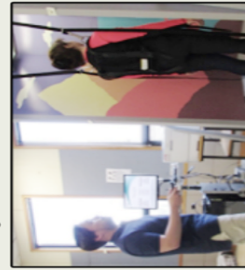


Figure 1. NeuroCom Equitest® Balance Manager System

## RESULTS

Sixty-three participants (30 female, 33 male) with mean age (SD) of 53.78 (16.17) years were recruited. Thirty-one (49%) participants reported at least one fall in the previous 12-months.

Table 2. Clinical variables with significant difference (p<0.05) between faller and non-faller

Independent Variables	Non-Faller (n=32)	Faller (n=31)	p-value
Composite Score	74.84 ± 4.77	72.16 ± 3.26	0.012
Dynamic Balance			
Knee flexors 20 degrees	8.52 ± 1.79	7.34 ± 2.06	0.018
Knee flexors 70 degrees	9.02 ± 2.11	7.47 ± 2.16	0.006
Knee extensors 20 degrees	9.89 ± 2.32	8.65 ± 2.13	0.020
Knee extensors 70 degrees	10.56 ± 2.33	8.86 ± 2.22	0.008
Physical Function			
Timed-Up and Go Test (sec)	6.74 ± 0.78	7.64 ± 1.29	0.001

Table 3. Clinical risk factors associated with risk of falling

Independent Variables	Adjusted OR	95% C.I.	p-value
Dynamic Balance Composite score	0.66	0.75-0.99	0.035*
Pain	1.00	0.97-1.04	0.884
Instability	0.21	0.02-2.05	0.180
Knee Muscle Strength	0.78	0.61-1.01	0.057
Physical Function	0.72	0.55-0.95	0.018*
Timed-Up and Go Test (sec)	2.44	1.17-5.08	0.017*

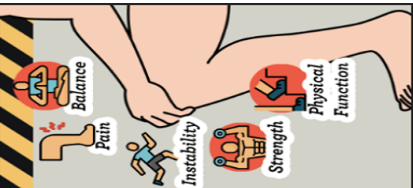
\*Significant at p<0.05, adjusted for age, gender and body mass index. OR: Odds Ratio; 95% CI: 95% confidence interval; \*\*OR: Odds Ratio and 95% Confidence Interval; C.I.: Confidence Interval; \*\*OR: Odds Ratio and 95% Confidence Interval; C.I.: Confidence Interval

## SUMMARY

- Fallers in knee OA had significantly lower dynamic balance as reflected in the Composite Scores.
- Compared to non-fallers, those who fell had significantly lower muscle strength of knee flexors and extensors.
- Decreased physical function showed increased risk of falling by two-fold. Attention must be given in assessing functional activities.
- Previously, knee instability and pain were considered contributors for falling in knee OA<sup>4</sup>. However, no association were found in this study which warrants.

## CONCLUSION

Given the prevalence of falls in knee OA, identification of risk factors is essential in creating effective prevention strategies. The study demonstrated that balance, knee muscle strength, and performance of physical function significantly differed from those with history of falling. Clinicians can be confident these are important risk factors that contribute to the risk of falling in individuals with knee OA.



## Appendix D: Preferred Reporting Items for Systematic reviews and Meta-Analyses checklist

### PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants; and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I <sup>2</sup> ) for each meta-analysis.	8



## PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Table 2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Table 4
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	Table 1
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).	13, Table 4
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).

## Appendix E: Protocol for conducting systematic review (PROSPERO)

**PROSPERO**  
International prospective register of systematic reviews

  
National Institute for  
Health Research

### Risk factors for falls in older adults with knee osteoarthritis: a systematic review

Donald Manlapaz, Cathy Chapple, Gisela Sole, Prasath Jayakaran

#### Citation

Donald Manlapaz, Cathy Chapple, Gisela Sole, Prasath Jayakaran. Risk factors for falls in older adults with knee osteoarthritis: a systematic review. PROSPERO 2015 CRD42015027582  
Available from: [http://www.crd.york.ac.uk/PROSPERO/display\\_record.php?ID=CRD42015027582](http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42015027582)

#### Review question

What are the risk factors for falls in older adults with knee Osteoarthritis?

#### Searches

A systematic search will be executed with a well-developed search strategy on the following electronic databases (Academic Search Complete, CINAHL, EMBASE, MEDLINE, PubMed, Science Direct, Scopus, SPORTDiscuss and Web of Knowledge) from their inception to 16th of October 2015. Search terms such as 'osteoarthritis,' 'osteoarthritis, knee,' 'accidental falls,' 'falls,' 'falls risk,' will be applied as keywords, MESH and subject heading. A comprehensive search strategy will be developed and will be applied in databases mentioned. No restriction on language or publication year will be applied.

#### Search strategy

[http://www.crd.york.ac.uk/PROSPEROFILES/27582\\_STRATEGY\\_20150927.pdf](http://www.crd.york.ac.uk/PROSPEROFILES/27582_STRATEGY_20150927.pdf)

#### Types of study to be included

Observational Studies: cohort, cross-sectional, case-control studies will be included

#### Condition or domain being studied

Knee Osteoarthritis. Osteoarthritis is a chronic and progressive joint disease. It is the most prevalent type of arthritis among older adults with knee more than hip involvement.

#### Participants/population

Inclusion criteria: Studies involving unilateral or bilateral knee OA in which the mean age of participants was 18 years old and above, with confirmed OA according to American College of Rheumatology criteria, radiographic evidence or by Kellgren-Lawrence classification and with or without history of falls. Exclusion criteria: Studies on participants with other type of inflammatory/autoimmune arthritis such as rheumatoid arthritis; comments, editorials and reviews; conference proceedings where the data are inaccessible from the authors.

#### Intervention(s), exposure(s)

Not applicable

#### Comparator(s)/control

Not applicable

#### Primary outcome(s)

Primary or secondary outcome measure of falls in the preceding 6-12 months and/or prospective falls over a 12-month period. In order to capture falls data, studies that investigated fear of falling and falls risk as a primary outcome, in addition to current falls or fall history, will also be included.

#### Secondary outcome(s)

Secondary outcomes measure will include other method of falls data attainment, standardized functional

assessment tools.

#### Data extraction (selection and coding)

One reviewer will screen and exclude articles by title using pre-determined criteria. The remaining articles will be screened by abstract. Two independent reviewers then will screen the full text articles, and a third will be consulted if consensus will not be reached. Where two articles published from the same study, only one will be selected for inclusion in the review to avoid duplication.

A data extraction form will be developed. The form will be piloted and will be used for synthesis of evidence. The following will be extracted from the included studies:

- Study design
- Participant's characteristics (sample size, mean age and gender)
- OA diagnosis and grading
- Risk factors
- Falls definition and method of falls attainment
- Odds ratios, 95% confidence intervals and p values will also be extracted for potential fall risk factors.

#### Risk of bias (quality) assessment

The risk of bias of the included articles will be carried out using Quality Index Tool, developed by Downs and Black. It has been reported to have high internal consistency, good test-retest reliability and good inter-rater reliability. The tool will be modified for items deemed to be not applicable to the intent of this review.

#### Strategy for data synthesis

We will provide a qualitative synthesis of the results from the included studies which include demographics, study design, falls attainment data, fall definition and incidence result. For risk factors with consistent definition and where results were reported in a similar fashion across several studies, a meta-analysis will be performed to obtain the pooled estimate of the size.

For the meta-analysis, odds ratio for association of a risk factor to fall will be extracted. If odd ratio or data needed is not reported, we will contact the corresponding author.

#### Analysis of subgroups or subsets

None planned

#### Contact details for further information

Mr Manlapaz  
donsevf@yaho.com

#### Organisational affiliation of the review

School of Physiotherapy, University of Otago  
<http://www.otago.ac.nz/physio/index.html>

#### Review team members and their organisational affiliations

Mr Donald Manlapaz. University of Otago, School of Physiotherapy  
Dr Cathy Chapple. University of Otago, School of Physiotherapy  
Dr Gisela Sole. University of Otago, School of Physiotherapy  
Dr Prasath Jayakaran. University of Otago, School of Physiotherapy

#### Collaborators

Ms Mandeep Kaur. University of Otago, School of Physiotherapy  
Ms Normala Mesbah. University of Otago, School of Physiotherapy

#### Anticipated or actual start date

15 October 2015

#### Anticipated completion date

31 March 2016



**Funding sources/sponsors**

University of Otago, Doctoral Scholarship,  
University of Otago, School of Physiotherapy, Centre for Health, Activity, and Rehabilitation Research

**Conflicts of interest**

None known

**Language**

English

**Country**

New Zealand

**Stage of review**

Review\_Ongoing

**Subject index terms status**

Subject indexing assigned by CRD

**Subject index terms**

Accidents; Adult; Humans; Osteoarthritis, Hip; Osteoarthritis, Knee; Risk Factors

**Date of registration in PROSPERO**

27 October 2015

**Date of publication of this version**

29 October 2015

**Revision note for this version**

Dr to Mr for Donald Manlapaz

**Details of any existing review of the same topic by the same authors**

Not applicable

**Stage of review at time of this submission**

The review has not started

<b>Stage</b>	<b>Started</b>	<b>Completed</b>
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

**Revision note**

Dr to Mr for Donald Manlapaz

**Versions**

## Appendix F: Search strategy for the systematic review

Supplementary file:

[http://www.crd.york.ac.uk/PROSPEROFILES/27582\\_STRATEGY\\_20150927.pdf](http://www.crd.york.ac.uk/PROSPEROFILES/27582_STRATEGY_20150927.pdf)

### Sample search strategy

An initial search was done last October 22, 2015 using the following search terms. The search terms will be re-ran just before the final analysis for an updated number of articles/studies.

