

An investigation into the relationship between kinesiophobia and outcomes of a lower limb exercise programme in knee osteoarthritis.

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Abbreviations

AA	Activity Avoidance
Activities of daily living	ADL
AAOS	American Association of Orthopaedic Surgeons
ACL	Anterior Cruciate Ligament
ANOVA	Analysis of Variance
ANT	Anterior
BMI	Body Mass Index
CINAHL	Cumulative Index to Nursing and Allied Health Literature
СМ	Centimetres
DNA	Do Not Attend
EPR	Electronic Patient Record
FABQ	Fear Avoidance Beliefs Questionnaire
FAPS	Fear-Avoidance of Pain Scale
FPQ	Fear of Pain Questionnaire
GP	General Practitioner
IL-6	Interleukin-6
KL	Kellgren and Lawrence
KOOS	Knee Injury and Osteoarthritis Outcome Score
MCID	Minimal Clinical Important Difference
МРа	Megapascals
MSK	Musculoskeletal
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NSAID	Non-Steroidal Anti-Inflammatories

ΟΑ	Osteoarthritis
OARSI	Osteoarthritis Research Society International
PASE	Physical Activity Scale for Elderly
PASS	Pain Anxiety Symptoms Scale
PL	Posterolateral
РМ	Posteromedial
PRP	Platelet-Rich Plasma Therapy
QoL	Quality of Life
SF	Somatic Focus
SMART	Specific Measurable Attainable Realistic and Timed
SD	Standard Deviation
SEBT	Star Excursion Balance Test
SPSS	Statistical Package for Social Sciences
тѕк	Tampa Scale of Kinesiophobia
TENS	Transcutaneous Electrical Nerve Stimulation
TKR	Total Knee Replacement
UK	United Kingdom
USA	United States of America
VAS	Visual Analogue Scale
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WHO	World Health Organisation
6MWT	6-minute walk test

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Dissemination of study findings

Conference Poster Presentations

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Publications

Molyneux J, Herrington L, Jones R. (2017) An investigation into the relationship between kinesiophobia and clinical outcomes following a lower limb exercise programme in knee osteoarthritis. Osteoarthritis and Cartilage. 25, (Supplement), S407.

Abstract

Osteoarthritis (OA) is one of the leading causes of pain and disability. Exercise has been recommended as a core treatment for OA. Exercise behaviour is an essential factor with kinesiophobia/fear of movement being a major clinical implication. Understanding exercise behaviour may provide a more comprehensive rehabilitation programme for individuals with knee osteoarthritis. Therefore, the purpose of the study was to investigate the relationship between kinesiophobia and outcomes of a lower limb exercise programme in knee osteoarthritis.

Fifty-four individuals with clinical and/or radiographic knee OA (mean age 63.4 years (range 47-79); 50% female) completed a 4-week, 8-session lower limb exercise programme. Tampa scale of kinesiophobia (TSK), physical activity scale for the elderly (PASE), Knee injury and osteoarthritis outcome score (KOOS), Y balance test, 6-minute walk test (6MWT) and the 30-second chair stand test with an activPAL[™] activity monitor were used with six standard physiotherapy questions asked to give the participants a voice during the research.

Significant results from baseline to 6-weeks post programme were reported in kinesiophobia, Y balance test, KOOS pain, quality of life, activities of daily living, symptoms, sport and recreation, PASE, 6MWT and the 30-second chair stand test. Furthermore, significant results for 7-days of stepping and transitions, and for cadence banding 110-120 steps per minute. Average steps per day increased from 7,491 to 8,166.

Our findings demonstrate that kinesiophobia and pain reduces after completing the exercise programme in participants with knee OA. During the exercise programme, as kinesiophobia reduced, so did the individuals pain, therefore baseline kinesiophobia scores could be important due to the correlation with pain changes. Further significant findings demonstrate that the programme increases objectively measured physical activity attributes and mobility in individuals with knee OA, therefore having a greater impact on developing and maintaining function.

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CHAPTER ONE

INTRODUCTION

Osteoarthritis (OA) is one of the leading causes of pain and musculoskeletal disability (National Institute of Clinical Excellence (NICE), 2014) and represents a typical chronic musculoskeletal condition (Guillemin et al., 2014). The term osteoarthritis defines a condition that results in a structural and functional failure of synovial joints (NICE, 2014) and occurs when the failure of the tissues within the joint are overwhelmed causing progressive cartilage loss, bony remodelling (osteophyte formation), capsular restriction and generalised muscle weakness (Felson, 2006). The clinical symptoms of OA include joint stiffness, pain, joint deformity, and swelling (Altman et al., 1986) with the main contributing factors to the development and progression being age, obesity, previous joint injury, genetics and abnormal mechanics (Felson et al., 2000).

The management of knee osteoarthritis can be placed into three categories, management. pharmacological, surgical, and conservative Usage of pharmacological treatments such as paracetamol and intra-articular injections provides a reduction in pain relief (NICE, 2014). However, both have complications e.g. renal toxicity, septic arthritis, and joint degradation (Cheng & Abdi, 2007; Lefkowith, 1999). Non-pharmacological core interventions recommended via the NICE guidelines (2014) include local muscle strengthening, general aerobic exercises, and education for their effectiveness in reducing pain and increasing function. Other interventions include weight reduction, foot orthotics, braces and TENS machines. Surgical interventions may be required, such as arthroscopic resection, osteotomies, and joint replacements, but come with risks such as infection, deep vein thrombosis and revision surgery, as a prosthesis life is approximately 15-years (Nyland et al., 2014; Kerkhoffs et al., 2012; Mantilla et al., 2003). Health professionals should ensure that core treatments have been provided with a review of self-management techniques before these options are offered (NICE, 2014). A conservative approach is usually the first choice for the management of knee OA, with exercise being an effective treatment with relatively

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few contraindications (Page et al., 2011) and evidence is readily available to support it (Kon et al., 2012).

A reduction in muscle strength is an independent determinant of pain and quality of life in individuals with knee osteoarthritis (Reid et al., 2015; Hall et al., 2006; Madsen et al., 1995). Weaker muscle strength around the quadriceps, gluteal muscles and reduced proprioception directly affect functional performance and have been associated risk factors for knee OA (Singh et al., 2016; Deasy et al., 2016; Van der Esch et al., 2014; Hurley et al., 1998). Increasing muscle strength can significantly reduce knee OA symptoms, pain and therefore improve the quality of life and activities of daily living (Thorlund et al., 2016; Lun et al., 2015; Henriksen et al., 2014; Messier et al., 2013; Segal & Glass, 2011; Jenkinson et al., 2009). Chapter 2 discusses exercise and the management of knee OA in more detail.

Further in chapter 2, the evidence for exercise studies is reviewed. Exercise has been recommended as a core treatment for knee osteoarthritis (NICE, 2014; McAlindon et al., 2014; Fernandes et al., 2013; Richmond et al., 2010; Mazieres et al., 2008). Exercise and physical activity are different due to physical activity being any bodily movement produced by muscles that requires energy expenditure such as carrying out household chores (World Health Organisation (WHO), 2010). Exercise is a subset of physical activity, which is planned with purposeful training to increase fitness and muscle strength (Bouchard et al., 2012; WHO, 2010; Caspersen et al., 1985). The World Health Organisation (WHO, 2010) recommend 150 minutes of moderate exercise, or at least 75 minutes of vigorous aerobic exercise per week for adults and older adults with exercises such as swimming, yoga, cycling and walking recommended (Figure 1). Exercise programmes for individuals with knee OA that include both muscle strengthening and aerobic exercises is recommended and should be completed 3 times per week (Juhl et al., 2014). Walking is the most common exercise employed by older adults (Hootman et al., 2003) with 10,000 steps per day being effective in improving health (Bravata et al., 2007). Individuals with knee OA walk approximately 4,000- 6,732 steps per day (Holsgaard-Larsen & Roos, 2012; Talbot et al., 2003) with less than 17% completing the recommended 10, 000 steps per day (White et al., 2014) and less than 6% completing the recommended guidelines of 100 steps per minute (Physical Activity for Americans, 2008). In

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addition, objectively measured data show that individuals with knee OA are more sedentary and complete less transitions (sit to stand etc.), than individuals without knee OA (Verlaan et al., 2015). Objectively monitoring physical activity is a valid and reliable measurement tool (Skender et al., 2016; Sliepen et al., 2016; Barden et al., 2016; Colbert et al., 2010; Verbunt et al., 2009; Liikavainio et al., 2007) compared to questionnaires (Plasqui & Westerterp, 2007). Activity monitors should be used in research (Matthews et al., 2013) to motivate and facilitate behaviour change (Bassett et al., 2017).



Figure 1. Recommended physical activity for adults and older adults (United Kingdom Chief Medical Officers' Guidelines, 2011).

Despite positive evidence regarding exercise, individuals with knee OA avoid exercise to prevent pain (Wallis et al., 2013) and are not achieving the recommended level of exercise (Farr et al., 2008) with 65% of individuals diagnosed

with knee OA being non-compliant with exercises (Bassett, 2003). Psychological factors such as fear of movement are as important as the physical characteristics (Nicolson et al., 2017b; Dobson et al., 2016) and this avoidance of exercise could be related to fear of movement. Kinesiophobia or fear of movement is a psychological impairment that results from a feeling of vulnerability to a painful injury or re-injury and therefore prevents individuals completing an activity (Kori et al., 1990). Kinesiophobia has been found to be a strong predictor for impaired physical performance, increased disability and it can predict future occupational disability (Beur & Linton, 2002; Vlaeyen & Linton, 2000; Crombez et al., 1999). Kinesiophobia is prevalent in individuals with knee OA with greater pain and functional limitations being reported in individuals with increased kinesiophobia (Sanchez-Heran et al., 2016; Shelby et al., 2012; Somers et al., 2009; Heuts et al., 2004). In addition, kinesiophobia is also common within chronic knee pain (Doury- Panchout et al., 2015; Holden et al., 2012; Piva et al., 2009), chronic musculoskeletal pain (Koho et al., 2001) and after surgical techniques such as joint replacements (Brown et al., 2016; Filardo et al., 2015; Wade et al., 2012) and post anterior cruciate ligament reconstruction (Hart et al., 2015b). The increase in kinesiophobia will initially cause longer hospital stays (Brown et al., 2016) and potentially prolong the rehabilitation process (Hart et al., 2015b). Equally important is the assessment of balance due to reduced postural stability in individuals with knee OA (Hinman et al., 2002; Hassan et al., 2001) which increases the risk of falling (Sorensen et al., 2014) and potentially altering pain due to fear of movement (Levinger et al., 2016; Bennell & Hinman, 2005). Chapter 2 discusses kinesiophobia, balance and the management of knee OA in more detail.

Psychological understanding of kinesiophobia is an essential factor of physical inactivity in exercise behaviour and therefore the objectives of this thesis are to investigate specific outcomes for individuals diagnosed with knee OA following a lower limb exercise programme. The main objective is to investigate the relationship of a lower limb exercise programme on kinesiophobia in individuals with knee OA. Further objectives include evaluating functional relationships using the Y balance test as a functional unilateral limb muscle strength test, evaluating physical activity in individuals with knee OA using the physical activity scale for the elderly (PASE) questionnaire, and objectively measuring activity behaviour using an activPAL[™]

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monitor. Evaluating the intensity of exercise programme using the Borg scale, level of pain using visual analogue scale (VAS) and evaluating changes after the exercise intervention in relation to pain, function, sport and recreation, activities of daily living and symptom, using the KOOS questionnaire. Finally, to gain an understanding of key subjective factors that the participants understand regarding exercise as an intervention using a semi- structured interview.

The structure of the thesis will review current literature linked to knee OA, pharmacological management, surgical management and conservative management. In addition, exercise and kinesiophobia will be reviewed to demonstrate innovation with the aim to fill the gap from the previous literature.

CHAPTER TWO

LITERATURE REVIEW

2. Database searches

Electronic databases were searched between October 2015 and May 2016, using keywords of kinesiophobia, knee osteoarthritis, exercise, and physical activity. Keywords were combined using Boolean operators 'AND'. Databases searched from- NHS evidence, cumulative index to nursing and allied health literature (CINAHL), Medline, Cochrane library, and Google scholar. QXMD medical application was downloaded which highlights new published research daily with key terms of knee osteoarthritis and kinesiophobia.

Keyword	Number of Articles
Kinesiophobia	547
Knee Osteoarthritis	25270
Kinesiophobia 'AND' Knee Osteoarthritis	10
Kinesiophobia 'AND' Osteoarthritis	14
Kinesiophobia 'AND' Exercise 'AND' Knee Osteoarthritis	1
Kinesiophobia 'AND' Physical Activity 'AND' Knee Osteoarthritis	3

Table 1.	Database	Literature	Search
	Batabaoo		000.011

2.1. Incidence of osteoarthritis

OA is the third most common condition in the United Kingdom (UK) (Zhang et al., 2010) with around 8.75 million people having sought treatment within primary care (Arthritis Research, 2013). In the United States of America (USA), it has been projected that 26.9 million adults are affected by OA (Centre of Disease Control, 2011) and approximately 250 million affected worldwide (Vos et al., 2012). OA is characterised by joint stiffness, pain, joint deformity, and swelling (Altman et al., 1986). Traditionally, OA is most notably associated with the elderly (Buckwalter & Martin, 2004), with 33% aged over 65 (Lawrence et al., 2008). However, 60% of adults aged over 50 are affected by the condition (Vad et al., 2002) with severe difficulties in physical functioning and pain causing long-term disability (Felson et al., 2000). Abnormal biomechanics, previous joint injury, and gender also play a more prevalent role in the progression of OA (Felson et al., 2000; Felson et al., 1995). Comparison of the incidence of OA highlights that hip OA is diagnosed in 88 adults per 100,000, hand OA is 100 per 100,000 and knee OA being the most common with 240 adults per 100,000 (Oliveria et al., 1995).

2.2. Incidence of knee OA

Ninety-percent of OA presentation has been reported within the lower limb with 44.7% of sufferers most commonly affecting the knee joint (Segal et al., 2004). An excessive utilisation of orthopaedic visits by individuals diagnosed with knee OA has been reported (Wright et al., 2010), with 1 in 5 adults aged 50 and over report constant pain, rising to 1 in 3 by 75 years of age (Arthritis Care, 2012). Current statistics report that 4.11 million adults within the UK have clinically diagnosed knee OA (Arthritis Research UK, musculoskeletal calculator, 2015) and this figure is expected to increase to 6.5 million by 2020 (Arthritis in General Practice, 2013). By 2030, 8.3 million people in the UK aged 45 could be diagnosed with knee OA (Arthritis in General Practice, 2013), whereas in the USA, it is expected that 67 million people will suffer from OA in 2030 (Hootman & Helmick, 2006). In the north west of England 18.77% (573,790) of the population have been diagnosed with severe knee OA with 20.16% (28,133) being reported within Wigan (Arthritis Research UK) - musculoskeletal calculator, 2015). Symptomatic

knee OA occurs in approximately 10-30% of individuals who report significant pain and disability (Hootman & Helmick, 2006).

2.3. Burden and cost of knee OA

Individuals who suffer from Knee OA require 3 to 5 times more healthcare interventions than 15-65 year olds (Nicholls et al., 2009). The majority of the population will access primary care for OA symptoms (Peat et al., 2001) with over 2 million individuals visiting the general practitioner each year (Arthritis Research UK, 2013), with a 12-mintue consultation costing £36 (Loza et al., 2009). Onward referrals into physiotherapy are common with 43% of UK general practitioner's (GP's) referring individuals for treatment (Walsh & Hurley, 2009). In contrast, Australian GP's first line of treatment is medication, with 68% referring onwards to orthopaedics compared to 18% referring into physiotherapy (Brand et al., 2014). In 2011, the National Health Service (NHS) spent £5 billion managing OA, in addition to people claiming incapacity for OA, which reached £2.4 billion (Chen et al., 2012). Indirect costs of symptomatic OA in the UK economy is estimated at £14.8 billion (Arthritis Research, 2013) compared to \$4 trillion within the USA (Hunter, 2011). Employees who are symptomatic with pain are more likely to have 3 days per year off (Kotlarz et al., 2010); leading to 36 million working days lost and approximately £3.2 billion lost in productivity due to physical function difficulties (Chen et al., 2012). Estimated annual costs per worker in Europe have been calculated at €11,000 (Salmon et al., 2016) compared to the USA, which ranges from \$9,801 for mild OA and \$22,111 for severe OA (Dibonaventura et al., 2012). Incidentally, the average medical cost for workers without osteoarthritis is \$7,901 (Dibonaventura et al., 2012). Long-term disability of knee OA is expected to increase by 50% over the next twenty years (Hunter, 2011), due to the ageing population, obesity and physical inactivity.

2.4. Diagnosis of knee OA

Individuals with knee OA generally present with an insidious discomfort with functional activities such as walking and climbing, general muscle weakness especially the quadriceps (Felson et al., 1997) with some individuals with a high pain tolerance fatiguing with activity. Progressive joint stiffness and contractures develop due to osteophytes, synovitis, or capsular scarring (Kraus et al., 2005). Warmth, swelling, and crepitus are common, with OA unlikely to cause pain at rest, which can

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differentiate diagnosis of infection and tumour (Lonner, 2003). Knee OA signs and symptoms can vary, with inside (medial tibio-femoral), outside (lateral tibio-femoral) and front (anterior patellofemoral) being affected. Higher pain levels have been suggested with lateral tibio-femoral knee OA compared to medial and intercondylar lesions (Arendt- Nielsen et al., 2010).

Radiographic evidence to diagnose knee OA is gold standard (Bijlsma et al., 2011) and can be classified via the Kellgren and Lawrence scale as grades 1 to 4. Grade 1 highlighting minor structural damage and grade 4 highlighting severe damage within the joint (Schiphof et al., 2008), the scale is valid, reliable and is the most commonly used grading scale (Arden & Nevitt, 2006), however it is not sensitive for early stage OA (Kijowski et al., 2006) (Figure 2). However, positive radiographic findings do not always correlate with signs and symptoms, with approximately 40% to 50% of individuals being asymptomatic with positive radiographic findings (Bijlsma et al., 2011; Altman et al., 1986) and 0.5% of radiographs revealing the need for treatment (osteonecrosis, osteochondral lesions, fracture and subluxation) (Skou et al., 2014). In addition, radiographic severity of knee OA is not significantly associated with improvements in pain after non-operative treatment (Skou et al., 2015).

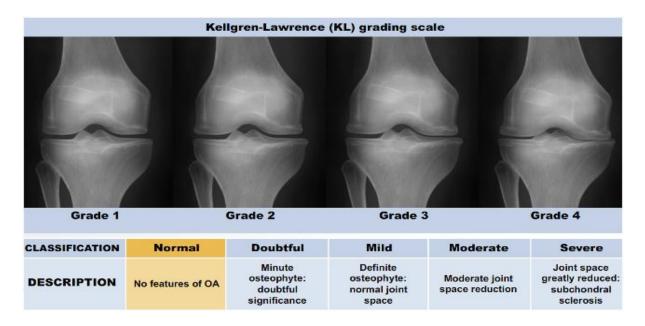


Figure 2 Classification of the Kellgren- Lawrence Scale.

Altman et al. (1986) compiled the American Rheumatism Association diagnostic criteria of OA which highlighted three alternative joint symptoms; firstly crepitus and morning stiffness; secondly bony enlargement or crepitus and morning stiffness; and

thirdly crepitus and bony enlargement (Table 2). In addition, the diagnostic criterion for OA has also been investigated by the European League against Rheumatism group (Zhang et al., 2010) and has 99% validity with individuals. Individuals must present with three of the six signs and symptoms, which include pain during activity, short-lived morning stiffness (less than thirty minutes), functional decline, crepitus, restricted movement, and bony enlargement. However, it has been suggested that these guidelines only reflect OA within its advanced stages, due to its very low sensitivity in relation to symptomatic x-rays (Peat et al., 2006).

<u>Table 2</u> American Rheumatism Association diagnostic criteria of OA (Altman et al., 1986)

Clinical & Laboratory	Clinical & Radiographic	Clinical (knee pain plus at	
(knee pain plus at least 5 of the	(knee pain plus at least 1 of	least 3 of the following)	
following)	the following)		
Age >50 years	Age >50 years	Age >50 years	
Stiffness <30 minutes	Stiffness <30 minutes	Stiffness <30 minutes	
Crepitus	Crepitus- plus osteophytes	Crepitus	
Bony Tenderness		Bony Tenderness	
Bony Enlargement		Bony Enlargement	
No Palpable Warmth		No Palpable Warmth	
ESR <40 mm/h			
RF <1:40			
Synovial fluid consistent with OA			
Sensitivity, 92%	Sensitivity, 91%	Sensitivity, 95%	
Specificity, 75%	Specificity, 86%	Specificity, 69%	

Other investigations such as ultrasound, would not penetrate the joint deep enough (Bijlsma et al., 2011), but could highlight any cartilage displacement (Naredo et al., 2005). Magnetic resonance imaging would highlight a vast amount of detailed internal pathology; however, this would be discouraged due to cost and time implications (Bijlsma et al., 2011). Invasive investigations such as diagnostic arthroscopy also are recommended to be avoided due to the surgical complications; however, it could be used when evidence of a loose body is present on x-ray or the patient reports locking (NICE, 2014).

Orthopaedic assessments using passive movements of the joints to assess the range of motion for capsular restriction and end feel was reported by Cyriax (2001) and supported by Fritz et al. (1998). The suggestion that a greater limitation of flexion compared with extension would indicate the involvement of the joint capsule; this restriction could be caused by irritation of the synovial membrane and joint capsule causing an inflammatory response. Validity and reliability of this assessment technique have been reviewed, with no difference in movement limitation being reported with individuals with and without lower limb disorders (Van Trijffel et al., 2010), particularly within knee and hip OA (Bijl et al., 1998).

2.5. Risk factors for the incidence of knee OA

2.5.1. Age

The prevalence of knee OA increases with age (Buckwalter & Martin, 2004), with a significant increase of onset from 55 to 75 years of age, with minimal increase after 75 (Jarvholm et al., 2005). Potential explanations for the increase in prevalence ranges from decreased strength, slower neurological response, reduced balance, decreased response of chondrocytes by growth factors and age related glycation end products (Verzijl et al., 2003). However, a significant number of symptomatic individuals with knee OA are younger than 65 years of age, due to the development of OA through biomechanical issues and injury (Deshpande et al., 2016). Specifically, Losina et al. (2013) found the diagnosis of symptomatic knee OA occurs much earlier, with an estimated median age of 55 years being reported with symptoms peaking between 55 and 64 years of age. With an ageing population in the UK, the risk of developing OA is likely to increase (Loeser, 2013) and further pressurise the healthcare services.

2.5.2. Gender

Knee OA is more common in females aged over 55 years (67%) (Silverwood et al., 2015; Bijlsma et al., 2011) compared to males before 50 years (Felson & Zhang, 1998). Statistics support this with females having more consultations for knee OA than males (2,650,000 versus 2,070,000) (Arthritis in General Practice, 2013). Females are twice as likely to experience pain and functional decline due to knee OA, potentially due to central pain processing which alters pain sensations (Staud,

2011) and other factors such as socioeconomic status, comorbid conditions and depressive symptoms (Glass et al., 2014).

2.5.3. Hormonal Effect

Inflammatory mechanisms involved with osteoarthritis such as elevated systemic markers including C reactive protein, clear synovial hyperplasia and dense mononuclear cell infiltrate (Bonnet & Walsh, 2005; Altman et al., 1986). Furthermore, hormones such as interleukin, leptin, and estrogen can produce enzymes responsible for the degranulation of cartilage (Valdes et al., 2010; Lago et al., 2008; McAlindon et al., 1999; Creamer & Hochberg, 1997; Nevitt & Felson, 1996).

2.5.4. Genetics

Genetic factors contribute to knee OA (Valdes et al., 2010) with approximately 39-65% in knee OA (Hochberg et al., 2013; Spector & McGregor, 2004) due to the inheritance of nuclear DNA, mitochondrial DNA, telomere length and related cellular and extracellular components.

2.5.5. Vitamin Deficiency

Vitamin K deficiency has been reported to produce a higher risk of progressing knee OA, due to its importance in regulating bone and mineralising cartilage (Misra et al., 2013). Vitamin D and calcium levels have important functions in bone health and musculoskeletal function, importantly with decreased muscle strength, gait changes, muscle pain, and postural sway (Sanghi et al., 2013; Wicherts et al., 2007). Despite this, vitamin D supplementation for knee OA is not recommended, as no significant changes have been reported in pain and cartilage volume (Jin et al., 2016).

2.5.6. Obesity

Individuals who are obese have an increased risk of progressing knee OA (Felson et al., 1998) and are 14 times more likely to develop the condition due to a higher compression forces (Harding et al., 2016). An increase in body mass index (BMI) by five units is associated with a 35% increased risk of knee OA (Jiang et al., 2012) with every kilogram of extra weight giving a 9-13 % increased risk of developing symptoms (Salih & Sutton, 2013; Cicuttini et al., 1996). The relative risk of obesity is higher in females than males (2.07/1.52) (Felson et al., 1988) with 33.2% of females

and 27.6 % men in the USA being classified as obese (Baskin et al., 2005). Interestingly, a prospective study reported that an 8 kilogram increase in weight between the ages of 20-29 substantially increases the incidence by 1.7 compared to ages 30-39 and 40-49 (Gelber et al., 1999). In England, a quarter of the population is obese (Salih & Sutton, 2013) and within Wigan 20.2% of children and 27% of adults is obese, with 65.3% being classified as having excess weight (Public Health Wigan, 2015). Consequently, obesity and knee OA coincide, with poor function and a greater risk of a sedentary lifestyle leading to increased disability and a reduction in quality of life (Ackerman & Osborne, 2012).

2.5.7. Muscle weakness

Quadriceps and gluteal muscle weakness have been associated with knee OA (Singh et al., 2016; Deasy et al., 2016; Van der Esch et al., 2014). A reduction in muscle strength is an independent determinant of pain and quality of life in individuals with knee osteoarthritis (Reid et al., 2015; Hall et al., 2006; Madsen et al., 1995), with weaker muscle strength and reduced proprioception directly affecting functional performance (Hurley et al., 1998). Gluteal muscle weakness would result in an abnormal movement pattern at the pelvis and increase pressure around the medial aspect of the knee joint (Block & Shakoor, 2010; Linley et al., 2010). Furthermore, gluteal weakness may increase the valgus or varus deformity at the knee joint, which is commonly associated with medial and lateral knee OA (Zazulak et al., 2007). Likewise, quadriceps muscle strength is the main muscle group to provide knee extension and knee joint stability (Sharma et al., 2001), with weakness being caused by arthogenic muscle inhibition (Hurley et al., 1998) through altered joint structure (Sharma et al., 2001). An increase in muscle strength especially with the quadriceps is linked to reducing the risk of symptomatic knee OA (Thorlund et al., 2016; Lun et al., 2015; Segal & Glass, 2011; Jenkinson et al., 2009).

2.5.8. Previous joint injury

A greater incidence of knee OA has been detected with people who had anterior cruciate ligament (ACL) ruptures and meniscal tears (Oiestad et al., 2009; Gillquist & Messner, 1999). ACL ruptures increase knee OA with a 13% risk (Oiestad et al., 2009), however, 50% of female soccer players (Lohmander et al., 2004) and 41-78% of male soccer players will develop knee OA within 15 years (von Porat et al., 2004).

Furthermore, ligament reconstructive surgery can increase knee OA by 20-50% (Kramer et al., 2007). Meniscal tears may account for 40-50% of knee OA (Felson, 2013), due to pain and structural damage. It has been suggested that 30-60% of adults aged 50 and over have incidental meniscal tears (Englund et al., 2008), with a multivariate regression of 3.0 being suggested for the development of OA following a menisectomy (Englund & Lohmander, 2004). Finally, the odds ratio for developing knee OA from a joint injury is 3.8 (Richmond et al., 2013) compared to ACL and menisectomy, which increases to 7.4 (Anderson & Loeser, 2010). However not all individuals who sustain joint injury will develop symptomatic knee OA (Holla et al., 2014).

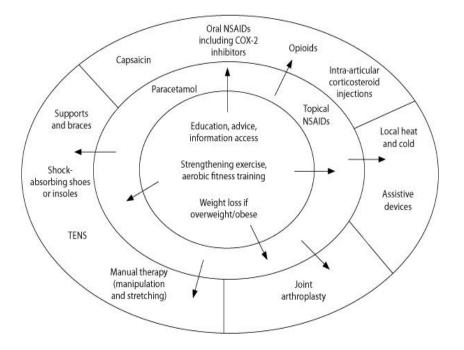
2.5.9. Occupation

Greater incidence of knee OA have been reported in occupations such as dockyard workers and miners (Felson, 2004) with activities such as kneeling and lifting increasing the risk of knee OA (Ingham et al., 2011; Kujala et al., 1995). In addition, heavy physical activity of more than 4 hours per day or walking 6 miles per week increased the risk of symptomatic knee OA (Felson et al., 2007). Despite this, the prevalence of knee OA is higher in the unemployed (Guillemin et al., 2014).

Given the factors in the development and progression of osteoarthritis, many treatment interventions are available for the treatment of osteoarthritis. These interventions will be introduced and evaluated in the next section.

2.6. Management of knee osteoarthritis

The management of knee osteoarthritis can be placed into three categories, pharmacological, surgical, and non-pharmacological management. Pharmacological management including medications and injections, surgical management including joint replacement surgery and non-pharmacological management such as education, exercise, manual therapy, weight loss, and devices such as orthotics (NICE, 2014), (Figure 3).



<u>Figure 3</u> Management of knee osteoarthritis, inner circle should be used as first line treatment (NICE, 2008).

2.6.1. Pharmacological

2.6.1.1. Medication

Medication for the treatment of knee OA has been thoroughly investigated and it has been highlighted that pharmacological treatment does provide symptom relief for knee OA (Zhang et al., 2010). In addition, pharmacological treatment through medication prescription via health care prescribers is higher than lifestyle management (Brand et al., 2014). Paracetamol and non-steroidal anti-inflammatories (NSAID) are recommended by osteoarthritis research society international (OARSI) (McAlindon et al., 2014) with paracetamol, being the most commonly used first choice medication (Zhang et al., 2010; Denoeud et al., 2005). However, a recent meta-analysis suggests that paracetamol should have no role in the treatment of knee or hip OA, irrespective of the dosage (Da Costa et al., 2016). Several studies support the use of NSAID medication in favour of paracetamol (Wegman et al., 2004), with 150 milligrams of diclofenac being the most effective treatment to reduce pain and improve function (Da Costa et al., 2016; Altman, 1999). Celecoxib have been shown to be effective and comparable to diclofenac and ibuprofen (MacDonald-Wood et al., 2013), however both can cause renal toxicity, and gastrointestinal ulceration in as many of 15% to 30% of individuals (Lefkowith, 1999).

Tanezumab decreases pain and stiffness in individuals with knee OA compared to placebo, with mean changes between 46-64% for pain and 48-65% for stiffness compared to 23% and 22% for the placebo (Lane et al., 2010). However, whilst using tanezumab an increase in joint replacements due to rapidly progressing OA have been reported (Balanescu et al., 2013; Holmes et al., 2012; Schnitzer et al., 2011). Further side effects of using tanezumab include paraesthesia, headaches, and upper respiratory tract infections (Lane et al., 2010). Other medications such as morphine and ketorolac may provide relief for 24 hours (Richards et al., 2016) and tramadol can be used for moderate to severe pain relief, although studies have been found it to be comparable to ibuprofen (Dalgin, 1997).

Usage of pharmacological treatments provides a reduction in pain relief and increases joint loading (Schnitzer et al., 1993), therefore it should be used in conjunction with non-pharmacological treatment (Cushnaghan et al., 1994).

2.6.1.2. Injections

Injection therapy has significantly increased over the last 15 years (Koenig et al., 2016) due to these being cost effective compared to conventional care (Rosen et al., 2016). Injections may give weeks, months or years of pain relief for individuals with knee OA (Goodwin & Dawes, 2004; Raynauld et al., 2003) with intra-articular injections being recommended to complement core treatments for knee OA (NICE, 2014). Injections such as corticosteroid and platelet-rich plasma therapy (PRP) are currently available to individuals with knee OA. Platelet-rich plasma injections have shown significant clinical improvements after 12 months (Duymus et al., 2016; Meheux et al., 2015; Achar et al., 2014) and report better clinical outcomes after 24 weeks compared to hyaluronic acid (Achar et al., 2014), especially in younger individuals with a minimal degree of cartilage degeneration (Kon et al., 2011). A minimum of two injections are appropriate (Kavadar et al., 2015) with an ultrasound-guided injection better, due to accuracy (Goodwin & Dawes, 2004).

Although injections are recommended by NICE (2014), the American Academy of Orthopaedic Surgeons (AAOS, 2013) suggests that there is inconclusive evidence to recommend corticosteroid injection and hyaluronic acid injections to individuals with knee OA (Jevsevar et al., 2013), especially in those with severe knee OA (Maricar et al., 2017). Furthermore, intra-articular steroid injections in individuals with symptomatic knee OA only has short term benefits (Babatunde et al., 2017), increases cartilage volume loss (McAlindon et al., 2017) and may result in higher joint loading (Briem et al., 2009).

2.6.1.3. Surgical intervention

Surgery for knee OA is available for people who experience reduced function, pain and stiffness that cause a considerable impact on their quality of life (NICE, 2014; Arthritis in General Practice, 2013). Importantly, health professionals should ensure that core treatments have been provided with a review of self-management techniques (NICE, 2014). It has been reported that by 2030 the rate of surgical interventions will be nearly 7 times that of 2005 (Kurtz et al., 2007), with knee arthroplasty surgery increasing by 297% from 2005 to 2040 (Otten et al., 2010). In the UK, projected estimations for joint replacement surgery in 2035 will rise from 45, 609 to 118,666 with projected counts being higher for females than males (Culliford et al., 2015, Culliford et al., 2012). In the USA, the surgery rate is expected to grow further by 673% from 2005 to 2030, leading to 3.5 million procedures (Kurtz et al., 2007), as a result of societal changes such as obesity and an ageing population (Hunter, 2011). Despite this it has been reported that 30% of surgical procedures are inappropriate (Herndon et al., 2001), especially in relation to knee OA (Kirkley et al., 2008).

Total knee replacements (TKR) are effective in providing pain relief, improving function, and quality of life after 12 months with moderate to severe knee OA (Skou et al., 2015). Surgeons are more likely to complete TKR surgery in individuals with severe OA and at a higher age range (average age being 73.3 years) (Verra et al., 2016). Uni-compartmental knee replacements can be used before a TKR is necessary and they highlight improved walking speed and step frequency (Webster et al., 2003). Arthroscopic resection is common in middle aged or older people with knee pain (Hawker et al., 2008), although no differences in pain and function have been shown (Zhang et al., 2008) and is not recommended by NICE (2014). Furthermore, a Cochrane review of eight studies highlighted that high tibial

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osteotomies reduces pain and improve function (Brower et al., 2014). However, there is no evidence to compare the osteotomy to other surgical techniques such as total knee replacement. Post-operative complications are causes of concern with approximately 32% of individuals undergoing knee surgery being at risk of post-operative complications (Sridhar et al., 2012). Serious adverse events post knee replacement surgery can occur with obese individuals at greater risk of infection (1.9%), (Kerkhoffs et al., 2012), deep vein thrombosis (1.5% for every 5 kilogram overweight), (Mantilla et al., 2003) and knee replacement revision surgery (1.79%) (Kerkhoffs et al., 2012). Similarly, younger individuals are likely to have a high revision rate based on a 15-year prosthesis life (Nyland et al., 2014).