### Search terms for Medline (modified for other databases)

#### Result: 851

1. osteoarthritis/
2. exp osteoarthritis/
3. osteoarthritis.tw.
4. degenerative arthritis.mp.
5. osteoarthrosis.mp.
6. arthrosis.mp.
7. osteoarthropathy.mp.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. knee/
10. knee Joint/
11. osteoarthritis, knee/
12. osteoarthritis knee.mp.
13. genu.mp.
14. gonarthrosis.mp.
15. 9 or 10 or 11 or 12 or 13 or 14
16. 8 and 15
17. accidental falls/
18. falls.mp.
19. falling.mp.
20. falls risk.mp.
21. risk factors/
22. 17 or 18 or 19 or 20 or 21
23. 16 and 22
24. 23 not arthroplasty.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
25. 24 not osteotomy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

## Appendix G: Data extraction form

---

### Data Extraction Form

---

<b>Reference No.</b>	
<b>Reviewer:</b>	<b>Date:</b>

**Citation:**

**Main objective of the study:**

**Eligibility**

Type of Study:

Inclusion Criteria:

Exclusion Criteria:

**Participants**

No. of eligible participants:

No. of completed:

Length of follow-up (if applicable):

Dropout rate:

No. of follow-up:

Age- Mean/range:

Geographic location:

Dates/Years of data collection:

Gender:

Recruitment setting:

**Methods**

Definition of OA:

Definition of fall:

Falls attainment:

List of factors/variables and measurements

Covariates/confounders:

### **Statistical Analysis**

Statistics used to report associations:

(OR/RR/HR/correlation) including statistical significance:

### **Results**


Factors identified/studied:

*Summary data of main findings*

### **Main Conclusion**


State main conclusion(s):


## Appendix H: Registration of the cross-sectional study protocol





**ANZCTR**  
Australian New Zealand Clinical Trials Registry


[CREATE ACCOUNT](#)    [LOGIN](#)

  
DEFINITIONS

  
HINTS AND TIPS

  
FAQs

  
REGISTER TRIAL

  
MY TRIALS

Trial Review







VIEW TRIAL AT REGISTRATION

VIEW HISTORY

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been endorsed by the ANZCTR. Before participating in a study, talk to your health care provider and refer to this [information for consumers](#)

< BACK

Trial registered on ANZCTR

<b>Registration number</b>		ACTRN12617000154303
<b>Ethics application status</b>		Approved
<b>Date submitted</b>		25/01/2017
<b>Date registered</b>		30/01/2017
<b>Date last updated</b>		11/01/2018
<b>Type of registration</b>		Prospectively registered

**Titles & IDs**

<b>Public title</b>	Factors associated with risk of falling among individuals with knee osteoarthritis
<b>Scientific title</b>	Factors associated with risk of falling among adults with knee osteoarthritis: a cross sectional study
<b>Secondary ID [1]</b>	None
<b>Universal Trial Number (UTN)</b>	
<b>Trial acronym</b>	
<b>Linked study record</b>	

**Health condition**

<b>Health condition(s) or problem(s) studied:</b>	
Osteoarthritis	
Falls	
<b>Condition category</b>	<b>Condition code</b>
Musculoskeletal	Osteoarthritis

**Intervention/exposure**

<b>Study type</b>	Observational
<b>Patient registry</b>	False
<b>Target follow-up duration</b>	
<b>Target follow-up type</b>	
<b>Description of intervention(s) / exposure</b>	This research will identify the factors that contribute to falling among adults with knee osteoarthritis (OA). The study will explore the relationship between falls in adults with knee OA and clinical characteristics of knee OA such as pain, instability, physical function, muscle strength and balance. Participants will attend a session of up to 45 minutes to assess the knee, answer questionnaires, and perform standard tests for balance, strength and physical function.
<b>Intervention code [1]</b>	Not applicable
<b>Comparator / control treatment</b>	No control group
<b>Control group</b>	Uncontrolled

<b>Secondary outcome [4]</b>	Fear of falling - Short Fall Efficacy Score - International
<b>Timepoint [4]</b>	Baseline, eight-week assessment, (16-week) post assessment

#### Eligibility

<b>Key inclusion criteria</b>	Participants with knee osteoarthritis meeting the clinical criteria of the American College of Rheumatology 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.
<b>Minimum age</b>	18 Years
<b>Maximum age</b>	No limit
<b>Gender</b>	Both males and females
<b>Can healthy volunteers participate?</b>	No
<b>Key exclusion criteria</b>	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 previous history of using exergaming will also be excluded.

#### Study design

<b>Purpose of the study</b>	Treatment
<b>Allocation to intervention</b>	Non-randomised trial
<b>Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)</b>	Allocation is not concealed.
<b>Methods used to generate the sequence in which subjects will be randomised (sequence generation)</b>	Not applicable
<b>Masking / blinding</b>	Open (masking not used)
<b>Who is / are masked / blinded?</b>	
<b>Intervention assignment</b>	Single group
<b>Other design features</b>	A mixed-methods, explanatory sequential study design will be conducted for piloting the Nintendo Wii Fit™ exergaming program in individuals with knee OA. This design emphasises quantitative analysis, which is followed by interviews or observations (qualitative) to help in analysing the findings. The quantitative part will be a one-way repeated measures design, while the qualitative part will be a focus group discussion.
<b>Phase</b>	Not Applicable
<b>Type of endpoint(s)</b>	Safety/efficacy
<b>Statistical methods / analysis</b>	

#### Recruitment

<b>Recruitment status</b>	Not yet recruiting		
<b>Date of first participant enrolment</b>			
<b>Anticipated</b>	1/09/2017	<b>Actual</b>	
<b>Date of last participant enrolment</b>			
<b>Anticipated</b>	1/12/2017	<b>Actual</b>	
<b>Date of last data collection</b>			
<b>Anticipated</b>	28/02/2018	<b>Actual</b>	
<b>Sample size</b>			
<b>Target</b>	12	<b>Current</b>	<b>Final</b>
<b>Recruitment outside Australia</b>			
<b>Country [1]</b>	New Zealand		
<b>State/province [1]</b>	Otago		

#### Funding & Sponsors

<b>Funding source category [1]</b>	University
<b>Name [1]</b>	University of Otago, School of Physiotherapy
<b>Address [1]</b>	325 Great King Street Dunedin 9016
<b>Country [1]</b>	New Zealand
<b>Primary sponsor type</b>	University
<b>Name</b>	University of Otago Doctoral Scholarship
<b>Address</b>	325 Great King Street Dunedin 9016
<b>Country</b>	New Zealand
<b>Secondary sponsor category [1]</b>	None
<b>Name [1]</b>	
<b>Address [1]</b>	
<b>Country [1]</b>	

#### Ethics approval

<b>Ethics application status</b>	Not yet submitted
<b>Ethics committee name [1]</b>	Health and Disability Ethics Committees - New Zealand
<b>Ethics committee address [1]</b>	133 Molesworth Street Thorndon Wellington 6011
<b>Ethics committee country [1]</b>	New Zealand
<b>Date submitted for ethics approval [1]</b>	31/08/2017
<b>Approval date [1]</b>	
<b>Ethics approval number [1]</b>	

#### Summary

<b>Brief summary</b>	<p>There is evidence of increasing number of falls in adults with knee osteoarthritis (OA). The increased risk of falling in individuals with knee OA may be due to balance impairment and disease-related symptoms. Exercise is recommended as one of the first lines of choice in the conservative management of knee OA. Doing exercise in a supervised group, practising Tai Chi, and participating in physical activities such as walking has been proven effective; however, there are alternative treatments that can be used that may provide possible therapeutic and rehabilitative effect in a novel and engaging way such as exergaming (exercise + gaming). The majority of published articles investigating the use of exergaming included healthy and patient population where the latter are mostly neurologic conditions such as Stroke, Parkinson's disease, and Multiple Sclerosis. Several exergames 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. This research aims to conduct an exergaming intervention using Nintendo Wii Fit™ games in individuals with knee osteoarthritis. The primary objective is to determine the feasibility of implementing an exergaming balance intervention. Also, the study aims to estimate changes in the outcome measure scores mainly for balance and risk of falling. Participants with knee osteoarthritis and history of falling will be recruited from Dunedin through community advertising. Individuals with knee OA and history of falling will be recruited following a set of inclusion and exclusion criteria. Recruitment will be from September 2017 to Dec 2017. Eligible participants will participate in 16-week study programme: eight weeks of usual care and three times per week of exergaming for eight weeks. Participants will also have to attend three assessment sessions (baseline, eighth-week, and 16th-week). A focus group discussion will be conducted after the intervention to explore participant's perceptions and experiences. During the assessment, participants will be asked to answer some questionnaire, survey, and perform standard tests for balance, strength and physical function. All 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. 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.</p>
<b>Trial website</b>	
<b>Trial related presentations / publications</b>	
<b>Public notes</b>	
<b>Private notes</b>	
<b>Attachments [1]</b>	<a href="http://www.anzctr.org.au/AnzctrAttachments/373367-Protocol_240717.docx">http://www.anzctr.org.au/AnzctrAttachments/373367-Protocol_240717.docx</a> (Protocol)