Average recovery times for knee replacements to return to low impact physical activity varies between 4.1 months and 6 months with a uni-compartmental replacement being 3.6 months (Papalia et al., 2012; Hooper & Leach, 2008; Argenson et al., 2008). Despite the return to activity, the amount of the physical activity reduced from 62.7 minutes pre- operation to 37.5 minutes after a total knee replacement, with sporting activity reducing from 34% pre-surgery to 5% postsurgery (Papalia et al., 2012; Hooper & Leach, 2008; Argenson et al., 2008). Preoperative rehabilitation focusing on the hamstring and quadriceps muscles can improve self-reported outcomes, activities of daily living and involvement in sports (Kean et al., 2011). Individuals with OA already fall short of public health guidelines for physical activity (Dunlop et al., 2011) and further reductions of activity postsurgery will have implications on other health related disorders or other arthritic joints. Lefevre et al. (2013) suggested that lack of willpower on part of the patient or negative advice from the orthopaedic surgeons could be plausible reasons regarding return to sport post-surgery. In addition to reduced physical activity, high level of psychological stress such as pain catastrophizing have been shown in post-surgical patients (Riddle et al., 2010), with 16% of patients still struggling with pain after 12 months (Papalia et al., 2012).

Reduced function and physical activity is a possibility after knee surgery with 34% of individuals completing activities such as cycling, swimming, and hiking after joint replacement surgery. However, 5-years after knee surgery only 5% of individuals were completing 2 hours a week of activity (Huch et al., 2005). Sports such as

tennis, football and down-hill skiing are not recommended after joint replacement (Huch et al., 2005) with low impact activities increasing and high impact activities decreasing (Waldstein et al., 2016).

Even though surgical management of knee OA is available, some individuals may not be suitable candidates for surgery, as they may be deemed too young for surgery or they may not want surgery. Surgery is of great expense to the NHS with over 70,000 surgical procedures for knee OA being performed in the UK in 2011, each costing approximately £20-30,000 per operation (Dakin et al., 2012), in addition the risk of post-operative complications are as high as 32% (Sridhar et al., 2012). It has been reported that by 2030 the rate of surgical interventions will be nearly 7 times that of 2005 (Kurtz et al., 2007), due to societal changes such as obesity and an ageing population (Hunter et al., 2011).

Doctors, surgeons, and health professionals should counsel individuals regarding exhausting conservative options for the treatment of knee OA, and if they have to undergo knee replacement surgery, physical activity, and exercise is essential so that long-term function of the surgery can be self-managed.

2.6.2. Conservative Management

Conservative management is usually the first choice for the management of knee OA, with weight loss, biomechanical devices such as orthotics or knee braces, manual therapy, education, and exercise recommended (NICE, 2014).

2.6.2.1. Weight loss

Obesity and being overweight costs the NHS approximately £5.1 billion each year (Scarborough et al., 2011). Jiang et al. (2012) reported a 35% risk of developing knee OA with a five-unit increase in the body mass index (BMI), therefore reducing weight can significantly reduce the symptoms of knee OA, by lowering compressive loads (Messier et al., 2011). Reducing body weight by 5-10% can have positive benefits for overall health (Nevitt & Lane, 1999) with an 11-pound weight loss during a 10-year period decreasing the risk of OA by 50% (Christensen et al., 2005; Felson

et al., 1992). A 10% reduction has been recommended for knee OA (Messier et al., 2011). Reducing weight through a combined fat and calorie restriction diet with increased physical activity, behavioural re-enforcement and an extended weight-maintenance programme may be required (Nevitt & Lane, 1999). Otherwise, gastric band surgery can considerably decrease pain, improve function, and improve knee range of motion with 100-pound weight loss over a 12-18 month period being recommended (Hooper, 2005). Further interventions to reduce load would be the use of biomechanical devices such as foot orthotics and knee braces which will be appraised in the next section.

2.6.3. Biomechanical Devices

2.6.3.1. Foot Orthotics

Foot orthotics and knee bracing are recommended to be used as an adjunct to core treatments for knee OA (NICE, 2014) with lateral wedge orthotics being reported to reduce pain and improve function (Baghaei Roodsari et al., 2016). In addition, the lateral wedge orthotic can reduce load within the knee by increasing foot pronation which re-aligns the femur and tibia into a more upright position (Jones et al., 2015; Russell & Hamill, 2011; Shelburne et al., 2008) and is more effective with medial compartment knee OA (Baghaei Roodsari et al., 2016). In addition, lateral wedge orthotics has been investigated to reduce the knee abduction moment, to reduce the load on the knee joint (Jones et al., 2013; Hinman & Bennell, 2009). Economically, for every £1 spent on orthotics, the NHS will save £4 (Boxer & Flynn, 2004). However, within the NHS, the primary response for treatment is pain and therefore this is addressed initially in individuals with knee OA, with orthotics not being prescribed, therefore issuing orthotics in conjunction with other treatments such as exercise and weight loss would be a long-term cost effective treatment (NICE, 2014).

2.6.3.2. Bracing

Valgus knee bracing also decrease pain, reduce joint stiffness and improve physical function (Steadman et al., 2016; Raja & Dewan, 2011). In theory, medial compartment knee OA is usually the most common area of degeneration due to the

varus knee movement during the gait cycle, with the knee brace applying a valgus force to decrease the load on the medial compartment resulting in a reduction in pain (Lindenfield et al., 1997). Systematic reviews and meta-analyses demonstrate that the valgus knee 'unloader' brace for medial knee OA reduces the knee adduction moment (Petersen et al., 2016), provides a small to moderate improvement in pain (Moyer et al., 2015) and does not hinder the disease progression (Steadman et al., 2016). Equally, quadriceps muscle strength increased from 36.8 n to 42.8 n with the use of braces (Matsuno et al., 1997). Incidentally, long-term usage of the knee brace with patient adherence is not high (Felson, 2009). Squyer et al. (2013) found a reduction in the usage of a knee brace after 2 years, with 25% of individuals with knee osteoarthritis reporting regularly use. Brace discomfort, skin irritation, poorly fitted and symptom relief where all reasons for not using the brace, therefore using the brace initially to reduce symptoms could be beneficial.

Despite this positive evidence, Duivenvoorden et al. (2015) compiled a Cochrane review and found inconclusive evidence for the benefit of pain, function, quality of life for the usage of lateral wedge insoles and valgus knee braces.

2.6.4. Physiotherapeutic Management

Physiotherapy treatments include core treatments that are included in the NICE (2014) guidelines such manual therapy, electrotherapy, education, and exercise. Alternative interventions such as acupuncture and massage are also being utilised within the NHS.

2.6.5. Manual therapy

Manual therapy within physiotherapy is widely used as a treatment for knee OA (Page et al., 2011), as it can reduce pain, improve function (Crossley et al., 2002; Deyle et al., 2000) and is a cost effective approach (Korthals-de Bos et al., 2003). Sixty-percent of physiotherapists within the United Kingdom use manual therapy, with thirty-six percent using manual therapy to increase range of motion and forty-six percent using it to decrease pain (Walsh & Hurley, 2009). Evidence for manual therapy is equivocal, due to the small amount of randomised control trials (Brakke et

al., 2012) and has been recommended as an adjunct to core treatment (NICE, 2014). For example, a systematic review of manual therapy for knee OA (3 studies with 280 subjects) highlighted that all studies reported short term benefits with inconclusive evidence for pain and function being reported for individuals with hip or knee OA (French et al., 2011).

People diagnosed with knee OA present with weak muscles and reduced proprioception that affects joint mechanics and functional ability (Hurley et al., 1998). Restricted joint mobility especially into knee flexion appears reduced with knee OA (Steultjens et al., 2000). Manual therapy has neuro-physiological (De Vocht et al., 2005) and biomechanical responses (Coppieters & Butler, 2008) by inhibiting and modulating pain (Courtney et al., 2010; Moss et al., 2007), activating the central nervous system (Murphy et al., 1995) and altering the inflammatory process by reducing blood and serum levels (Teodorczyk- Injeyan et al., 2006; Smith et al., 1994). In conjunction, releasing entrapped synovial folds, relaxing hypertonic muscles, disrupting articular adhesions and releasing stiff motion segments (Shekelle, 1994) have been reported.

Specifically related to knee OA, positive effects of manual therapy provided better outcomes on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) after 9-weeks, which highlighted short-term benefit (Fitzgerald et al., 2016), with a single thirty-minute manual therapy session, significantly increasing the knee range of movement (Taylor et al., 2014). Passive knee mobilisations into extension significantly improved extension with positive effects on pain and reduced function (Kappetijin et al., 2014) and self-manual therapy decreased pain at 4-weeks and increased flexion and extension at 4 and 12-weeks (Cheawthamai et al., 2014).

Various manual techniques and protocols have been used within clinical trials for knee OA, techniques such as grade four medial mobilisations with tibial adduction and grade four lateral mobilisations with tibial abduction completed twice per week for four weeks (Cheawthamai et al., 2014). Anterior gliding at the knee joint, posterior gliding, distal gliding of the patella and distraction of the knee in flexion/extension have been completed to increase range of movement and enhance pain modulation (Courtney et al., 2016; Ko et al., 2009). Other techniques such as mobilisations with

movement are beneficial (Hing et al., 2009; Wilson, 2001), with significant improvements for knee flexion and immediate pain relief being suggested for the early OA knee management (Takasaki et al., 2013).

Manual therapy in conjunction with exercise provides greater relief and functional improvements (Abbott et al., 2015; Crossley et al., 2015; Rhon et al., 2013; Ko et al., 2009; Deyle et al., 2005), with improvements in the 6-minute walk test (Deyle et al., 2000). Various timeframes have been reported for improvements, 8-weeks (Deyle et al., 2000), 12 sessions (Abbott et al., 2015) and a 9-month period (Crossley et al., 2015).

2.6.6. Electrotherapy

Electrotherapy is a common treatment modality used in physiotherapy with 66% of physiotherapists in the United Kingdom using modalities such as ultrasound, pulsed shortwave, interferential and transcutaneous electrical nerve stimulation (TENS) (Walsh & Hurley, 2009). Within the United States of America (USA), forty-five percent of physical therapists use electrotherapy "often" for reducing pain in the treatment of knee OA (MacIntyre et al., 2013). NICE do not support the use of unproven electrotherapy modalities such as interferential, ultrasound and pulsed shortwave in the treatment of knee OA (NICE, 2014). Even though many physiotherapists use electrotherapy, medical literature does not support the use of electrotherapy in OA (McCarthy et al, 2006; Wrightson & Malanga, 2001; Sutcki & Kroeling, 2000). Primary reasons for not supporting the use of electrotherapy are due to the limited treatment length, inconsistent dosage, uncontrolled treatment area, and mechanical frequencies (Fransen, 2004). Additionally, electrotherapy is a passive treatment that is relatively expensive to use and encourages dependence on the therapist (Osiri et al., 2000) and should be discouraged from use by clinicians.

2.6.6.1. Transcutaneous Electrical Nerve Stimulation (TENS)/Interferential

TENS is the only electrotherapeutic modality for which there is some evidence, as it is safe, relatively inexpensive and can be used independently by individuals, however it must be used as an adjunct treatment (NICE, 2014). TENS and interferential have been shown to reduce pain, however limited robust evidence is available due to the limited number of high quality trials (Zeng et al., 2015). Contrastingly, the use of TENS and interferential are not effective for pain relief (Rutjes et al., 2009). OARSI guidelines are uncertain about the usage of it (McAlindon et al., 2014) with no benefits being shown in a randomised control trial using TENS in conjunction with education and exercise (Palmer et al., 2014)

2.6.6.2. Ultrasound

Ultrasound is the most commonly used electrotherapy modality with over forty-six percent of physical therapists in the USA endorsing ultrasound as a treatment for knee OA (MacIntyre et al., 2013). Ultrasound is safe to use on a short term basis (Ulus et al., 2012) and has positive effects in reducing pain and improving function especially increasing greater outcomes with the 6-minute walk test (6MWT) (Mascarin et al., 2012). Systematic reviews suggest that pulsed ultrasound is more effective in pain relief with WOMAC scores being significantly better (Tascioglu et al., 2010) with continuous ultrasound having minimal differences (Zeng et al., 2014). However, more rigor and adequately powered studies are required to enhance the quality of evidence (Loyola- Sanchez et al., 2010). OARSI guidelines do not recommend ultrasound for clinical use (McAlindon et al., 2014).

2.6.6.3. Laser therapy

Laser therapy is used in physiotherapy due to being effective in modulating inflammatory mediators and cells such as macrophages and neutrophils (Alves et al., 2013). Previous studies report limited effectiveness in pain, strength and joint activity (Tascioglu et al., 2004; Bulow et al., 1994). However, laser therapy can reduce symptoms in individuals with knee OA (Bjordal et al., 2003) with a significant reduction in nocturnal pain, pain on walking and pain on walking upstairs (Soleimanpour et al., 2014; Alghadir et al., 2014) being reported. Furthermore, application of short-term laser in specific acupuncture points in conjunction with an exercise programme is effective in reducing pain and improving quality of life (Al-Rashoud et al., 2014). However, the best available evidence via a systematic review and meta-analysis does not support laser therapy (Huang et al., 2015).

2.6.6.4. Pulsed Shortwave

Pulsed shortwave is commonly utilised within the United Kingdom (Al-Mandil & Watson, 2006) due to the reduction in inflammation (Goldin et al., 1981). Shortwave can be effective in the management of chronic pain in individuals with knee OA (Masala et al., 2014), however a systematic review by McCarthy et al. (2006) found pulsed shortwave electrotherapy is not clinically significant with no difference on pain and function.

2.6.6.5. Shockwave

More recently, the use of shockwave therapy for the treatment of knee OA is becoming more common. Four to seven weekly treatment sessions have been effective in reducing pain and improving function, with no adverse reactions reported (Zhao et al., 2013). Further research is required to highlight the benefits of shockwave therapy, in the early or late stages of OA compared with conventional treatment (Zhao et al., 2013).

2.6.7. Massage

Massage therapy is one of the most commonly utilised treatments in the USA by individuals suffering with musculoskeletal conditions (Barnes et al., 2008). Within the UK, massage for the treatment of OA is being undertaken by 5% of physiotherapists (Walsh & Hurley, 2009). Massage consists of applying direct hands on contact with a body part to manipulate tender muscle groups as well as muscles that are in spasm (Shengelia et al., 2013). Massage can be used to alleviate pain, reduce stress and anxiety, and aid relaxation (Ernst, 2002), with a systematic review supporting its use in musculoskeletal treatment and being clinically relevant for up to 9-months (Forestier et al., 2016). Atkins & Eichler. (2013) found that 20 minutes of massage, twice per week for 5-weeks, improved pain and reduced stiffness, yet reported limited change to the range of motion within the specific joints. Equally, Yip & Tam (2008), reported positive effects with 6 sessions of 30 minutes of massage over 3-week period. Specifically related to knee OA, whole body massage therapy can reduce pain with eight weekly, 1-hour sessions (Juberg et al., 2015; Perlman et al.,

2012). However this level of pain relief would potentially only last for a few weeks (Perlman et al., 2006), consequently massage as a treatment for knee OA is not recommended by NICE (2014).

2.6.8. Hydrotherapy

Hydrotherapy for knee OA significantly improves pain, reduces disability, and improves quality of life (Silva et al., 2008). Water buoyancy and warm water reduces the weight that passes through the joints, enabling individuals to move relatively freely with minimal pain (Hinman et al., 2007). For example, a waist-deep step up in the pool indicating a 50% reduction in load (Rahman et al., 2009). In a recent Cochrane review, moderate quality of evidence for hydrotherapy has been highlighted with small short-term improvements in pain and disability and a small effect of quality of life (Bartels et al., 2016). Mean duration of hydrotherapy being 12weeks. Similarly, Hinman et al. (2007) reported a 72% improvement in global pain and a 75% in physical function, with the benefits of hydrotherapy being maintained at 6-weeks as well as 84% continuing with activity. Furthermore, hydrotherapy is extremely beneficial for obese individuals with severe OA, with early access to the warm water and pressure reduction on the joints assisting pain and movement (Bennell et al., 2014; Lim et al., 2010). Comparing land-based activity to hydrotherapy has been shown to have similar effects on symptoms; however, hydrotherapy has a slightly higher compliance rate than land-based activity (84% to 75%) (Lund et al., 2008; Foley et al., 2003).

2.6.9. Alternative therapy used in the NHS

Alternative therapy is becoming a popular treatment for knee OA (Herman et al., 2005), primarily due to the beliefs that it is free from adverse reactions (Vitetta et al., 2008). Acupuncture, yoga, pilates, and Tai chi are methods currently used within the NHS.

2.6.9.1. Acupuncture

Acupuncture is the most common complementary therapy practiced (Barnes et al., 2008; Manyanga et al., 2014), due to the positive effects on pain (Berman et al., 2004; Witt et al., 2005; Scharf et al., 2006; Kwon et al., 2006; Lu et al., 2010; Shengelia et al., 2013; Spaeth et al., 2013; Hinman et al., 2014; Ginnerup- Neilsen et al., 2016). Approximately, 60% of physiotherapists within the UK use acupuncture for the treatment of knee osteoarthritis (Walsh & Hurley, 2009), with less than 25% of Norwegian physiotherapists using acupuncture for knee OA (Jamtvedt et al., 2008). Within the USA, 0.52% of the population received acupuncture as a treatment for knee OA (Dhawan et al., 2014).

Acupuncture can reduce pain due to the functional modulation capacity within the brain and the descending pain pathway (Chen et al., 2015), it is completed by energising specific points throughout the body with small thin needles to unblock energy pathways (Shengelia et al., 2013). Specific points that reduce symptoms in knee OA are ST 34, Ex-LE 4, ST 36, SP 9, SP 10 (Taechaarpornkul et al., 2009) with the number of treatments ranging from 2 to 26 (Kwon et al., 2006). However, the number of needles that can be used for knee OA can range from two to six (Selfe & Taylor, 2008). Using fewer needles can cause greater pain relief (Kam et al., 2002); both are sufficient but are not clinically significant (Taechaarpornkul et al., 2009).

Evidence to support acupuncture for the treatment of knee OA is moderate (Witt et al., 2006; Jamtveldt et al., 2008; Hou et al., 2015) with 69% of individuals reporting excellent responses to acupuncture and it should be recommended in conjunction with other therapies (Kam et al., 2002). Vickers et al. (2012) compiled a metaanalysis that supports using acupuncture for 8-weeks, as it significantly reduced pain and improved function, however, the results were not reported as being clinically significant, and the benefits decreased over time. Manyanga et al. (2014) completed a systematic review and found that acupuncture can cause significant reductions in pain, but its usage did not meet the minimal clinical difference threshold.

Controversy remains regarding acupuncture with NICE (2014), OARSI (McAlindon et al., 2014) and the American Association of Orthopaedic Surgeons (AAOS, 2013)

not recommending it for the use in knee OA, due to the majority of studies being clinically insignificant with inconsistent or inconclusive evidence (Manheimer et al., 2010; Nelson et al., 2014). Examples of the inconsistencies being reported include acupuncture having no benefit with people over 50 years of age diagnosed with moderate or severe chronic knee pain (Hinman et al., 2014), yet the American college of rheumatology recommends the use of acupuncture for chronic or severe OA (Hochberg et al., 2012). More robust evidence is required (Hou et al., 2015), especially in the primary care setting (Nelson et al., 2014).

2.6.10. Education

Education or advice regarding self-management is recommended as a core intervention for individuals with knee OA (NICE, 2014; McAlindon et al., 2014; Fernandes et al., 2013; Richmond et al., 2010; Mazieres et al., 2008). Knee OA is a complex condition, which involves having an understanding of the bio-psychosocial aspects. It is important to understand that the structural changes within the knee do not always account for musculoskeletal pain with socioeconomic and environmental factors being involved. Understanding the individual's beliefs, occupation, finances, time management, and social supports are important to successful treatment (Hurley & Walsh, 2009). Specific education in regards to the mechanics of the condition, physiology and treatment options can enhance the treatment of OA, with simple examples being to have a brief discussion about activity and load modification (Zhang et al., 2010), such as walking instead of running, (American Academy of Orthopaedic Surgeons, 2008). The Enabling Self-management and Coping with Arthritic Knee Pain through Exercise (ESCAPE- knee programme) is a 12-session programme, completed twice per week, which involves education and exercise. Education such as coping strategies to understand why the pain is present and what might be causing it are included with an exercise programme being completed, which is designed for individuals with knee OA. This programme has produced better clinical outcomes, such as pain reduction, increased function and an increased quality of life (Hurley et al., 2007; Hurley et al., 2012). In addition, individuals with knee OA had positive experiences of the programme and became more confident with self-managing the condition. Long-term analysis of the ESCAPE programme was found to be cost effective and although the individuals function declined over

time, the improvements were better compared to standard care (Hurley et al., 2012). Further education in regards to the use of thermotherapy is encouraged as an adjunct treatment alongside core treatments as part of the self-management process (NICE, 2014).

2.6.11. Exercise & Physical Activity

Most physiotherapists consider exercise and physical activity as part of the clinical role (Shirley et al., 2010) with both being established as part of the routine examination and treatment for chronic musculoskeletal (MSK) conditions. Physiotherapists within a primary care setting are in a unique position to incorporate this, with the aim of improving physical fitness. Exercise and physical activity are different due to physical activity being any bodily movement produced by muscles that requires energy expenditure such as carrying out household chores (WHO, 2010). Exercise is a subset of physical activity, which is planned with purposeful training to increase fitness and muscle strength (Bouchard et al., 2012; WHO, 2010; Caspersen et al., 1985).

Physical activity has been described as a miracle cure for the treatment and prevention of pathology (Academy of Medical Royal Colleges, 2015). The World Health Organisation (WHO, 2010) recommends 150 minutes of moderate, or at least 75 minutes of vigorous aerobic exercise per week. Recommendations include muscle strength activities that work all major muscle groups on at least 2 days per week (Verhagen & Engbers, 2009). Research has highlighted that 50% of the recommended levels (72 minutes) appears sufficient to provide some improvement, with 60 minutes of daily activity being more appropriate for weight control (Lee et al., 2010). Higher physical activity is associated with maintained physical function, highlighting the importance of encouraging physical activity in older adults at risk of osteoarthritis (Batsis et al., 2015) and many other conditions such as fibromyalgia, diabetes and hypertension (Pederson & Saltin, 2006; Warburton et al., 2006). Individuals with musculoskeletal conditions have significantly poorer physical fitness and complete less physical activity compared to the normal population (Penninx et al., 2001), with individuals with knee OA spending two-thirds of their daily time being sedentary (Lee et al., 2015). Lower physical activity levels are associated with knee

OA, with a strong correlation highlighted in Spain and the UK (Herbolsheimer et al., 2016). Levels of physical inactivity have increased, with 72% of the population in England, Portugal, Sweden, and Norway not meeting the recommended guidelines, with 23% of individuals accumulating 10 hours of sedentary time per day with only 36 minutes of moderate to vigorous activity per day (Loyen et al., 2016). Incidentally, England reported the most physically inactive population and Norway showing the highest levels of sedentary time (Loyen et al., 2016). Physical inactivity is now identified as the 4th leading cause of global mortality (WHO, 2010; Hu et al., 2004) with adults spending approximately 46%-73% of waking hours sedentary (Holm et al., 2015), this may be detrimental in the short term and long term. It was estimated in 2006-2007, that physical inactivity cost the NHS approximately £936 million (Allender et al., 2007), with physical inactivity in conjunction with obesity costing approximately £5.1 billion (Scarborough et al., 2011).

Walking is the most common form of exercise and physical activity employed by older adults (Hootman et al., 2003) with recent data suggesting that adults walk between 6,540 and 9,676 steps per day (Tudor-Locke et al., 2009), with end stage knee OA individuals walking 6,732 steps per day (Holsgaard-Larsen & Roos, 2012). Walking 10,000 steps per day is effective in improving health (Bravata et al., 2007) and is more likely to meet physical activity guidelines. Increasing specific walking goals enhances self-efficacy and promotes the sense of accomplishment (Bellentani et al., 2008), with an increase of 1,000 being suggested (Fabricatore, 2007). However, the American college of sports medicine recommending at least 7,000 steps a day for developing and maintaining function (Garber et al., 2011; Tudor-Locke et al., 2011). Furthermore, over the last 20 years the arthritis foundation has developed activity programmes for people with OA, such as the walk with ease programme, which has increased physical activity by improving muscle strength and walking performance (Talbot et al., 2003). Other programmes such as the arthritis foundation exercise programme, arthritis foundation aquatic programme and a Tai Chi programme (Callahan et al., 2008) can be completed solo or as a group to improve physical activity, improve walking, reduce depression, and reduce pain. More recently, White et al. (2014) found that 16.7% of men and 12.6% of women walked more than 10,000 steps per day, with only 6% of men and 5% of women meeting the guidelines of 150 minutes per week including 100 steps per minute

(Physical Activity for Americans, 2008). Despite this, Dore et al. (2013) suggested that individuals with knee abnormalities should avoid completing more than 10,000 steps per day, due to an increase in bone marrow lesions and greater risk of cartilage pathology.

Increasing physical activity is an important aspect of rehabilitation, with the usage of activity monitors being an effective way to improve health by significantly increasing activity and reducing BMI (Bravata et al., 2007). Advantages of using an activity monitor are that they are not subject to bias, easy to measure activity, compared to self-reporting diaries and they are relatively small (Lee et al., 2015). Harris et al. (2009) utilised an activity monitor to record an average daily step count for healthy older people registered within a general practice, participants achieved an average of 6,443 steps, with the step count declining with age. Increased step counts were associated with activities such as dog walking and long walks. In addition, further studies show that low physical activity recordings on activity monitors are associated with a poor quality of life (Fox et al., 2007) and depression (Yoshiuchi et al., 2006). Therefore using a step count goal may be a positive factor to increase physical activity (Bravata et al., 2007) with a reported effect size of 2,000 more steps being suggested (Kang et al., 2009). Specifically relating to individuals with knee OA, Holsgaard- Larsen & Roos. (2012) used an armband activity monitor with individuals with end stage knee and hip OA and found that high physical activity is possible. In addition, Farr et al. (2010) completed a pre- and post-intervention study using activity monitors, comparing resistance training and self-management techniques, both groups registered 26.2 minutes of activity per day, with the resistance-training group increasing their activity by 18% and maintained a higher level of activity at 9 months. Questionnaire based physical activity measures are more often utilised in clinical practice due to the ease to administer and cost, however response bias and social desirability report imprecise results (Shepherd, 2003). Correlating activity monitor data with a specific physical activity questionnaire would provide a cost effective approach to understanding physical activity behaviour.

2.6.11.1. Biochemical effects of exercise

Exercise has been suggested to have a systemic anti-inflammatory effect (Petersen & Pedersen, 2005) with a single session resulting in an intra-articular antiinflammatory response through interleukin-10 (Helmark et al., 2010) and a reduction in C-reactive protein (Fedewa et al., 2016). Steensberg et al. (2000) found that during a prolonged single-leg stand an increase in interleukin-6 (IL-6) was produced, similar amounts of IL-6 were associated with concentric and eccentric activity (Jonsdottir et al., 2000) which contributes to the acute phase of healing (Gleeson, 2000). Adequate nutrition of the joint depends on the pump effect of synovial fluid, as the joint fluid viscosity increases through movement (Miyaguchi et al., 2003), inflammatory exudate will be removed from the joint (Cochrane et al., 2005). Following this, a higher cartilage proteoglycan content (Mikesky et al., 2006), an increase in mitochondriogenesis (Holloszy & Coyle, 1984) and an elevated oligiomatrix protein which effects cartilage matrix (Andersson et al., 2006), therefore preventing cartilage degeneration (Mikesky et al., 2006). Endocrine function is also important in OA, with the potential effects between leptin and adiponectin on the inflammatory process (Scotece et al., 2011). Physical activity is advantageous for people with a high baseline cartilage (Teichtahl et al., 2016) as mechanical stresses regulate cartilage structure (Cochrane et al., 2005; Huang et al., 2003) with a 48year-old person able to withstand 15.4 megapascals (MPa) before cartilage fatigue (Bellucci & Seedhom, 2001) with average forces of running and jumping being 4-9 MPa (Hall et al., 1991). Joint compressive forces have been measured at approximately 119% of body weight when cycling at 60 watts and 40 revolutions per minute, while shear forces range from 5-7% of body weight (Bini et al., 2010; Kutzner et al., 2012).

2.6.11.2. Exercise and OA

Exercise is the most used physiotherapeutic practice for knee OA (Walsh & Hurley, 2009). Physiotherapists are ideally placed to prescribe and provide exercise programmes due to the specific training in movement dysfunction, exercise prescription and behavioural interventions such as pacing and planning (Walsh & Hurley, 2009), with 80% of physiotherapists advocating exercise as a treatment for knee OA (Spitaels et al., 2017). Exercise has been recommended as a core

treatment for knee osteoarthritis (NICE, 2014; McAlindon et al., 2014; Fernandes et al., 2013; Richmond et al., 2010; Mazieres et al., 2008), as it entails little financial outlay, is safe to complete and is well tolerated by most people with lower limb OA (Bennell & Hinman, 2011). In addition, exercise can improve psychological wellbeing (Dunn et al., 2001), reduce depression, improve quality of life (Bagnato et al., 2014), and improve weight control (Warburton et al., 2006). Recently, an online survey in the USA reported that 75% of individuals with osteoarthritis were interested in attending a targeted exercise programme (Davis et al., 2016). Individual exercises and class-based programmes have been shown to improve function and reduce pain in knee OA with greatest improvements for individual programs (p>0.50) compared to class based (p<0.40) (Fransen & McConnell, 2008) with regular exercise being important (French et al., 2014). However, Jessep et al. (2009) found greater improvements with group therapy sessions, which significantly decreases cost (reduced to £320 from £583). Further advantages from class-based programmes are social interaction and the ability to minimize resources (Bennell & Hinman, 2011). However, difficulties tailoring the exercise programme being the only disadvantage (Bennell & Hinman, 2011).

Exercise recommendations for individuals with knee OA suggest being completed 3 times per week and focus on improving aerobic capacity, quadriceps strength and general muscle strength of the lower limb (Juhl et al., 2014). Strong evidence suggests that individuals with knee OA have a 20-40% quadriceps strength deficit compared with controls and a 12% quadriceps decrease in asymptomatic women with OA (Palmieri-Smith et al., 2010; Ikeda et al., 2005). Despite this, individuals with knee OA tend to avoid physical activity to prevent pain (Wallis et al., 2013). Strength training improves function with a 71% improvement in knee extension strength (Baker et al., 2001; Penninx et al., 2001; Keefe et al., 2004; Schilke et al., 1996) whereas stronger hip abductors can reduce the compressive force at the knee (Hinman et al., 2007; Hassan et al., 2001). Both improve function, reduce pain, and increase physical activity (Rogind et al., 1998), in contrast a reduction in strength will likely cause cartilage atrophy (Mikesky et al., 2006). Systematic and Cochrane reviews by Fransen and McConnell (2008), and Lange et al. (2008) suggest exercise as an integral aspect of rehabilitation for knee OA with a mixture of cardiovascular and/or resistance land based exercise strongly recommended (Hochberg et al.,

2012). Li et al. (2016) reported within a systematic review and meta-analysis that resistance exercises are beneficial to reduce pain, alleviate stiffness, and improve physical function. Body weight, weight machines, and resistance bands are examples of the resistance exercises. Henriksen et al. (2014) reported positive effects of a supervised exercise programme using the KOOS questionnaire on quality of life, symptoms, sports and recreation, activities of daily living and pain, the latter being statistically significant. Strength and balance exercises focused around the trunk, hip, and knees using free weights and elastic bands were utilised with participants that attend the programme 3 times per week for a 12-week period. However, the programme did not meet any of the minimal clinically important changes and no objective measurements of physical activity were utilised, which could be associated with pain sensitivity. In addition, Lund et al. (2008) reported clinically significant findings using the KOOS questionnaire for pain, symptoms, sports and recreation and activities of daily living after an exercise programme. Balance and resistance exercises using free weights, rubber bands, and body weight were used with participants attending a 50-minute session, twice per week over an 8-week period. Incidentally, quality of life was not clinically significant. Strength was measured using an isokinetic dynamometer, which is a valid and reliable tool (Abernethy et al., 1995), however is a very expensive piece of equipment, with the isokinetic machine costing \$40,000 (Stark et al., 2011) and the relationship to actual function is questioned. In comparison, Thorstensson et al. (2005) completed a 6week high intensity exercise programme, which participants attended twice weekly. Exercises included the use of a trampette, single leg rising from siting and floor exercises such as sit-ups and hip abduction, participants were advised to work at 60% of their maximum heart rate. No significant differences was reported using the KOOS for pain, function, symptoms and sports, however, guality of life after 6-weeks improved (p=0.05). Strength was measured using the lateral step up, rising on one leg from sitting from the lowest possible height, maximum single leg mini squats in 30 seconds and single leg hop. These tests are not recommended by OARSI and are mainly used for individuals with anterior cruciate ligament injuries and ankle injuries. Despite this, high-intensity training can be superior with the elderly population with psychological issues (Singh et al., 2005).

Equally important is the relationship of exercise and weight loss in individuals with knee OA, as a greater weight loss results in a reduction of symptoms (Penninx et al., 2001), with a 12 pound weight loss reducing the risk of knee OA by 50% (Felson et al, 1992). O'Reilly et al. (2004) found that the average reduction of 44 kilograms provided 89% of individuals with knee OA with completely pain-free symptoms. Elsewhere, Messier et al. (2013) combined diet and exercise which consisted of aerobic activity (30 minutes) and strength training (20 minutes), a 10-15% reduction of weight over an 18-month period reduced pain, increased quality of life and increased function compared to diet and exercise alone. Although these results provided positive effects of exercise and weight-loss, no statistically significant differences on the progression of OA via an x-ray or MRI was found (Hunter et al., 2015). On the other hand, as little as 5% weight-loss can significantly reduce disability in knee OA (Christensen at al., 2007).

2.6.11.3. Strength and Flexibility

Strengthening exercises should include all major muscles of the lower limbquadriceps, hip abductors/extensors, hamstrings, and gastrocnemius with the American Geriatrics Society (2001) guidelines including flexibility, strength, and aerobic activity. Range of motion at the knee joint is an important factor as at least 70 degrees of knee flexion is required for walking, 83 degrees of knee flexion for stairs, 93 degrees of knee flexion for getting from a chair and neutral extension (Wrightson & Malanga, 2001). Recommendations for flexibility are completing a single repetition static stretches for each muscle group with 5-15 seconds hold, to be completed once daily. Progressing to a full range of movement stretch, 3-5 stretches per muscle group, holding the stretch for 20-30 seconds, to be completed 3-5 per week (American Geriatrics Society, 2001). Kokonen at al. (2007) advocate static stretching to improve function and would also improve the transition to an exercise programme, however a systematic review by Shrier (2004) concluded that stretching does not improve function, although the specificity of the stretching was not highlighted, therefore questioning the validity of the review. Strength based training should initially commence with low to moderate (40-60% of maximal voluntary contraction) isometric activity with a 1-10 submaximal contraction with a hold for 1-6 seconds daily. Isotonic exercises are also recommended with 10-15 repetitions for a

low level (40% of a 1 maximum repetition), 8-10 repetitions for a moderate level (40-60% of a 1 maximum repetition), and 6-8 repetitions for a high level (greater than 60% of a 1 maximum repetition). These are to be completed 2-3 times per week with aerobic activity focusing on low to moderate activity (40-60% of the maximum volume of oxygen or heart rate or a 12-14 rating of perceived exertion) for 20-30 minutes per day, 2-5 times per week. Other exercise prescription could include completing high repetitions with low load (> 12 maximum repetition) for muscular endurance and low repetitions with high load (3-5 maximum repetition) for optimal strength (Fleck & Kraemer, 2014; Peterson et al., 2005; Kraemer & Ratamess, 2004). Bartholdy et al. (2017) concluded via a meta-regression analysis of randomised controlled trials that this process of exercise prescription is recommended, as it provides superior outcomes for knee extensor strength, but not in pain or disability. Minshull & Gleeson (2017) suggested exercise prescription should include specificity, overload, and progression, with correct use of these principles, muscles will become stronger, faster, and more resistant to fatigue. Minshull & Gleeson (2017) conclude that individuals with knee OA have pain and this should be taken into account when prescribing an exercise programme, as it could result in ineffective strengthening. Progressive strength training is tolerable in individuals with knee OA (Skoffer et al., 2016).

2.6.11.4. Balance

Balance is also required as part of the rehabilitation programme, as postural instability may result from weakness around the quadriceps, altered neuromuscular control or pain (Bennell & Hinman, 2005). An increase in falls during dynamic activities can be caused by postural instability (Sorensen et al., 2014) and reduced proprioception (Knoop et al., 2011). Individuals with knee OA display poorer postural stability than controls (Hinman et al., 2002; Hassan et al., 2001) with a reported 27% being at risk of instability (Nguyen et al., 2014) due to fear of movement and impaired function. Decreased postural stability causes difficulties performing activities of daily living and recreation, which hinders quality of life and has a significant influence on fear avoidance (Levinger et al., 2016). Postural stability declines with age and those with good postural stability experience a better quality of life (Shumway-Cook et al., 2000). However, dynamic balance can be improved with

an exercise programme, especially in the anterior and medial directions (AI-Khlaifat et al., 2016). Incidentally, no clinical recommendations for specific balance exercises are available due to limited evidence (Chaipinyo & Karoonsupcharoen, 2009).

2.6.11.5. Complementary exercise

Complementary exercise programmes such as Yoga and Tai chi are becoming more common with Yoga being recommended by the Arthritis Foundation in the USA to promote joint flexibility and lower stress levels (Ebnezar et al., 2012; Bukowski et al., 2006). Yoga combines exercise with relaxation and meditation techniques. Exercises such as stretching, breathing, and relaxation with focus on specific postures, with poses being used to build strength and enhance flexibility (Shengelia et al., 2013). Yoga is safe and accessible for older adults with knee OA (Cheung et al., 2014) with a higher yoga adherence being correlated with improved function, sleep quality, and quality of life (Cheung et al., 2016). Clinical evidence for using yoga as a treatment for knee OA is positive, with an 8-week (Cheung et al., 2014) or 12-week (Brenneman et al., 2015) programme reducing pain, improving function and increasing muscle strength. Furthermore, improvements in the 6-minute walk test and 30-second chair stand test have been reported in individuals with knee OA completing yoga (Brenneman et al., 2015). In addition, hatha yoga has been found to be better than therapeutic exercises as an adjunct to TENS and ultrasound in the treatment of knee OA (Ebnezar et al., 2012). Mindfulness is also linked to yoga and has been reported to have a positive effect on pain and depression in participants with knee OA (Skowronek et al., 2014). In addition, Tai chi is a form of mind-body exercise that includes meditation, gentle movements, and deep breathing combined within a class format (Shengelia et al., 2013). Tai chi can improve both psychological and physical health among people with chronic conditions (Wang et al., 2004). Tai chi has positive evidence in reducing pain and stiffness specifically in knee OA (Tsai et al., 2013; Wang et al., 2009; Wang et al., 2004). Equally, Tai chi has positive effects for muscle strength and flexibility to improve physical function (Escalante et al., 2010) and improve balance to reduce falls (Mat et al., 2015; Song et al., 2003). Completing 60 minutes of Tai Chi twice per week for 12-weeks also reduces depression, improves self-efficacy, improves aerobic capacity, and improves quality

of life in individuals with knee OA (Wang et al., 2009). Similarly, 4 sessions of Tai chi over a 2-week period produced similar outcomes compared to a standard course of physical therapy (Wang et al., 2016), however in this study no patient blinding was completed. Despite Tai chi providing encouraging evidence for pain control, patient compliance is reduced by 20% compared to hydrotherapy (Fransen et al., 2007) with a large randomised control trial being recommend to further determine its effectiveness (Mat et al., 2015).

2.6.11.6. Patient Adherence to exercise

Strong evidence is available regarding exercise, a global under-utilization is present (Dobson et al., 2016; Mitchell & Hurley, 2008) and uncertainty remains about the role of exercise in the United Kingdom. Nicolson et al. (2017a) found that individuals with knee OA actually rated the effectiveness of exercise and education significantly lower than physical therapists with the belief that adequate pain relief is needed to engage in physical activity and most individuals are unaware of the benefits of exercises (Poitras et al., 2010; Eccleston & Eccleston, 2004). An example of these beliefs have been reported by Holden et al. (2012), with individuals believing that exercise is beneficial for mild OA (40%), but then drops to 20% for severe OA. Furthermore, Craig et al. (2009) reported major issues within the UK as only 5% of knee OA sufferers are achieving the recommended level of activity with 57% of the population being objectively inactive (Godino et al., 2014). Healthcare costs due to physical inactivity range from 1% to 4% (Janssen, 2012) which cost £8.3 billion in 2009 (Chief Medical Officer, 2009). Non-adherence to exercise is common (Marks, 2011) with Bassett (2003) reporting that 65% of individuals are likely to be noncompliant with physiotherapy exercises and consequently having negative effects on outcomes and healthcare costs (Jack et al., 2010). Adherence has been defined 'as to which a person's behaviour corresponds to the recommended intervention' (WHO, 2003). Understanding individual exercise behaviours and habits should be established as part of the routine examination and treatment for chronic musculoskeletal conditions especially in relation to physical activity, as it is essential so that the adherence to exercise is understood (De Bruijn & Rhodes, 2011) and an improvement in functional recovery is gained (Doury-Panchout et al., 2015). Strong evidence is available to link low in-treatment adherence with exercise (Sluijs et al.,

1993), as increased pain during exercise being a major barrier to adherence (Dobkin et al., 2006; Minor & Brown, 1993). Clinicians need to emphasise messages that pain should not prevent individuals completing therapeutic activities (Waddell et al., 2004), as regular exercise is associated with a reduced likelihood of progressive problems (McLean et al., 2007). Physiotherapists working in primary care area are in a unique position to incorporate this change of behaviour through screening procedures at the earliest point of contact, as past disability behaviour predicts future behaviour (Dobson et al., 2016). Physiotherapy specific management could influence the outcome of rehabilitation (Beur & Linton, 2002; Crombez et al., 1999) by involving the patient within the consultation to limit on-going investigations, implement specific measurable attainable realistic and timed (SMART) goals to improve health outcomes (NICE, 2008) specifically improving physical fitness (Moseng et al., 2014), decreasing pain and strengthening health beliefs (Larsson et al., 2016). Helplessness, self-efficacy, coping, ill-health beliefs, and social support are all behavioural factors associated with OA (Hurley et al., 2003). Helplessness occurs when individuals feel they have no control over the condition with ill-health beliefs such as OA is inevitable with age, incurable pain indicating damage especially with activity and these thoughts cause fear of pain, which causes fear of movement (Dekker et al., 1992). Incorporating coping strategies and self-efficacy with exercise can be important (Hurley et al., 2003), to reduce health beliefs and specifically fear of movement (Keefe et al., 1990). Hurley et al. (2007) found that individuals had an 82% adherence with using individualised treatment, with prescription of specific exercises most acceptable to encourage adherence that instils confidence, reassurance and coping strategies. If absent, a lower functional performance could increase the risk of knee OA (Thorstensson et al., 2005). Furthermore, increasing compliance to utilise exercise as a self-management treatment can reduce medical visits and healthcare costs over 12 months (Gay et al., 2016). Holm et al. (2015) found that individuals with a long-term musculoskeletal condition who completed a physiotherapy exercise programme to improve their general physical activity increased from 29% to 42% and those individuals who could not function reduced from 7% to 1%. Techniques that are commonly utilised by physiotherapists to promote exercise adherence range from education about the benefits of exercise, exercise diaries, goal setting, follow up appointments to review exercises and referrals to exercise programmes (Nicolson et al., 2017a).

Furthermore reducing the cost of exercise could potentially increase adherence, with Cochrane et al. (2005) highlighting that 53% of participants continued with exercise versus 19% when they had to pay. The physiotherapist who is completing the study has a strong focus on active treatment methods such as physical activity/exercise.

Psychological factors such as fear of movement, lack of confidence and previous experience are as important as the physical characteristics (Nicolson et al., 2017b; Dobson et al., 2016; Holden et al., 2012; Campbell et al., 2001; Symmons, 2001; Sluijs et al., 1993). Psychological understanding of kinesiophobia, which is a fear of movement that results in pain (Kori et al., 1990), is also an essential factor of physical inactivity in exercise behaviour. The level of physical activity is significantly lower amongst individuals with chronic pain and kinesiophobia (Larsson et al., 2016, Stubbs et al., 2014) which could cause a barrier to treatment because of a pain related fear (Doury-Panchout et al., 2015). Therefore, a psychometric evaluation prior to treatment is recommended to increase adherence (Nicolson et al., 2017a), as exercise and activity declines over time in individuals with knee OA (Fransen et al., 2015; Fransen et al., 2009). However, it is not known in individuals with knee OA if they have high levels of kinesiophobia and whether these can be altered with exercise?

2.6.12. Kinesiophobia

Kinesiophobia is a psychological impairment that has been defined as 'an irrational and debilitating fear of movement and activity that results from a feeling of vulnerability in regard to a painful injury or re-injury' (Kori et al., 1990). In addition, Vlaeyen et al. (1995) introduced fear of movement and developed a fear avoidance model, in which disability is present due to the individual's fear of physical movements that would elicit pain. The model highlighted a cycle chain of events such as pain- fear of movement- avoidance- disability and pain. Lethem et al. (1983), first described fear of movement with the fear avoidance model of exaggerated pain and more recently, Hurley et al. (2010) indicating that individuals may develop kinesiophobia from a functional impairment through negative attitudes and beliefs about their problems. Furthermore, it has a negative influence on the outcome of rehabilitation with a high level of kinesiophobia presenting poorer rehabilitation

outcomes in individual post total joint replacement (Filardo et al., 2015). In addition, an increased level of fear avoidance have been shown to be directly related to increased disability (Leeuw et al., 2007; Cook et al., 2006), impaired physical performance, increased self-reported disability and it can predict future occupational disability (Crombez et al., 1999; Beur & Linton, 2002; Vlaeyen & Linton, 2000). Woolf et al. (2008) reported increased pain, increased blood pressure, increased heart rate, and increase muscular tension in individuals with high kinesiophobia.

Increased levels of kinesiophobia have been shown in the general population and health care providers (Beur & Linton, 2002) with approximately 54% of individuals in primary care having difficulty with it (Lundberg et al., 2006) and men having a higher frequency than women (Branstrom & Fahlstrom, 2008). Fear of movement interferes with descending pain-inhibitory systems and facilitates neuroplastic changes in the spinal cord during painful stimulation, which ends with pain sensitisation (Goodin et al., 2009). Consequently, this pain sensitisation causes functional decline that in turn causes depression and disturbed sleep that can increase psychological distress (Bijlsma et al., 2011). Sleep efficiency, central sensitisation and catastrophising in chronic pain is an important clinical implication for treatment planning (Campbell et al., 2015), as sleep disruption amplifies pain perception (Smith & Haythornthwaite, 2004) and increases the risk of developing pain (Gupta et al., 2007).

Koho et al. (2001) investigated fear of movement and physical activity in participants with chronic musculoskeletal pain with a higher level of kinesiophobia and low physical activity level being demonstrated at baseline. Nevertheless, at 6 months, the high kinesiophobia group increased physical activity and reduced kinesiophobia to a low and medium level and they maintained that level for 12 months. Further evidence highlights that increased kinesiophobia is linked to an increase in delayed onset muscle soreness post activity (Trost et al., 2011; George et al., 2007) with a reduction in strength output (Trost et al., 2011). In addition, Elfving et al. (2007) reported that individuals with low back pain, who completed 2-4 hours of physical activity per week, had higher kinesiophobia. However, some studies suggest that fear avoidance is not directly associated with physical activity (Griffin et al., 2012; Lundberg et al., 2011; Alschuler et al., 2011; Heneweer et al., 2009). Patients and general practitioners' have fatalistic opinions of pain, especially osteoarthritis and its' progression with radiographic features of OA being strongly associated with pain

(Neogi et al., 2009), these cognitive and behavioural factors are involved in the progression of chronic of pain (Innes, 2005).

Kinesiophobia has been shown to be the strongest predictor of functional outcome with knee pain (Holden et al., 2012; Piva et al., 2009) with individuals with OA more likely to catastrophise about pain and also have greater levels of physical disability (Keefe et al., 2000). In post-knee surgery, such as total knee replacements due to severe osteoarthritis, fear of pain and avoidance of movement are strongly correlated with post-operative pain and recovery after surgery, for up to 1 year (Filardo et al., 2015). Pain reduction is the primary reason for a total knee replacement (Hawker et al., 1998); however, 30% of knee replacements have a chronic fear of pain and movement and therefore not adhering to the post-operative exercise protocol (Wade et al., 2012). Furthermore, a link between range of motion and kinesiophobia post-total knee replacement can be seen for up to 1 year. Similarly, individuals with high kinesiophobia are likely to have a greater hospital stay (4 days), greater intensity of pain and less knee flexion (Brown et al., 2016). However, Domenech et al. (2013) suggested kinesiophobia is not clinically significant with knee pain in a study with 47 total knee replacements.

Further evidence suggests that kinesiophobia is evident in individuals with knee OA after anterior cruciate ligament reconstruction (Hart et al., 2015b) potentially prolonging the rehabilitation process. Doury- Panchout et al. (2015) reported that individuals without kinesiophobia walked further than individuals with kinesiophobia when completing the 6-minute walk test, which would then affect knee function, daily functioning, and rehabilitation programmes. In addition, Al-Obaidi et al. (2003) found walking at a faster speed as a significant indicator of kinesiophobia in individuals with low back pain.

Author /Source	Purpose	Methods	Sample	Findings
Tackacs et al. (2017)	Evaluation between dynamic balance and other outcomes related to medial knee OA before and after an exercise programme.	10-week supervised exercise programme. Outcome measurements: Western Ontario and McMaster universities osteoarthritis index (WOMAC); Brief Fear of movement scale; Community Balance and Mobilty Scale; Muscle Strength	40 Subjects with medial knee OA, greater than KL grade 2, aged between 50-80 years of age.	Fear of movement reduced after the exercise programme.
Sanchez- Heran et al. (2016)	Evaluation between postural stability, degree of pain catastrophizing, and fear avoidance beliefs in knee OA.	Cross sectional, descriptive study. Outcome measurements used: Multi-Directional Functional Reach (MDFRT); Pain Catastrophizing Scale; Tampa Scale of Kinesiophobia; Fear Avoidance Beliefs Questionnaire; Visual Analogue Scale; Western Ontario and McMaster universities Osteoarthritis Index (WOMAC) and Chronic Pain Self- Efficacy Scale.	80 Subjects with knee or combined knee and hip OA from 4 primary care centres.	Pain catastrophizing and fear avoidance are related to postural stability.
Hart et al. (2015a)	Aim to compare knee, trunk, pelvis, hip, and ankle kinematics between people with lateral knee OA post anterior cruciate ligament reconstruction.	Cross sectional study.	19 post anterior cruciate ligament reconstruction with lateral knee OA and 25 healthy individuals.	Knee and trunk movement related to worse knee pain, confidence, and kinesiophobia.
Hart et al. (2015b)	Aim to compare fear of movement in people with and without knee OA following anterior cruciate ligament reconstruction.	Cross sectional study. Outcome measurements; Knee Injury and osteoarthritis score (KOOS); Tampa Scale of Kinesiophobia; International knee documented committee and anterior knee pain scale; and performance based test- hopping and one leg rise task.	66 individuals post anterior cruciate ligament reconstruction (5-12 years).	Greater kinesiophobia and worse knee confidence in individuals with knee OA post anterior cruciate ligament reconstruction, than those without knee

<u>Table 3</u> Specific articles relating to kinesiophobia and knee OA (July, 2017)

				OA
Doury- Panchout et al. (2015)	Assess kinesiophobia on the recovery of individuals following total knee arthroplasty, also to investigate if kinesiophobia was more common in obese patients.	Cohort study. Outcome measurements; Six minute walk test; Tampa Scale of Kinesiophobia; Pain intensity; Maximum passive flexion; Body mass index	89 individuals within a hospital setting, post total knee arthroplasty.	Patients without kinesiophobia walked further than those with. No difference between obese and non-obese groups.
Urquhart et al. (2015)	Examine cognitive and behavioural factors and pain at the knee.	Systematic review	14 studies, 8 high quality.	Moderate evidence found for a relationship between cognitive factors and knee pain.
Tengman et al. (2014)	Physical activity level, function and fear of movement. 20 years post anterior cruciate ligament injury. Outcomes were related to degree of osteoarthritis.	Outcome measurements: Tegner activity sale; International physical activity questionnaire (IPAQ); Lysholm scale; Knee Injury and osteoarthritis score (KOOS); One leg hop; Vertical jump; Side hops; Tampa Scale of Kinesiophobia.	103 participants; 33 ACL's treated with physiotherapy and surgery; 37 ACL's treated with physiotherapy alone; 33 gender and age match controls.	ACL's had lower Lysholm scale, KOOS and Tegner scores with IPAQ scores were similar. ACL's scored 33 and 32 on the TSK. Lower scores for KOOS and Lysholm for moderate to high OA.
Unver et al. (2014)	Determine the association of pain, stair climbing, and fear of falling in knee OA.	Outcome measurements: Going up and down scale; Tampa Scale of Kinesiophobia;	15 healthy and 21 pre total knee arthroplasty patients.	Positive significant correlation between stair climbing, fear of falling and pain
Shelby et al. (2012)	To establish a fear of movement scale for the use in OA.	Outcome measurement: Tampa Scale of Kinesiophobia	1136 community based individuals.	

Evidence to link kinesiophobia with OA is limited with Shelby et al. (2012) proposing it is becoming more prevalent, consequently causing a considerable concern surrounding adults with knee OA, and the role of exercise in the management of their condition. Shelby examined fear of movement using the Tampa scale of kinesiophobia (TSK) with 1,136 participants with hip, knee or hip and knee OA. Similarly, Somers et al. (2009) completed a study investigating pain catastrophizing and pain related fear in relation to pain, psychological disability, physical disability, and walking speed within knee osteoarthritis. One hundred and six participants with persistent pain for 6 months completed a coping strategies questionnaire, arthritis impact measurement scale, gait analysis and the TSK. Pain catastrophising and psychological disability is reported to be significant in the variance of pain. Prior to these studies, Heuts et al. (2004) studied pain related fear in osteoarthritis by using the TSK, with daily functioning influencing the level of pain and the level of pain related fear being significantly associated with functional limitations. More recently fear avoidance and pain catastrophising have been shown to be related to postural stability using the TSK in 80 knee osteoarthritic participants (Sanchez-Heran et al., 2016). Despite this, Tackacs et al. (2017) found that a 10-week partially supervised exercise programme including balance and strength exercises completed 4-times per week significantly reduced fear of movement using the brief fear of movement scale. However, in a recent systematic review in relation to kinesiophobia and osteoarthritis, Urquhart et al. (2015) highlighted that kinesiophobia is deemed to be a behavioural factor and no significant relationship being found between knee pain and kinesiophobia. Very few studies have investigated kinesiophobia in individuals with OA and the importance of the role prior, during and after rehabilitation or surgery (Gunn et al., 2017). Kinesiophobia has a vital role within the whole rehabilitation process, as high kinesiophobia is associated with physical inactivity (Nelson et al., 2014; Hapidou et al., 2012), therefore targeted intervention is required to increase physical activity (Bergsten et al., 2012). However, Walsh & Hurley (2009) compiled the first physiotherapy survey in the management of knee OA with only 1% of physiotherapists addressing fear avoidance.

2.6.13. Outcome Measures used in knee OA

Outcomes measures need to be reliable, valid, and sensitive to change with the minimal clinical important difference reported. On review of the literature it is clear

that a variety of outcome measures have been used for research on knee OA, Dobson et al. (2013) recommended a minimum core set of performance based measures such as the 30-second chair stand test and the 6-minute walk test. Other performance-based tests include the timed up and go, step test and the 4x 10 metre fast-paced walk test. The step test is a commonly used test in practice to assess dynamic balance (Hinman et al., 2002), however no significant change was reported whilst using the step test with an exercise programme in hip and knee OA (Hinman et al., 2007). Evidence to use the step test or the timed up and go are not recommended due to the current evidence from a systematic review (Dobson et al., 2012).

In addition to physical tests, patient-reported measures of knee function are essential in clinical practice and research. Current self-reported questionnaires such as the Knee injury and Osteoarthritis Outcome Score (KOOS), Lysholm knee scoring scale, Tegner activity score and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) are commonly used. Primary aims of the Lysholm scoring scale are mainly knee joint instability (Lysholm & Gillquist, 1982) and may be used in conjunction with the Tegner score (Tegner & Lysholm, 1985), both measures may provide inadequate reliability for individual outcomes (Collins et al., 2011). The WOMAC is a valid and reliable measurement tool for pain and disability specifically for hip and knee OA (Kersten et al., 2010; Yang et al., 2007), however, the validity of the WOMAC for younger people with OA has been analysed with the suggestion to use the KOOS for specific functional activities (Roos & Toksvig-Larsen, 2003). Pain related fear outcome questionnaires such as the Tampa scale of kinesiophobia (TSK), fear avoidance beliefs questionnaire (FABQ), fear of pain questionnaire (FPQ), fear-avoidance of pain scale (FAPS) and pain anxiety symptoms scale (PASS) have been used in practice. Critically, Lundberg et al. (2011) found limited psychometric properties in the questionnaires, limited responsiveness, and sensitivity for the usage in clinical practice. However, they concluded that fearavoidance is best measured by using the FABQ; pain related fear is best measured by using the PASS, with kinesiophobia being best measured by using the TSK (Lundberg et al., 2011). Accelerometry is a cost effective, valid and reliable tool for measuring activity (Skender et al., 2016; Sliepen et al., 2016; Barden et al., 2016; Colbert et al., 2010; Verbunt et al., 2009; Liikavainio, et al., 2007) and is superior

compared to questionnaires and heart rate monitoring (Plasqui & Westerterp, 2007). Hip accelerometers can be more precise than wrist or ankle devices (Rosenberger et al., 2016), due to wrist and ankle devices counting movements during heel tapping, leg swinging or cycling (Mudge et al., 2007; Karabulut et al., 2005) and they do not count steps when the wrist is stationary (Chen et al., 2016). Still, many of the devices such as fitbit flex, garmin vivo-fit and jawbone over estimate activity within the ranges of 1.5% to 9.6% (Chen et al., 2016) and can be very accurate at speeds of 3 miles per hour and less accurate at slower speeds with virtually no steps being recorded between 1-2 miles per hour (Bergman et al., 2008). However, the activPAL[™] monitor collates data at 1 mile per hour and can collect other data such as sedentary time, upright postures and energy expenditure (Kanoun, 2009). More importantly, the majority of studies using accelerometers are completed in the laboratory, which potentially alters gait parameters (Del- Din et al., 2016).

2.6.13.1. 6-minute walk test

The 6-minute walk test (6MWT) is an easy to administer test to assess aerobic walking capacity, dynamic balance whilst changing direction and maximal distance covered in a 6-minute period with the test being recommended by Osteoarthritis Research Society International (Dobson et al., 2013). Solway et al., (2001) suggested the test is more reflective of physical activities and better tolerated than other walk tests. Steffen et al. (2002) reported standard values for the 6MWT in healthy individuals aged between 60-89 years of age. Men aged 60-69 averaged 572 metres (SD 92) compared to 538 (SD 92) for females, men aged 70-79 averaged 527 (SD 85) compared to 471 (SD 75) for females and men aged 80-89 averaging 417 (SD 73) and females 392 (SD 85). Coincidentally, individuals with knee OA complete the 6MWT on average 430 metres (SD 18) (Stevens- Lapsley et al., 2012). Specific post-exercise intervention for individuals with knee OA ranges from 392 metres to 573 metres (Brenneman et al., 2015; Simao et al., 2012; French et al., 2011). Test- retest reliability for the 6-minute walk is 0.90 at baseline and 0.88 after 18-weeks (Enright 2003); the standard error of measurement is 26.29 metres (Kennedy et al., 2005); and the minimal detectable change being 61.34 metres in adults with a mean age of 63.7 years (Kennedy et al., 2005). However, French et al. (2011) suggested a median change score of 35 metres in individuals with knee OA

following a physiotherapy intervention. Encouragement during the test must be standard, as it can have an impact on the results (Crapo et al., 2002).

2.6.13.2. 30-second chair stand test

A 30-second chair stand test will be used to test balance, functional mobility, and strength. It is a valid and core outcome measurement tool for individuals with OA and community dwelling elderly adults (Jones et al., 1999; Gill et al., 2012), and is recommended by Osteoarthritis Research Society International (Dobson et al., 2013). Inter-rater and intra-rater reliability for hip and knee osteoarthritis is 0.93 to 0.98 (Gill et al., 2008), the standard error of measurement for hip osteoarthritis being 1.27 and the minimally clinical important difference being two repetitions (Wright et al., 2011). Rikli & Jones. (2013) found the average repetitions for females being 15 (60 years) to 9 (90 years) with 17 (60 years) to 9 (90 years) for males. Specific post-exercise intervention for individuals with knee OA have a mean range from 8.8 repetitions to 14.6 repetitions (Brenneman et al., 2015; Gill et al., 2009).

2.6.13.3. Y balance test

The Y balance test is a quick, efficient, objective, portable, and consistent tool and will be used to evaluate dynamic and asymmetrical balance whilst utilising muscle strength and flexibility at the hip, knee and ankle joints (Plisky et al., 2006). Research from a similar test named the star excursion balance test (SEBT) has further developed the Y test with Gribble et al. (2012) suggesting using three planes of movement to assess postural stability- anterior (ANT), posteromedial (PM) and posterolateral (PL). Intra-rater reliability for the one tester ranged from 0.85 to 0.91 with anterior reach 0.91, posteromedial 0.85, and posterolateral 0.90, and a composite score of 0.91. Inter-rater reliability between the two testers ranged from 0.99 to 1.0 with anterior 1.0, posteromedial 0.99, posterolateral 0.99, and composite score 0.99 (Plisky et al., 2009). In addition, the minimal clinical difference has been reported as 3.5% in college athletes (Chimera et al., 2015). Anterior and medial directional reaches for dynamic balance in the symptomatic knee using the star excursion balance test (SEBT) significantly improved with exercise, however only anterior dynamic balance improved in the contralateral knee (Al-Khlaifat et al., 2016). Clearly, this is an important outcome measurement as there are currently no clinical guidelines available for specific balance exercises for people with OA; due to the

limited evidence available (Chaipinyo & Karoonsupcharoen, 2009). The Y balance test has also been shown to highlight injury risk of up to 2.5 in men and 6.5 in females with asymmetries between limbs greater than 4 centimetres (Plisky et al., 2006). Critical analysis of the SEBT and Y balance test is that the protocol can be very time consuming (Hertal et al., 2000) with the elevated stance leg on the official Y balance apparatus may be a barrier to reaching further (Coughlan et al., 2012). In addition, gender differences specifically into the anterior reach have been found, as females have greater hip flexion than males, which potentially may be due to different muscle activation patterns (Fullam et al., 2014).

2.6.13.4. Tampa Scale of Kinesiophobia

The Tampa Scale of Kinesiophobia (TSK) is a brief, reliable and a valid measure to link fear of movement with knee OA (Shelby et al., 2012) with good internal consistency- 0.68-0.80 (Hapidou et al., 2012). Lundberg et al. (2011) suggested the TSK as the best outcome measure available to measure kinesiophobia and is one of the most widely used questionnaires for pain belief and pain related fear of movement/re-injury (Monticone et al., 2013). Correlational analyses have been found between the TSK and the numeric scale of pain (moderate correlation-r-0.683) and the WOMAC questionnaire (strong correlation-r-0.843) (Bhatt et al., 2015). Further, significant associations have highlighted KOOS pain and KOOS ADL with fear of movement and increased age having a lower likelihood of fear of movement (Gunn et al., 2017). Tkachuk & Harris. (2012) suggest utilising the TSK for future practice, as it may allow individuals to experience movements that they might normally avoid. It consists of 17 items scored on a 4-point scale, from strongly disagree, disagree, agree and strongly agree. After inverting questions 4, 8, 12, and 16, a score is calculated. The scores range from 17 to 68. High kinesiophobia can be classified with a score of 37 out of 68 (Branstrom et al., 2008; Vlaeyen et al., 1995), while those below are considered low scores with Kori et al. (1990) reporting an increased pain and disability with a greater score with the TSK. In addition, Koho et al. (2001) found that the mean score in 97 chronic musculoskeletal clients with high kinesiophobia was 37 with a test-re-test reliability of 0.89. Osteoarthritic and musculoskeletal pain average scores have been reported as 24.5 (Heuts et al., 2004) and 42 (Sullivan et al., 2003). Previous minimal detectable changes have ranged from 9.2 points chronic MSK pain (Ostelo et al., 2007) to 13 points (George

et al., 2006) for low back pain, however the most recent evidence for a minimal detectable change for chronic MSK conditions is a change of 5.6 (Hapidou et al., 2012). Furthermore, the TSK can be divided into two subscales, somatic and activity avoidance. Questions 3, 5, 6, 7, 11 on the TSK highlight a somatic focus (SF) that suggests that something is seriously wrong with the body and questions 1,2,10,13, 15 and 17 highlight activity avoidance (AA), which suggests that avoiding activity might prevent an increase in pain (Roelofs et al., 2007; Heuts et al., 2004). Mean results for the TSK SF and AA on individuals with OA range from 10 to 14 (Roelofs et al., 2012; Roelofs et al., 2007), no minimal detectable change is available for the TSK-SF and TSK-AA.

2.6.13.5. Physical Activity Scale for the Elderly

Physical activity was measured using the physical activity scale for the elderly (PASE), which is a valid and reliable measurement tool (Martin et al., 1999). It is a self-administered questionnaire, which assesses a wide range of activities such as leisure time activity, household activity, and work related activity (Dunlop et al., 2010). The PASE measures the level of self-reported physical activity in individuals aged 65 and over and is comprised of items regarding occupation, household, and leisure activities during a 7-day period. It consists of 12 questions, which takes 5-15 minutes to administer regarding the frequency and duration of leisure activity. The total PASE score is calculated by multiplying either the time spent in each activity (hours per week) or participation in an activity. The overall scores ranges' from 0-400. Mean scores have been established in the general population for older adults, with the mean score being 102.9 (SD 64.1) and the median score being 90 (Washburn et al., 1993). Age and gender specific mean scores have been investigated with men aged between 65-69 scoring 144.3 (SD 58.6), 70-75 scoring 102.4 (SD 53.7) and 76-100 scoring 101.8 (SD 45.7). Furthermore, women score slightly less than men do, with women aged between 65-69 scoring 112.7 (SD 64.2), 70-75 scoring 89.1 (SD 55.5) and 76-100 scoring 62.3 (SD 50.7) (Washburn et al., 1993). Washburn et al. (1993) further reported excellent test-retest reliability of the PASE over a 3-7 week interval (0.75) in an elderly population and 0.77 for hip OA. In addition, the minimal detectable change for the PASE in participants with hip OA has been developed with light intensity physical activity being 35 points difference, moderate intensity physical activity being 28 points, vigorous physical activity being

10 points and a total PASE score of 87 points (Svege et al, 2012). Incidentally, the PASE has adequate correlation with the 6-minute walk test (0.35) and knee strength (0.41) (Martin et al., 1999). Critical analysis of the PASE highlights that much of the research has been completed on the elderly population (65 years +) and it has been demonstrated that it cannot predict physical health measures such as cardiovascular fitness and flexibility (Logan et al., 2013). However, positive correlations with waist circumference have been reported, in which the questionnaire could be utilised to engage with individuals to become active (Logan et al., 2013).

2.6.13.6. Knee injury and Osteoarthritis Outcome Score (KOOS)

The Knee injury and Osteoarthritis Outcome Score (KOOS) is a valid, highly reliable, and responsive for evaluating changes after OA interventions (Roos et al., 1998) including younger sufferers (French et al., 2011; Roos & Toksvig-Larsen, 2003). Incidentally, this is a questionnaire that consists of 42 questions covering Pain; Symptoms; Function in Daily Living Function in Sport and Recreation and Knee-Related Quality of Life, with zero highlighting extreme problems and 100 no problems. Following this, the score is then normalised to a 0-100 scale with the higher score being better. It roughly takes 10 minutes to administer. Specific mean measurements over the 5 subscales for individuals awaiting a total knee replacement show that ADL's has a mean score of 58.33 (SD 2.41), symptoms 48.08 (SD 2.64), sport/recreation 18.72 (SD 3.42), quality of life 26.12 (SD 2.98) and pain 48.22 (SD 2.63) (Stevens- Lapsley et al., 2012). In addition, the minimal detectable changes across the subscales show 13.4 for pain, 15.5 for symptoms, 15.4 for ADL's, 19.6 for sport/recreation and 21 for quality of life (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008; Roos & Toksvig-Larsen, 2003). However, Roos & Toksvig-Larsen. (2003) suggest a minimal perceptible change of 8-10 points. Clinical changes for symptom changes range from 1 to 21, for pain 3.1 to 16; for ADL's 0.9 to 23.5; for sport/recreation 0.5 to 12.2 and for quality of life 5.1 to 13.2 (Thorstensson et al., 2005; Henriksen et al., 2014; Salacinski et al., 2012; McQuade & de Oliveria, 2011; Wang et al., 2011; Lund et al., 2008). Clearly, a wide variety of changes have been researched. Furthermore, the KOOS has a test-retest reliability ranging from 0.8- 0.94 for knee OA (Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008) and may be even more responsive to change compared the WOMAC questionnaire (Roos & Toksvig-

Larsen, 2003; Roos et al., 1998). However, a disadvantage regarding the KOOS is the amount of items asked (42) in comparison to the WOMAC (24), which could be problematic if used alongside other outcome measures (Roos & Toksvig-Larsen, 2003). Also, construct validity and reliability for the KOOS sport and recreation is lower in comparison to the other subscales (Peer & Lane, 2013).