#### Contacts

<b>Principal investigator</b>	
<b>Name</b>	Mr Donald Manlapaz

## Appendix I: Ethical approval and Maori Consultation (cross-sectional)



H16/120

Academic Services  
Manager, Academic Committee, Mr Gary Witte

Dr C Chapple  
School of Physiotherapy

21 October 2016

Dear Dr Chapple,

I am writing to let you know that, at its recent meeting, the Ethics Committee considered your proposal entitled "Factors associated with risk of falling among adults with knee osteoarthritis".

As a result of that consideration, the current status of your proposal is:- **Approved**

For your future reference, the Ethics Committee's reference code for this project is:- H16/120.

The comments and views expressed by the Ethics Committee concerning your proposal are as follows:-

While approving the application, the Committee would be grateful if you would respond to the following:

### **Future use of data (question 6.5)**

In question 6.5 of the application form you indicate that data generated from the study may be available for use in future research. The Committee asks that reference to this is included on the Information Sheet and Consent Form.

Please provide the Committee with copies of the updated documents, if changes have been necessary.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.



Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

<http://www.otago.ac.nz/healthandsafety/index.html>

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

[gary.witte@otago.ac.nz](mailto:gary.witte@otago.ac.nz)

[jo.farronediaz@otago.ac.nz](mailto:jo.farronediaz@otago.ac.nz)

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

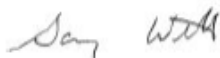
The Human Ethics Committee (Health) asks for a Final Report to be provided upon completion of the study. The Final Report template can be found on the Human Ethics Web Page <http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

The Human Ethics Committee asks for a Final Report to be provided upon completion of the study. The Final Report template can be found on the Human Ethics Web Page

<http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>

Yours sincerely,



Mr Gary Witte  
Manager, Academic Committees  
Tel: 479 8256  
Email: [gary.witte@otago.ac.nz](mailto:gary.witte@otago.ac.nz)

c.c. Professor L A Hale Dean School of Physiotherapy



# NGĀI TAHU RESEARCH CONSULTATION COMMITTEE

## TE KOMITI RAKAHAU KI KĀI TAHU

Tuesday, 01 November 2016.

Dr Catherine Chapple,  
School of Physiotherapy,  
DUNEDIN.

Tēnā Koe Dr Catherine Chapple,

### **Factors associated with risk of falling among adults with knee osteoarthritis**

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 01 November 2016 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

*"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."*

The Committee considers the research to be of importance to Māori health.

The Committee notes and commends that ethnicity data is to be collected using the questions on self-identified ethnicity and descent contained in the latest census.

The Committee commends the researchers on the thought that has gone into expressing values that are important to Māori within this research proposition.

The Committee suggests dissemination of the research findings to relevant Māori health organisations regarding this study, including Taeora Tinana, Māori Physiotherapists within the New Zealand Society of Physiotherapists.

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Otākou Incorporated  
Kāti Huirapa Rūnaka ki Puketeraki  
Te Rūnanga o Moeraki*



NGĀI TAHU RESEARCH CONSULTATION COMMITTEE  
*TE KOMITI RAKAHAU KI KĀI TAHU*

We wish you every success in your research and the committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 01 November 2016 to 1 May 2018.

Nāhaku noa, nā



PR MRC

Mark Brunton  
Kaiwhakahaere Rangahau Māori  
Research Manager Māori  
Research Division  
Te Whare Wānanga o Otago  
Ph: +64 3 479 8738  
Email: mark.brunton@otago.ac.nz  
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Ōtākou Incorporated  
Kāti Huirapa Rūnaka ki Puketeraki  
Te Rūnanga o Moeraki*



**KNEE BALANCE**

UNIVERSITY  
of  
**OTAGO**  
Whare Wānanga o Ōtago  
NEW ZEALAND

Do you have a  
sore or stiff knee?

Knee  
osteoarthritis  
and  
balance study

We are studying the relationship between falls and knee osteoarthritis symptoms.

If you are over 18 years old and would like to take part this research, we would like to hear from you.

If you are eligible, we will invite you to come to the School of Physiotherapy for up to 45 minutes to assess your knee.

We will ask you to complete some questionnaires, and perform standard tests for balance, strength, and physical function.

For more information please contact:

School of Physiotherapy  
Clinical Research Administrator  
Email: [clinicalresearch.physio@otago.ac.nz](mailto:clinicalresearch.physio@otago.ac.nz)  
Tel: 03 479 4979  
or 0800 687 489

This project has been approved by the University of Otago Human Ethics Committee. (Health). Reference: H16/120.

## Appendix K: Agreement for talent release



# Agreement for Talent Release

I authorise the University of Otago to use my photograph, video images, name and/or profile for promotional and similar purposes pertaining to the University of Otago. The University of Otago shall be the exclusive owner of all photographs, video images and text, including copyright therein, and I acknowledge that I am not entitled to payment or any other compensation for the use of such material.

The University will always use discretion when using my image and/or profile and will not use it to discredit me in any way.

I confirm that I have no criminal convictions, that there are no criminal charges pending against me, and that nothing in my personal circumstances is such that use of my image or information about me for promotional or similar purposes could cause the University embarrassment or bring it into disrepute.

I understand that the University will endeavour to give me the opportunity, before relevant materials are produced, to view my image and/or information in the form in which it is proposed to be used but that it cannot guarantee to do so. Accordingly, I formally waive any right to approve the use of my image or information. I also accept that subsequent use of such image(s) or information may proceed without (further) consultation.

I understand that I have the right (by advising the Registrar of the University in writing) to have the University cease using my image and information for the purposes described above, provided that the University may continue using my image and information until existing stocks of material are exhausted or existing promotions are completed and for such reasonable period as may be required for replacement material to be produced.

I confirm that I have attained the age of 18 years and have the right to contract in my own name.

### Talent

Name Zohreh Jafarian  
Signature Zohreh Jafarian  
Address 235 school of physiotherapy - Great King St  
Email Zohreh.jafarian@postgrad.otago.ac.nz  
Mobile 0223093366 Date 22/09/2017

### Authorised Signatory for the University of Otago

Name Donald Manlapaz  
Signature PhD candidate @manlapaz  
Position PhD candidate Date 22/09/2017

## Appendix L: Assessment form (cross-sectional)

Participant's ID No: \_\_\_\_

Date: \_\_ / \_\_ / \_\_\_\_

Time: \_\_: \_\_

### I. Demographic Information:

Age: \_\_\_\_\_

Gender:  Male  Female

Height: \_\_\_\_\_ cm

Weight: \_\_\_\_\_ kg

BMI: \_\_\_\_\_ kg/m<sup>2</sup>

Which ethnicity group do you belong to? *Mark the space or spaces that apply to you.*

- New Zealand European
  - Maori
  - Samoan
  - Cook Island Maori
  - Tongan
  - Niuean
  - Chinese
  - Indian
  - Other (such as Dutch, Japanese) please state
- 

### II. Examination of the knee:

1. Most symptomatic Knee:  Right  Left  Bilateral

**2. American College of Rheumatology (ACR) clinical criteria for classification of knee osteoarthritis (Altman et al., 1986)**

OA of the knee: Clinical

Knee pain

At least 3 of 6:

- Age > 50 years
- Stiffness < 30 mins
- Crepitus
- Bony tenderness
- Bony enlargement
- No palpable warmth

<b>Checklist for exclusion criteria</b>
<input type="checkbox"/> No previous lower limb injury / surgery in previous 12 months
<input type="checkbox"/> No consultation with orthopedic specialist for knee OA, or commencement of new medication for OA (previous 1 month)
<input type="checkbox"/> No other forms of arthritis particularly inflammatory disease
<input type="checkbox"/> Not having any treatment / physiotherapy management of the knee

**3. History of falls:**

<p><i>a. Have you slipped, tripped or fallen in the last year?</i></p> <p><i>Definition: A fall is defined as an event in which person unintentionally comes to rest on the ground or other lower levels.</i></p>	<p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p><i>If yes, how many falls in the last year?</i></p>	<p>No of fall/s: _____</p>
<p><i>b. Can you get out of a chair without using your hands?</i></p>	<p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p><i>c. Have you avoided some activities because you are afraid you might lose your balance?</i></p>	<p><input type="checkbox"/> YES</p> <p>Activities: _____</p> <p><input type="checkbox"/> NO</p>

**Is the participant eligible to participate in the study?**

Included

Excluded

***Reason for exclusion:***

\_\_\_\_\_

\_\_\_\_\_

### III. Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0

**INSTRUCTIONS:** *This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.*

**Symptoms.** *These questions should be answered thinking of your knee symptoms during the **last week**.*

S1. Do you have swelling in your knee?