2.6.13.7 Visual Analogue Scale (VAS)

The visual analogue scale (VAS) is a horizontal line, 10 centimetres in length, with word descriptors anchored below the line and is widely used in a diverse setting for the measurements of pain including knee OA (Pham et al., 2003). A higher score in the VAS indicates greater pain with severe pain scores categorised between 75-100 millimetres, moderate pain 45-74 millimetres, mild pain 5-44 millimetres and no pain 0-4 millimetres (Jensen et al., 2003). The minimal detectable change for the VAS ranges from 1.1 centimetre change (Wolfe & Michaud, 2007) for rheumatoid arthritis to 1.37 centimetre change for rotator cuff injuries (Tashjian et al., 2009), with the validity being reported between 0.71 -0.78. It is simple, quick, easy to use and a reliable measurement to use for adult pain (Bijur et al., 2001).

2.6.13.8 Borg scale for rating of perceived exertion

Physical activity intensity level will be measured using the modified Borg scale for rating of perceived exertion. Perceived exertion is how demanding you feel like your body is working during an activity. It is a subjective measurement with the scale ranging from 6 to 20, with 6 meaning no exertion at all and 20 means maximal exertion (Borg, 1998) with moderate activity being reported between12 to 14 (Borg, 1998). A high correlation between the Borg scale and heart rate exists, and can provide a good estimate of actual heart rate during exercise (Borg, 1998) with validity between 0.80-0.90 (Chen et al., 2002).

2.6.13.9. ActivPAL™

Recommendations for best practice suggest activity monitoring should be objectively monitored (Matthews et al., 2013) with limited research being available on the variability of physical activity and sedentary behaviour using the activPAL[™] (Edwardson et al., 2016). Accelerometers have been used in populations with OA

(Farr et al., 2008, Freedson et al., 1998) and have high reliability between units (ICC= 0.97 to 0.99) (McClain et al., 2007). An activPAL[™] is a device that measures the postural aspect of inactivity such as postural transitions from sitting/lying, standing, walking, energy levels, steps per day, and cadence also being measured, with an accurate count rate beginning at 1.5 miles per hour (Grant et al., 2008). Activity monitors are recommended to be worn between 3 to 7-days, providing insights into week and weekend days (Tomkins-Lane & Haig, 2012; Matthews et al., 2012; Hart et al., 2011; Trost et al., 2005). Fewer days than 7-days can introduce bias due to the activity differences by day of the week and older individuals, who are likely to be retired (Kocherginsky et al., 2017). Accelerometer data compared with healthy individuals found that individuals with knee OA are physically less active (12.7 hours per day, compared to 13.6 hours), complete less walking bouts (154 to 215), complete less steps (4,402 to 6,943), complete less transitions (37 to 44) and have a reduced cadence (87 to 99) (Verlaan et al., 2015). Cadence parameters have been devised with low intensity categorised as less than 110 steps per minute and high intensity greater than 110 steps per minute (Hankinson et al., 2013). Most adults aged 60-79 typically walk 2.5 miles per hour (Bohannon, 2007) which equates to approximately 100 steps per minute (Tudor- Locke et al., 2009). Activity levels using an activPAL[™] have been utilised with sedentary behaviour being classified as less than 3,000 steps per day, with further parameters being classified as low activity (3,000 to 7,499 steps per day), somewhat active (7,500 to 9,999 steps per day), active (10,000 to 12,499 steps per day) and greater than 12,500 being highly active (Hills et al., 2014). Gender differences in individuals with knee OA whilst using an activPAL[™] have been reported with women completing more transitions (51.08 SD 16.82 compared to 50.53 SD 15.80) and remaining vertical than men (3.50 SD 1.80) compared to 3.32 SD 1.70). Although men complete more steps (5,086 SD 2,905 compared to 4,544 SD 2,725) and use more energy (32.51 SD 1.25 compared to 32.33 SD 1.24) (Tonelli et al., 2011). Finally, monitoring steps are motivational and may facilitate behaviour change, as they are measured easily and understandable to the layperson (Bassett et al., 2017)

2.6.14. Gap in the literature

The prevalence of knee OA is expected to increase by 50% over the next twenty years due to an ageing population, obesity and societal trends such as lack of activity (Hunter, 2011). Exercise is recommended as core treatment for individuals diagnosed with knee OA (NICE, 2014; McAlindon et al., 2014; Fernandes et al., 2013; Richmond et al., 2010; Mazieres et al., 2008) due to the positive effects on pain, function and activities of daily living (Li et al., 2016; Wang et al., 2016; Brenneman et al., 2015; Henriksen et al., 2014; Escalante et al., 2010; Fransen & McConnell, 2008; Lund et al., 2008). With only 5% of individuals with knee OA reaching the recommended levels of exercise (Craig et al., 2009) an understanding on how psychological and functional relationships work which may provide a more comprehensive rehabilitation programme for individuals with knee OA. Only one recent study investigated the effects of exercise on kinesiophobia (Tackacs et al., 2017), with positive effects post-exercise programme. However, the brief fear of movement scale questionnaire was used instead of the recommended questionnaire for kinesiophobia, which is the TSK (Lundberg et al., 2011). Furthermore, kinesiophobia was measured pre- and post- intervention. This study aims to investigate the changes in kinesiophobia throughout a physiotherapy exercise programme using the TSK at baseline, session 4, session 8 and 6-weeks after the exercise programme. Further novelty of the study will highlight the changes in physical activity in individuals with knee OA. Physical activity behaviour was measured both subjectively using the PASE questionnaire and objectively using an activPAL[™] activity monitor and data was used to correlate outcomes from the PASE questionnaire, as this would be clinically cheaper to administer in the NHS. In addition, data from the activPAL[™] provided detailed data such as upright time, sedentary time, energy expenditure, stepping, and cadence on the health behaviour of individuals with knee OA. Intensity of the exercise programme using the Borg scale, aerobic fitness using the 6MWT, muscle strength using the 30-second chair stand test and dynamic balance using the Y balance test was utilised to review the functional relationships during and after the exercise programme such as muscle strength, aerobic fitness, and balance. Physiotherapy research has been greatly influenced by the biomedical model of health using quantitative methodology (Hutchinson, 2004). Following the exercise programme, a content analytical

approach was used to listen to the participant's voice by completing a short set of standard questions, which was written so that the patient's voice can be heard and themes extracted from the answers. Content analysis can incorporate text into the research question (Anderson et al., 2001) with the researcher extracting specific themes or ideas to investigate this as the main aspect of analysis (Henri, 1992).

This thesis aims to determine what effects a lower limb exercise programme has on kinesiophobia, balance, pain, and activity, with the desired outcome highlighting that a reduction in pain with exercise will also reduce kinesiophobia, and allow individuals to individually self- manage their symptoms without a fear of movement.

2.6.15. Primary Research Question

 To determine whether kinesiophobia scores change following a structured supervised lower limb exercise programme for knee osteoarthritis delivered in a routine NHS physiotherapy setting.

Null Hypothesis- A structured supervised lower limb exercise programme does not reduce kinesiophobia scores in individuals diagnosed with knee OA.

2.6.16. Secondary Outcome Measures

 To determine whether pain using the visual analogue scale (VAS) and KOOS, function, sport and recreation, activities of daily living and symptoms change following a structured supervised lower limb exercise programme for knee osteoarthritis delivered in a routine NHS physiotherapy setting.

Null Hypothesis- A structured supervised lower limb exercise programme will not increase function, sport and recreation, activities of daily living and reduce pain and symptoms.

 To determine whether functional unilateral limb muscle strength changes using the Y balance test following a structured supervised lower limb exercise programme for knee osteoarthritis delivered in a routine NHS physiotherapy setting. **Null Hypothesis-** A structured supervised lower limb exercise programme will not does not increase functional unilateral limb muscle strength in individuals diagnosed with knee OA.

 To determine whether physical activity changes using the PASE questionnaire and an activPAL[™] monitor following a structured supervised lower limb exercise programme for knee osteoarthritis delivered in a routine NHS physiotherapy setting.

Null Hypothesis- A structured supervised lower limb exercise programme will not increase physical activity in individuals diagnosed with knee OA.

- To determine whether kinesiophobia score changes are correlated to changes in pain and physical activity.
- To determine whether the PASE questionnaire is correlated to an an activPAL[™] monitor.
- To determine the intensity of exertion during a structured supervised lower limb exercise programme for knee osteoarthritis delivered in a routine NHS physiotherapy setting using the Borg scale.
- To determine key factors that individuals think about exercise as an intervention using a semi- structured interview.

CHAPTER THREE METHODS

3.1. Research Environment

The assessment and treatment work was completed in the Physiotherapy Department within Leigh Health Centre. The chief investigator, Jimmy Molyneux is a specialist musculoskeletal physiotherapist and routinely uses exercises as part of his treatments. The Physiotherapy Department is situated in Leigh Health Centre, The Avenue, Leigh, WN7 1HS.

3.2. Ethics

Legal requirements state that no research should commence or participants recruited to a clinical trial until there is a favourable opinion from a research ethics committee (Good Clinical Practice Guidelines, 1997). High quality information with integrity must be included, which covers every aspect of the research process (Long & Fallon, 2007). Seeking informed consent (Department of Health, 2009), avoiding harm (Chartered Society of Physiotherapy, 2011), respecting anonymity and confidentiality for those who are taking part (Grinyer, 2002) to ensure that participation is voluntary without any conflict of interest (Department of Health, 2009). Ethical approval was approved by the University of Salford (HSCR 15/80) on 30th October 2015 (Appendix 1). A proportionate review for ethical approval for the study was sought from the South West Cornwall and Plymouth Research and Ethics committee. Amendments to the patient information sheet and the written informed consent forms was revised to allow the participants to understand what they were consenting to. Resubmission was completed and South West Cornwall and Plymouth Research and Ethics committee granted ethical approval on the 8th February 2016 (Appendix 2). All research management and governance was in place from Bridgewater Community Healthcare Foundation Trust before commencement of the study (Appendix 3). Strict eligibility criteria minimised any potential risks with the exercise class being clinically accepted as normal care. Therefore, subjects did not incur any further risks or potential hazards from their inclusion in the study. Written informed consent was requested from all individuals

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who were eligible for inclusion into the study and a patient information sheet was issued with relevant contact details.

Individuals were informed that participation in the study was voluntary and that they were free to withdraw at any time, without giving any reason and without any medical care or legal right being affected. Individuals were given opportunities to ask any questions via telephone, email or face to face. Trial registration was completed on ClinicalTrials.gov (NCT02734342) and the template for intervention description and replication (TIDieR) guidelines was used to fully describe the study (Hoffman et al., 2014) (Appendix 16).

3.3. Participants

Experimental research requires strict application of standardised procedures to reduce systematic bias (Hicks, 1998), however this approach, whilst still being subject to potential selection bias would make it easier to argue the validity of study (Harris et al., 2006). Standardisation of practices such as inclusion/exclusion criteria, exercise sessions, assessment, and completion of physical tests were exerted to improve credibility and transferability (Winter, 2000). Validated and reliable outcome measures were used, with the application of standardised statistical tests also being used within the final analysis to provide positive epistemology and repeatability (Morgan & Harmon, 2001; Winter, 2000).

3.4. Inclusion Criteria

All individuals referred to physiotherapy were invited to participate who had a clinical diagnosis of knee OA using the American College of Rheumatology guidelines, which are 95% sensitive and 69% specific for the diagnosis of osteoarthritis (Altman et al., 1989). Individuals aged 45 and above were invited into the study (NICE, 2014) with specific clinical symptoms to include stiffness for less than thirty minutes; crepitus; bony tenderness; bony enlargement and no palpable joint warmth, individuals must elicit three of the six symptoms to be included in the study. Individuals who had a radiographic diagnosis were also included in the study, as x-rays are gold standard in the diagnosis of OA with a greater specificity (Bijlsma et al., 2011; Altman et al., 1989).

3.5. Exclusion criteria

Reasons for exclusion from the study included previous lower limb joint injection within three months; previous hip or knee joint replacement; any severe cognitive, cardio- respiratory, musculoskeletal or neurological diagnosis that prevents participants from exercising; insoles or braces and ligament instability. Individuals with a body mass index (BMI) over 40 had a choice of completing in the study or be signposted to the NHS weight management service, as per service specification. Other minor health related issues were reviewed prior to the commencement of the study to ensure safe practice.

3.6. Recruitment

Referrals to the physiotherapy department came from orthopaedic consultants, general practitioners, musculoskeletal clinical assessment unit, other allied health professionals such as podiatrists and self-referral. Once the referrals were received, a specialised physiotherapist triaged the referral and then the administration staff sent out appointment letters for an initial assessment (Appendix 12), with individuals contacting the department via telephone for an appointment time. Equally, if the individual walks into the department and requests an appointment, an appointment was issued. Individuals either choose to attend, decline the appointment or do not attend (DNA) without contact. Individuals who were deemed eligible were issued with the information leaflets and were encouraged to discuss their potential participation with a specialist physiotherapist and relatives/visitors. The individual's national health number was then passed to the chief investigator and the patient was given 24 hours to consent to be assessed for inclusion into the study. Individuals had the option to be included in the study, decline participation, and choose 1:1 treatment with a physiotherapist. After 24 hours, the chief investigator telephoned potential individuals to answer any further questions they may have. If they were willing to participate, an appointment was made available to suit the participant's needs. A written informed consent form was completed when they arrived for their appointment (Appendix 4) and was stored in the electronic patient record. Individuals who opted into the study had the option to opt out of the study at any time during the programme and consider other physiotherapeutic treatment options. Other forms of interventions during the study were not permitted such as the provision of injections or orthotics; on the other hand, analgesic and anti- inflammatory medication was permitted and documented. Due to economic reasons, the chief investigator assessed all the participants entering. No remuneration or expenses were issued to the individuals.

3.7. Sample size

Quantitative sampling is important so that the results of the study can be generalised back to the population (Marshall, 1996), therefore a power calculation was conducted to obtain a sample size. Using previous research on kinesiophobia using the tampa scale of kinesiophobia as an outcome measurement (Sanchez-Heran et al., 2016), the mean value of the TSK was 29.09 with a standard deviation of 7.78, and therefore a total number of 44 participants was required for the study to be statistically significant. An illustration of the calculation included a sample size of 80, statistical power of 0.95 and a type 1 error of 5% (Cohen, 1988). Incidentally the smallest detectable change for the TSK is 9.2 (Ostelo et al., 2007) and 13 being reported for the minimal clinical difference (George et al., 2006), both are for low back pain and 5.6 for chronic musculoskeletal conditions (Hapidou et al., 2012).

3.8. Procedures

A 60-minute initial assessment, which included range of movement and muscle strength of the hip, knee, and ankle, was completed. In participants with bilateral symptoms, the symptomatic knee was assessed. The chief investigator completed a full explanation of the study and the individual was opted in or out. Following written informed consent, study participants opted into the study and were issued with an educational arthritis research leaflet and a patient information sheet. The patient information sheet includes a brief description, contact telephone numbers (Appendix 5), and an advice sheet supported by the Chartered Society of Physiotherapy and the Arthritis Research Campaign (Appendix 6). Questionnaires and physical outcome measurements were also completed at this time and an activPAL[™] monitor

was attached to the right thigh. Participants were asked to attend eight exercise sessions within a group class environment that lasted for 1 hour and each individual was asked to dress in comfortable clothing and trainers. Participants attended the class, twice per week for four weeks. Clinical guidelines suggest two to three exercise sessions per week to attain a positive response in symptoms (Juhl et al., 2014; Roddy et al., 2005). Exercise is a standard intervention for knee osteoarthritis within the National Health Service. The exercise programme has been developed through clinical and research evidence. During the hour, participants completed a visual analogue scale (VAS) for pain prior to starting the class followed by completing a 5-minute warm up. The exercise class commenced with 14 exercises, which are specific to strengthening the lower limb and improve aerobic capacity. Participants recorded the number of repetitions and progression of exercises were patient led (Appendix 7). Each exercise was timed for 2-minutes with approximately 1-minute in between each exercise. After seven exercises, a 5-minute hydration break was completed. After each exercise class, a cool down was completed, with the participant completing a visual analogue scale (VAS) for pain and the Borg scale for patient specific maximal exertion. Participants were advised to have a recovery day after the class to prevent overloading (De Carlo & Armstrong, 2010). The group class operated from the physiotherapy department gymnasium in Leigh Health Centre, supervised by a specialist physiotherapist, who received three hours training by the chief investigator, which consisted of reviewing each exercise station, outcome measurements, and documentation. In addition to the training, the specialist physiotherapist did have the authority to alter the exercise programme as some exercises may be pain provoking than others and may potentially pose further risks such as falls. Both the chief investigator and specialist physiotherapist offered telephone support to any of the participants during department open times. Participants also received text message reminders the day before each exercise class to increase attendance, which is cost effective (Haynes et al., 2013) and has moderate supportive evidence (Gurol-Urganci et al., 2013). At the end of the allocated sessions, all participants were referred to a local health centre for further exercise, and issued with a six-week follow up assessment with the chief investigator. Six-weeks was chosen by the chief investigator due to time constraints within the physiotherapy department, a longer time lapse would be more beneficial to attain patient adherence. At six-weeks a 60-minute, routine physiotherapy objective

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assessment to re-assess range of movement and muscle strength of the hip, knee, and ankle was undertaken. In addition, an activPAL[™] physical activity monitor was placed on the right thigh by the chief investigator and continuously used for 7-days. Furthermore, a short set of questions that was recorded in written format took place to elicit if exercise has reduced the participants symptoms (Figure 4- Process Map).

3.9. Description of the exercise programme

The exercise programme included 14 specific lower limb exercises. Each exercise was timed for 2-minutes with approximately 1-minute in between each exercise. After seven exercises's a 5-minute hydration rest was incorporated. The information regarding the each exercise is as follows:

3.10 Warm up

5 minutes including marching on the spot; hamstring, quadriceps and calf stretches; lumbar spine side bends; pelvis rotations; thoracic rotations and shoulder circumduction

3.11. Exercises

Hip extension over plinth- participants recorded the number of repetitions in 1minute on each leg.

Treadmill- participants recorded the highest speed that they reach during the 2minutes.

Monster walks- participants stand inside a tubi-band and were advised to take 5 backward steps to increase the resistance. Once completed, the participants was advised to maintain the resistance and then march on the spot for 10 steps and then gradually step forward to reduce the resistance in the band. Participants recorded how many steps they have completed in 2-minutes.

Step ups with or without weights- participants recorded the number of step-ups in 1minute on each leg. Participants did use a 2-kilogram weight if they felt able.

Crab walking- participants were asked to step sideways whilst having a tubi- band around the ankles and to record how many steps are taken in 2-minutes.

Heel raises- participants recorded the number of repetitions. Exercise were completed slow and steady.

Wall squat with exercise ball- participants recorded the number of repetitions in 2minutes.

Trampette- participants recorded the number of repetitions of either marching on the spot or single leg hopping.

Exercise bike- participants recorded the resistance level they comfortably managed for 2-minutes.

Step machine- participants recorded the resistance level they comfortably managed for 2-minutes.

Cross-trainer- participants recorded the resistance level they comfortably managed for 2-minutes

Mini squats with exercise band around knee- participants recorded the number of repetitions in 2-minutes.

Tilt board- participants were asked to maintain their balance on both feet. If the exercise was too easy, participants completed single leg exercises. Participants recorded how many times they have lost balance.

Single leg balance with ball throwing- participants were asked to record the number of times that they lost balance in 1-minute on each leg.

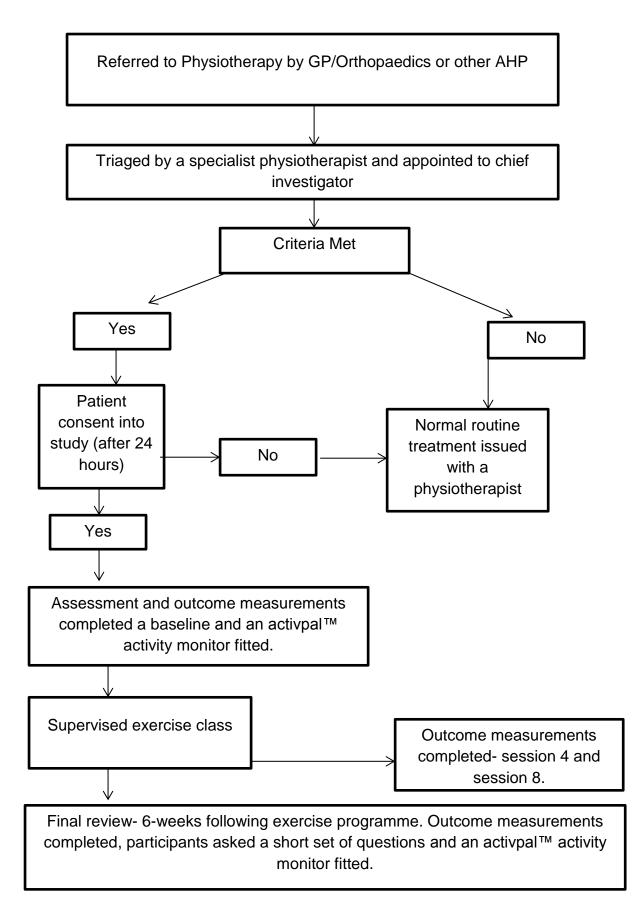


Figure 4. Process-Map

3.12. Procedures- Outcome measurements

3.12.1. Outcome Measures

An integral aspect of the study is the completion of outcome measurements, whereby eight were chosen specifically for the study. Participant's BMI was also measured, as this is a local service specific requirement and it may also allow sub classification at a later date. Participants completed three questionnaires, the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Appendix 8), Tampa Scale of Kinesiophobia (TSK) (Appendix 9) and the Physical activity scale for the elderly (PASE) (Appendix 10). Participants were also required to complete three physical tests, the Y balance test, 30-second chair stand test and 6-minute walk test. All testing was completed at baseline, session 4, session 8, and 6-weeks post-exercise intervention. Furthermore, participants were issued with an activPAL[™] activity monitor at baseline and 6-weeks post-exercise, so that physical activity can be monitored and should be worn continuously throughout the day for 7-days during waking hours.

During the exercise programme, it was essential that the healthcare practitioner and the patient monitored the pain response, as quite often overdosing with exercises can cause severe pain. Pain was measured using the visual analogue scale as it is simple and a reliable measurement to use (Bijur et al., 2001) and has been recommended for clinical trials for knee OA (Pham et al., 2003). Operationally a VAS is a horizontal line (Figure 5), 10 centimetres in length, with word descriptors anchored below the line, a 1.1 centimetre change is recommended as the minimal clinically significant difference (Wolfe & Michaud, 2007).

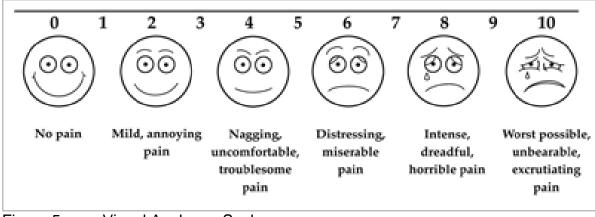


Figure 5 Visual Analogue Scale

Participants were asked to mark on the line the point that they feel represents their perception of their current pain. The score is then determined by measuring in millimetres from the left hand end of the line to the point that the patient marks.

Furthermore, physical activity intensity level were measured using the modified Borg scale for rating of perceived exertion .Perceived exertion is how demanding you feel like your body is working during an activity. It is a subjective measurement with the scale ranging from 6 to 20, where 6 means no exertion at all, 9 corresponds to very light activity, 13 corresponds to working some-what hard, a score of 17 means individuals will be working very hard and 20 means maximal exertion (Borg, 1998). Moderate activity being reported between 12 to 14 (Borg, 1998) (Figure 6). Participants were asked to rate how heavy and strenuous the exercise programme felt to them and not compare with others, this included all areas such as physical stress, effort and fatigue.

Rating of Perceived Exertion
Borg RPE Scale6
7Very, very lightHow you feel when lying in bed or
sitting in a chair relaxed.
Little or no effort.9
9
9
10
11Very lightLittle or no effort.10
11Fairly lightTarget range: How you should feel
with exercise or activity.12
13
14
15
16Somewhat hardHow you felt with the hardest work
you have ever done.17
19
20Very, very hard
Maximum exertionDon't work this hard!

Figure 6 Borg Scale

3.12.2. ActivPAL™

The activPAL[™] activity monitor (figure 7) was issued to monitor physical activity and should be worn continuously for 7-days during waking hours. It is a small monitor that is placed on the anterior aspect of the upper thigh and can determine body position, such as sitting, lying, upright positions and movements between these postures, stepping and stepping speed. The device was calibrated by the chief investigator via a USB connection with a windows compatible computer, so that the start times and end times can be assigned to improve consistency (device calibrated to start at 12 am the day of application and end 7-days after at 12 am). Following calibration, the activPAL[™] was covered with a waterproof dressing (figure 8) and mefix tape with an arrow highlighting placement position (figure 9) and then was attached by the principal investigator to the thigh by tegaderm tape (figure 10) and mefix tape (figure 11). Following this process, the activPAL[™] was placed on the right thigh, to standardise which leg the activPAL[™] is attached to. If the participant experienced any irritation from the adhesive dressing, the participant was advised to attach the activPAL[™] to the opposite leg. Participants were issued with an

activPAL[™] advice sheet and asked not to remove the activPAL[™] during the 7-days (Appendix 15). Subjects with less than 2-days of measurements due to device malfunction, device removal, or allergies were excluded from the activity data analysis (Tonelli et al., 2011). Data recorded by the activPAL[™] was downloaded using PAL technologies software (version 7.2.32), with activity being summarised over 24-hour periods in graphs and quantitative formats. Once downloaded, analysis included the total amount of time spent sedentary (sitting and lying), walking, upright positions, postural transitions (movements from seated positions to upright), cadence and energy expenditure.



Figure 7 activPAL™ monitor



Figure 8 activPAL[™] in waterproof dressing



Figure 9 activPAL[™] in mefix tape



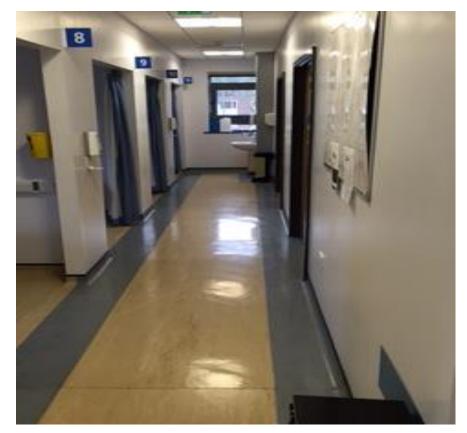
Figure 10 activPAL[™] fitted with tegaderm

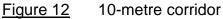


Figure 11 activPAL[™] attached with mefix

3.12.3. 6-minute walk test

The 6-minute walk test should take approximately 6-7 minutes to administer. It is important to standardise the track for clinical and research purposes, therefore a flat walking area within the physiotherapy department measuring 10 metres in length. Boundaries of the course and turn points were marked and highlighted to the participant by the chief investigator. At the end of each walk way a chair was available for resting. Participants were advised to wear comfortable footwear (e.g. trainers) during the test. Practice tests were not completed. The chief investigator was situated with a stop-watch at one end of the 10 metre course (figure 12) which was close enough to observe for any distress during testing. Resting periods were allowed but included in the time and participants were informed of timings at half way (3-minutes) and 1-minute to the end of the test. No verbal encouragement was given during the test.





3.12.4. Y balance test

Prior to completing the Y balance test (figure 13), bilateral leg lengths of each participant were measured, so that a normalised score can be calculated at the end of the test (Gribble & Hertel, 2003). Normalisation was completed by dividing each individual score by the participant's leg length and then multiplying by 100. Measurements were from the anterior superior iliac spine to the medial malleolus. To improve consistency, participants completed the test barefooted, and it involved standing with the toes just behind the clearly marked red starting line on an elevated footplate approximately 2.5 centimetres in height. Whilst maintaining a single leg stand participants were asked to push a rectangular block with the foot along the plastic tubing in each of the directions ANT, PM and PL. The PM and PL pipes are positioned 135 degrees from the ANT pipe with 45 degrees between the posterior pipes. Six practice trials were completed (3 practice trials on each limb), which decreases the learning effect without hindering the performance of the test

(Robinson & Gribble, 2008). The order of testing was completed to minimise fatigue by alternating standing limb, it commenced with left anterior (figure 14), right anterior, left posteromedial (figure 16), right posteromedial, left posterolateral (figure 15) and right posterolateral. Each reach distance was recorded by reading the distance the rectangular block has reached closest to the nearest half centimetre. Participants were not be allowed to touch the floor, rest his/her foot on the rectangular block, move the stance foot or remove hands from the hips during the test. Also, the test was invalid if the participants did not return to the starting position. The test took approximately 10-15 minutes to administer.

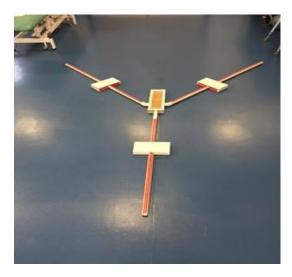


Figure 13 Y balance test

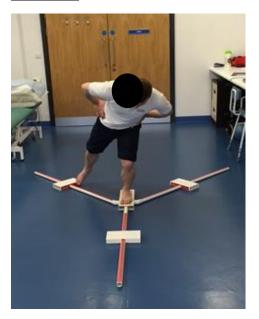


Figure 15 Y balance test- posterolateral

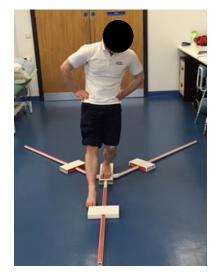


Figure 14 Y balance test- anterior reach



Figure 16 Y balance test- posteromedial

3.12.5. 30-second chair stand test

The aim of the test was to record the number of sit to stands in 30-seconds and took approximately 30-40 seconds to administer. Participants were advised to wear comfortable shoes during the test. Commencing the test, the participant sat on a chair with their arms crossed and held to the chest in a position that allows them to place their feet flat on the floor. The chair had a straight back without arms and measured 44 centimetres, the same chair was used for each individual participant test. The chief investigator demonstrated the test and then stood in close proximity to observe technique, to ensure that a full stand and a full sit was completed. A battery operated stopwatch was used to time the 30-seconds. A practice trial of one or two repetitions was encouraged. At the signal 'go' the participant raised to a full stand (body erect and straight) and then returned to the initial seated position (figure 17). The participant was encouraged to complete as many full stands as possible within the 30-seconds, however no verbal encouragement was given during the test.

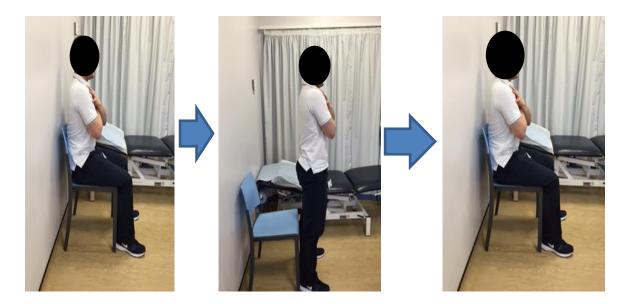


Figure 17 Sit to stand technique

3.12.6. Standard physiotherapy questions

Shared decision-making and using a patient centred approach is an important aspect in the assessment and management of OA (NICE, 2008). Furthermore, listening to individuals and understanding the barriers to change is essential to bridge the gap between evidence and patient care (De Bruijn & Rhodes, 2011), so that individuals can implement self-management techniques to improve and maintain their health (General Medical Council, 2014). Standard physiotherapy questions were used to issue the patient with the opportunity to discuss their care (NHS Constitution, 2012; NICE, 2008) and for the individuals to be open and honest about their experiences. The chief investigator asked all the questions and wrote the responses word for word down on a piece of paper (Appendix 11).

3.13. Timeline

	Baseline	1	2	3	4	5	6	7	8	Post
TSK	✓				✓				✓	√
KOOS	✓				~				~	~
Y Test	✓				~				~	√
PASE	✓				✓				✓	√
30-second	✓				√				√	√
chair test										
6MWT	~				~				~	√
VAS	~	~	~	~	~	~	~	~	~	√
Borg		~	~	~	~	~	~	~	~	
ActivPAL™	~									~

<u>Table 4</u> Timeline for outcome measurements

3.14. Data Analysis

Demographic information such as age, height, weight, and body mass were stored in the local NHS electronic patient record. Analysis of this data included mean range, median range, and standard deviation. Each outcome measurement was recorded and analysed at baseline, session 4, session 8, and 6-weeks post-exercise class using mean, median, and standard deviations. Specific statistical tests using Statistical Package for Social Sciences (SPSS) was used. Data was reviewed for normality prior to data analysis with the Kolmogorov-Smirnov tests being completed. Normal distribution was highlighted in the KOOS, PASE, 6MWT, 30-second chair stand, and Y balance test, therefore a repeated measure of analysis of variance (ANOVA) was completed to investigate the mean variability within the participant's scores (parametric method). Normal distribution was not found in the TSK; therefore, a Friedman test was completed with a post hoc Wilcoxon sign ranks test, also being used. Data collected from the activPAL[™] was analysed using a pre- post intervention test, with the paired t-test being completed. In addition, confidence interval adjustments using a Bonferroni correction was applied to all the data to reduce a type one error with a significance level being set at 0.05 (Armstrong, 2014). In addition, further analysis was completed to investigate the null hypothesis using correlational analysis, the Pearson correlation coefficient for parametric data was completed to analyse the PASE and activPAL[™] standing, PASE and activPAL[™] stepping, PASE and activPAL[™] walking, and PASE and KOOS pain. Whereas, the Spearman's correlation coefficient for non-parametric data was completed for the PASE and TSK, and KOOS pain and TSK, with -1 highlighting a perfect negative correlation and +1 highlighting a perfect positive correlation (Rumsey, 2003; Portney & Watkins, 2000; Altman, 1990). Qualitative data analysis was reviewed from the semi-structured interviews using content analysis, which will be fully transcribed, reviewed and placed into themes after the interview had taken place.

CHAPTER FOUR RESULTS

This chapter will detail the results of the study whereby the effect of an exercise programme in individuals with knee OA was assessed. Demographic information such as age, height, weight, and body mass was stored in the local NHS electronic patient record. Analysis of this data will include mean range, median range, standard deviation (SD) and interquartile range (IQR). Each outcome measurement was recorded and analysed at baseline, session 4, session 8 and 6-weeks post-exercise programme using mean, median, and standard deviations. Recruitment commenced in March 2016 and ended in January 2017.

4.1 Baseline Characteristics

Ninety- five individuals diagnosed with knee OA were invited into the study. Thirtyone individuals did not consent to complete the exercise programme and were reappointed with another physiotherapist. Ten individuals completed the 60-minute assessment and then e-mailed and telephoned the chief investigator directly after to decline participation. Fifty- four individuals with knee OA participated in the study, 27 males and 27 females with a mean age of 63.35 (SD 8.1) years; age range 47-79 years; mean height 1.64 (SD 0.34) metres; height range 1.49-1.91 metres; mean mass 78.37 (SD 21.22) kilograms; mass range 57.15-120.6 kilograms; mean body mass index 27.12 (SD 4.08). Twenty- one participants (38.9%) were employed and thirty-three (61.1%) were non-workers. Thirty-five (64.8%) referrals into the study came from physiotherapists, fourteen (25.9%) from GP's and five (9.3%) from the musculoskeletal clinical assessment service.

4.2 Knee OA Criteria

All participants were over 45 years of age, 17 participants (31.5%) diagnosed with grade 2 Kellgren and Lawrence scale (KL); 19 participants (35.2%) diagnosed with grade 3 KL; 12 participants (22.2%) diagnosed with grade 4 KL, all with medial compartment OA, and six participants diagnosed using the American College of Rheumatology criteria (11.1%).

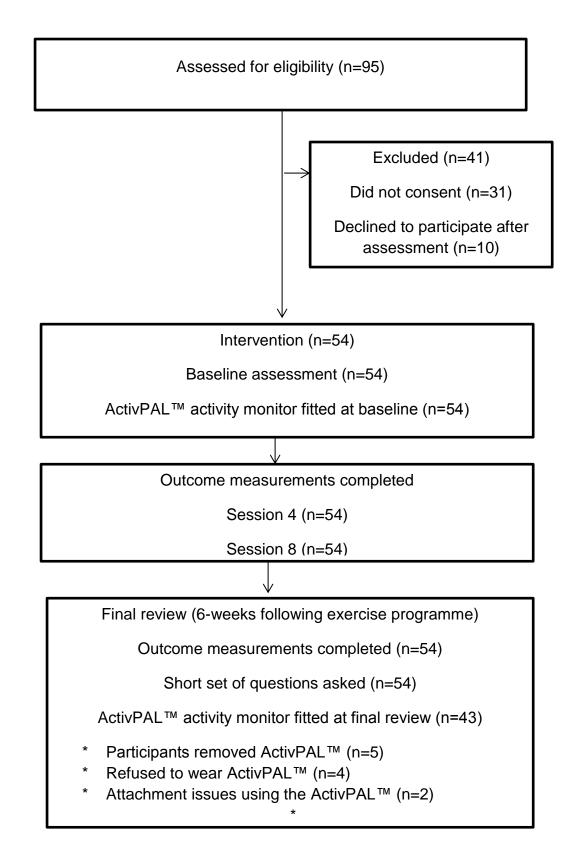


Figure 18. Participant flow diagram

4.3 Outcome Measurements

4.3.1 Tampa Scale of Kinesiophobia

The median, IQR, median points and percentage difference between sessions, p-values, and changes in kinesiophobia scores are shown in table 5. Table 5 and figure 19 show the median points scored after completing the TSK at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Twenty-eight (52%) participants recorded high kinesiophobia scores at baseline (37 and over), 19 (35%), at session 4, 13 (24%) at session 8, and 14 (25.9%) 6-weeks post-exercise programme. Of the 14 participants who scored highly on the TSK after 6-weeks post-exercise programme, 12 scored highly at baseline and remained high throughout the exercise programme. Two participants scored low at baseline, but had a re-occurrence of their symptoms at the 6-week follow-up, which increased kinesiophoba scores from 30 points to 39 points, and 29 points to 37 points. Those participants whose kinesiophobia remained high had a mean age 59.71 years, mean body mass index of 28.89 and five had KL grade 3, four had KL grade 4, two had grade 2 and three diagnosed through the ACR criteria. In addition, the mean pre KOOS pain levels of 46.69 and post mean KOOS pain levels of 45.88 was recorded for the individuals with higher kinesiophobia scores. Participants baseline scores recorded a median of 37 (IQR 9.25), at session 4 a median score of 33.5 (IQR 11), at session 8 a median score of 32 (IQR 8.5) and 6-weeks post-exercise programme, a median score of 33 (IQR 12).

A Friedman test was conducted to evaluate the null hypothesis that there would be no significant changes in kinesiophobia scores following the exercise programme (N=54). The results of the Friedman test indicated a significant time effect, Chi-Square = 26.39, df = 3, p<0.001. Secondary analysis using the Wilcoxon signed ranks test data indicated a non- significant result from baseline to session 4 (p= 0.052), however from baseline to session 8 (p= 0.002), baseline to 6-week postexercise programme (p<0.001) was statistically significant.

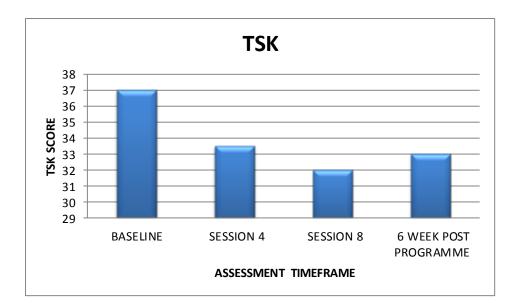


Figure 19 Median TSK

Table 5 Median TSK (* Significant value)

Timeframe	TSK score	Change	Percentage	P-value from
	(IQR)	between	of change	baseline
		sessions	between	
			sessions	
Baseline	37 (IQR 9.25)			
Session 4	33.5 (IQR 11)	-4.5 points	-9.46%	0.052
Session 8	32 (IQR 8.5)	-1.5 points	-4.48%	0.002*
6-week post	33 (IQR 12)	+1 points	+3.13	<0.001*
Total Change	4 points		-10.81%	

4.3.2. Tampa Scale of Kinesiophobia-Activity Avoidance

The median, IQR, median points and percentage difference between sessions and changes in activity avoidance using questions 1, 2, 10, 13, 15, and 17 from the TSK are shown in table 6. Table 6 and figure 20 show the median points scored after completing the TSK at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a median of 9.5 (IQR 3.25), at session 4 a median score of 9 (IQR 4.25), at session 8 a median score of 8.5 (IQR 3.25) and 6-weeks post-exercise programme a median score of 8 (IQR 4). Forty-two of the participant scores reduced after the 6-weeks after the exercise programme (77.8%), two participant's scores remained the same (3.7%), and ten of the participant's scores increased (18.52%).

A Friedman test was conducted to evaluate the null hypothesis that there would be no significant changes in activity avoidance following the exercise programme (N=54). The results of the Friedman test indicated a non-significant time effect, Chi-Square =7.29, df = 3, p= 0.063.

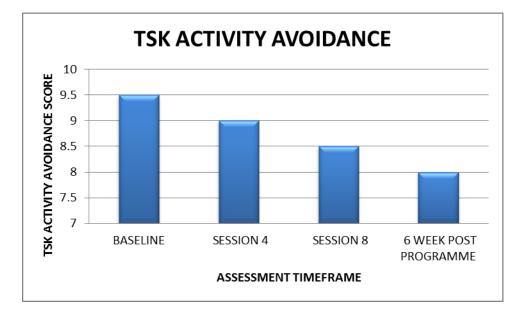


Figure 20 Median TSK Activity Avoidance

Table 6Median TSK Activity Avoidance

Timeframe	TSK score (IQR)	Change between	Percentage of
		sessions	change between
			sessions
Baseline	9.5 (IQR 3.25)		
Session 4	9 (IQR 4.25)	-0.5	-5.26%
Session 8	8.5 (IQR 3.25)	-0.5	-5.56%
6-week post	8 (IQR 4)	-0.5	-5.88%
Total change	1.5 points		-15.79%

4.3.3. Tampa Scale of Kinesiophobia- Somatic Focus

The median, IQR, median points and percentage difference between sessions, p-values, and changes in somatic focus using questions 3,5,6,7, and 11 from the TSK are shown in table 7. Table 7 and figure 21 show the median points scored after completing the TSK at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a median of 14 (IQR 5), at session 4 a median score of 14 (IQR 4), at session 8 a median score of 13 (IQR 4.25) and 6-weeks postexercise programme a median score of 12 (IQR 5). Thirty-one of the participant scores reduced after the 6-weeks after the exercise programme (57.41%), nine participant's scores remained the same (16.6%), and fourteen of the participant's scores increased (25.9%).

A Friedman test was conducted to evaluate the null hypothesis (N=54). The results of the Friedman test indicated significant time effects, Chi-Square = 22.81, df = 3, p<0.001. Wilcoxon signed ranks test data indicated significant results from baseline to session 4 (p= 0.048), baseline to session 8 (p= 0.002) and baseline to 6-weeks post-exercise programme p<0.001.

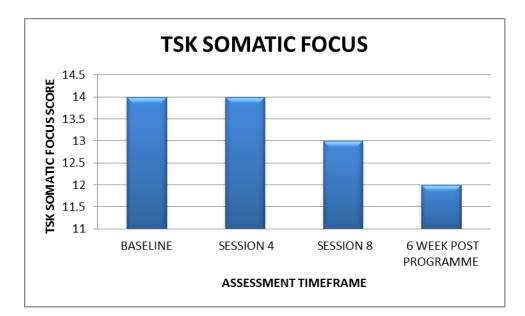


Figure 21 Median TSK Somatic Focus

<u>Table 7</u> Median TSK Somatic Focus (* Significant value)

Timeframe	TSK score	Change	Percentage	P-value from
	(IQR)	between	of change	baseline
		sessions	between	
			sessions	
Baseline	14 (IQR 5)			
Session 4	14 (IQR 4)	0	0%	0.048*
Session 8	13 (IQR 4.25)	-1	-7.14%	0.03*
6-week post	12 (IQR 5)	-1	-7.69%	<0.001*
Total change	2		-14.29%	

4.3.4. KOOS

Participants baseline total KOOS score recorded a mean 35.03 (SD 11.46), at session 4 a mean score of 49.34 (SD 10.24), at session 8 a mean score of 46.08 (SD 9.79) and 6-weeks post-exercise programme a mean score of 56.48 (SD 11.76).

4.3.5. KOOS Symptoms

The mean, SD, mean difference between sessions, p-values, and changes in KOOS symptoms are shown in table 8. Table 8 and figure 22 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline KOOS symptoms score recorded a mean of 41.67 (SD 18.78), at session 4 a mean score of 49.34 (SD 14.09), at session 8 a mean score of 49.03 (SD 20.29), and 6-weeks post-exercise programme a mean score of 56.48 (SD 19.19).

Between session analysis from baseline to session 4, 40 (74.1%) participants improved, 8 (14.8%) participants did not improve, and 6 (11.1%) remained the same. Between sessions 4 to session 8, 32 (59.26%) participants improved, 17 (31.48%) participants did not improve, and 5 (9.25%) participants remained the same. Between session 8 to 6-weeks post- exercise programme, 32 (59.26%) participants improved, 12 (22.22%) participants did not improve, and 10 (18.52%) participants remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.59, F (3, 51) = 11.73, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001), from baseline to session 8 (p=0.05) and baseline to 6-weeks post-exercise programme (p<0.001).

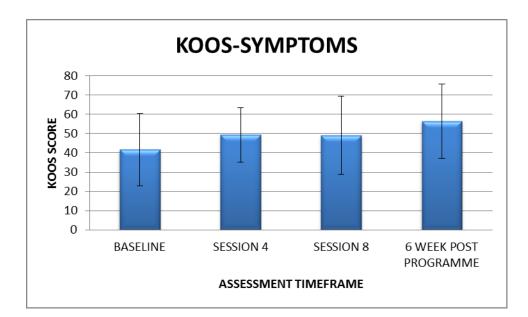


Figure 22 Mean KOOS symptoms

Table 8Mean KOOS symptoms (* Significant value)

Timeframe	Mean KOOS	Change between	P-value from
	symptoms (SD)	sessions	baseline
Baseline	41.67 (18.78)		
Session 4	49.34 (14.09)	+7.67	<0.001*
Session 8	49.03 (20.29)	-0.31	0.05*
6-week post	56.48 (19.19)	+7.45	<0.001*
Total change	14.81	·	

4.3.6. KOOS Pain

The mean, SD, mean difference between sessions, p-values, and changes in KOOS pain are shown in table 9. Table 9 and figure 23 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline KOOS pain score recorded a mean of 41.06, (SD 17.46) at session 4 a mean score of 47.79 (SD 14.83), at session 8 a mean score of 51.18

(SD 21.82), and 6-weeks post-exercise programme a mean score of 56.53 (SD 22.21).

Between session analysis from baseline to session 4, 32 (59.26%) participants improved, 17 (31.48%) participants did not improve, and 5 (9.25%) remained the same. Between sessions 4 to session 8, 32 (59.26%) participants improved, 19 (35.19%) participants did not improve, and 3 (5.6%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 29 (53.7%) participants improved, 17 (31.48%) participants did not improve, and 8 (14.8%) participants remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.72, F (3, 51) = 6.58, p= 0.001. Pairwise comparison of the data indicated a non-significant result from baseline to session 4 (p= 0.06), however from baseline to session 8 (p=0.009) and baseline to 6-weeks post-exercise programme (p<0.001) was statistically significant.

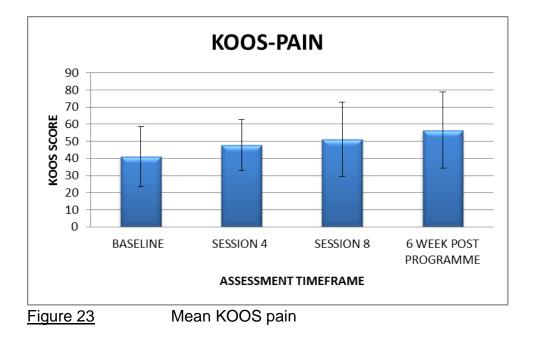


Table 9Mean KOOS pain (* Significant value)

Timeframe	Mean KOOS pain	Change between	P-value from
	(SD)	sessions	baseline
Baseline	41.06 (17.46)		
Session 4	47.79 (14.83)	+6.73	0.06
Session 8	51.18 (21.82)	+3.39	0.009*
6-week post	56.53 (22.21)	+5.35	<0.001*
Total change	15.47		

4.3.7. KOOS Activities of daily living

The mean, SD, mean difference between sessions, p-values, and changes in KOOS activities of daily living are shown in table 10. Table 10 and figure 24 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline KOOS activities of daily living score recorded a mean of 46.9 (SD 21.62), at session 4 a mean score of 54.33 (SD 18.04), at session 8 a mean score of 57.44 (SD 25.31), and 6-weeks post-exercise programme a mean score of 61.39 (SD 20.97).

Between session analysis from baseline to session 4, 30 (55.6%) participants improved, 20 (37.03%) participants did not improve, and 4 (7.4%) remained the same. Between sessions 4 to session 8, 35 (64.18%) participants improved, 16 (29.63%) participants did not improve, and 3 (5.6%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 26 (48.15%) participants improved, 26 (48.15%) participants did not improve, and 2 (3.7%) participants remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.74, F (3, 51) = 5.89, p= 0.002. Pairwise comparison of the data indicated a non-significant result from baseline to session 4 (p= 0.09),

however from baseline to session 8 (p=0.038) and baseline to 6-weeks postexercise programme (p=0.01) this was statistically significant.

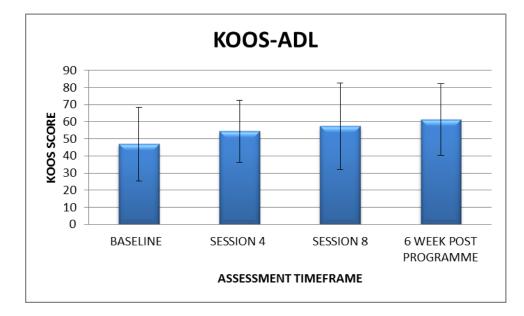


Figure 24 Mean KOOS Activities of daily living

Table 10Mean KOOS Activities of daily living (* Significant value)

Timeframe	Mean KOOS	Change between	P-value from
	Activities of daily	sessions	baseline
	living (SD)		
Baseline	46.9 (21.62)		
Session 4	54.83 (18.04)	+7.93	0.09
Session 8	57.44 (25.31)	+2.61	0.038*
6-week post	61.39 (20.97)	+3.95	0.01*
Total change	14.49		

4.3.8. KOOS Sport and recreation

The mean, SD, mean difference between sessions, p-values, and changes in KOOS sport and recreation are shown in table 11. Table 11 and figure 25 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme

Participants baseline KOOS sport and recreation score recorded a mean of 21.39 (SD 29.71), at session 4 a mean score of 29.07 (SD 21.06), at session 8 a mean score of 32.41 (SD 26.22), and 6-weeks post-exercise programme a mean score of 32.94 (SD 27.13).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.8, F (3, 51) = 4.14, p= 0.011. Pairwise comparison of the data indicated a non-significant result from baseline to session 4 (p= 0.25), however from baseline to session 8 (p=0.010) and baseline to 6-weeks post-exercise programme (p= 0.029) was statistically significant.

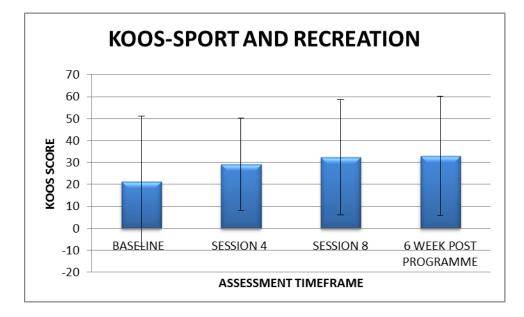


Figure 25 Mean KOOS Sport and recreation

Table 11Mean KOOS Sport and recreation (* Significant value)

Timeframe	Mean KOOS Sport	Change between	P-value from
	and recreation (SD)	sessions	baseline
Baseline	21.89 (29.71)		
Session 4	29.07 (21.06)	+7.18	0.25
Session 8	32.41 (26.22)	+3.34	0.010*
6-week post	32.94 (27.13)	+0.53	0.029*
Total change	11.05		

4.3.9. KOOS Quality of Life

The mean, SD, mean difference between sessions, p-values, and changes in KOOS quality of life are shown in table 12. Table 12 and figure 26 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme

Participants baseline KOOS quality of life score recorded a mean of 24.15 (SD 19.39), at session 4 a mean score of 37.06 (SD 17.74), at session 8 a mean score of 40.33 (SD 24.21), and 6-weeks post -exercise programme a mean score of 43.08 (SD 23.47). Between session analysis from baseline to session 4, 36 (66.7%) participants improved, 7 (12.96%) participants did not improve, and 11 (20.37%) remained the same. Between sessions 4 to session 8, 29 (53.7%) participants improved, 16 (29.63%) participants did not improve, and 9 (16.7%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 30 (55.6%) participants improved, 20 (37.04%) participants did not improve, and 4 (7.41%) participants remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.5, F (3, 51) = 16.94, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001),

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baseline to session 8 (p<0.001) and baseline to 6-weeks post-exercise programme (p<0.001).

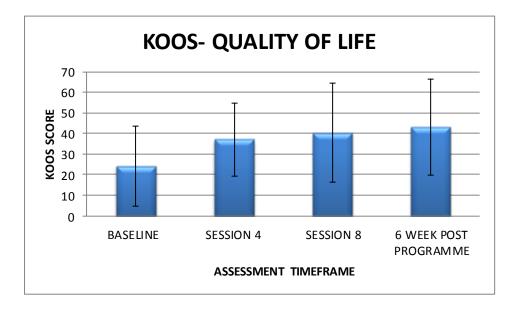


Figure 26 Mean KOOS Quality of Life

Table 12Mean KOOS Quality of Life (* Significant value)

Timeframe	Mean KOOS	Change between	P-value from
	Quality of Life (SD)	sessions	baseline
Baseline	24.15 (19.39)		
Session 4	37.06 (17.74)	+12.91	<0.001*
Session 8	40.33 (24.21)	+3.27	<0.001*
6-week post	43.08 (23.47)	+2.75	<0.001*
Total change	18.93		

4.3.10. Y balance test

The Y balance test gives information about the individuals balance capabilities, the raw score data from the Y balance test was normalised, dividing by the participant's leg length and multiplying by 100, this gives a unit of percentage of limb length.

4.3.11. Y balance test- affected limb anterior directional reach

The mean, SD, mean and percentage difference between sessions, p-values, and changes in the Y balance scores for the anterior directional reach for the affected limb and contralateral limb side are shown in table 13 and table 14. Figure 27 and 28 show the mean centimetres scored whilst completing the Y balance test at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a mean of 46.96 centimetres (SD 11.56) for the affected anterior reach, at session 4 a mean score of 52.19 centimetres (SD 11.85), at session 8 a mean score of 54.02 centimetres (SD 16.64), and 6-weeks post-exercise programme a mean score of 55.98 centimetres (SD 14.94).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.65, F (3, 51) = 9.33, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001), baseline to session 8 (p= 0.006) and baseline to 6-weeks post-exercise programme (p<0.001).

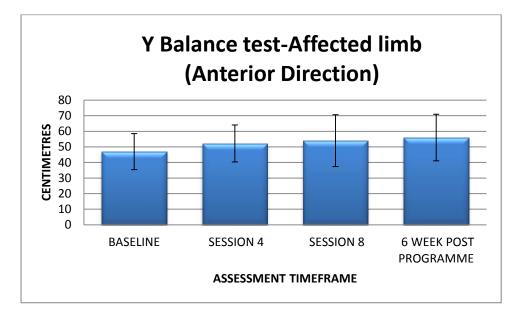


Figure 27 Y balance test- affected limb anterior directional reach

4.3.12. Y balance test- contralateral limb anterior directional reach

Participants baseline score recorded a mean of 48.11 centimetres (SD 11.25) for the contralateral limb anterior reach, at session 4 a mean score of 54.95 centimetres (SD 10.39), at session 8 a mean score of 54.52 centimetres (SD 16.51), and 6-weeks post-exercise programme a mean score of 55.99 centimetres (SD 14.69).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.63, F (3, 51) = 10.16, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001), baseline to session 8 (p=0.012) and baseline to 6-weeks post-exercise programme p<0.001.

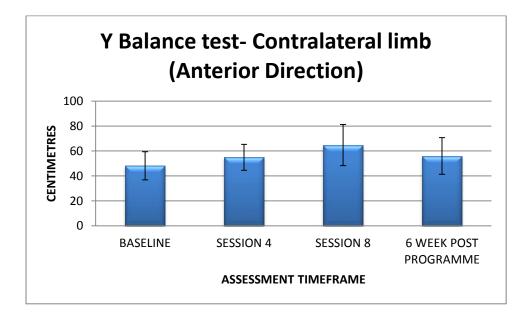


Figure 28 Mean Y balance test- contralateral limb anterior directional reach

<u>Table 13</u> Y balance test- anterior directional reach. Asymmetry change.

(* Significant value).

Timeframe	Affected	P value From baseline	Contralateral	P value From baseline	Change (<4cm)
Baseline	46.96		48.11		1.16
Session 4	52.19	<0.001*	54.95	<0.001*	2.76
Session 8	54.02	0.006*	54.52	0.012*	0.5
6 week post	55.98	<0.001*	55.99	<0.001*	0.01
Total change	9.03		7.88		

Table 14	Y balance test- anterior directional reach. Percentage of change.

Timeframe	Affected	% between	Contralateral	% between
		session change		session change
		(MCID 3.5%)		(MCID 3.5%)
Baseline	46.96		48.11	
Session 4	52.19	11.2%	54.95	14.22%
Session 8	54.02	3.51%	54.52	-0.78%
6 week post	55.98	3.63%	55.99	1.78%

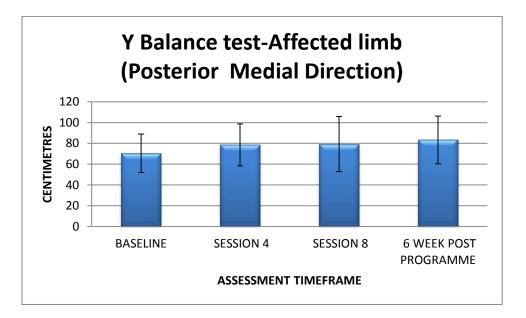
4.3.13. Y balance test- affected limb posterior medial directional reach.

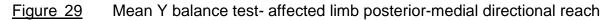
The mean, SD, mean and percentage difference between sessions, p-values, and changes in the Y balance scores for the posterior medial directional reach for the affected limb and contralateral limb side are shown in table 15 and table 16. Figure

29 and 30 show the mean centimetres scored whilst completing the Y balance test at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a mean of 70.47 centimetres (SD 18.51) for the affected posterior medial reach, at session 4 a mean score of 78.59 centimetres (SD 20.18), at session 8 a mean score of 79.40 centimetres (SD 26.53), and 6-weeks post- exercise programme a mean score of 83.36 centimetres (SD 22.95).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.63, F (3, 51) = 10.9, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001), baseline to session 8 (p= 0.017) and from baseline to 6-weeks post-exercise programme (p<0.001).





4.3.14. Y balance test- contralateral limb posterior medial directional reach

Participants baseline score recorded a mean of 71.29 centimetres (SD 19.65) for the contralateral posterior medial reach, at session 4 a mean score of 79.67 centimetres (SD 16.99), at session 8 a mean score of 79.94 centimetres (SD 25.45), and 6-weeks post- exercise programme a mean score of 83.45 centimetres (SD 23.55).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.56, F (3, 51) = 13.51, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p= 0.01), baseline to session 8 (p= 0.010) and from baseline to 6-weeks post-exercise programme (p<0.001).

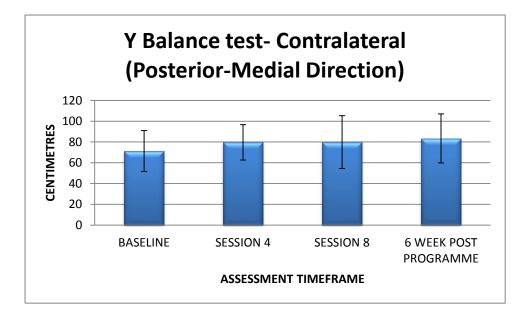


Figure 30 Mean Y balance test- contralateral limb posterior-medial directional reach

<u>Table 15</u> Y balance test-posterior medial directional reach. Asymmetry change. (*Significant value).

Timeframe	Affected	P value	Contralateral	P value	Change
		From		from	(<4cm)
		baseline		baseline	
Baseline	70.47		71.29		0.82
Session 4	78.59	<0.001*	79.67	0.01*	1.08
Session 8	79.40	0.017*	79.94	0.010*	0.54
6 week post	83.36	<0.001*	83.45	<0.001*	0.09
Total change	12.89		12.16		

<u>Table 16 Y balance test-posterior medial directional reach. Percentage of change.</u>

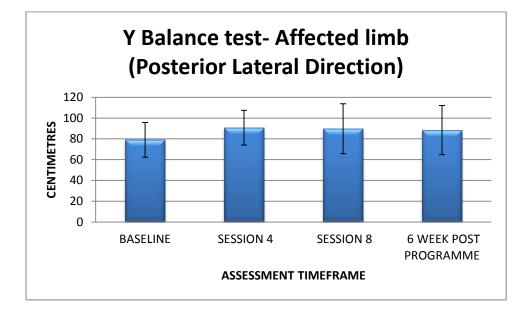
Timeframe	Affected	% between	Contralateral	% between
		session change		session change
		(MCID 3.5%)		(MCID 3.5%)
Baseline	70.47		71.29	
Session 4	78.59	11.52%	79.67	11.75%
Session 8	79.40	1.03%	79.94	0.34%
6 week post	83.36	12.5%	83.45	4.39%

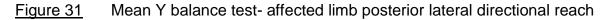
4.3.15. Y balance test- affected limb posterior lateral directional reach.

The mean, SD, mean and percentage difference between sessions, p-values, and changes in the Y balance scores for the posterior lateral directional reach for the affected limb and contralateral limb side are shown in table 17 and table 18. Figure 31 and 32 show the mean centimetres scored whilst completing the Y balance test at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a mean of 79.09 centimetres (SD 16.68) for the affected posterior lateral reach, at session 4 a mean score of 90.75 centimetres (SD 16.67), at session 8 a mean score of 89.72 centimetres (SD 24.03), and 6-weeks post-exercise programme a mean score of 88.48 centimetres (SD 23.62).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.52, F (3, 51) = 15.5, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001), baseline to session 8 (p= 0.004) and from baseline to 6-weeks post-exercise programme (p= 0.016).





4.3.16. Y balance test- contralateral limb posterior lateral directional reach.

Participants baseline score recorded a mean of 79.99 centimetres (SD 16.37) for the contralateral limb posterior-lateral reach, at session 4 a mean score of 90.29 centimetres (SD 17.21), at session 8 a mean score of 89.96 centimetres (SD 24.09), and 6-weeks post-exercise programme a mean score of 91.38 centimetres (SD 21.98).

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.56, F (3, 51) = 13.46, p<0.001. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001) and baseline to session 8 (p= 0.014) and baseline to 6-weeks post-exercise programme (p<0.001).

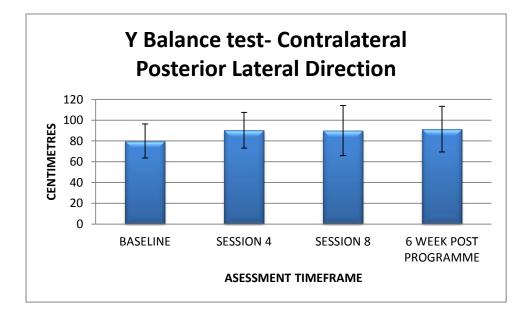


Figure 32 Mean Y balance test- contralateral posterior lateral directional reach

<u>Table 17</u> Y balance test- posterior lateral directional reach. Assymetry change.(* Significant value)

Timeframe	Affected	P value From baseline	Contralateral	P value From baseline	Change (<4cm)
Baseline	79.09		79.99		0.9
Session 4	90.75	<0.001*	90.29	<0.001*	0.46
Session 8	89.72	0.004*	89.96	0.014*	0.24
6 week post	88.48	0.016*	91.38	<0.001*	2.9
Total change	9.39		11.39		

Table 18 Y balance test-posterior lateral directional reach. Percer	ntage of change
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Timeframe	Affected	% between	Contralateral	% between
		session change		session change
		(MCID 3.5%)		(MCID 3.5%)
Baseline	79.09		79.99	
Session 4	90.75	14.74%	90.29	12.88%
Session 8	89.72	-1.13%	89.96	-0.37%
6 week post	88.48	-1.38%	91.38	1.58%

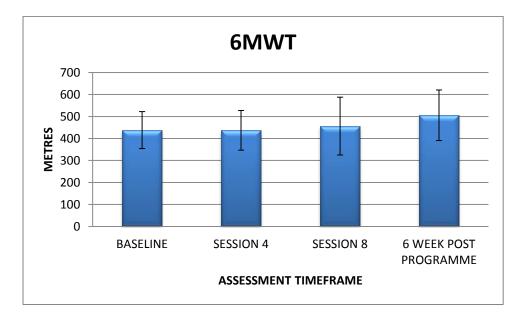
4.3.17. 6-minute walk test

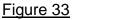
The mean, SD, mean and percentage difference between sessions, p-values, and changes in the 6MWT are shown in table 19. Table 19 and figure 33 show the mean metres walked whilst completing the 6MWT at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a mean of 438.33 metres (SD 84.16), at session 4 a mean score of 437.32 metres (SD 90.14), at session 8 a mean score of 456.57 metres (SD 131.43), and 6-weeks post-exercise programme a mean score of 505.28 metres (SD 114.89).

Between session analysis from baseline to session 4, 26 (48.15%) participants improved, 22 (40.74%) participants did not improve, and 6 (11.1%) participants remained the same. Between sessions 4 to session 8, 37 (68.52%) participants improved, 13 (24.07%) participants did not improve, and 8 (7.41%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 38 (70.37%) participants improved, 13 (24.07%) participants did not improve, and 3 (5.6%) participants remained the same

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.74, F (3, 51) = 5.93, p= 0.002. Pairwise comparison of the data indicated a non-significant result from baseline to session 4 (p= 1) and baseline to session 8 (p= 1), however baseline to 6-weeks post-exercise programme (p= 0.02) was statistically significant.





Mean 6-minute walk test

Table 19Mean 6-minute walk test (* Significant value)

Timeframe	6MWT	score	in	Change	between	P-value	from
	metres (SD)		sessions	in	baseline	
				metres			
Baseline	438.33 (84.16)					
Session 4	437.32 (90.14)		-1.01		1	
Session 8	456.57 (131.43)		+19.25		1	
		,					
6 week post	505.28 (114,89)		+48.71		0.02*	
Total abanda	66.95						
Total change	00.90						

4.3.18. 30-second chair stand test

The mean, SD, mean and percentage difference between sessions, p-values, and changes in the 30-second chair stand test are shown in table 20. Table 20 and figure 34 show the mean centimetres scored whilst completing the 30-second chair stand test at baseline, session 4, session 8 and 6-weeks after the exercise programme.

Participants baseline score recorded a mean of 12.48 repetitions (SD 3.82), at session 4 a mean score of 14.87 repetitions (SD 4.98), at session 8 a mean score of 16.26 repetitions (SD 6.55), and 6-weeks post-exercise programme a mean score of 16.70 repetitions (SD 6.83). Between session analysis from baseline to session 4, seen 40 (74.1%) participants improved, 9 (16.67%) participants did not improve, and 5 (9.26%) remained the same. Between sessions 4 to session 8, 40 (74.1%) participants improved, 6 (11.1%) participants did not improve, and 8 (14.81%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 29 (53.7%) participants improved, 12 (22.2%) participants did not improve, and 13 (24.1%) participants remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.56, F (3, 51) = 13.52, p= <0.01. Pairwise comparison of the data indicated a significant result from baseline to session 4 (p<0.001),

baseline to session 8 (p<0.001) and baseline to 6-weeks post-exercise programme (p<0.001).

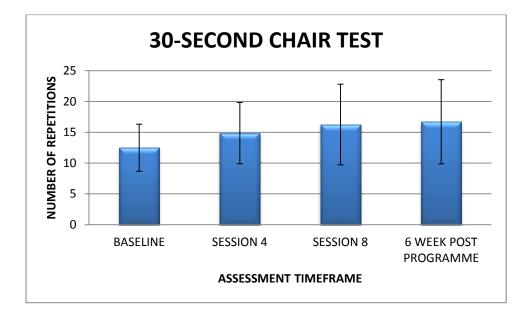


Figure 34 Mean 30- second chair stand test

Table 20Mean 30- second chair stand test (* Significant value)

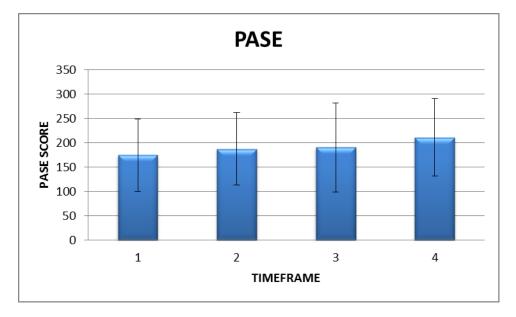
Timeframe	Mean 30-second	Change between	P-value from
	chair stand test	sessions in	baseline
	score in repetitions	repetitions	
	(SD)		
Baseline	12.48 (3.82)		
Session 4	14.87 (4.98)	+2.39	<0.001*
Session 8	16.26 (6.55)	+1.39	<0.001*
6-week post	16.70 (6.83)	+0.44	<0.001*
Total change	4.22		

4.3.19. Physical Activity Scale for the Elderly

The mean, SD, mean difference between sessions, p-values, and changes in the PASE are shown in table 21. Table 21 and figure 35 show the mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme

Participants baseline score recorded a mean of 174.90 (SD 74.54), at session 4 a mean score of 187.39 (SD 74.08), at session 8 a mean score of 190.48 (SD 91.33), and 6-weeks post-exercise programme a mean score of 211.37 (SD 79.59). Between session analysis from baseline to session 4, 32 (59.26%) participants improved, 19 (35.19%) participants did not improve, and 3 (5.6%) participants remained the same. Between sessions 4 to session 8, 27 (50%) participants improved, 25 (46.29%) participants did not improve, and 2 (3.7%) participants remained the same. Between session 8 to 6-weeks post-exercise programme, 34 (62.96%) participants improved, 19 (35.19%) participants did not improve, and 1 (1.85%) participant remained the same.