Never       Rarely       Sometimes       Often       Always

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never       Rarely       Sometimes       Often       Always

S3. Does your knee catch or hang up when moving?

Never       Rarely       Sometimes       Often       Always

S4. Can you straighten your knee fully?

Never       Rarely       Sometimes       Often       Always

S5. Can you bend your knee fully?

Never       Rarely       Sometimes       Often       Always

**Stiffness.** *The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.*

S6. How severe is your knee joint stiffness after first wakening in the morning?

None       Mild       Moderate       Severe       Extreme

S7. How severe is your knee stiffness after sitting, lying or resting later in the day?

None       Mild       Moderate       Severe       Extreme

#### **Pain**

P1. How often do you experience knee pain?

Never       Monthly       Weekly       Daily       Always



What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None      Mild      Moderate      Severe      Extreme

P3. Straightening knee fully

None      Mild      Moderate      Severe      Extreme

P4. Bending knee

None      Mild      Moderate      Severe      Extreme

P5. Walking on flat surface

None      Mild      Moderate      Severe      Extreme

P6. Going up or down stairs

None      Mild      Moderate      Severe      Extreme

P7. At night while in bed

None      Mild      Moderate      Severe      Extreme

P8. Sitting or lying

None      Mild      Moderate      Severe      Extreme

P9. Standing upright

None      Mild      Moderate      Severe      Extreme

**Function, daily living.** *The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.*

A1. Descending stairs

None      Mild      Moderate      Severe      Extreme

A2. Ascending stairs

None      Mild      Moderate      Severe      Extreme

A3. Rising from sitting

None      Mild      Moderate      Severe      Extreme

A4. Standing

None      Mild      Moderate      Severe      Extreme

A5. Bending to floor/pick up an object

None      Mild      Moderate      Severe      Extreme

A6. Walking on flat surface

None      Mild      Moderate      Severe      Extreme

A7. Getting in/out of car

None      Mild      Moderate      Severe      Extreme

A8. Going shopping

None      Mild      Moderate      Severe      Extreme

A9. Putting on socks/stockings

None      Mild      Moderate      Severe      Extreme

A10. Rising from bed

None      Mild      Moderate      Severe      Extreme

A11. Taking off socks/stockings

None      Mild      Moderate      Severe      Extreme

A12. Lying in bed (turning over, maintaining knee position)

None      Mild      Moderate      Severe      Extreme

A13. Getting in/out of bath

None      Mild      Moderate      Severe      Extreme

A14. Sitting

None      Mild      Moderate      Severe      Extreme

A15. Getting on/off toilet

None      Mild      Moderate      Severe      Extreme

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc.)

None       Mild       Moderate       Severe       Extreme

A17. Light domestic duties (cooking, dusting, etc.)

None       Mild       Moderate       Severe       Extreme

**Function, sports and recreational activities.** *The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.*

SP1. Squatting

None       Mild       Moderate       Severe       Extreme

SP2. Running

None       Mild       Moderate       Severe       Extreme

SP3. Jumping

None       Mild       Moderate       Severe       Extreme

SP4. Twisting/pivoting on your injured knee

None       Mild       Moderate       Severe       Extreme

SP5. Kneeling

None       Mild       Moderate       Severe       Extreme

### **Quality of Life**

Q1. How often are you aware of your knee problem?

Never       Monthly       Weekly       Daily       Constantly

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all       Mildly       Moderately       Severely       Totally

Q3. How much are you troubled with lack of confidence in your knee?

Not at all       Mildly       Moderately       Severely       Extremely

Q4. In general, how much difficulty do you have with your knee?

None       Mild       Moderate       Severe       Extreme

#### IV. Knee Outcome Survey- Activities of Daily Living Scale

**Instructions:** The following questionnaire is designed to determine the symptoms and limitations that you experience because of your knee while you perform your usual daily activities. Please answer each question by checking the statement that best describes you over the last 1 to 2 days. For a given question, more than one of the statements may describe you, but please mark **ONLY** the statement that best describes you during your usual daily activities

##### Symptoms

**#6. To what degree does buckling of your knee affect your daily activity level?**

\_5\_ I never have buckling of my knee.

\_4\_ I have buckling of my knee, but it does not affect my daily activity level.

\_3\_ Buckling affects my activity slightly.

\_2\_ Buckling affects my activity moderately.

\_1\_ Buckling affects my activity severely.

#### V. Sensory Organization Testing (*SMART EquiTest®*)

##### Summary:

Percentage Equilibrium Score: \_\_\_\_\_

Percentage Composite Score: \_\_\_\_\_

*Please see attached printed result (numeric data and raw data)*

#### VI. Strength Testing (*Nicholas MMT, 01160 Handheld dynamometer*)

	<b>Knee Flexor</b> <i>(Prone)</i>	<b>Result (kg)</b>	<b>Knee Extensors</b> <i>(Sitting)</i>	<b>Result (kg)</b>
<b>Nominated Knee: _____</b>	Position: <i>0-20 degrees flexion</i>		Position: <i>0-20 degrees flexion</i>	
	Position: <i>70-90 degrees flexion</i>		Position: <i>70-90 degrees flexion</i>	

## VII. Physical Performance Measure: Timed and Go Test (TUG)

Test	Time
a. Timed Up and Go test <i>(time in seconds)</i>	

Participant's Signature: _____	Date: _____
Assessor's Signature: _____	Date: _____

# Appendix M: Sensory Organization Test result using NeuroCom Equitest® system

Evaluation Note
Print Options

Mask patient information

Patient Name: Test, Test

12/2/2014

Limits Of Stability 14:50:51

Modified CTSIB 14:47:01

Motor Control Test 14:43:16

Sensory Organization Test 14:35:43

Name: Test, Test      ID: fc74e3a-b9fa-49db-a91a-927d674c561a  
 Date of Birth: 1/1/1969      Height: 5'6"      File: FD/c74e3a-b9fa-49db-a91a-927d674c561a.XDRX  
 Referral Source: Not Specified      Operator: Not Specified  
 Diagnosis: Not Specified      Date: 12/2/2014  
 Comments:      Time: 14:35:43

### Sensory Organization Test

(Sway Referenced Gain: 1.0)

#### Equilibrium Score

Condition	Score
FALL	95
1	90
2	85
3	90
4	80
5	30
6	25
Composite	61

13% Below Norm Score

#### Sensory Analysis

Category	Score
SOM	90
VIS	85
VEST	35
PREF	90

#### Strategy Analysis

FALL Hip 25 50 75 Ankle

Conditions 1 2 3 4 5 6

Mark: Δ X ◇ + □ ▷

#### COG Alignment

**Data Range Note:** NeuroCom Data Range: 16 - 59

Post Test Comment:  Mark test as invalid

Neurocom System Version 9.2, copyright ©1989-2014 Neurocom®, All Rights Reserved.

**VIEW OPTIONS**

- Numeric
- Comprehensive
- COG Trace
- Raw Data

**PRINT OPTIONS**


- Numeric
- Comprehensive
- COG Trace
- Raw Data

Edit Comment

Print

Main Menu

## Appendix N: Registration and protocol of the feasibility study





# ANZCTR


Australian New Zealand Clinical Trials Registry


LOG OFF


Logged in as Donald Manlapaz  
(Account details)

  
DEFINITIONS

  
HINTS AND TIPS

  
FAQs

  
REGISTER TRIAL

  
MY TRIALS

### Trial Review

VIEW TRIAL AT REGISTRATION

VIEW HISTORY

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been endorsed by the ANZCTR. Before participating in a study, talk to your health care provider and refer to this [information for consumers](#)

< BACK

### Trial registered on ANZCTR

<b>Registration number</b>	(i)	ACTRN12617001108303
<b>Ethics application status</b>	(i)	Approved
<b>Date submitted</b>	(i)	25/07/2017
<b>Date registered</b>	(i)	28/07/2017
<b>Date last updated</b>	(i)	17/04/2019
<b>Date data sharing statement initially provided</b>	(i)	17/04/2019
<b>Date results information initially provided</b>	(i)	17/04/2019
<b>Type of registration</b>	(i)	Prospectively registered

**Titles & IDs**

<b>Public title</b>	Exergaming to improve balance and decrease the risk of falling in adults with knee osteoarthritis: a feasibility study
<b>Scientific title</b>	Implementation of an exergaming intervention to improve balance and reduce the risk of falling in individuals with knee osteoarthritis: a feasibility study
<b>Secondary ID [1]</b>	None
<b>Universal Trial Number (UTN)</b>	
<b>Trial acronym</b>	
<b>Linked study record</b>	