A one-way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis (N=54). The results of the ANOVA indicated significant time effects, Wilks' Lambda = 0.74, F (3, 51) = 5.88, p= 0.02. Pairwise comparison of the data indicated a non-significant result from baseline to session 4 (p= 0.182), and baseline to session 8 (p=0.501) however when assessing between baseline to 6-weeks post-exercise programme (p= 0.02) this was statistically significant.





Mean PASE

Table 21Mean PASE (* Significant value)

Timeframe	Mean PASE (SD)	Change between	P-value from
		sessions	baseline
Baseline	174.90 (74.54)		
Session 4	187.39 (74.08)	+12.49	0.182
Session 8	190.48 (91.33)	+3.09	0.501
6-week post	211.37 (79.59)	+20.89	0.02*
Total change	36.47		

4.3.20. Borg scale

The mean, SD and changes in the Borg scale score are shown in figure 36. Participants mean score after exercise class number 1 was 13.5 (SD 2.65), after exercise class 2, 13.76 (SD 2.63), after exercise class 3, 13.22 (SD 3.29), after exercise class 4, 13.98 (SD 2.03). After exercise class 5, the mean score was 14.07 (SD 2.22), after exercise class 6, 13.6 (SD 2.93), after exercise class 7, 13.8 (SD 3.07) and after exercise class 8, 13.29 (SD 4.18).

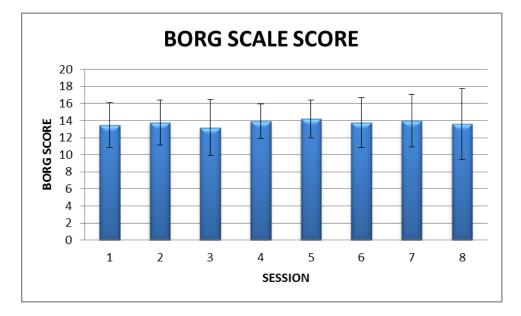


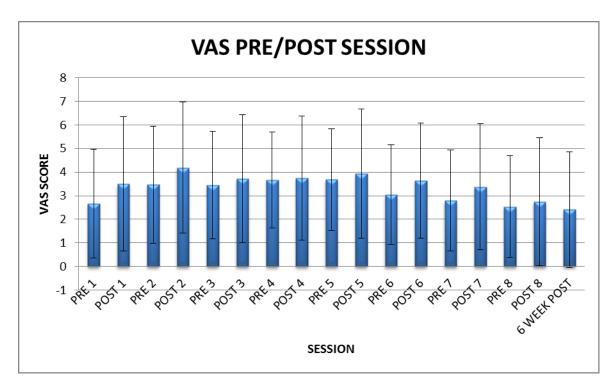
Figure 36 Mean Borg score

4.3.21. Visual Analogue Scale

The mean, SD and changes in the VAS are shown in table 22. Table 22 and figure 37 show the mean VAS scores pre and post each exercise session and 6-weeks after the exercise programme. Participants lowest mean score was recorded 6-weeks post-exercise programme (2.41) with the highest mean score being recorded after session 2 of the exercise programme (4.16).

	Mean Pre session (SD)	Mean Post session (SD)	
Session 1	2.67 (SD 2.31)	3.5 (SD 2.85)	
Session 2	3.46 (SD 2.47)	4.16 (SD 2.78)	
Session 3	3.44 (SD 2.28)	3.72 (SD 2.71)	
Session 4	3.67 (SD 2.03)	3.76 (SD 2.63)	
Session 5	3.68 (SD 3.04)	3.93 (SD 2.74)	
Session 6	3.04 (SD 2.11)	3.6 (SD 2.44)	
Session 7	2.79 (SD 2.14)	3.37 (SD 2.67)	
Session 8	2.54 (SD 2.16)	2.74 (SD 2.72)	
6-weeks after programme	2.41 (SD 2.45)		

Table 22Mean VAS score pre and post-exercise sess	sion.
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4.3.22. Summary of data

Table 23 Summary of data

Outcome	Baseline- mean/median	Session 4- mean/median	Session 8 mean/ median	6-week post- mean/ median	Total mean/ median change	P value	MDC
TSK	37	33.5	32	33	4	<0.001	5.6
	(Median)	(Median)	(Median)	(Median)	(Median)		
TSK AA	9.5	9	8.5	8	1.5	0.063	N/A
	(Median)	(Median)	(Median)	(Median)	(Median)		
TSK SF	14	14	13	12	2	<0.001	N/A
	(Median)	(Median)	(Median)	(Median)	(Median)		
KOOS ADL	46.9	54.83	57.44	61.39	14.49	0.002	15.4
KOOS Pain	41.06	47.79	51.18	56.53	15.47	<0.001	13.48
KOOS Symptoms	41.67	49.34	49.03	56.48	14.81	<0.001	15.5
KOOS QoL	24.15	37.06	40.33	43.08	18.93	<0.001	21
KOOS Sport	21.89	29.07	32.41	32.94	11.55	0.011	19.6
PASE	174.90	187.39	190.48	211.37	36.47	0.02	35/28 /10
6MWT	438.33	437.32	456.57	505.28	66.95	0.002	61.34
30 second chair stand test	12.48	14.87	16.26	16.70	4.22	<0.001	2
Y test- Affected limb anterior	46.95	52.19	54.02	55.98	9.03	<0.001	8.7
Y test- Contralateral limb anterior	48.11	54.95	54.52	55.99	7.88	<0.001	8.7
Y test- Affected limb post-lat	79.09	90.75	89.72	88.48	9.39	<0.001	11.5

Y test Contralateral limb post-lat	79.99	90.29	89.96	91.38	11.39	<0.001	11.5
Y test- Affected limb post-med	70.47	78.59	79.40	83.36	12.89	<0.001	10.3
Y test Contralateral limb post-med	71.29	79.67	79.94	83.45	12.16	<0.001	10.3

4.4. ActivPAL[™]

Forty-three participants completed pre and post activity monitoring over a 7-day period, 19 males, and 24 females with a mean age of 64.36 (SD 8.92) years. Fourteen participants (32.6%) diagnosed with grade 2 KL; 14 participants (32.6%) diagnosed with grade 3 KL; 10 participants (23.3%) diagnosed with grade 4 KL and five participants diagnosed using the American College of Rheumatology criteria (11.5%). Fifteen participants (34.9%) were employed and twenty- eight (65.1%) were non-workers (five participants' data where excluded due to the activity monitor being removed and data not being collected, 4 individuals refused to wear the monitor for the 2nd time and 2 participants were unable to wear the monitor due to attachment issues). Weekday and weekend data was analysed separately.

4.4.1. Sedentary time

4.4.1.1. Pre-post sedentary time 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 24. Table 24 and figure 38 show the mean sedentary time pre and post-exercise programme. Participant's sedentary activity increased from 122.57 hours (SD 14.35) to 123.75 hours (SD 13.98) over the 7-day collection, with 25 participants (58.14%) increasing sedentary time before and after the exercise class compared to 18 participants (41.86%) whose sedentary time decreased. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean sedentary timeframe scores before and after the exercise class. The results of the paired t-test was not significant, t (42) = 0.91, p= 0.37.

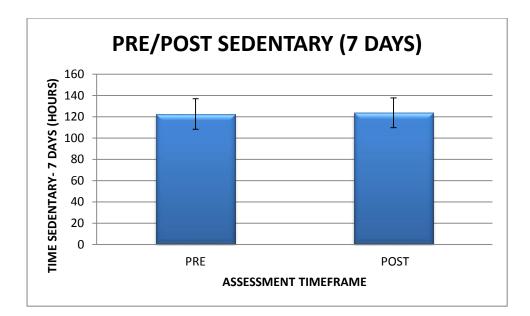


Figure 38 Mean Pre/Post sedentary (7-days)

<u>Table 24</u>	Mean, SD and differences Pre/Post sedentary (7-days)
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Activity	Pre Programme	Post	Mean	P-value
		Programme	Difference	
Sedentary	122.57 (SD	123.75 (SD	+ 1.18	0.37
(Hours)	14.35)	13.98)		

4.4.2. Upright activity

4.4.2.1. Pre-post upright activity 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 25. Table 25 and figure 39 show the mean upright activity pre and post-exercise programme. Participant's upright activity reduced from 33.17 hours (SD 12.29) to 32.01 hours (SD 11.20) over the 7-day collection, with 19 participants (44.19%) increasing upright time before and after the exercise class compared to 24 participants (55.81%) whose upright activity decreased. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean standing timeframe scores before and after the exercise class. The results of the paired t-test was not significant, t (42) = 1.07, p= 0.29

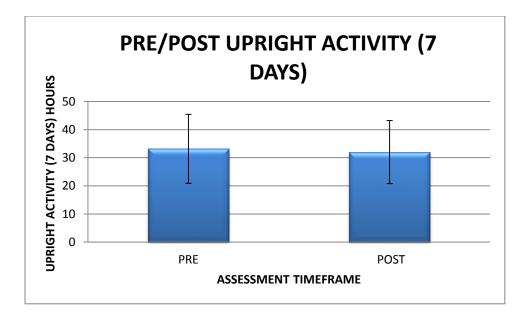


Figure 39 Mean Pre/post upright activity (7-days)

<u>Table 25</u> Mean, SD and differences Pre/Post upright activity (7-days)

Activity	Pre Programme	Post	Mean	P-value
		Programme	Difference	
Upright (hours)	33.17 (SD	32.01 (SD	-1.16	0.29
	12.29)	11.20)		

4.4.3. Walking

4.4.3.1. Pre-post walking 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 26. Table 26 and figure 40 show the mean walking time pre and post-exercise programme. Participant's walking activity increased from 11.33 hours (SD 3.71) to 12.02 hours (SD 4.01) over the 7-day collection. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean walking timeframe scores before and after the exercise class. The results of the paired t-test was not significant, t (1.92) = 0.62, p= 0.61.

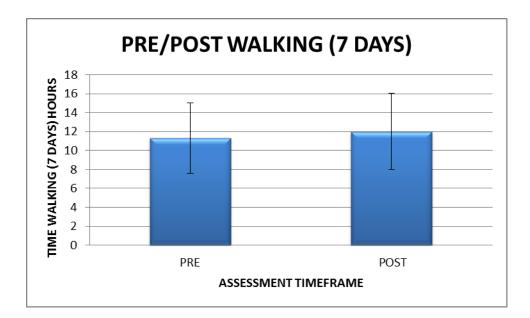


Figure 40 Mean Pre/post walking (7-days)

<u>Table 26</u> Mean, SD and differences Pre/Post walking (7-days).

Activity	Pre Programme	Post	Mean	P-value
		Programme	Difference	
Walking (hours)	11.33 (SD 3.71)	12.02 (SD 4.01)	0.69	0.61

4.4.4. Stepping activity

4.4.4.1. Pre-post stepping activity 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 27. Table 27 and figure 41 show the mean stepping time pre and post-exercise programme. Participant's stepping activity increased from 52,521.84 steps (SD 20,303.99) to 56,459.91 steps (SD 21,711.18) over the 7-day collection, with 27 participants (62.79%) increasing stepping activity before and after the exercise class compared to 16 participants (37.21%) whose stepping activity decreased. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean steps per day scores before and after the exercise class. The results of the paired t-test was significant, t (42) = 2.14, p= 0.04. Indicating an increase in steps from pre-test (mean=52,521.84 steps, SD 20,303.99, N=43) to the post-test (mean=56,459.91 steps, SD 21,711.18). Mean increase of 3,938.07 steps,

with the 95% confidence intervals for the differences between the means of 228.89 steps to 7,647.25 steps.

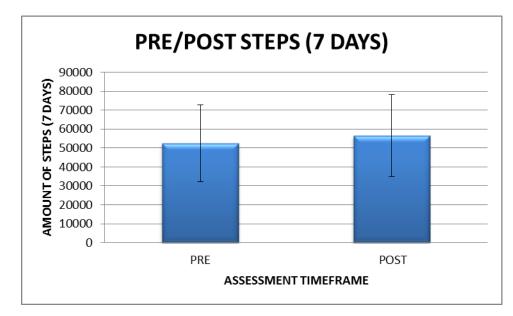


Figure 41 Mean Pre/post stepping (7-days)

<u>Table 27</u> Mean, SD and differences Pre/Post stepping (7-days) (*Significant value)

Activity	Pre Programme	Post	Mean	P-value
		Programme	Difference	
Steps	52,521.84 (SD	56,459.91 (SD	3,938.07	0.04*
	20,303.99)	21,711.18)		

Participant's amount of classified stepping activity increased on all 7-days for participants completing 10,000 to 12,499 steps and increased on 4-days for participants completing greater than 12,000 steps. A decrease in classified stepping activity on 6-days for participants completing 3,000 to 7,499 steps per day and 4-days for participants completing 7,500 to 9,999 steps per day (Table 28 and Table 29).

<u>Table 28</u> Parameters that classify activity and amount of steps each day, before the exercise programme.

Assessed Day	Individuals completing <3,000 steps	Individuals completing 3,000-7499 steps	Individuals completing 7,500-9,999 steps	Individuals completing 10,000- 12,499 steps	Individuals completing >12,500 steps
1	2 (4.65%)	20 (46.5%)	13 (30.23%)	5 (11.63%)	3 (6.98%)
2	1 (2.33%)	24 (55.81%)	10 (23.26%)	5 (11.63%)	2 (4.65%)
3	2 (4.65%)	20 (46.5%)	7 (16.28%)	5 (11.63%)	9 (20.93%)
4	5 (11.63%)	20 (46.5%)	11 (25.58%)	4 (9.30%)	3 (6.98%)
5	4 (9.30%)	22 (51.16%)	9 (20.93%)	3 (6.98%)	5 (11.63%)
6	3 (6.98%)	21 (48.84%)	12 (27.91%)	2 (4.65%)	5 (11.63%)
7	1 (2.33%)	23 (53.49%)	9 (20.93%)	4 (9.30%)	6 (13.95%)

<u>Table 29</u> Parameters that classify activity and amount of steps each day, after the exercise programme.

Assessed Day	Individuals completing <3,000 steps	Individuals completing 3,000-7,499 steps	Individuals completing 7,500-9,999 steps	Individuals completing 10,000- 12,499 steps	Individuals completing >12,500
1	4 (9.30%)	17 (39.53%)	9 (20.93%)	6 (13.95%)	7 (16.28%)
2	1 (2.33%)	21 (48.84%)	6 (13.95%)	7 (16.28%)	8 (18.60%)
3	1 (2.33%)	18 (41.86%)	12 (27.91%)	6 (13.95%)	6 (13.95%)
4	3 (6.98%)	20 (46.5%)	9 (20.93%)	5 (11.63%)	6 (13.95%)
5	7(16.28%)	17 (39.53%)	9 (20.93%)	7 (16.28%)	3 (6.98%)
6	6(13.95%)	18(41.86%)	8 (18.60%)	5(11.63%)	6(13.95%)
7	5(11.63%)	19 (44.19%)	9 (20.93%)	6(13.95%)	4 (9.30%)

4.4.5. Energy expenditure

4.4.5.1. Pre-post energy expenditure 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 30. Table 30 and figure 42 show the mean energy expenditure pre and post-exercise programme. Participant's energy expenditure reduced from 237.86 (SD 17.65) to 236.71 (SD 9.41) during the 7-day collection, with 23 participants (53.48%) increasing energy expenditure before and after the exercise class compared to 20 participants (46.52%) whose energy expenditure decreased. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean energy expenditure scores before and after the exercise class. The results of the paired t-test was not significant, t (42) = 0.45, p= 0.65.

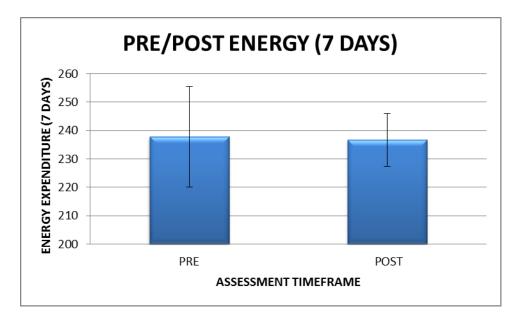


Figure 42 Mean Pre/post energy expenditure (7-days)

<u>Table 30</u>	Mean, SD and differences Pre/Post energy expenditure (7-days)
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Activity	Pre Programme	Post	Mean	P-value
		Programme	Difference	
Energy	237.86 (SD	236.71 (SD	-1.15	0.65
	17.65)	9.41)		

4.4.6. Transitions

4.4.6.1. Pre-post transitions 7-day collection

The mean, SD, mean difference between sessions and p-values are shown in table 31. Table 31 and figure 43 show the mean transitions pre and post-exercise programme. Participant's transitions increased from 319.07 (SD 81.42) to 365.25 (SD 104.79) during the 7-day collection, with 33 participants (76.74%) increasing transitions before and after the exercise class compared to 11 participants (25.58%) whose transitions decreased. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean transitions timeframe scores before and after the exercise class. The results of the paired t-test was significant, t (42) = 5.19, p<0.001. Indicating an increase in transitions from pretest (mean= 319.07 transitions, SD 81.42, N=43) to the post-test (mean= 365.23 transitions, SD 104.81). Mean increase of 46.16, with the 95% confidence intervals for the differences between the means of 28.21 transitions to 64.12 transitions.

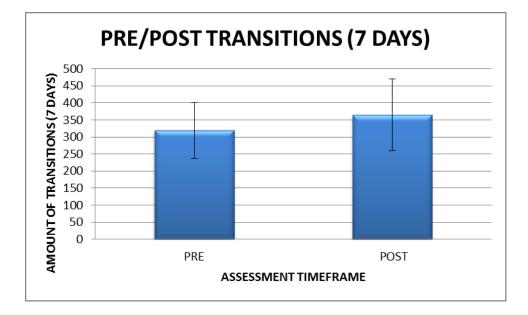


Figure 43 Mean Pre/post transitions (7-days)

<u>Table 31</u> Mean, SD and differences Pre/Post transitions (7-days) (*Significant value)

Activity	Pre Program	me	Post		Mean	P-value
			Programme		Difference	
Transitions	319.07	(SD	365.25	(SD	46.16	<0.001*
	81.42)		104.79)			

4.4.7. Cadence

4.4.7.1. Pre-post cadence 7-day collection

The mean, SD, mean difference between cadence bands and p-values are shown in table 32. Table 32 and figure 44 show the mean cadence bands pre and postexercise programme. Participant's cadence increased at every cadence bands until cadence band 130 onwards. A paired sample t-test was conducted to evaluate whether a statistically significant difference existed between the mean cadence timeframe scores before and after the exercise class. The results of the paired t-test was significant at cadence band 110-120, t (42) = 2.38, p= 0.022. Indicating an increase in cadence from pre-test (mean= 7,421.95, SD 6,900.59, N=43) to the posttest (mean= 9,041.02, SD 7,225.88). Mean increase of 1,619.07, with the 95% confidence intervals for the differences between the means of 244.73 to 2,993.41. Other cadence bands were not statistically significant.

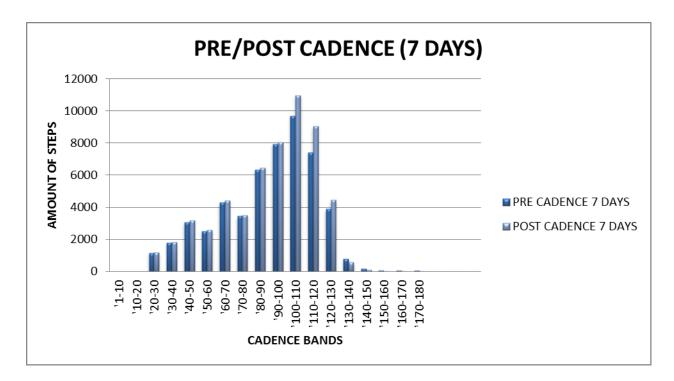


Figure 44 Pre/Post Cadence (7-days)

<u>Table 32</u>	Mean, SD and differences Pre/Post Cadence (7-days) (*Significant
value)	

Cadence Bands	Baseline	6-week post programme	Mean Difference	P valve
20to30	1,148.74	1,185.07	36.33	0.484
30to40	1,776	1,810.33	34.33	0.649
40to50	3,070.56	3,167.16	96.60	0.402
50to60	2,513.39	2,580.51	67.12	0.486
60to70	4,287.86	4,439.86	152	0.292
70to80	3,462.98	3,508.60	45.63	0.701
80to90	6,344.28	6,462.37	118.09	0.623
90to100	7,938.88	8,059.21	120.33	0.775
100to110	9,695.58	10,979.58	1284	0.101
110to120	7,421.95	9,041.02	1,619.07	0.022*
120to130	3,892.05	4,451.58	559.53	0.263
130to140	789.21	578.33	-210.88	0.186
140to150	179.49	124.60	-54.88	0.184
150to160	87.81	25.81	-62	0.129
160to170	71.81	8.42	-63.39	0.213
170to180	70.79	35.35	-35.44	0.264

4.4.8. Weekday and Weekend Data.

The mean, mean differences between assessments and p-values of all weekday (Monday-Friday) and weekend (Saturday and Sunday) for activPAL[™] activity are shown in table 33 and 34. Significant values were recorded for weekday steps, walking and energy expenditure.

Activity	Baseline	6-week post programme	Mean Difference	P valve
Sedentary	87.09	87.73	+0.64	0.52
Upright	23.94	23.35	-0.59	0.48
Walking	8.07	8.71	+0.64	0.03*
Steps	37,457.12	40,834.47	+3,377.35	0.03*
Energy Expenditure	166.52	169.29	+2.77	0.03*
Transitions	265.51	265.37	-0.14	0.98

Table 34 ActivPAL[™] data (weekend)

Activity	Baseline	6-week post programme	Mean Difference	P valve
Sedentary	35.48	36.02	+0.55	0.389
Upright	9.23	8.67	-0.56	0.29
Walking	3.26	3.31	+0.05	0.77
Steps	15,127.67	15,623.35	+495.67	0.62
Energy Expenditure	67.34	67.44	+0.09	0.83
Transitions	101.84	99.77	-2.07	0.62

4.4.9. Summary of ActivPAL[™] data

Activity	Baseline	6-week post programme	Mean Difference	P valve
Sedentary	122.57	123.75	+1.18	0.37
Upright	33.17	32.01	-1.16	0.29
Walking	11.33	12.02	+0.69	0.61
Steps	52,521.84	56,459.91	+3,938.07	0.04*
Energy Expenditure	237.86	236.71	-1.15	0.65
Transitions	319.07	365.25	+46.16	<0.001*

<u>Table 35</u> ActivPAL[™] data (7-days) (*Significant value)

4.5. Correlational Analysis

Correlational analysis was undertaken to determine if different variables are correlated. Correlations between the KOOS pain and kinesiophobia (TSK); physical activity (PASE) and kinesiophobia (TSK); KOOS pain and physical activity (PASE); physical activity (PASE) and activPAL[™] upright positioning; physical activity (PASE) and activPAL[™] walking; and physical activity (PASE) and activPAL[™] stepping data were investigated.

4.5.1. KOOS pain and tampa scale of kinesiophobia.

A spearman's rho was conducted to evaluate whether a correlation between KOOS pain and kinesiophobia (TSK) exists before, during and after the exercise class. The results of the correlation suggests that the two variables have a moderate negative correlation at baseline and 6-weeks after the exercise programme (coefficient -0.48/ -0.44) (Table 36).

<u>Table 36</u> Correlation between KOOS pain and kinesiophobia. (*Significant value)

Timeframe	Coefficient	Significance
Baseline	-0.48	0.73
Session 4	-0.10	0.46
Session 8	-0.21	0.12
6- weeks post programme	-0.44	0.01*

4.5.2. Physical activity scale for the elderly and tampa scale of kinesiophobia.

A Spearmans rho was conducted to evaluate whether a correlation between physical activity (PASE) and kinesiophobia (TSK) exists before, during and after the exercise class. The results of the correlation suggest that the two variables are not correlated (Table 37).

Table 37	Correlation betwee	en physical activity	y and kinesiophobia.
	00110101011 001110	on physical activity	, and tanoolophobia.

Timeframe	Coefficient	Significance
Baseline	0.14	0.92
Session 4	-0.13	0.34
Session 8	0.06	0.64
6- weeks post programme	0.07	0.63

4.5.3. KOOS pain and physical activity scale for the elderly

A Pearson correlation was conducted to evaluate whether a correlational between KOOS pain and physical activity (PASE) exists before, during and after the exercise class. The results of the correlation suggest that the two variables have a strong positive correlation at session 8 (coefficient 0.96) and a weak positive correlation at

session 4 (coefficient 0.32) and 6-weeks post programme (coefficient 0.21) (Table 38).

<u>Table 38</u> Correlation between KOOS pain and physical activity scale for the elderly.

Timeframe	Coefficient	Significance
Baseline	0.15	0.28
Session 4	0.32	0.82
Session 8	0.96	0.49
6-weeks post programme	0.21	0.14

4.5.4. Physical activity scale for the elderly and activPAL[™] upright positions.

A Pearson correlation was conducted to evaluate whether a correlational between physical activity (PASE) and activPAL[™] upright positioning data existed before and after the exercise class. The results of the correlation suggest that the two variables have a moderate positive correlation at baseline (coefficient 0.51) and 6-weeks post programme (coefficient 0.45) (Table 39).

<u>Table 39</u> Correlation between physical activity scale for the elderly and activPAL[™] upright positions. (*Significant value)

Timeframe	Coefficient	Significance
Baseline	0.51	0.000*
6-weeks post programme	0.45	0.003*

4.5.5. Physical activity scale for the elderly and activPAL[™] walking

A Pearson correlation was conducted to evaluate whether a correlational between physical activity (PASE) and activPAL[™] walking data existed before and after the exercise class. The results of the correlation suggest that the two variables have a strong correlation at baseline (coefficient 0.78) and a weak correlation 6-weeks post programme (coefficient 0.33) (Table 40).

<u>Table 40</u> Correlation between physical activity scale for the elderly and ActivPAL[™] walking. (*Significant value)

Timeframe	Coefficient	Significance
Baseline	0.78	0.62
6-weeks post programme	0.33	0.03*

4.5.6. Physical activity scale for the elderly and activPAL[™] stepping

A Pearson correlation was conducted to evaluate whether a correlational between physical activity (PASE) and activPAL[™] stepping data existed before and after the exercise class. The results of the correlation suggest that the two variables have a moderate to strong correlation at baseline (coefficient 0.63) and a weak correlation 6-weeks post programme (coefficient 0.32) (Table 41).

<u>Table 41</u> Correlation between physical activity scale for the elderly and activPAL[™] stepping. (*Significant value)

Timeframe	Coefficient	Significance
Baseline	0.63	0.69
6-weeks post programme	0.32	0.04*

4.6. Qualitative Analysis

During the study, a semi-structured interview was completed after the 6-weeks exercise programme. Six questions were explored and were then examined to determine what aspects of the programme influenced the individuals such as key factors that the participants thought about exercise as an intervention for knee OA and weather exercise had reduced their symptoms. Responses were written on a piece of paper and reviewed using a content analytical approach to extract themes.

Question 1 asked the participants how was the condition affecting them, in relation to pain and function (such as hobbies/work). Analysis of this question was to investigate if the participants improved after the exercises or had no improvement. Fifty- two participants (96.29%) answered the question with 15 participants (28.85%) reporting no improvement and 37 participants (71.15%) reporting improvements

<u>Table 42</u> Question 1: How is the condition affecting you? Pain, Function (Hobbies/Work)

Participant number	Improvement comment	No improvement comment
1	'initial pain has gone that kept me up at night'	
2	'great, not effecting anything, back to normal'	
3		'still in pain, medium, but depends on activity. Knealing and decorating. Swells when pain increases'
4	'think pain has reduced, reduced medication down to 1 and was on 4, may not even need 1'	
5	'pain reduced with exercises, I've bought a little stepper to continue with exercises'	
6	'less pain, improved'	
7		'pain still present, but just get on with it, got to keep going, able to complete gardening'
8	'very little pain, able to complete most activities'	
10	'not as bad as it was 6-weeks ago, slightly improved'	
11	'not as bad as it was. General day	

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	to day ok'.	
12	'now, hardly effecting pain,	
	because kept up with exercises'	
13		'struggling at the moment, in
10		pain all the time, which affects
		me on the cross-trainer'
14	'a lot better than it was'	
15		'affecting walking'
16	'not too bad'	
17	'my sharp pain is not present	
17	anymore'	
18	'pain has eased, feels stiff when	
10	getting up with slight pains, but not	
	all the time'	
19	'only time is walking upstairs, but it	
10	has better by 85%'	
20	'good days and bad days, still	
20	giving way, but it's no worse. I've	
	not noticed the ache as much'	
21	'felt ok, until I twisted it and it	
~ 1	swelled, but has since eased off'	
22		'no different to what the pain
22		was before, not altered the pain'
23	'started at gym and pain has	was before, not altered the pain
20	eased, varies from each day'	
24		'pain worse, struggling with
21		walking especially downhill, use
		walking polls to walk feels like
		old lady'
25	'not a lot of pain, can't complete	
	playing golf due to swinging, which	
	is a problem'	
26	'pain has eased and I don't wear a	
	strap or support anymore'	
27	'knee pain has reduced and I'm still	
	working'	
28	'pain reduced, used to walk up	
	Rivington and get to the gardens	
	and come back down, which is	
	hard work'	
29	'sometimes downstairs is worse	
	when leg is bad, with occasional	
	pain on walking. Pain varies, 90%	
	feels ok, 10% is bad'	
30		'cycling is fine, only walking, no
		pleasure in hobbies walking due
		to aching, 5 hours building a car
		increased pain'

31		'feel pain on right knee when turning and feel like I'm ready to drop. Able to do things, but still feeling pain whilst walking'
32	'no pain, feel good'	
33	'my surgeon is very happy, not as much pain, much better'	
34	'try to do things what I do, not really as painful, I don't think'	
35		'just the same'
36	'the pain has reduced and it only affects me when I walk fast and I still can't get up from the ground'	
37	'it is a lot better, very little problems with it'	
38	'do feel pain has reduced. After exercise still has good days and bad days'	
40	'it's not effecting me as much, kneeling down increases the pain with a twinge every now and again'	
41		'on a day to day basis, the pain affects me all the time'
42	'I'm fine really, doesn't affect me much now other than going upstairs, which I get sometimes'	
43		'still painful, just have to grin and bear it. Get on with life and do what I can, then I stop'
44	'not really effecting me now'	
45		'since stopping physio pain has become worse'
46		'struggling at the moment, locking a lot more, putting pressure on the right knee'
47		'pain still present, walking not much of a problem and stairs are still worse'
48		'going for TKR at a private hospital'
49	'not affecting me at all, not on any medication anymore'	
50	'can't say it affects me, occasional pain, not there all the time, weather doesn't help'	

51	'not effecting me as much, still painful at night'	
52	'not so bad at the moment, bearable. Feels successful, as from January I had a lot of pain and it has eased, it's not right at the moment, but definitely 100% better'	
53	'Fabulous'	
54	'pain almost gone'	

Question 2 asked the participants if the intensity or variability of the pain was the same during the day, specifically in the morning or afternoon. Analysis of this question was to investigate if the participants improved after the exercises or had no improvement. Fifty- two participants (96.29%) answered the question with 15 participants (28.85%) reporting no improvement with the intensity and variability of the pain and 37 participants (71.15%) reporting improvements.

Table 43 Question 2: Is the intensity/variability the same? AM/PM

Participant number	Improvement comment	No improvement comment
1	'lot easier'	
2	'eased greatly'	
3		'intensity is the same, feels I need a new knee'
4	'no pain at present'	
5	'pain is better, still gets pain when kidneys are playing up'	
6	'not as intense, still get it'	
7	'better in the morning'	
8	'pain gone'	
10	'pain morning after exercises, eased off, didn't have a lot of pain, feels like a lack of confidence'	
11		'Deep squats/knealing causes pain, sit-stand regular'
12		'night time worse, must be because of angle of leg'
13		'on painkillers all the time'
14		'long walking increases pain'
15	'varies, up and down stairs, but I	

	have no reason to moan about	
	pain'	
16	'Better'	
17	'most of the time'	
18	'slight aching whilst getting up, but	
	not moaning as much'	
19	'a lot better'	
20	'not aching as much, weather and	
	activity causes problems'	
21	'pain has eased and feel great'	
22		'yes'
23	'no, it's not'	
24		'same'
25	'Easier'	
26	'No'	
27	'easier, not like it was'	
28	'no, walking quicker and easier'	
29	'no'	
30	'varies from day to day, more good	
	days than bad days'	
31		'yes, still the same'
32	'knee is better'	
33	'twisting is not the same as before,	
	it is better'	
34		'by the end of the day, the
		aching is the same'
35		'depends on activity, just the
		same'
36	'knee used to hurt at night, now	
	less pain and stairs are easier'	
37	'pain has reduced all day'	
38	'feel pain has reduced'	
40	'better, not bothering me as much'	
41	'no, it varies. Worse in the morning	
	and after strenuous workouts, not	
	much pain after exercise'	
42	'no'	
43		'same really, now and again it
		gets worse'
44	'not all the time, but it can come on	
	with up and down stairs. Also, this	
	is really bad but I've noticed it with	
	tight pants on when I bend my	
	knee'	
45		'yes, bad in the morning and
		walking around as well'
46		'yes'
47	'stairs in painful, but able to walk	
	without problems'	

48		'yes'
49	'feels better, only used ibuprofen gel once'	
50	'no, slightly better, not doing exercises and it starts to come back'	
51	'no slightly less'	
52	'no'	
53	'pain reduced, in fact no pain'	
54		'yes'

Question 3 asked the participants what aggravated and eased the symptoms. Fortyeight participants (88.9%) reported aggravating factors, with 11 (22.92%) participants reporting going upstairs and downstairs, 8 (16.67%) walking, 6 (12.5%) twisting, 3 (6.25%) running, 3 (6.25%) sitting and 1 (2.08%) for golf, 1 (2.08%) for football and 1 (2.08%) for standing. Forty participants (74.1%) reported easing factors with 17 (42.5%) participants reporting movement eases their symptoms, 12 (30%) for rest, 7 (17.5%) for tablets and 2 (4.17%) for swimming/hydrotherapy. Three participants (6.25%) reported that nothing eases the symptoms

Table 44 Question 3: What are the aggravating and easing factors?

Participant number	Easing comment	Aggravating comment
1		'sitting is still a bit stiff, has a little 'clunk' slightly'
2		'rushing around, unexpected movement'
3	'Swimming and hydro eases the pain the day after'	'increased pain with pressure, like work, so I need to rest'
4		'mainly up/downstairs with a cup of tea or carrying something'
5	'Nil'	'nil'
6		'frustrating that I can't run. Started playing tennis, sometimes with a little pain, sometimes not'
7	'sitting for 10 minutes'	'standing for 45 minutes, walking on pavement'
8	'nothing at the present time'	'not tried dancing yet though'
10	'can do most things'	
11		'can't run upstairs'

12	'movement eases'	'any twisting aggravates'
13	'painkillers ease it for a short time'	
14	'Rest'	'long walking'
15		'sloped surfaces are difficult with
10		a movement that might catch it
16	'sitting eases the pain'	'walking to far aggravates the
10		pain, but I can walk further than
		I did before'
17		'walking and getting out of
		breath and standing for 30mins
		aggravate the pain'
18	'moving eases'	'sitting to standing causes pain'
19	'rest easing the pain'	'up and downstairs, playing
	5 1	football (60mins) and it was sore
		a few days after
20		'jogging on a treadmill for
		10mins at about 10/11km, road
		running, but I can play 13 holes
		of golf and walk 6 miles'
21	'walking eases pain'	'twisting, golf and feels stiff, 30
		mins in car increases pain'
22	'painkillers ease it'	'standing with a straight leg and
		I have to manipulate it to move'
23	'movement eases the pain'	'not sure, it can be fine and then
		starts up again'
24		'walking aggravates pain'
25		'twisting aggravates whilst
		golfing and going up to many
		stairs, 87 steps on holiday
		increased pain, but 13 at home
- 00	(stratabies assas it)	is ok'
26	'stretching eases it'	'getting out of a car and coming
27	walking asses the pain'	downstairs are worse'
21	'walking eases the pain'	'sitting for any periods (few hours maybe)'
28	'walking eases the pain'	'bit wary of stairs'
29	'rest and heat eases pain'	stairs when it's bad'
30	'eases- 2-3 minutes sitting'	'prolonged walking and twisting'
31		;don't know, discussed with the
		wife what causes the pain and
		we think that the weather does'
		we think that the weather does
32		'getting up from chair, sudden
		twists and getting out of a car'
33	'Moving around'	'especially in bed'
34	'co-codamol and tramadol eases it'	'upstairs and downstairs
		aggravates the pain'
35	'eases when I sit down and stick	
	my leg up and use anti-	

	inflammatories and paracetamol'	
36	'pool exercises easing it and	'uneven surfaces aggravate it'
00	making me confident'	anoven canacce aggravate h
37	'exercise eases it'	'I would say bending it'
38	'eases by walking the dog, house	'worse in the morning and then
	work and doesn't bother me now	build up through the day, also
	everytime I sit down to eat'	up and down stairs'
40	'rubbing it with ibuprofen makes it	'kneeling down quickly and
	go away'	bending quickly increases the
	5	pain'
41	'exercise eases the pain'	[·] whilst I'm on my feet to long
		and walking seems to cause
		problems'
42	'a cure would be buying a	'walking upstairs, sitting for any
	bungalow'	length of time such as after tea,
		the pain increases, so I have to
		go and make a brew'
43	'taking it easier eases the problem'	'bending knees causes it to lock
		and click'
44	'Tablets eases it and exercise'	'ok now, up and down stairs,
		that's all'
45	'rest eases the pain'	walking and bending increase
		the pain'
46	'co-codamol eases the pain'	'sat in a chair or turning quickly
47		increases the pain'
47	'tablets ease the pain'	'stairs aggravate the pain, up
40	To be beneat a little bit of everaine	and down'
48	'To be honest a little bit of exercise	'increasing the amount of steps
	eases the pain'	and stairs aggravate the
49	'avaraina anna tha nain knooling	symptoms'
49	'exercise eases the pain, knealing	'if I bang or knock it, that would
	eases the pain'	increase the pain'
50	'movement helps'	'worse thing, stiffness in
		morning and after sitting for a
		period'
51	'sitting eases the pain'	'walking on it too much and
	5	somedays are worse than
		others'
52	'rubbing, rest and moving ease it'	'twisting aggravates it,
		increasing the pain on the
		inside, cold weather also
		increases pain'
53	'moving eases it, I sat on a train for	'stairs, I'm very cautious, no
	6 hours without a problem, initially I	problems doing it, stiff in the
	was scared I couldn't move'	morning'
54	'not doing things eases the pain'	'twisting generally and prolong
		stair activity'

Question 4 asked the participants if the knee pain was preventing them from doing something that they like or have to do. Analysis of this question was to investigate if anything prevented the participants from doing things after the exercise programme or did not prevent. Fifty- two participants (96.29%) answered the question with 17 (32.69%) participants reporting that the condition was preventing them doing something that they like or have to do such as golf, running, hill walking, dance class, motorcycling, touch rugby, ladder work, building, and driving. Whereas, thirty-five (67.31%) participants answered that it was not preventing them from doing anything.

Table 45Question 4: Is it preventing you from doing something you like or haveto do?

Participant number	Preventing	Not preventing
1		'No'
2		'No, it does not'
3	'Yes'	
4	'8 1/2 miles walking, managed 7 miles, but pain stopped it'	
5		'No'
6		'No, less pain than ever'
7		'not really, changed activity levels to address pain'
8		'not preventing anything at the moment'
10	'yes, playing golf, not played due to confidence, thinking of going to the golf range'	
11		'not really'
12	'prevents running, don't run often'	
13	'yes, golf and cross trainers, which are normal activities'	
14		'not now'
15	'can't play to touch or referee, due to the pain'	
16		'No not really'
17		'still go walking around shops, doesn't stop me'
18		'No'
19		'No'
20	'I would like to run, especially road running'	

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21	'affecting golf, especially the swing,	
	at work I find it hard due to	
	occupation'	
22		'No'
23		'No'
24	'hill walking with occasional flat walking'	
25	'Golf'	
26		'No'
27		'No'
28	'yes, dance classes, scared of twisting knee'	
29		'not preventing it, might twinge a bit'
30		'amended lifestyle, don't have to do anything, cut down of duties'
31		'not really, used to run a long
01		time ago'
32		'not preventing me doing
		anything, sometimes getting out of the car'
33		'not now'
34		'no'
35		'no, just get on with it, long
		walking maybe'
36		'don't think so'
37		'no , don't let it prevent me that's how I approach my anxiety'
38	'Yes'	
40		'No'
41	'yes, building, which is my job'	
42	, , , , , , , , , , , , , , , , , , ,	'No'
43	'yes, motorcycling and riding a push bike'	
44		'No'
45		'Not preventing me from going to work, still got to do that, so I take strong painkillers'
46		'no it doesn't'
47		'not really no, will still attempt to do things'
48	'yes, ladder work and sporting activity'	
49		'hard to answer, doesn't stop me, I can't play football/run, but I'm 65'
50		'no, bit wary of completing certain things'

51	'I consider how far I'm going to walk before I have to walk, long distance walking I won't do it'	
52	'don't think I could complete a long distance drive, after 20 minutes it hurts'	
53		'not previously doing anything, cautious sometimes, but I do what I can'
54		'no, got to get on with things'

Question 5 asked the participants if they felt that the exercises eased the pain. Analysis of this question was to investigate if exercise improved or did not improve the participant's pain. Fifty- two participants (96.29%) answered the question with 47 participants (90.38%) reporting that they felt that exercises eased the pain, with 5 participants (9.62%) stating that exercise did not ease the pain.

Table 46 Question 5: Did you feel the exercises eased your pain?

Participant number	Improvement with exercise comment	No improvement with exercise comment
1	'a lot yes'	
2	'Yes'	
3		'Feels like the knee is stronger, but pain still present, after dog walking'
4	'yes, it did short term. Since finished exercises, slight increase in pain'	
5	'Yes'	
6	'yes'	
7		'no'
8	'yes'	
10	'natural progression of healing'	
11	'yes'	
12	'definitely'	
13	'thought it was good and then had a set-back, felt little twinges on certain things'	
14	'yes'	
15		'no'
16	'yes, think so, not as half as painful as it was'	
17	'not made it worse'	

18	'yes'	
19	'yes'	
20	'Yes, of course'	
21	'Definitely'	
22	'Yes, a little bit, enjoyed class'	
23	'Yes, not at first, but as I went on	
20	the pain eased'	
24	'Yes'	
25	'Yes'	
26	'Yes'	
27	'Yes'	
28	'Yes'	
29	'It has stopped it'	
30	'exercise programme eased pain,	
50	can move more freely in the	
	morning'	
31		'no'
32	'not preventing anything'	
33	'Yes'	
34	'Yes'	
35	'go to the gym, just the same'	
36	'yes, unless its co-incidental'	
37	'yes, winter months might increase	
57	pain due to the cold weather, so	
	will wait and see'	
38	Did not answer	
40	'yes, wonder why I have to punish	
40	myself with exercises'	
41	'Yes'	
42	'Yes'	
43		'not sure of that, not totally, felt
10		stronger and I have built a gym
		at home'
44	'Yes'	
45	'yes, when I was doing it, seem to	
	ease off and I noticed that going up	
	and down stairs improved'	
46	'not the time it didn't, but since not	
	doing the exercises the pain has	
	increased.'	
47	'Exercise has helped. Got me out	
	and walking again'	
48	'Yes'	
49	'Yes'	
50	'Yes'	
51	'Yes'	
52	'Yes'	
53	'Definitely'	
54	'initially it did, it was almost gone'	

Question 6 asked the participants what they felt improved the pain. Twenty- six participants (48.15%) answered the question, with ten participants (38.46%) advocating exercises and being physically active to improve pain. Six participants (23.08%) wanted to be referred for acupuncture, four participants (15.38%) were referred to an orthopaedic surgeon with one participant (3.85%) being listed for a total knee replacement and one participant (3.85%) being referred for an injection. Other beliefs range from hydrotherapy, rest and anti-inflammatory creams.

Table 47 Question 6: What do you feel eases the pain?

Participant number	What improved the pain? Patient beliefs?
1	'exercise'
2	'not resting, being active everyday'
3	'hydrotherapy, feels the heat and swimming eases the pain and I'm able to bend the leg better in water'
4	'exercises, lots easier, but still painful'
5	No answer
6	No answer
7	'rest, cream (anti-inflammatory), arnica. Feels ok, Not wanting a surgical intervention, not keen on injection, as it only works for so long'
8	No answer
10	'feels it's a ligament type pain, can cope with arthritic pain. Going to continue with exercises, joined a gym and completed ½ hour playing football in net'
11	'enjoyed the exercise class, felt confident'
12	'exercises, no tablets. Did not wont activpal™ fitted, found it uncomfortable last time'
13	'referral to orthopaedic'
14	No answer
15	'referral to surgeon'
16	No answer
17	No answer
18	No answer
19	No answer
20	No answer
21	No answer
22	'Keen for acupuncture'
23	No answer
24	'Injection or acupuncture'
25	'Monster walks increased pain on heels'

26	No answer
27	No answer
28	No answer
29	'Doesn't want to take pills'
30	No answer
31	'rest, unless its old age, would like some acupuncture'
32	'Yes, exercises'
33	No answer
34	'Wants to try acupuncture'
35	'Don't do strenuous activity, which decreases the pain and I like the
	stepper and cross trainers. I'm happy to continue at gym'
36	No answer
37	'Exercises'
38	'Exercise'
40	No answer
41	No answer
42	No answer
43	No answer
44	No answer
45	'Acupuncture'
46	'Acupuncture- referred to physiotherapy specifically for this'
47	'Going to local hospital for another injection. I've had 3 injections over
	the last 3 years and they have helped'
48	'Having a total knee replacement at private clinic'
49	'Yes, exercise'
50	No answer
51	No answer
52	No answer
53	No answer
54	'Would like to try injection or see orthopaedics. Refused activPAL™'

CHAPTER FIVE

DISCUSSION

The aim of this thesis was to determine the effect an exercise programme has on various clinically assessed measures in a sample of individuals with knee osteoarthritis. No study has investigated multiple outcomes throughout the course of an exercise programme such as psychological (kinesiophobia), clinical (pain and function), physiological (strength, balance and aerobic capacity) as well as listening to the individuals voice via semi-structured interviews. Our results demonstrate that an 8-session exercise programme in the NHS reduces kinesiophobia, pain and symptoms, increases quality of life, sporting and recreation activities and physical activity. In addition, the programme increased dynamic balance, aerobic capacity, strength, stepping, and cadence. This chapter will discuss the clinical trial sequentially as reported in the results chapter, the sample, and outcome measurement changes in relation to the hypotheses with comparative analysis to previous research, patient feedback, and overall clinical implications.

5.1. Sample

In total fifty-four individuals with knee OA participated in the study and completed the eight outcome measurements with forty-three of these individuals completing the pre- and post-activity monitoring over a 7-day period, which is similar to a previous study on exercise (French et al., 2013). Patient choice is a very important factor in healthcare research (Department of Health, NHS Choice framework, 2016) and this was taken into account with eleven participants failing to complete the full activity monitoring (20% drop out). Reasons for the incomplete data collection range from the activity monitor being actively removed and data not being collected, refusal to wear the monitor for the second time and the inability to wear the monitor due to attachment issues. The mean age of the participants was 63.35 years, similar to previous studies (Bennell et al., 2012; Kennedy et al., 2005) and would adhere to the fact that 60% of adults diagnosed with knee OA are aged over 50 (Vad et al., 2002). In addition, the youngest participant was 47 years old, which also suggests that symptoms can occur in younger people (Deshpande et al., 2016) and an equal amount of females and males participated in the study (27 each). The mean body

mass index of the participants was 27.12, which is within range from previous studies (Hart et al., 2015b- BMI 26; Henriksen et al., 2014-BMI 28.1), which defines the average participant as being overweight (NICE, 2014). An increase in BMI with every kilogram is associated with a 9-13% increased risk of symptoms (Salih & Sutton, 2013), with 65.3% of the population in Wigan being classified as overweight (Public Health Wigan, 2015). Radiographic images are gold standard for confirming knee OA (Bijlsma et al., 2011) with the use of the Kellgren and Lawrence scale being used, as it is valid and reliable grading scale (Arden & Nevitt, 2006). Seventeen participants were diagnosed with Kellgren and Lawrence grade 2, 19 participants diagnosed with grade 3 and 12 participants diagnosed with grade 4, which is similar to previous studies (Mikesy et al., 2006; Thorstensson et al., 2005). In addition, six participants were diagnosed using the American College of Rheumatology criteria, as this is 99% valid (Zhang et al., 2010). Therefore, we can show that our sample is suggestive of individuals with medial knee OA.

5.2. Tampa Scale for Kinesiophobia

Null Hypothesis 1- A structured supervised lower limb exercise programme does not reduce kinesiophobia scores in individuals diagnosed with knee OA.

The first hypothesis proposed that exercise via a lower limb exercise programme would reduce kinesiophobia in individuals with knee OA. Over half of the participants recorded high levels of kinesiophobia at baseline (52% scored 37 and over), with the median baseline score of 37 being scored, which is classified as high kinesiophobia (Branstrom et al., 2008; Vlaeyen et al., 1995). Incidentally, previous research into kinesiophobia reported an average score of 24.5 with osteoarthritic pain (Heuts et al., 2004), which is lower than our study. However, our score is lower than the average score for musculoskeletal conditions, which is 42 (Sullivan & Standish, 2003). At session 4 of the exercise programme, high kinesiophobia remained in 24% of the participants and the median score reduced to 33.5. At session 8, which was the end of the exercise programme, high kinesiophobia remained in 24% of the participants, with the median score also reducing to 32. However, at the 6-week post-exercise programme high kinesiophobia remained in 25% of the participants with the median kinesiophobia remained in 25% of the participants with the median kinesiophobia remained in 25% of the participants

were recorded with between session results from baseline to session 8 and baseline to 6-week post programme. In a study by Koho et al. (2001), they also concur with the current study, finding a higher level of kinesiophobia at baseline in individuals with chronic low back pain, which reduced after 6 months of physical activity. Critically, Koho et al. (2001) stated that the individuals reported a 1-year history of low back pain and very high levels of pain and disability, however in the current study length of time with symptomatic knee OA was not accounted for. Equally as important, Tackacs et al. (2017) reported a mean reduction of 4.6 points in kinesiophobia after an exercise programme in individuals with medial knee OA. However the outcome measurement used during this study was the brief fear of movement scale, which is based on the TSK, but the reliability of this measurement tool have not been investigated and the exercise programme was partially supervised for a 10-week period. Both studies found a reduction in kinesiophobia over time, which highlights the importance of assessing for kinesiophobia during the initial assessment to allow the therapist and patient to collaborate a physical activity programme with specific goals that will reduce the fear of movement sooner and potentially reduce the chronic processes that can be related to kinesiophobia.

Although no evidence has been completed in relation to the minimal clinical detectable change in knee OA, the median change of 4 during this study does not appear to meet the minimal clinical detectable change of 5.6 for generalised chronic pain (Hapidou et al., 2012) or even 9.2 for low back pain (Ostelo et al., 2007). After all an increased level of kinesiophobia in primary care has been shown with 54-56% of individuals having a high of level of kinesiophobia (Branstrom et al., 2008; Lundberg et al., 2006, Beur & Linton, 2002) with it often being poorly assessed in primary care (Linton & Boersma, 2003) as well as the orthopaedic setting. Furthermore, kinesiophobia is evident in individuals diagnosed with knee OA postanterior cruciate ligament reconstruction and has links with lower scores with KOOS sport and recreation and KOOS activities of daily living (Hart et al., 2015b). Therefore, addressing kinesiophoba during the initial assessment would benefit the patient and the therapist/consultant, as individuals who interpret pain as not threatening confront the situation, maintain daily activities, are more likely to recover quicker (Domenech et al., 2013) and are less likely to experience problems (McLean et al., 2007). Those scoring high in kinesiophobia may need further interventions

such as more education in relation to physical activity and the management of knee OA, more re-assurance using motivational interviewing skills during the initial phase of the rehabilitation programme or even sign-posting to a more experienced therapist that specialises in the conditions. This is supported by Fletcher et al. (2016) who found individuals with a high level of pain knowledge are associated with lesser activity related fear, therefore, implementing a pain education programme prior to the exercise programme would further enhance the outcomes of our programme.

The Tampa scale of kinesiophobia has a 2-factor solution with activity avoidance and somatic focus being applied in research for chronic low back pain (Roelofs et al., 2011). Activity avoidance using questions 1, 2,10,13,15 and 17 from the Tampa scale of kinesiophobia (Roelofs et al., 2007) was used. Median baseline scores was recorded at 9.5, which reduced at session 4 to a median score of 9. At session 8, a reduction to 8.5 was recorded with a further reduction to 8 being recorded at 6weeks post-exercise programme. Over the 8 sessions, the activity avoidance score reduced, this would correlate with Koho et al. (2001), who found increased physical activity and reduced kinesiophobia after 6 months. TSK activity avoidance in 254 participants with general osteoarthritic pain highlighted a mean score of 13.9 (SD 3.8) (Roelofs et al., 2007), which is slightly higher than our study. Specific knee OA data highlighted a mean score of 17.61 (SD 5.69) for TSK activity avoidance from 47 individuals, with a moderate negative correlation being reported with a forward multidirectional reach (Sanchez- Heran et al., 2016). In addition to activity avoidance, the Tampa scale of kinesiophobia also can highlight somatic focuses using questions 3,5,6,7 and 11 (Roelofs et al., 2007). Median baseline score of 14 was recorded, with no difference in score at session 4. At session 8, a reduction to 13 was recorded with a further reduction to 12 being recorded at 6-weeks post-exercise programme. Comparative analysis with the TKS somatic focus in 254 participants with osteoarthritic pain highlighted a mean of 10.6 (SD 3.2) (Roelofs et al., 2007). Specific knee OA data for TSK somatic focus from 47 individuals highlighted a mean score of 10.1 (SD 3.26) which is slightly lower than our study. Critically, both TSK-AA and TSK-SF have only been assessed without any form of intervention such as an exercise programme, with the current study being the first to investigate an exercise programme for individuals with knee OA using the TSK throughout the programme. During this study, the TSK-AA and TSK-SF reduced throughout the exercise programme, therefore reducing the fear of functioning and disability, and potentially allowing the individuals to participate in activities in good physical and psychological health. Potential advantages of using the TSK-AA and TSK-SF in the clinical setting could highlight specific experiences of kinesiophobia. Individuals, who score low of the TSK, may actually have pain-related fear in relation to either somatic focus or activity avoidance and this could be addressed for diagnostic purposes, clinical decision making to signpost individuals and treatment outcomes.

Correlational analysis between the TSK and KOOS pain highlighted a moderate negative correlation between the TSK and KOOS pain subscale at baseline and 6weeks post programme (r=-0.48/-0.44), therefore as kinesiophobia reduces, the resulting pain scores on the KOOS pain score will increase (pain reduces). Higher kinesiophobia is related to poor self-reported knee function (Hartigan et al., 2013), decreased knee confidence (Hart et al., 2015) and reduced balance (Ishak et al., 2017), and in the current study was found to be high at baseline. Exercise has an analgesic effect (Verhoeven et al., 2016; Koltyn et al., 2014); however, initial engagement with exercise is associated with pain (Meeus et al., 2015) with 57% of pain being caused by movement (Vlaeyen et al., 1999). Pain relieving effects of exercise are often slow acting, therefore as the KOOS pain score increased throughout the study, the associated reduction in kinesiophobia occurred. Further correlations between kinesiophobia and the PASE questionnaire highlighted that these were not correlated throughout the study, even though an expectation of the current study was that as kinesiophobia reduces, physical activity would increase to allow the individuals with knee OA to self-manage their condition with exercise. Evidence shows that kinesiophobia can be associated with physical inactivity (Nelson et al., 2014; Hapidou et al., 2012; Elfving et al., 2007; Koho et al., 2001), contrary to this, evidence is available to suggest that kinesiophobia may not be not be associated with inactivity (Griffin et al., 2012, Lundberg et al., 2011; Alschuler et al., 2011; Heneweer et al., 2009). However, significant associations between kinesiophobia and OA have been highlighted with greater physical disability and inactivity (Bergsten et al., 2012; Somers et al., 2009) with moderate positive correlations being found (r=0.44-0.48) (Shelby et al., 2012). Critically, the short duration of the current study, which was 4-weeks of exercise, followed by a 6-week review, could have been a factor for kinesiophobia and the PASE not to be

correlated, as Koho et al. (2001) found greater changes in physical activity at 6 months with high kinesiophobia individuals.

This study is the first study to investigate changes in kinesiophobia using the TSK throughout an exercise programme for individuals with knee OA. Critically, this current study was a 4-week fully supervised exercise programme, in which kinesiophobia reduced and then increased at the 6-week review. The increase at six –weeks could have been related to the individuals not being supervised during that time, or that the individuals did not complete any structured physical activity during that timeframe due to cost issues, time, and lack of motivation.

In summary, the exercise programme used in this study-reduced kinesiophobia, activity avoidance and somatic focus in individuals diagnosed with knee OA. Statistically significant results were reported, although clinically significant changes did not meet the minimal detectable changes.

Therefore, in conclusion, the null hypothesis was rejected, as kinesiophobia was significantly reduced after completing a lower limb exercise programme.

5.3. KOOS

Null Hypothesis 2- A structured supervised lower limb exercise programme will not increase function, sport and recreation, activities of daily living and reduce pain and symptoms.

The second hypothesis proposed that exercise via a lower limb exercise programme would reduce pain and symptoms and increase function, sport and recreation and activities of daily living in individuals with knee OA. The outcome measurement tool used to test the hypothesis was the KOOS questionnaire, as it is a valid and highly reliable outcome measurement tool for evaluating change in individuals with OA after interventions (Roos et al., 1998).

5.3.1. KOOS- Pain

At the 6-week review compared to baseline, the pain subscale significantly improved, the maintained improvement at the 6-week review could be related to the individual's

adherence to the exercises. However, between baseline and session 4 no significant improvement was found, this could relate to the individuals starting an exercise programme or even commencing exercises that they never completed before and after the first few sessions developing pain due to working the muscles. From session 4 onwards, the exercise programme provided the individuals with reduced pain sensitivity (Schaible & Grubb, 1993) and improved muscle strength (Thorlund et al., 2016). Evidence for the KOOS pain subscale suggests a minimal detectable mean change of 13.48 (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008), therefore the current study found a clinical significant finding, as a mean change of 15.47 was recorded. Previous studies that have looked into exercise as an intervention report baseline mean KOOS pain scores ranging from 50.9 (Lund et al., 2008), 56.5 (Henriksen et al., 2014), 60 (Thorstensson et al., 2005), 65 (Wang et al., 2011), 66.2 (Salacinski et al., 2012) and 66.7 (McQuade & de Oliveria, 2011). Our mean baseline score was 41.06, which is much lower than these studies. It is possible that factors such as only including individuals with medial knee OA only (Henriksen et al., 2014); including a younger age range (35-65) (Thorstensson et al., 2005) and a lower KL scale (Salacinski et al., 2012) could be reasons for different scores. The current study included any form of knee OA (medial, lateral and patella-femoral), age range from 45 years plus and any individuals with KL or ACR diagnosis of knee OA. Post-intervention KOOS pain mean changes for these studies after completing an exercise intervention range from 3.1 (Thorstensson et al., 2005), 6.1 (Henriksen et al., 2014), 10.1 (Salacinski et al., 2012), 11 (Wang et al., 2011), 13.9 (McQuade & de Oliveria, 2011) and 16 (Lund et al., 2008). Our mean change post-intervention is on the higher side in comparison to the other studies (15.47), potentially due to the type of exercises that were included, all the studies included free weights and tubiband, with no reports of aerobic activities such as walking and cycling, as a mixture of cardiovascular and strength training is recommended (Hochberg et al., 2012). Incidentally, the current study reported a mean range of 41.06-56.53, which is within similar mean scores of 48.22, which have been reported for individuals with knee OA, prior to knee replacement surgery (Stevens-Lapsley et al., 2012).

5.3.2. KOOS-Symptoms

At the 6-week review compared to baseline, the symptoms subscale significantly improved. The KOOS symptoms subscale suggests a minimal detectable mean change of 15.5 (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008), therefore, a non-clinical significant finding was recorded in this study with a mean change of 14.81. However, a minimal perceptible change of 8-10 points has been suggested (Roos & Toksvig-Larsen, 2003), therefore the current study having a positive effect on the symptoms of individuals with knee OA. Preexercise intervention scores range from 41 (Lund et al., 2008), 58.3 (Henriksen et al., 2014), 63 (Thorstensson et al., 2005), 63 (Wang et al., 2011), 64 (McQuade & de Oliveria, 2011), 64.3 (Salacinski et al., 2012), our baseline mean for the KOOS symptoms was on the lower side in comparison to other studies (41.67). Postintervention mean changes for these studies range from 1 point for a high intensity exercise programme (Thorstensson et al., 2005), 4.1 (Henriksen et al., 2014), 6.6 (Salacinski et al., 2012) 7.7 (McQuade & de Oliveria, 2011), 8 (Wang et al., 2011) and 21 (Lund et al., 2008), our mean change post intervention was 14.81. Increased weight would potentially cause greater symptoms, as greater weight loss reduces symptoms in individuals with knee OA (Penninx et al., 2001; Felson et al., 1992). The current study reported a higher body mass index of 27.12 compared to previous studies, which the body mass index ranges from 22.4 to 28.9 (Salacinski et al., 2012; Henriksen et al., 2014; Lund et al., 2008). Critically, in the current study the body mass index of the individuals was not measured after the exercise intervention, so it cannot be clear if the reductions in the symptoms was totally down to the exercise programme and not related to weight loss. However, the current study reported a mean range of 41.67-56.48, which is within similar mean scores of 48.02, which have been reported for individuals with knee OA, prior to knee replacement surgery (Stevens-Lapsley et al., 2012).

5.3.3. KOOS- Activities of daily living

At the 6-week review compared to baseline, the activities of daily living subscale significantly improved. However, between baseline and session 4 no significant improvement was found, which potentially means that from baseline to session 4 the

exercise programme provided the individuals with reduced activities, which could be related to pain (Altman et al., 1986) and reduced function (Felson et al., 2000).

Evidence for the KOOS activities of daily living subscale suggests a minimal detectable mean change of 15.4 (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008), therefore, a non-clinical significant finding was recorded (mean change 14.49). Previous studies that include exercise as an intervention report baseline scores ranging from 40.6 (Lund et al., 2008), 52.6 (Salacinski et al., 2012), 65 (Henriksen et al., 2014), 69 (Thorstensson et al., 2005), 75 (Wang et al., 2011) and 76.5 (McQuade & de Oliveria, 2011), our baseline mean was 46.9. Post mean changes for these studies range from 0.9 (Thorstensson et al., 2005), 4.2 (Henriksen et al., 2014), 7 (Wang et al., 2011), 14.5 (McQuade & de Oliveria, 2011), 20.1 (Salacinski et al., 2012) and 23.5 (Lund et al., 2008), our mean change post intervention was 14.49. Activities of daily living can highlight occupational factors such as individuals that work and individuals that do not work. The current study had 21 non-workers and 33 workers, which could reflect the baseline mean score to be on the lower aspect of the scoring. Differences between workers and non-workers highlight that workers who work 4 or more hours per day in a physical job or walk 6 miles per week have an increased the risk of knee OA (Felson et al., 2007), however prevalence of knee OA is higher in the unemployed (Guillemin et al., 2014). The current study reported a mean range of 46.9-61.39, which is within similar mean scores of 58.33, which have been reported for individuals with knee OA, prior to knee replacement surgery (Stevens-Lapsley et al., 2012).

5.3.4. KOOS- Sport and recreation

At the 6-week review compared to baseline, the sport and recreation subscale significantly improved. However, between baseline and session 4 no significant improvement was found. The KOOS sport and recreation subscale suggests a minimal detectable mean change of 19.6 (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008), therefore, a non-clinical significant finding was recorded in this study with a mean change of 11.5. Pre exercise intervention scores range from 27.6 (Henriksen et al., 2014), 34 (Thorstensson et al., 2005), 40 (McQuade & de Oliveria, 2011), 62 (Wang et al., 2011) and 72 (Salacinski

et al., 2012), our baseline mean was 21.39. Post mean changes for these studies range from 0.5 (Thorstensson et al., 2005), 3 (Wang et al., 2011), 5.1 (Henriksen et al., 2014), 6 (McQuade & de Oliveria, 2011) and 12.2 (Salacinski et al., 2012), our mean change post intervention was on the higher side in comparison to other studies (11.55). Within the current study, sporting activity was not recorded; however, individuals that completed the exercise programme increased the scores, which could be because as the pain reduced during the programme, the sporting activity increased. During the exercise programme, an increase in sporting activity was highlighted, with the greatest increase being reported from baseline to session 4, this increase in sporting activity may be due to the individuals including the exercise session within the scoring, as squatting was included on the programme and is also included in the scoring matrix. Scoring this subscale of the KOOS may be inappropriate due to the disability of the individuals of knee OA, especially in the more advanced individuals (Collins et al., 2011), however not scoring all individuals will remove the improvements gained in more demanding activities after treatment (Roos & Toksvig-Larsen, 2003)

5.3.5. KOOS- Quality of life

At the 6-week review compared to baseline, the quality of life subscale significantly improved. The KOOS quality of life subscale suggests a minimal detectable mean change of 21 (Collins et al., 2011; Goncalves et al., 2009; De Groot et al., 2008; Ornetti et al., 2008), therefore, a non-clinical significant finding was recorded (mean change 18.93). Pre exercise intervention scores range from 37.1 (Henriksen et al., 2014) 40 (Thorstensson et al., 2005), 43.7 (McQuade & de Oliveria, 2011), 49.7 (Salacinski et al., 2012), 57 (Lund et al., 2008) and 66 (Wang et al., 2011), our baseline mean was 24.15. A lower score on the KOOS quality of life in comparison to the other KOOS variables show that the current study also had lower pain and symptom score, which would affect quality of life in individuals with knee OA. Post mean changes for these studies range from 5.1 (Thorstensson et al., 2005), 5.8 (Henriksen et al., 2014), 8 (Wang et al., 2011), 9.5 (Salacinski et al., 2012), 12.6 (McQuade & de Oliveria, 2011) and 13.2 (Lund et al., 2008). The mean changes in the current study highlight that the post intervention is higher in comparison to other studies (18.93) and could be related to a lower baseline quality of life score, a reduction in pain or a reduction in symptoms.

Further critical analysis of the literature highlight a wide variety of exercise sessions that have been completed, from a maximum of 36 sessions (Henriksen et al., 2014) to 12 sessions (Thorstensson et al., 2005). Exercise prescription ranging from free weights and exercise bands with a pre-specified protocol for progression such as gradually increasing from 60-65% 10 repetition maximum to 80-85% (McQuade & Oliveria, 2011), compared to individually increasing the exercise (Thorstensson et al., 2005). Further varieties of exercises, such as single leg sit to stand, one leg hop and single leg squatting (Thorstensson et al., 2005), compared to cycling (Salacinski et al., 2012) and trunk, hip and knee bodyweight exercises (Henriksen et al., 2014). The current study only completed eight exercise sessions over a four-week period, individuals who completed the programme progressed or regressed, as they felt necessary with each exercise. In addition, a mixture of strength, balance, and cardiovascular exercises were included in the programme, to address general fitness as well as muscular strength. As a result of the exercise programme only pain was found to be clinically significant, although statistically significant improvements were seen in symptoms, quality of life, sport/recreation and activities in individuals diagnosed with knee OA.

5.3.6. VAS

The VAS was used to measure and monitor pain, as it is a simple and reliable measurement tool (Bijur et al., 2001). Prior to commencing the exercise sessions, the mean score ranged from 2.67 to 3.68 and after the sessions ranged from 2.74 to 3.93. Baseline scores for the participants pain prior to exercising was 2.67, with the greatest increases at session 4 (3.67) and session 5 (3.68), then the score levels decreased to 2.41 6-weeks after the exercise programme. Baseline scores for the participants pain after completing the exercise class was 3.5, with the greatest increases at session 2 (4.16) and session 5 (3.93), then the score levels decreased to 2.74 at session 8. These scores could reflect the exercise class was causing increased pain after session 2 due to the participants not being accustomed to the programme or exercise in general. Furthermore, older individuals who complete the VAS may find it difficult to complete after the exercise programme, due to cognitive and motor skills issues (Hawker et al., 2011). The mean reduction in pain was clinically significant, as a change in 1.1 is the MDC (Wolfe & Michaud, 2007). Doi et al. (2008) found similar results from an 8-week exercise programme, with pain

reducing from 4.3 points to 2.2 points; however, the exercise sessions in this study were completed at home. Furthermore, the VAS is a subjective measurement of pain and is less valuable when comparing individuals over time, due to variables that can be associated with pain such as time of day, intensity of activity and psychometric/psychosocial issues.

Therefore, in conclusion, the null hypothesis was rejected, as exercise reduced pain and symptoms, and increased function, sport and recreation and activities of daily living.

5.4. Y balance

Null Hypothesis 3- A structured supervised lower limb exercise programme will not does not increase functional unilateral limb muscle strength in individuals diagnosed with knee OA.

The third hypothesis proposed that the exercise programme would improve balance. Dynamic balance was measured using the Y balance test, as these directions are relevant for lower limb muscle strength around the hip and knee, with the anterior direction activating the quadriceps and in particular, vastus medials (Earl & Hertal, 2001) and the medial and lateral direction were using the hip abductors.

5.4.1. Anterior direction

At the 6-week review compared to baseline, the Y balance test anterior direction significantly improved. The minimal detectable change (MDC) score for the Y balance anterior direction is a mean change of 8.7 centimetres was reported in an athletic population (Shaffer et al., 2013), therefore, clinically significant findings were recorded for the affected limb anterior direction with a mean change of 9.03 centimetres, but not the contralateral limb anterior direction (mean change 7.88 centimetres). In addition, the affected limb for the anterior directional reach was higher in relation to the minimal clinical important difference (MCID) of 3.5% in young athletes (Chimera et al., 2015) at baseline, session 4, session 8 and 6-weeks post exercise programme, but the contralateral limb was only higher at session 4. Each reach provided no asymmetries greater than 4 centimetres, which would reduce injury risk (Plisky et al., 2006). Comparative research completed by Al-Khlaifat et al.