**Health condition**

<b>Health condition(s) or problem(s) studied:</b>	
Knee osteoarthritis	
<b>Condition category</b>	<b>Condition code</b>
Musculoskeletal	Osteoarthritis
Physical Medicine / Rehabilitation	Physiotherapy

**Intervention/exposure**

<b>Study type</b>	Interventional
<b>Description of intervention(s) / exposure</b>	<p>In this study, the Nintendo Wii Fit™ games and balance board system will be utilised as an exergaming intervention. A trained physiotherapist will conduct the balance exergaming in a set-up exergaming room at the School of Physiotherapy.</p> <p>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 that 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.</p> <p>Participants will perform balance exercise for 45 to 60 minute, three times per week for an eight-week period. The games will include Table Tilt, Soccer Heading and Penguin Slide. These games 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.</p>
<b>Intervention code [1]</b>	Rehabilitation
<b>Intervention code [2]</b>	Treatment: Devices
<b>Comparator / control treatment</b>	No control group
<b>Control group</b>	Uncontrolled

**Outcomes**

<b>Primary outcome [1]</b>	Feasibility outcome:
	Recruitment- the number of participants recruited in three months
<b>Timepoint [1]</b>	From baseline to (16 week) post intervention

## Appendix O: Ethics approval and Maori consultation forms (feasibility study)



Health and Disability Ethics Committees  
Ministry of Health  
133 Molesworth Street  
PO Box 5013  
Wellington  
6011  
  
0800 4 ETHICS  
hdec@moh.govt.nz

24 October 2017

Mr Donald Manlapaz  
School of Physiotherapy, University of Otago  
325 Great King Street  
Dunedin 9016

Dear Mr Manlapaz

Re:	Ethics ref:	17/STH/183
	Study title:	Implementation of an exergaming intervention to improve balance and reduce the risk of falling in individuals with knee osteoarthritis: a feasibility study

I am pleased to advise that this application has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

### Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au)). However <https://clinicaltrials.gov/> is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
3. Before the study commences at a *given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

### After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 23 October 2018.




Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine  
Chairperson  
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

## Appendix P: Assessment form (feasibility study)

Participant's ID No: \_\_\_\_

Date: \_\_ / \_\_ / \_\_\_\_

Time: \_\_: \_\_

### I. Demographic Information:

Age: \_\_\_\_\_

Gender:  Male  Female

Height: \_\_\_\_\_ cm

Weight: \_\_\_\_\_ kg

BMI: \_\_\_\_\_ kg/m<sup>2</sup>

Which ethnicity group do you belong to? *Mark the space or spaces that apply to you.*

- New Zealand European
  - Maori
  - Samoan
  - Cook Island Maori
  - Tongan
  - Niuean
  - Chinese
  - Indian
  - Other (such as Dutch, Japanese, Tokelauan) please state
- 

### II. Eligibility:

4. Most symptomatic Knee:  Right  Left  Bilateral

**5. American College of Rheumatology (ACR) clinical criteria for classification of knee osteoarthritis (Altman et al., 1986)**

OA of the knee: Clinical

Knee pain

At least 3 of 6:

- Age > 50 years
- Stiffness < 30 mins
- Crepitus
- Bony tenderness
- Bony enlargement
- No palpable warmth

-----

- Access to TV
- Willing for Wii Fit to be set up in home

Exclusion criteria	
<input type="checkbox"/>	Previous lower limb injury / surgery in previous in 12 months
<input type="checkbox"/>	Consultation with orthopedic specialist for knee OA, or commencement of new medication for OA (previous 1 month)
<input type="checkbox"/>	Presence of other forms of arthritis particularly inflammatory disease
<input type="checkbox"/>	Having any treatment / physiotherapy management of the knee
<input type="checkbox"/>	Inability to understand and comply with trial information or instruction
<input type="checkbox"/>	Failed AHA screening
<input type="checkbox"/>	Unable to attend treatment sessions/assessments for 6-month period

Is the participant taking any pain medication/s?       Yes  No

If yes, list down medication/s: \_\_\_\_\_

Is the participant taking any other medication/s?       Yes  No

If yes, list down medication/s: \_\_\_\_\_

**6. History of falls:**

<i>a. Have you slipped, tripped or fallen in the last year?</i> <small>Definition: A fall is defined as an event in which person unintentionally comes to rest on the ground or other lower levels.</small>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<i>If yes, how many falls in the last year?</i>	No of fall/s: _____
<i>What activity you are doing?</i>	Activity: _____
<i>Where did it happen?</i>	Place: _____
<i>b. Can you get out of a chair without using your hands?</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<i>c. Have you avoided some activities because you are afraid you might lose your balance?</i>	<input type="checkbox"/> YES Activities: _____ <input type="checkbox"/> NO

**7. AHA Cardiovascular Screening**

Resting Systolic Blood Pressure (mmHg)	
Resting Diastolic Blood Pressure (mmHg)	
Resting Hear Rate (bpm)	

- Know cardiovascular disease:  Yes  No
- Cardiovascular symptoms:  Yes  No
- Cardiovascular risk factors:  None  ≤ 2  > 2
- IDDM:  Yes  No
- Severe pulmonary disease:  Yes  No

Assessment of Risk (from AHA/ACSM Screening Questionnaire)

A1	≤45 male, ≤55 female, °history, °symptom, °risk factors	No further testing required	<b>SAFE</b> to exercise moderate or vigorous level.  If pulmonary disease or IDDM, monitor
A2	>45 male, >55 female, °history, °symptom, °risk factors	No further testing required  Could monitor HR, BP, RPE if exercise intensity increases	<b>SAFE</b> to exercise to moderate level.  If pulmonary disease or IDDM, monitor
A3	>45 male, >55 female, °history, °symptom, ≥ 2risk factors	No further testing required  Could monitor HR, BP, RPE if exercise intensity increases	<b>SAFE</b> to exercise to moderate level.  If pulmonary disease or IDDM, monitor
B	Known history (clinically stable) NYHA Level I or II	Further screening  Exercise testing required Supervisor to monitor HR, BP, RPE until safely established and patient can self-monitor	If cleared by further screening, safe to exercise with supervision.  If pulmonary disease or IDDM = <b>EXCLUDED</b>
C	Known history (unstable) NYHA Level III or IV		<b>EXCLUDED</b>
D	Severe cardiovascular disease		<b>EXCLUDED</b>
Patient is <b>SAFE</b> to exercise: <input type="checkbox"/> NO <input type="checkbox"/> YES- with monitoring <input type="checkbox"/> YES – no monitoring required			

Findings / Comments:

---



---

Is the participant eligible to participate in the study?

- Included  Excluded

*Reason for exclusion:*

---



---

### III. Knee injury and Osteoarthritis Outcome Score (KOOS), *English version*

**INSTRUCTIONS:** *This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.*

**Symptoms.** *These questions should be answered thinking of your knee symptoms during the **last week**.*

S1. Do you have swelling in your knee?

Never       Rarely       Sometimes       Often       Always

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never       Rarely       Sometimes       Often       Always

S3. Does your knee catch or hang up when moving?

Never       Rarely       Sometimes       Often       Always

S4. Can you straighten your knee fully?

Never       Rarely       Sometimes       Often       Always

S5. Can you bend your knee fully?

Never       Rarely       Sometimes       Often       Always

**Stiffness.** *The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.*

S6. How severe is your knee joint stiffness after first wakening in the morning?

None       Mild       Moderate       Severe       Extreme

S7. How severe is your knee stiffness after sitting, lying or resting later in the day?

None       Mild       Moderate       Severe       Extreme

#### **Pain**

P1. How often do you experience knee pain?

Never       Monthly       Weekly       Daily       Always

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None      Mild      Moderate      Severe      Extreme

P3. Straightening knee fully

None      Mild      Moderate      Severe      Extreme

P4. Bending knee

None      Mild      Moderate      Severe      Extreme

P5. Walking on flat surface

None      Mild      Moderate      Severe      Extreme

P6. Going up or down stairs

None      Mild      Moderate      Severe      Extreme

P7. At night while in bed

None      Mild      Moderate      Severe      Extreme

P8. Sitting or lying

None      Mild      Moderate      Severe      Extreme

P9. Standing upright

None      Mild      Moderate      Severe      Extreme

**Function, daily living.** *The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.*

A1. Descending stairs

None      Mild      Moderate      Severe      Extreme

A2. Ascending stairs

None      Mild      Moderate      Severe      Extreme

A3. Rising from sitting

None      Mild      Moderate      Severe      Extreme

A4. Standing

None      Mild      Moderate      Severe      Extreme

A5. Bending to floor/pick up an object

None      Mild      Moderate      Severe      Extreme

A6. Walking on flat surface

None      Mild      Moderate      Severe      Extreme

A7. Getting in/out of car

None      Mild      Moderate      Severe      Extreme

A8. Going shopping

None      Mild      Moderate      Severe      Extreme

A9. Putting on socks/stockings

None      Mild      Moderate      Severe      Extreme

A10. Rising from bed

None      Mild      Moderate      Severe      Extreme

A11. Taking off socks/stockings

None      Mild      Moderate      Severe      Extreme

A12. Lying in bed (turning over, maintaining knee position)

None      Mild      Moderate      Severe      Extreme

A13. Getting in/out of bath

None      Mild      Moderate      Severe      Extreme

A14. Sitting

None      Mild      Moderate      Severe      Extreme

A15. Getting on/off toilet

None      Mild      Moderate      Severe      Extreme

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc.)

None      Mild      Moderate      Severe      Extreme

A17. Light domestic duties (cooking, dusting, etc.)

None       Mild       Moderate       Severe       Extreme

**Function, sports and recreational activities.** *The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.*

SP1. Squatting

None       Mild       Moderate       Severe       Extreme

SP2. Running

None       Mild       Moderate       Severe       Extreme

SP3. Jumping

None       Mild       Moderate       Severe       Extreme

SP4. Twisting/pivoting on your injured knee

None       Mild       Moderate       Severe       Extreme

SP5. Kneeling

None       Mild       Moderate       Severe       Extreme

### Quality of Life

Q1. How often are you aware of your knee problem?

Never       Monthly       Weekly       Daily       Constantly

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all       Mildly       Moderately       Severely       Totally

Q3. How much are you troubled with lack of confidence in your knee?

Not at all       Mildly       Moderately       Severely       Extremely

Q4. In general, how much difficulty do you have with your knee?

None       Mild       Moderate       Severe       Extreme



#### IV. Knee Outcome Survey- Activities of Daily Living Scale

**Instructions:** The following questionnaire is designed to determine the symptoms and limitations that you experience because of your knee while you perform your usual daily activities. Please answer each question by checking the statement that best describes you over the last 1 to 2 days. For a given question, more than one of the statements may describe you, but please mark **ONLY** the statement that best describes you during your usual daily activities

##### #6. To what degree does buckling of your knee affect your daily activity level?

\_5\_ I never have buckling of my knee.

\_4\_ I have buckling of my knee, but it does not affect my daily activity level.

\_3\_ Buckling affects my activity slightly.

\_2\_ Buckling affects my activity moderately.

\_1\_ Buckling affects my activity severely.

#### V. Short Falls Efficacy Scale – International

We would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		<b>Not at all concerned</b>	<b>Somewhat concerned</b>	<b>Fairly concerned</b>	<b>Very concerned</b>
		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
1	Getting dressed or undressed	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2	Taking a bath or shower	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3	Getting in or out of a chair	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4	Going up or down stairs	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5	Reaching for something above your head or on the ground	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
6	Walking up or down a slope	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
7	Going out to a social event (e.g. religious service, family gathering or club meeting)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

**VI. Sensory Organization Testing (SMART EquiTest®)**

**Summary:**

Percentage Equilibrium Score: \_\_\_\_\_

Percentage Composite Score: \_\_\_\_\_

*Please see attached printed result (numeric data and raw data)*

**VII. Strength Testing (Nicholas MMT, 01160 Handheld dynamometer)**

	<b>Knee Flexor (Prone)</b>	<b>Result (kg)</b>	<b>Knee Extensors (Sitting)</b>	<b>Result (kg)</b>
<b>Nominated Knee: _____</b>	Position: <i>0-20 degrees flexion</i>		Position: <i>0-20 degrees flexion</i>	
	Position: <i>70-90 degrees flexion</i>		Position: <i>70-90 degrees flexion</i>	

**VIII. Physical Performance Measure: Timed and Go Test (TUG)**

<b>Test</b>	<b>Time</b>
<b>b. Timed Up and Go test</b> <i>(time in seconds)</i>	<b>TUG 1:</b> <b>TUG 2:</b> <b>TUG 3:</b>

## IX. Physiological Profile Assessment

a. Edge contrast sensitivity (MET)

Score

1	2	3	4	5	6
7	8	9	10	11	12
13	14	15	16	17	18
19	20	21	22	23	24

b. Reaction time – Hand

Practice

1.	<input type="text"/>	ms
2.	<input type="text"/>	ms
3.	<input type="text"/>	ms
4.	<input type="text"/>	ms
5.	<input type="text"/>	ms

Test

1.	<input type="text"/>	ms
2.	<input type="text"/>	ms
3.	<input type="text"/>	ms
4.	<input type="text"/>	ms
5.	<input type="text"/>	ms
6.	<input type="text"/>	ms
7.	<input type="text"/>	ms
8.	<input type="text"/>	ms
9.	<input type="text"/>	ms
10.	<input type="text"/>	ms

c. Proprioception

1.	<input type="text"/>
2.	<input type="text"/>
3.	<input type="text"/>
4.	<input type="text"/>
5.	<input type="text"/>

d. Strength

Knee extension

<input type="text"/>	kg
<input type="text"/>	kg
<input type="text"/>	kg

e. Balance

Firm

Sway EO	<input type="text"/>
Sway EC	<input type="text"/>

Foam

Sway EO	<input type="text"/>
Sway EC	<input type="text"/>

Participant's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Assessor's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

EXERGAMING  
TO IMPROVE  
BALANCE AND  
DECREASE RISK  
OF FALLING

**INTERVENTION KIT**

Balance exercises and Home exercise diary

Centre for Health, Activity, and Rehabilitation  
Research – School of Physiotherapy  
University of Otago

## **List of recommended exercises**

### **Warm-up**

#### **Aerobic training menu**

Hula hoop

Step basic

Jogging

Boxing

### **Balance Exercises**

\*Soccer heading

\*Ski Slalom

\*Table tilt

\*Ski Jump

Penguin slide

Tightrope walk

Balance bubble

Snowboard slalom

Lotus focus

### **Cool down**

#### **Aerobic training menu**

Hula hoop

Step basic

Jogging

Boxing

## Instructions for using RPE during exercise.

*During the exercise test we want you to pay close attention to how hard you feel the exercise work rate is. The feeling should reflect your total amount of exertion and fatigue, combining all sensations of physical stress, effort and fatigue. Don't concern yourself with any one factor such as leg pain, shortness of breath or exercise intensity, but try to concentrate on your total inner feeling of exertion. Try not to underestimate or overestimate your feelings of exertion; be as accurate as you can.*

### **Category scale for Rating of Perceived Exertion (RPE)**

#### Category Scale

6	
7	Very very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very very hard
20	

Treatment recording form  
(Supervised sessions)

Participant ID: \_\_\_\_\_

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Most symptomatic Knee:  Right  Left  Bilateral

Nominated knee:

Right knee

Left knee

General observation:

--

ROM/Muscle strength/Function:

--

Physical Activity (changes):


Falls / instability:


Session Number: \_\_\_\_\_

Time started: \_\_\_\_\_

Time finished: \_\_\_\_\_

Name of Game	Average RPE	Time	Comments
Warm Up			
Ex 1			
Ex 2			
Ex 3			
Ex 4			
(Ex 5)			
Cool down			

Comments:

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---

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## Home exercise diary (sample form)

### WEEK 1

#### Session 1

Date \_\_/\_\_/\_\_ Time started: \_\_\_\_\_ Time finished \_\_\_\_\_

Name of Game	Average RPE	Comments
Warm Up		
Ex 1		
Ex 2		
Ex 3		
Ex 4		
(Ex 5)		
Cool down		

#### Session 2

Date \_\_/\_\_/\_\_ Time started: \_\_\_\_\_ Time finished \_\_\_\_\_

Name of Game	Average RPE	Comments
Warm Up		
Ex 1		
Ex 2		
Ex 3		
Ex 4		
(Ex 5)		
Cool down		

## Appendix R: Focus group discussion script

Good afternoon to all and welcome to our session. Thank you for taking the time to join us and talk about your experiences joining the study. My name is Miranda Buhler and Donald, who is here with us, will assist me. We are both PhD students of the School of Physiotherapy, University of Otago. I will be facilitating the discussion today and Donald will act as a note-taker. At any point of this discussion, he is not allowed not interfere or influence the discussion.

You were invited because you have participated the Exergaming balance study. The purpose of this group is to discuss your experiences and perceptions after being part of the exergaming programme investigating on the feasibility of using Nintendo Wii Fit™ to improve balance and reduce the risk of falling.

My role is to facilitate the discussion. I will be asking you questions and in some instances asking for further clarification or follow-up. It is really important that we hear from all of you, do not feel offended if I interrupt you in order to let another member of the group speak that we have not yet heard. I will be encouraging everybody to contribute their ideas and thoughts. There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we're just as interested in negative comments as positive comments, and at times the negative comments are the most helpful.

You've probably noticed the microphone. We're tape recording the session because we don't want to miss any of your comments. We will be on a first name basis and we won't use any names in our reports. You may be assured of complete confidentiality.

To help the discussion go smoothly some 'house rules':

- Please state your name (e.g. Miranda) before you contribute
  - We've placed name cards on the table in front of you to help us remember each other's names and to remind you that you need to mention your name first every time you contribute
- As much as possible, please do not speak over each other

- Lastly, please do not hesitate to correct me if I do not understand your view. We are really interested to know the experiences, views and opinions of the topic we are discussing.

Does anybody have any questions? I think we are now ready to start. Well, let's begin.

### Introduction:

<ul style="list-style-type: none"> <li>• Introduction</li> <li>• Purpose of the focus group</li> <li>• House rules</li> </ul>	<b>1. As a starter, could you please tell us your name and what is your favourite holiday location/spot in New Zealand?</b>
	<b>2. What was the first thing that came to your mind when you heard or read the word “exergaming” (exercise and gaming)?</b>

Think about your experiences in participating in our study. Recall your visits in the school particularly during testing and Wii Fit™ sessions.

### Key topic (1):

Feasibility <ul style="list-style-type: none"> <li>• Design (8 weeks of usual care, 8 weeks of exergaming, programme period)</li> <li>• Assessment (duration, number of assessment)</li> <li>Intervention (duration, number of assessment)</li> </ul>	<b>3. How did you find attending the testing or assessment sessions?</b>  <i>Probes/ Follow-up:</i> - Is the duration of the assessment enough, too long or too short? - Is the frequency of assessment (first, second, and final assessment) fine? - clarity of the instructions / questions during the assessment  <b>4. How did you find attending Wii Fit™ sessions in the school?</b>  - Is the duration of the intervention enough, too long or too short? - Are the number exergaming sessions (3 times a week) fine?
---	--

Let us talk about this time your experiences in playing the Wii Fit™. Donald will show some screenshots of the Wii Fit games interface and other related pictures to help you recall the exergaming intervention you did.

### Key topic (2):

Experiences in playing Wii Fit™ (system):	<b>5. Think back of playing Wii Fit games that you felt was particularly good. Briefly, tell us what made it good?</b>  <i>Probes/ Follow-up:</i>
---	---

<ul style="list-style-type: none"> <li>- Interaction with the system and games (software)</li> <li>- Game interface (software)</li> <li>- Wii accessories such as balance board, Wii remote, Wii sensor (hardware)</li> </ul> <p>Acceptability</p>	<p><i>Was it interesting?</i> <i>How was your interaction with the Wii Fit system (games)?</i></p> <p><i>Listen for:</i> <i>Enjoyment, motivation, competitiveness</i></p> <p><b>6. What do you think the least about playing Wii Fit™? Tell us what made it disappointing?</b></p> <p><i>Probes/ Follow-up:</i> <i>Any problems encountered with system?</i> <i>Any technical issues experience?</i></p> <p><i>Listen for:</i> <i>Dislikes</i> <i>Games were boring</i></p>
--	--

Lastly, since this is a feasibility study and we are after the safety of this intervention:

**Key topic (3):**

<p>Safety</p>	<p><b>7. Was there an instance, while playing Wii Fit™ games, you feel uncomfortable or unsafe?</b></p> <p><i>Probes/ Follow-up:</i> <i>Any fear of falling?</i> <i>Any discomfort (knee or other parts of the body)?</i></p>
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Our discussion today was to help us understand your perceptions and experiences in this exergaming programme using Wii Fit™

	<p><b>8. What did we miss? Is there anything that we should have talked about but didn't?</b></p>
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Thank you very much for participating in our focus group discussion. As we mentioned in the beginning of all information in this discussion will be kept confidential. You will be given a summary of the transcript of this discussion so that you can correct and clarify your answers if there will be mistakes.

## Appendix S: Focus group codes

NVivo 12.00

License Key: NVD12-LZ000-BH020-8RE8A

### Feasibility of the study

#### **Assessment/Testing**

Files\\FGD-Pilot - § 2 references coded [ 1.78% Coverage]

Reference 1 - 0.54% Coverage

From the start to end, the instructions were very clear.

Reference 2 - 1.24% Coverage

I did enjoy it, I want to say that I enjoyed the whole process and I'm pleased that I've seen it and had a go on it so mmhh, it was worthwhile.

Files\\FGD1- Nvivo - § 3 references coded [ 1.20% Coverage]

Reference 1 - 0.69% Coverage

Yeah very clear and not too complicated and not too demanding and I could understand how it related to the old knee issue

Reference 2 - 0.36% Coverage

The timing was fine... the input was ok, it wasn't onus

Reference 3 - 0.15% Coverage

Nicely spaced out I guess

Files\\FGD2-Nvivo - § 5 references coded [ 1.49% Coverage]

Reference 1 - 0.34% Coverage

It was, and for me it was not that difficult, even with the knee pain and back pain

Reference 2 - 0.17% Coverage

I think I found it, it was like just right

Reference 3 - 0.15% Coverage

It was not too short and not too long

Reference 4 - 0.46% Coverage

I think it was quite straight forward, I didn't have any difficulty with understanding the instructions...

Reference 5 - 0.38% Coverage

Sometimes it seems quite tricky. Like you know, answering the questions...mild, moderate, always...

#### **Intervention**

Files\\FGD-Pilot - § 2 references coded [ 6.25% Coverage]

Reference 1 - 3.03% Coverage

I found them quite fun and I didn't find them too taxing or too hard because we would just do each game for a short time. I imagined that it was just so you could see that I was doing it properly, you could get an idea of where I was at in it but it was a good brief length of time so it wasn't a hassle coming or anything and it was enjoyable.

Reference 2 - 3.22% Coverage

The duration of the whole programme is fine. The frequency I sometimes found hard if I had things on in the evenings during the week. Because I work every day, I don't get home till about six o'clock and then you have dinner, so sometimes it was harder to do it on a week day but I would just try and, I would do it sometimes twice on the weekend instead...

Files\\FGD1- Nvivo - § 7 references coded [ 12.62% Coverage]

Reference 1 - 1.58% Coverage

You always felt relaxed and yeah, and I used to actually find it quite good, there were a couple of times when there might have been somebody else there and you could kind of encourage them as well as you know, get a bit of a boost out of them as well so yeah, I found that quite good.

Reference 2 - 2.84% Coverage

I found the, at home sessions, yeah like it was up to you what you put into it so you could you know, adjust your times. Some days I may have only had half an hour that I had spare and I would you know, work out the exercises and do them to fit that timing...but when we came into here, we had a set you know, one hour say so that timing was you know, you made allowances for that timing anyway.

Reference 3 - 1.23% Coverage

I enjoyed participating in the study because it was quite, there was a little bit of fitness in it and there as a little bit of action and you were doing things outside that I wouldn't normally

Reference 4 - 1.60% Coverage

It was a bit difficult just to allocate time in the evenings and occasionally in the mornings I'd, just organising a space in the day to do it...and oh suddenly oh, five or six days had gone past and I haven't done anything but routine once you set it up was yep, not too difficult...

Reference 5 - 2.30% Coverage

I enjoyed going through the process and the various games...yeah it was new. The first month or first four or five weeks I guess actually took a lot of time actually getting my head around the mechanics of it as opposed to the being familiar with how much, which button to push and, yeah that kind of thing...so it was a while before I felt that I was getting something from the game if you know what I mean.

Reference 6 - 2.69% Coverage

Three times... sometimes it was fitting those in through the week which was the difficulty in the sense that you know, you'd have something come up, you'd think oh my goodness, I'm gonna have to do another session before that gets in so it was making sure you yeah, did enough sessions before you knew you were coming in here and then yeah, fixing...you know at the end of the day, it was like I did start getting up quite early in the morning before I went to work to do it...

Reference 7 - 0.36% Coverage

I might've, half an hour seemed to be the optimum length of time

Files\\FGD2-Nvivo - § 7 references coded [ 3.39% Coverage]

Reference 1 - 0.30% Coverage

Each session was kind of taking half an hour for me which I think alright

Reference 2 - 0.62% Coverage

When I finished, I'd spend you know, more time, you know playing some other games as with the kids, they enjoyed it as well

Reference 3 - 0.75% Coverage

I was eager to move into the exercise which could help me and I did, most of them it was like one hour but of course, in between, I'm not familiar with the TV or connecting you know...

Reference 4 - 0.86% Coverage

I think it's a good decision, it was a good decision to have a session here because I was kind of a bit forcing myself to do the other sessions because I was kind of delaying you know, I'm not a regular exerciser

Reference 5 - 0.33% Coverage

It was good to have this session otherwise I would probably skip some sessions. But if you said you know, four sessions, I imagine I wouldn't be able to do that.

#### Reference 6 - 0.20% Coverage

Two sessions there, one session here, it was doable

NVivo 12.00

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### Acceptability

#### Positive experiences

#### Files\\FGD-Pilot - § 5 references coded [ 13.36% Coverage]

##### Reference 1 - 3.08% Coverage

I liked were the cognitive ones where you had to use your brain, the Tilt City, the Tilt Table and the bubble one I quite liked as well but the two tilt ones, I felt like I was using my brain a lot and therefore was focussing on that rather than the fact that I was having to move as well, the movement sort of naturally came as part of the game.

##### Reference 2 - 2.27% Coverage

It's interesting, it's challenging, I kept wanting to improve because you have to, both of those games, or all of those games actually you need to have got through all levels to be able to feel that you've completed that game so I enjoyed it.

##### Reference 3 - 2.25% Coverage

I don't especially like doing exercise, that's why I'm overweight so the ones that allowed me to exercise as a sort of secondary thing while I was working on the mental thing, that's what I liked 'cause it didn't seem so much like exercise to me.

##### Reference 4 - 4.34% Coverage

I used to do yoga and I do quite like yoga so I think that just had the benefit for me of finding yoga more enjoyable than actual exercise, aerobic exercise anyway so the yoga didn't have that challenge level but it was enjoyable because yoga itself is something that interests me whereas the other ones, the ski jump or the cycling, free running, those sorts of things to me were just purely exercise and therefore mentally I was just thinking eh exercise, I don't like it

##### Reference 5 - 1.41% Coverage

Batteries ran out at one point but that's all otherwise no, everything was very easy and intuitive so I could work out how to use everything easy enough.

#### Files\\FGD1- Nvivo - § 12 references coded [ 13.01% Coverage]

##### Reference 1 - 2.31% Coverage

I enjoyed them, I thought they were a lot of fun and I quite enjoyed, I thought things were made quite easy, you know shown, we were shown things and the exact, you know it was quite easy to learn something and I think too it was quite, it was good, I never, you never felt that you couldn't do something or were put into a situation where it was too difficult that you couldn't do it, does that make sense, yeah.

##### Reference 2 - 1.23% Coverage

I enjoyed participating in the study because it was quite, there was a little bit of fitness in it and there as a little bit of action and you were doing things outside that I wouldn't normally do.

##### Reference 3 - 0.19% Coverage

It was definitely something new

##### Reference 4 - 1.02% Coverage

I would never buy a Wii Fit you know...but then having this presented and looking, I thought oh that's actually quite good, it could be something to look into type thing, so yeah.

Reference 5 - 0.34% Coverage

Yep, once that got into the feel of it, yeah it was enjoyable

Reference 6 - 1.23% Coverage

I guess I chose games that were different, used slightly different parts of my brain or my body etc. and balance that up a bit and certain games were...challenging for those aspects I guess, that's why I chose them. I felt challenged about that to ok, I'm gonna do a bit better next time

Reference 7 - 1.03% Coverage

I couldn't keep up to the rhythm or when my rhythm went off, it made me think ok well what was I doing wrong or and then I'd do the next session and do it a bit better, why was that better. It was a bit, it was a wee bit of a challenge or...an interest to understand why

Reference 8 - 2.42% Coverage

I enjoyed them, like probably competitively as well so competing against yourself every time and so I liked ones that were quite challenging and I'd always try and beat my next, you know or beat my last score and yeah, I was very competitive and even so that when I came in for here, you know if I saw a score, I wanted to beat that one that was on the screen and be the best you know, so it was always a, you know, great achievement

Reference 9 - 0.89% Coverage

I'm quite competitive and so that was what was driving me...and making me want to you know, oh I'm gonna do it one more time and oh I'm gonna do it another time

Reference 10 - 0.66% Coverage

It was quite interesting how I reacted in the sense of trying to get it better and again the points system coming in

Reference 11 - 0.11% Coverage

It was interesting

Reference 12 - 0.73% Coverage

It has made me more aware of balance and rhythm and how you're working and what not. Yeah no I thought it was quite a good exercise

Files\\FGD2-Nvivo - § 15 references coded [ 7.70% Coverage]

Reference 1 - 0.67% Coverage

I enjoyed the games. At the start I was a bit not so fast or you know, I'm a bit slow, or taking time to co-ordinate my and my, you know my mind, co-ordinating it all

Reference 2 - 0.24% Coverage

I was happy because my mind is always focussed on exercise

Reference 3 - 0.38% Coverage

Getting old, then I think are you, if you don't lose it, you're going to lose it you know...

Reference 4 - 0.69% Coverage

It's worthwhile going for exercise because there's a lot of people as long as the going is good, they are with you but the day the going is bad, they haven't got time.

Reference 5 - 0.90% Coverage

I do, after my exercise I'm good as gold, I haven't got a problem. But sometimes if the weather packs up and that humidity is high, then even though I've done my exercises, I'm still getting pain right down my calves

Reference 6 - 0.33% Coverage

Yeah one here and two at home, yeah. Oh I enjoyed it, I enjoyed the (laughs) game

Reference 7 - 0.46% Coverage

Sometimes I played the game and then if I feel, I said no I have to do it again, I don't want that failure



(laughs)

Reference 8 - 0.10% Coverage

It was a good thing for me

Reference 9 - 0.08% Coverage

I think it did help

Reference 10 - 0.55% Coverage

Even though I don't play those games and, we don't have any of those and we don't watch TV quite often, you know it was easy to navigate

Reference 11 - 0.61% Coverage

It was quite easy and it's also kind of forcing you to you know, beat other, you'll see that some others, I dunno, maybe they are a particular person

Reference 12 - 0.63% Coverage

It took time but then I mastered it till then I ran for the other one, then I failed it... but I said never mind, as long as I've mastered it, it's alright

Reference 13 - 0.83% Coverage

It is not easy you know, to do all of us but because and for the other ones, you are getting a score and you know, you know trying to beat the others and maybe that's why I was more engaging with the others.

Reference 14 - 0.46% Coverage

It's kind of positive reinforcement I think, is giving you some sort of a feeling that you achieve something.

Reference 15- 0.14% Coverage

If I fail once, I would try it again

### **Negative experiences**

Files\\FGD-Pilot - § 2 references coded [ 6.85% Coverage]

Reference 1 - 4.24% Coverage

It's a little bit boring and, well I mean I didn't find them hard but I don't, I just don't find exercise enjoyable unless there's a side benefit, so I'm thinking for a while I was doing aqua-jogging and I liked that 'cause I'd go with my friend and we would just talk the whole time so it was like catching up with a friend that had exercise at the same time. So some of those games that were just, seemed to be more focussing on the exercise didn't interest me as much

Reference 2 - 2.61% Coverage

I enjoyed it for that period but I don't think it would be something that I would force myself to keep doing. The fact that I knew I had to come and see you every week and I had to record it made me do it but I could see myself not regularly doing it if I was to have a machine at home all the time.

Files\\FGD1- Nvivo - § 6 references coded [ 5.34% Coverage]

Reference 1 - 0.84% Coverage

Well perhaps the accuracy of the software was a bit lacking but (chuckles), well there's a certain amount of familiarity to gaming in that as well

Reference 2 - 0.72% Coverage

I sometimes used to get annoyed with the people speaking back at you, that would be the only thing that I found rather annoying

Reference 3 - 1.07% Coverage

I was probably more frustrated with myself when I think about like the whole bad, anything or that I didn't like was that I would get frustrated with myself if I didn't achieve something

Reference 4 - 1.60% Coverage

Watching the same screen over and over is yeah, so down the track if I sort of, if I was going to use it and

I'm thinking about maybe getting hold of one but I think I'd probably find that the repetitive screen thing a bit off putting after six months of doing the penguin thing and...

Reference 5 - 0.29% Coverage

I think I might want a different screen to look at.

Reference 6 - 0.82% Coverage

I think if you just stayed on the same stage all the time, you would then find, oh you wouldn't play anymore because you were always achieving so

Files\\FGD2-Nvivo - § 2 references coded [ 1.64% Coverage]

Reference 1 - 0.83% Coverage

...I'm not familiar with the connection and how to go about this...even though I've done the computers but still, as you get older, I haven't used the computer since 1997, that was the last I used ...

Reference 2 - 0.80% Coverage

it is really difficult especially with all my, with the pain so I did cheat a little bit (group laughter), instead of.. I was...this, because you know, when you had the pain, it was difficult...

NVivo 12.00

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### Safety

Files\\FGD-Pilot - § 2 references coded [ 4.86% Coverage]

Reference 1 - 2.21% Coverage

Yes, in the beginning, I felt a bit unsafe until I got used to the concept of stepping on and off the board, especially for the step, step plus, those things where you're having to look at the screen but you're stepping on and off the board...

Reference 2 - 2.65% Coverage

I was a bit anxious then that I might miss the board or fall off or go over the edge but over time, oh it didn't take very long actually, I just got used to the space how far I needed to step to be on it or off it so I got used to that but in the beginning, that did seem a bit unsafe to me, I felt unsafe.

Files\\FGD1- Nvivo - § 3 references coded [ 1.01% Coverage]

Reference 1 - 0.43% Coverage

I nearly lost my balance, but no I...no I never felt unsafe at all

Reference 2 - 0.33% Coverage

No I didn't feel unsafe, tired sometimes, I mean I didn't

Reference 3 - 0.26% Coverage

No, didn't feel at risk or anything like that

Files\\FGD2-Nvivo - § 1 reference coded [ 0.79% Coverage]

Reference 1 - 0.79% Coverage

...when I was doing the cycling and sometimes there were little like, I want to go up, I want to get out and how to get out, so I went up to the... and I could look over, I could see the blue water...