(2016) found the anterior reach in 14 individuals was statistically significant after an exercise programme, with mean anterior reaches pre-exercise programme being 64 centimetres and post-exercise programme between 69.36 to 70.33 centimetres, with a mean change of 5.06 to 6.02 centimetres. Our results show a lower pre- and postexercise programme mean reaches of 46.36 centimetres and 55.98 centimetres. However, the current study reported a greater mean change from baseline to 6weeks after the exercise programme on the affected limb (9.03 centimetres) compared to the contralateral limb (7.88 centimetres). This increase in the anterior directional reach could be limited due to gender, as females have greater hip flexion than males, which potentially alters muscle activation patterns and changes the reaches (Fullam et al., 2014), the current study has equal amount of females and males, therefore separate analysis of this may provide results that are more thorough. Although muscle strength does not affect the directional reaches whilst completing dynamic balance activities (Thorpe & Ebersole, 2008), no clinical guidelines are available for specific balance exercises for people with OA; due to the limited evidence available (Chaipinyo & Karoonsupcharoen, 2009). The exercise programme used in this study increased muscle strength and also increased the affected limb anterior, posterior-medial and posterior-lateral directional reaches, which highlights that muscle strength effects dynamic balance and potentially reduces symptoms be provided functional support to the knee joint and reduce the risk of falls (Sorensen et al., 2014).

5.4.2. Posterior-Medial direction

At the 6-week review compared to baseline, the Y balance test poster-medial direction significantly improved. The minimal detectable change (MDC) score for the Y balance posterior-medial direction is a mean change of 10.3 centimetres (Shaffer et al., 2013), therefore, clinically significant findings were recorded for both affected limb (mean change 12.89 centimetres) and contralateral limb (mean change 12.16 centimetres). In addition, both posterior-medial directional reaches were significantly higher in relation to the minimal clinical important difference (MCID) of 3.5% (Chimera et al., 2015) at session 4 and 6-week post exercise programme; whereas session 8 on both limbs was below the 3.5%. Each reach from baseline to 6-week post-exercise programme provided no asymmetries greater than 4 centimetres, therefore reducing the risk of further injury (Plisky et al., 2006). Bouillon & Baker

(2011) compared 53 adults aged between 23-39 years and middle-aged adults ranging from 40-54 years. Mean posterior-medial reaches ranged from 97 centimetres and 105 centimetres from adults aged between 23-39 years and 88 centimetres and 99 centimetres for middle-aged adults. Specifically related to the older adult, Zhuang et al. (2014) found improvements in the medial direction of the SEBT after an exercise programme with a 12.9% change for the left limb and 13.4% for the right limb. Our results show a significantly lower poster-medial directional reach ranging between 70.47 centimetres for the affected limb to 71.29 centimetres on the contralateral limb. In summary, the exercise programme used in this study improved posterior- medial dynamic balance in individuals diagnosed with knee OA and is clinically significant, therefore increasing strength around the hip as well as the quadriceps with exercise programmes should be include both hip and knee exercises.

5.4.3. Posterior-Lateral direction

At the 6-week review compared to baseline, the Y balance test poster-lateral direction significantly improved. The minimal detectable change (MDC) score for the Y balance posterior-lateral direction is a mean change of 11.5 centimetres (Shaffer et al., 2013), therefore, clinically significant findings were recorded for the contralateral limb only (mean change 11.39 centimetres) but not the affected limb (mean change 9.39 centimetres). Despite this, both posterior-lateral directional reaches were significantly higher in relation to the minimal clinical important difference (MCID) of 3.5% (Chimera et al., 2015) at session 4 only, whereas session 8 and 6-week post exercise programme was below the 3.5%. Each reach from baseline to 6-week post-exercise programme provided no asymmetries greater than 4 centimetres (Plisky et al., 2006). Further analysis of the posterior-lateral directional reach with 64 healthy adults with a mean age of 25 years found the mean posteriorlateral reaches ranged between 97 and 98 centimetres (Shaffer et al., 2013). Our results show lower poster-lateral directional reaches at baseline ranging between 79.09 to 79.99 centimetres and similar results 6-weeks post-exercise programme (88.48 to 91.38 centimetres). In summary, the exercise programme used in this study improved posterior- lateral dynamic balance in individuals diagnosed with knee OA.

5.4.4. 30-second chair stand test

The 30-second chair stand test was used to assess balance, functional mobility and strength (Gill et al., 2012). Mean baseline scores for the 30-second chair stand test was 12.48 repetitions, with an increase to 14.87 repetitions at session 4. At session 8, a further increase of 16.26 repetitions was recorded, which increased to 16.70 repetitions 6-weeks after the exercise programme. Minimal detectable change (MDC) for the 30-second chair stand test is two repetitions (Wright et al., 2011), therefore a clinical significant finding was recorded (mean change 4.22 repetitions).

The 30-second chair stand test is a recommended test for knee OA (Dobson et al., 2012), with sit to standing being an important activity in daily living (Kennedy et al., 2002). However, evidence to suggest that individuals with knee OA avoid using the affected limb whilst completing a sit to stand movement (Huber et al., 2016), due to pain and muscle weakness, with altered movement patterns (Mizner & Synder-Mackler, 2005) causing an inability to co-ordinate muscle control when rapidly lowering to chair (Davidson et al., 2013). Furthermore, physical condition can reduce the amount of repetitions, with older, frail individuals completing several attempts, primarily due to altered movement strategies such as increasing the forward and backward ranges in the trunk and hip when standing and sitting, whereas healthy individuals utilise lower limb muscles to move (Millor et al., 2013).

Previous research investigating the 30-second chair stand test in individuals with knee OA by Abbott et al. (2013) found an improvement in the test following a supervised exercise and manual therapy session, mean baseline scores of 10.39 repetitions increased by 1.60 repetitions at the 1 year follow up. Similarly, Bennell et al. (2012) increased repetitions from 9 at baseline to 11.1 repetitions after a 12-week exercise programme, which improved to 11.6 at 1-year follow-up. Gill et al. (2009) found an improvement after a moderate intensity supervised exercise session, which was completed for 1 hour, twice per week for 6-weeks. Mean baseline scores of 6.8 repetitions, increased to 9.7 repetitions at week 7 and then minimally reduced to 8.8 repetitions at 15-weeks. Similarly, Brenneman et al. (2015) reported increases in the 30-second chair stand test following a yoga programme for individuals with knee OA. Baseline mean scores of 13.3 repetitions increased to 14.6 repetitions. Despite this

positive evidence, French et al. (2013) found reductions in the test following a 30minute exercise and manual therapy session completed once per week for 6-8 weeks. Baseline scores of 13.6 repetitions reduced to 13.17 repetitions at the 9week follow up and further reduced to 12.8 repetitions at 18-weeks. Our results highlight a higher increase in the amount of repetitions completed (16.70) and a greater increase in the pre-post intervention repetitions (4.22), which indicates that the exercise programme used in the study significantly increases balance, functional mobility and strength in individuals diagnosed with knee OA.

5.4.5. 6-minute walk test

The 6-minute walk test was used to assess aerobic walking capacity and dynamic balance (Dobson et al., 2013). Mean baseline scores for the 6-minute test was 438.3 metres, which decreased to 437.2 metres at session 4. At session 8, an increase to 456.57 metres was recorded, which increased to 505.28 metres at 6-weeks after the exercise programme. Minimal detectable change (MDC) scores for the 6-minute walk test is 61.34 metres, therefore a clinical significant finding was recorded (mean change 66.95 metres).

Walking distance during the test tends to increase, with the largest increases reported during the first four tests, this could relate to the learning effects whilst completing the test (Pinna et al., 2000). Contrary to the increase in the 6MWT over repeated tests, completing the 6MWT, over 30-metre or longer course is recommended; with a reported 8% lower score being reported with a 10-metre course (Beekman et al., 2013). Older individuals may choose a higher gait speed over a longer walking distance greater than 20-metres, with a slower gait speed over a shorter distance (Najafi et al., 2009). Further evidence of individuals limping, shuffling, shorter step length, age, and weight contributing to a lower score (Pepera et al., 2012; Enright & Sherrill, 1998). In addition, a greater number of turns with a shorter course is associated with a shorter distance (Ng et al., 2011; Enright et al., 2003), with overall continuous courses increasing the distance achieved (Sciurba et al., 2003). However, in a primary care setting it is very difficult to find a course, which is the correct distance, which forces clinicians to complete the course on a 10-metre course, in which the current study completed.

Previous research by French et al. (2011) increased from 405 metres to 447 metres post-standard physiotherapy exercise sessions. Further increases in the 6- minute walk test were found by Brenneman et al. (2015) post yoga programme with individuals distance walking increasing from 532 metres to 573 metres and Simao et al. (2012) increased from 392 metres to 410 metres after completing specific squatting exercises. Therefore, the lower limb programme in the current study increased individuals with knee OA ability to walk further, this could be related to a an increase in muscle strength, improved dynamic balance, reduced pain or a reduction in kinesiophobia. Further studies would complete the 6MWT over a greater course length to reduce turns and reduce gait speed.

5.4.6. Borg

The Borg scale was used to measure the perceived level of exertion (Borg, 1998). Mean scores throughout the 8-session exercise programme ranged from 13.22 to 14.07. Baseline scores for the participants perceived exertion was 13.5, with the greatest increases at session 4 (13.98) and session 5 (14.07), then the score levels decreased to 13.29 at session 8. Scores of 12 to 14 have been reported as moderate activity in which the individuals were working 'somewhat hard' (Borg, 1998), which can significantly influence knee OA (Esser & Bailey, 2011). Moderate activity has been linked with improved function and reduced pain for up to 6-months (Fransen et al., 2015); therefore, the individuals in the current study should have improved function and reduced pain for that period. Furthermore, the participants can utilise the positive aspects of using the Borg scale, which would assist with a self-management programme as the perceived exertion can be completed anywhere (Borg, 1998).

Therefore, the null hypothesis was rejected, as functional unilateral limb muscle strength significantly increased after completing a lower limb exercise programme.

5.5. PASE

Null Hypothesis 4a - A structured supervised lower limb exercise programme assessed by questionnaire will not increase physical activity in individuals diagnosed with knee OA

Physical activity was measured using the PASE questionnaire, which is a valid and reliable measurement tool in healthy adults, aged 65 and over (Logan et al., 2013; Martin et al., 1999) and has been used in OA research (Quicke et al., 2016; Bennell et al., 2012). Mean baseline scores for the PASE were 174.90, with an increase to 187.39 at session 4. At session 8, a further increase of 190.48 was recorded, which increased to 211.37 6-weeks after the exercise programme. Minimal detectable change (MDC) score for the PASE varies with different intensities of physical activity, mean changes of 35 for light physical activity, 28 for moderate activity and 10 for vigorous activity (Svege et al, 2012) therefore, a clinically significant finding was recorded (mean change 36.47). Lower baseline scores have been reported, ranging between 120 points (Chmelo et al., 2013) and 155 points (Dunlop et al., 2011), with an increase of 23% in the PASE after one year, 48% of individuals remaining the same and 29% of individuals reducing activity (Dunlop et al., 2011).

Whilst completing the PASE questionnaire is a cost effective and easy to administer measurement tool to measure physical activity (Svege et al., 2012), misinterpretation by the individuals completing the questionnaire can be problematic, with inaccurate recollection of activities such as duration and intensity being reported (Welk, 2002). Underestimation and overestimation are common issues with the usage of the PASE whilst measuring physical activity, with individuals likely to overestimate higher intensity activity compared with lower intensity (Bonnefoy et al., 2001). Specific evidence highlights an underestimation of approximately 2 hours and 45 minutes for older adults completing the PASE (Washburn et al., 1990). In addition, physical activity questionnaires are prone to bias with social desirability or cognitive issues related to inputting incorrect data (Durante & Ainsworth, 1996; Jobe & Mingay, 1989).

Bennell et al. (2012) found that the PASE increased during a 12-week, 4 sessions per week exercise programme, which consisted of 70 minutes of lower limb exercises. Improvements ranged from 151 points at baseline and 172 points at 12-weeks. Further long-term analysis increased the score of the PASE, as at 32-weeks

a score of 163 was recorded and at 52-weeks a score of 180 points being recorded. In addition, Quicke et al. (2016) found an increase in the PASE after a 12-week lower limb exercise programme, improvements from 177 points at baseline, to 192.1 points at 3 months and 190.5 points 6 months post intervention. The average PASE scores in our study were higher than other studies, which increased throughout the study. Potential reasons for this increase could be due to the wide age in our cohort (47-79 years of age), participant's overestimation in physical activity, cognitive issues whilst completing the questionnaire, as the current study had a mean age of 63 years, which contradicts previous research, which reported decreased scores on the PASE with increasing age (Washburn et al., 1993).

Therefore, the null hypothesis was rejected, as exercise increased physical activity in individuals diagnosed with knee OA.

5.6. ActivPAL™

Null Hypothesis 4b - A structured supervised lower limb exercise programme objectively assessed will not increase physical activity in individuals diagnosed with knee OA

Whilst physical activity was measured with the PASE questionnaire, it is known that subjective measurements underestimate/overestimate the actual physical activity that individuals perform (Svege et al., 2012; Haqiwara et al., 2008, Bonnefoy et al., 2001). Therefore, in order to get a complete picture of the changes in physical behaviour an activPAL [™] activity monitor was used by the individuals at two different time points, at the baseline assessment and 6-week post- exercise class. Recommendations suggest wearing an activity monitor for 4-7 consecutive days to accurately assess activity patterns (Hart et al., 2011; Trost et al., 2005), fewer than 7 days introduces bias due to differences with activity by day of the week (Kocherginsky et al., 2017). This is the first study to objectively measure physical activity behaviour such as stepping activity, upright activity, sedentary activity, transitions, cadence, and energy expenditure in individuals with knee OA before and after an NHS delivered lower limb exercise programme.

5.6.1. Sedentary time

Mean 7-day sedentary time recorded non-significant results, as sedentary time increased from 122.57 hours to 123.75 hours. Potential reasons for this increase in sedentary time could be due to the post- exercise responses such as joint and muscle pain or even lack of aerobic fitness. Alternatively, the participants could potentially be generally physically inactive or in occupations that are inactive, with office occupations spending 1.5 hours longer in a sedentary posture compared to delivery staff (Tigbe et al., 2011), further investigations into occupations within the current study could have provided a more detailed response. The protocol for wearing the activPAL[™] stated that all participants were advised to wear the monitor for 7-days without taking the activPAL[™] off. Sedentary time can be classified as sitting and lying, the current study did not take into account sleeping times, especially in relation to when the individuals went to bed and when they woke up, as this could significantly alter the amount of sedentary time. However, an increase in sedentary time especially whilst sleeping could potentially be a positive aspect of the study, as pain often wakes individuals with knee OA whilst sleeping. Further research could investigate sleeping patterns with the potential use of a diary to monitor sleep and waking time. On the contrary, the activPAL[™] can actually misclassify certain activities such as seat perching, kneeling and crouching (Sellers et al., 2016), but it is much better than a questionnaire, as sedentary times are significantly underestimated using a questionnaire (Clemes et al., 2012). Similar results in sedentary time have been highlighted over a 4-day period with individuals with knee OA being more sedentary than healthy individuals (65% versus 57%), demonstrating lesser short bouts of sitting (less than 1 minute) (8 versus 13), and similar amounts of long sitting (29 versus 33) (Verlaan et al., 2015). In summary, the lack of change in the sedentary time highlights that the individuals who completed the study are still at risk of symptoms of knee OA such as muscle weakness and pain.

5.6.2. Upright

Mean 7-day upright activity recorded non-significant results, as upright activity reduced from 33.17 hours to 32.01 hours. Upright positions may be relevant to measure activities of daily living such as occupation and housework (Taraldsen et

al., 2011). Specifically related to knee OA, Tonelli et al. (2011) reported that over a 7day monitoring period, upright postures were recorded, with nearly 50% of the monitoring period being recorded in a upright posture (between 3.2 and 3.5 days). In addition, De Groot et al. (2008) found that individuals with knee OA spend more time upright compared to healthy individuals; however, upright activity monitoring was completed for 48 hours, which increases the risk of bias. Since knee OA is becoming more prevalent in the younger population, occupational status is important, with aspects of physical activity being relevant during working hours. Evidence has shown that office occupations have considerable less upright activities per day (3.9 hours) compared to delivery type occupations (6 hours) (Tigbe et al., 2011). Contrary to this, individuals who work in an upright occupation may spend more leisure time being sedentary and those in a sedentary job may spend more time completing leisure activity. Further analysis of occupations, hobbies, and daily activities within the current study would enhance the data. In summary, individuals with knee OA spend less time standing over a 7-day period, this could be due to occupation, pain, fatigue or more positively that they are moving around more frequently.

5.6.3. Walking

Mean 7-day walking activity recorded non-significant results, as walking increased from 11.33 hours to 12.02 hours. Walking is the most common exercise employed by older adults (Hootman et al., 2003) with activity monitoring being advantageous due to the fact that large amounts of data can be collected under normal walking conditions (Kobsar et al., 2014a). Verlaan et al. (2015) found that individuals with knee OA completed less walking over a 4-day period compared to healthy individuals, whereas the current study, individuals with knee OA spent more time walking over a 7-day period after an exercise programme. Different variables include body mass index (increased in Verlaan et al. 2015), grade of knee OA (grade 3-4 only in Verlaan et al. 2015) and a higher age range (56-81 years in Verlaan et al. 2015). These variables could reduce walking bouts due to an increase in joint loading, pain, and occupational issues, as active occupations such as delivery staff are 15 minutes more physically active per day than office occupations (Tigbe et al., 2011). In summary, the exercise programme for individuals with knee OA increased 7-day walking; this could be a positive outcome from the exercise programme by improving muscle strength and walking performance (Talbot et al., 2003).

5.6.4. Stepping

Mean 7-day stepping activity recorded statistically significant results, with stepping increasing from 52,521.84 steps to 56,459.91 steps, indicating a mean increase of 3,938.07. Stepping activity increased in 67.79% of the participants after the exercise class compared to 32.21% participants. Mean daily steps day increased from 7,503 to 8,065, which is higher than the previous studies reported, such as 6,732 (Holsgaard- Larsen & Roos, 2012), 5,900-6,900 (Tudor-Locke et al., 2009), 4,402-6,943 (Verlaan et al., 2015) and 4,000 (Talbot et al., 2003). In addition, our results are higher than the 7,000 steps per day recommended for developing and maintaining function (Garber et al., 2011; Tudor-Locke et al., 2011) and are greater than the vigorous physical activity guideline of 5,950 steps (Farr et al., 2008). Furthermore, our study shows that participant's weekday daily walking of 10,000 plus steps increased by 37%. ActivPAL[™] data highlighted 45 recordings of participants walking 10,000 plus steps at the pre-testing stage compared to 62 post- testing.

Consequently, walking greater than 10,000 steps per day has been reported to increase bone marrow lesions in individuals with knee OA (Dore et al., 2013), contrary to this Oiestad et al. (2015) reported no difference between stepping activity and further degenerating the knee. Both studies are different, with Dore et al. (2013) not excluding individuals with end stage knee OA and using pedometers to measure stepping activity, in which, pedometers underestimate activity (Tyo et al., 2011). Oiestad et al. (2015) reported walking considerable less steps (6,981) and a much lower prevalence of knee OA compared to Dore et al. (2013) (57% compared to 28%).

Weekend stepping activity increased from 15,127.67 steps to 15,623.35 steps, indicating a mean increase of 495.67 and therefore recording a statistically non-significant result (p=0.62). Mean weekend daily steps day increased from 7,563 to 7,811 which is within the activity classification as 'somewhat active' (Hills et al., 2004). Participant's weekend walking of 10,000 plus steps increased by 23.5% with activPAL[™] data highlighting 17 recordings of participants walking 10,000 plus steps pre-testing compared to 21 post- testing. Monitoring stepping activity can be motivational and potentially facilitate behaviour change, as it is easy to complete, objective, the results are understandable to the layperson and the results can be

used in research for public health messages (Tyron, 2013). Incidentally, an increase of 2,500 steps can positively facilitate behaviour changes (Bassett et al., 2017). In summary, the exercise programme enabled individuals with knee OA to complete further stepping activity, potentially due to a reduction in pain, reduction in kinesiophobia or an increase in muscle strength.

5.6.5. Energy Expenditure

Mean 7-day energy expenditure recorded non-significant results, in which energy expenditure reduced from 237.86 to 236.71. Exergy expenditure is an important aspect of health, as a reduction in energy expenditure has been linked to decreased physical mobility in older adults (Manini et al., 2006). Individuals within the current study reduced energy expenditure could be potentially due to spending more time sedentary and less time is upright postures. However, Tonelli et al. (2011) reported a daily energy expenditure of between 32.33 and 32.51, which is lower than the current study. Variables that could potentially confound energy expenditure could be age, body weight, OA severity, social support, pain, and kinesiophobia, however within the current study both pain and kinesiophobia reduced. Furthermore, occupation can be a variable, which influences energy expenditure, with paid employment significantly expending higher levels of energy (Manini et al., 2006). Sixty-six percent of the participants in the current study were unemployed or retired, which potentially could be a reason for a lower energy expenditure score. In summary, individuals with knee OA who completed the exercise programme expended less energy after the intervention, which could lead to further physical mobility issues.

5.6.6. Transitions

Mean 7-day transitions recorded statistically significant results, with transitions increasing from 319.07 transitions to 365.25 transitions, indicating a mean increase of 46.16 transitions. Monitoring transitions can be a valuable measure, as it may review changes in activity and highlight changes in physical activity (Taraldsen et al., 2011). Tonelli et al. (2011) reported higher transition averages over a 7-day period, with transitions ranging from 50.53 to 51.08 transitions per day without completing any interventions. Whereas, Verlaan et al. (2015) reported a lower mean range of 37 transitions over a 7-day monitoring period. Both studies analysed individuals with

end stage knee OA. The current study found a pre-intervention daily average of 45.58 transitions, which is similar to De Groot et al. (2008) who reported 46 transitions per day. However, post-intervention daily average transitions for the current study was 52.18 transitions per day, which is greater than Tonelli et al. (2011) and suggests that the exercise programme reduced pain, increased muscle strength to allow the participants to complete more daily transitions.

5.6.7. Cadence

Mean 7-day cadence increased throughout at every cadence bands until cadence band 130 onwards with statistically significant results at cadence band 110-120 steps per minute. Reduced walking speeds are associated with knee OA to reduce joint load and pain within the knee joint (Purser et al., 2012; Robon et al., 2000) with faster walking speeds associated with increased joint loading (Ward & Powers, 2004). Most adults aged between 60-79 years walk at around 100 steps per minute (Tudor- Locke et al., 2009; Bohannon, 2007), which can be classified as moderate physical activity, with 110 steps per minute reported as high intensity (Hankinson et al., 2013). Comparative analysis highlights that cadence parameters ranges from 87 steps per minute in individuals with end stage knee OA to 99 steps per minute in healthy individuals (Verlaan et al., 2015). Within the current study, cadence increased from pre-intervention to post-intervention at all the banding levels. Increases in the individual's cadence is associated with a reduction of pain, reduction of kinesiophobia, increased muscle strength, decreased symptoms and increased dynamic balance after the exercise programme. Specifically significantly increasing at banding 110-120 steps per minute, this indicates that the individuals were completing moderate to vigorous activity levels, which also corresponds with the Borg scale score in the current study. Moderate activity has been linked with improved knee function and reduced pain for up to 6-months in individuals with knee OA (Fransen et al., 2015). In summary, our study shows that individuals with knee OA increase their cadence after an exercise programme, this could be due to a reduction in pain, reduction in kinesiophobia, increased muscle strength, increased dynamic balance, or increased aerobic fitness.

Therefore, the null hypothesis was partially rejected for 7-day transitions, stepping activity and at cadence band 110-120 steps per-minute; however, it

was accepted for sedentary time, upright positions, energy expenditure, and walking time.

5.7. Correlational Analysis

Based on the results of the current study, selected variables such as physical activity (PASE), pain (KOOS pain) and activPAL[™] upright activity and stepping were statistically analysed, to evaluate the strength of the relationship. Firstly, a correlation between pain (KOOS) and physical activity (PASE) was completed with a strong correlation being found at session 8 of the exercise programme (r=0.96), however, weak positive correlations were found at session 4 (0.32) and 6-weeks post programme (0.21). Measuring physical activity using the PASE questionnaire has been significantly correlated with pain in individuals with knee pain with age and gender being moderators of the PASE scores (Martin et al., 1999), potentially due to physical activity levels and pain levels. The current study found a significant correlation at session 8, which was the final session of the exercise programme. Reduction of pain, reduction of kinesiophobia, increased muscle strength, and increased aerobic fitness alongside being supervised in an exercise class by a physiotherapist could potentially be reasons why this correlation was significant at session 8. In contrast, at session 4, weak correlations between pain and physical activity were found, pain did not significantly reduce during these sessions and reduced after session 4.

Further correlations, between physical activity (PASE) and activPAL[™] variables such as upright positioning, walking, and stepping activity were completed. Strong positive correlations were found between physical activity and activPAL[™] walking and activPAL[™] stepping at baseline assessment, moderate correlations between physical activity and activPAL[™] upright positioning at baseline and 6-weeks post programme. Similar evidence found a significant correlation between the physical activity (PASE) and stepping using a Kenz Lifecorder EX (NL-2200), with higher daily stepping correlating with a high PASE score (Chmelo et al., 2013). Within the current study, a weak correlation was found with physical activity and activPAL[™] stepping activity at 6-weeks post-intervention, a potential reason for this weak correlation,

could be due to an increase in kinesiophobia which would be related to both physical activity and stepping.

5.8. Content Analysis

Listening to the patient's voice is an essential aspect in research as it can provide a deeper understanding of the research topic and have a greater scope of enhancing practice (Johnson et al., 2007). Furthermore, it can enhance the relationship between the NHS, patients and the public (Five-year forward view, NHS, 2014). A content analytical approach was used to listen to the participant's voice by completing a short set of standard questions. Content analysis can incorporate text into the research question with specific themes being extracted from the interview.

Fifty- two participants completed question one, which asked the participants about how the condition (knee OA) was affecting them in relation to pain, function and completing hobbies and work. Two participants did not complete the semi-structured interview, as they did not want to complete it. Themes were extracted from the interview and it was decided that question one was divided into participants who reported improvement and participants who reported no improvement. Fifteen participants (28.85%) reported no improvement in the condition with 37 participants (71.15%) reporting improvements. Pain was the dominant reason reported by the participants, with a variety of explanations mentioned, such as 'pain still present, but just get on with it, got to keep going, able to complete gardening' (participant 7), 'no different to what the pain was before, not altered the pain' (participant 22) and 'struggling at the moment, locking a lot more, putting pressure on the right knee' (participant 13), which could have been an adverse reaction to the exercise programme. Wilcox et al. (2006) found pain as a barrier to exercise, with the experience of pain during exercise, occurrence of pain preventing exercise and pain experienced after exercises reducing the compliance for individuals to participate in exercise. In addition, Holden et al. (2012) reported uncertainty about the benefits of exercise on knee pain; this is due to the perception of the knee problems. Walking was the main theme extracted that caused pain. Positive aspects of the questioning highlighted that even though the participants reported no improvement in the condition, some participants reported the use of exercises was being completed. Hendry et al. (2006) characterised individuals with knee OA who reported pain and

negative experiences as *'retired from exercise'* due to the exercises increasing symptoms and preventing individuals completing their preferred activities. Correlating the interview questions from the 15 participants that reported no improvement highlight 6 participants had a reduction in the KOOS pain score, 2 participants had a reduction in the KOOS symptoms score, 11 participants improved on the 6MWT, 13 participants improved on the 30 second chair stand test and 14 participants improved in the PASE score. In addition, 9 participants had high kinesiophobia.

Fifty- two participants answered question two which asked the participants if intensity/variability was the same after the exercise programme, specifically during AM and PM. Fifteen participants (28.85%) reported no improvement with the intensity and variability of the pain and 37 participants (71.15%) reported improvements. Themes were extracted from the interview and it was decided that question two was divided into participants who reported improvement and participants who reported no improvement. Activity related themes were reported by the participants that caused pain, with a variety of explanations mentions, such as 'deep squats/kneeling causes pain, sit-stand regular' (participant 11), 'long walking increases pain' (participant 14) and 'yes, bad in the morning and walking around as well' (participant 45). Correlating the interview questions from the 15 participants that reported no improvement highlight 5 participants had a reduction in the KOOS symptoms score.

Question three asked the participants what they felt aggravated and eased the pain. Forty-eight participants (92.31%) reported aggravating factors, with 11 (22.92%) participants reporting going upstairs and downstairs, 8 (16.67%) walking, 6 (12.5%) twisting, 3 (6.25%) running, 3 (6.25%) sitting, 1 (2.08%) for golf, 1 (2.08%) for football and 1 (2.08%) for standing. Forty participants reported easing factors with 17 (42.5%) participants reporting movement easing their symptoms, specifically swimming, walking and stretching, 12 (30%) for rest and 7 (17.5%) for tablets such as co-codamol, ibuprofen and tramadol.

Question four asked the participants if anything was preventing them from doing things after the exercise programme. Fifty- two participants answered the question with 17 (32.69%) participants reporting that the condition was preventing them doing

something that they like or have to do such as golf, running, hill walking, dance class, motorcycling, touch rugby, ladder work, building, and driving. Specific examples being, '8 1/2 miles walking, managed 7 miles, but pain stopped it' (participant 4), 'don't think I could complete a long distance drive, after 20 minutes it hurts' (participant 52) and 'I would like to run, especially road running' (participant 20). Two participants reported psychological barriers, 'yes, playing golf, not played due to confidence, thinking of going to the golf range' (participant 10) and 'yes, dance classes, scared of twisting knee' (participant 28). Fear of a specific activity and perceived negative outcomes are common psychological barriers to exercises, which could occur when pushing beyond physical limits (Wilcox et al., 2006). Whereas, thirty- five (67.31%) participants answered that it was not preventing them from doing anything.

Question five asked the participants if the exercise programme improved or did not improve the pain. Fifty- two participants answered the question with 47 participants (90.38%) reporting that they felt that exercises eased the pain, comments such as *'yes, think so, not as half as painful as it was'* (participant 16), *'exercise programme eased pain, can move more freely in the morning'* (participant 30), *'exercise has helped, got me out and walking again'* (participant 47) and *'yes, not at first, but as I went on the pain eased'* (participant 23). Hendry et al. (2006) classified these exercise behaviours as *'long-term active'* as they reported positive attitudes and are encouraged to exercise. Furthermore, Petursdottir et al. (2010) and Campbell et al. (2001) reporting positive effect of an exercise programme, with individuals reporting better outcomes in dressing, balance and controlling weight. Five participants (9.62%) stated that exercise did not ease the pain; this could be due to the participant's perception of the exercise programme (Campbell et al., 2001).

Question six asked the participants what they felt eases there pain. Twenty- six participants (50%) answered the question, with ten participants advocating exercises and being physically active to improve pain. Six participants wanted to be referred for acupuncture; four participants were referred to an orthopaedic surgeon with one participant being listed for a total knee replacement and one participant being referred for an injection. Other methods of pain relief methods reported were hydrotherapy, rest, and anti-inflammatory creams.

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In summary, 90% of the participants felt that the exercise programme improved there knee pain, 71% reported an improvement in function, hobbies and work, with 71% reporting an improvement in the intensity and variability of the knee problems. Activities that aggravated the symptoms were physical activities such as walking, twisting, and stair climbing, whilst more intense activities such as running, golf, and football were reported. Tablets and rest were passive easing factors with swimming being reported as an active easing factor. Exercise as a treatment for knee OA, was not beneficial for everyone in the study, as requests for acupuncture, referral to orthopaedics and one individual was listed for a joint replacement.

5.9. Clinical Implications

Within the United Kingdom (UK), we have the privilege to have a publicly funded National Health Service (NHS), which was founded in 1948. Core principles for the NHS were introduced such as healthcare being free at the point of delivery, healthcare will meet the needs of everyone, and assessment and treatment will be based on clinical need (NHS Choices, 2016). Subsequently, 60 years on, the department of health issued further key principles such as aspiring to the highest standards, being accountable to the public and providing best value of taxpayer's money (Department of Health, 2012). Current economic changes within the UK means the hierarchy within the NHS has become more focused on targets, reducing staff, achieving foundation trust status, and financial efficiency. An illustration of this is that the NHS will record a financial deficit of approximately £3 billion for 2015/2016, which is the largest deficit in the history of the NHS (Dunn et al., 2016). Furthermore, local public health budgets will be reduced each year by approximately 3.9% until 2020 and will have a significant impact on the NHS (Dunn et al., 2016). Fundamental changes to the delivery of care has been suggested through supporting individuals to self-manage their own condition and removing a one size fits all approach to healthcare due to the diversity of patient needs (Betancourt & King, 2000). Public Health England have prioritized prevention through incentivising and supporting health behaviour (NHS 5 year forward view, 2014), with evidence based practice being an essential component to support the treatment and care of individuals (Liberating the NHS, 2010). Furthermore, offering individuals the chance to participate in research to transform services, improves health outcomes, and accelerates cost effective health innovation (NHS 5 year forward view, 2014). Allied

health professionals have the skills and enthusiasm to make a greater impact on the health of the UK public (Public Health England, 2014). Public health is important to improve the health of the population, but also to prevent illness and disability (Department of Health, 2014). Department of Health (2012), define health improvement as 'people being helped to live healthy lifestyles, make healthy choices and reduce health inequalities'.

Our findings demonstrate that kinesiophobia and pain reduces after completing an exercise programme in participants with knee OA. During the exercise programme, as kinesiophobia reduced, so did the individuals pain, therefore baseline kinesiophobia scores could be important due to the correlation with pain changes. Further significant findings demonstrate that the programme increases objectively measured physical activity attributes and mobility in individuals with OA, therefore having a greater impact on developing and maintaining function. Kinesiophobia requires consideration in the management of knee OA, as it is associated with pain severity, disability, poor rehabilitation outcomes and negative response to treatments (Sullivan, 2013; Bergsten et al., 2012; Sullivan & Adams, 2010; Somers et al., 2000). Health care professionals should listen to the feelings, behaviours that individuals report, and specifically indicating kinesiophobia. Early interventional management of kinesiophobia will improve the rehabilitation process and has been shown to increase physical activity levels and reduce chronic behaviour patterning (Swinkels-Meewisse et al., 2003). The use of a triage questionnaire to target the psychological aspects of knee OA, so that the barriers of behaviour change can be assessed before the individuals enter the NHS could be beneficial. The questionnaire could address the individual's beliefs and attitudes, as higher levels of psychological issues equals higher physical inactivity levels (Beckwee et al., 2013). During the assessment phase of rehabilitation, potential recommendations for physiotherapists could be the use of motivational interviewing techniques to motivate individuals to exercise and graded programmes which have been proven effective in reducing kinesiophobia (Thorn et al., 2007; Sullivan & Adams, 2010). In addition, the use of cognitive behavioural programmes to include education, stress reduction, paced exercises and mediation may be more appropriate (Al-Obaidi et al., 2003; Vlaeyen et al., 2001). Furthermore, implications during the treatment phase of the rehabilitation process highlight that manual therapy, injections and medications may help with

pain, however they have limited value in individuals with high kinesiophobia due to the psychological reliance on these interventions (AI-Obaidi et al., 2003; Vlaeyen et al., 2001).

Individuals with high kinesiophobia are likely to have a greater hospital stay (4 days), greater intensity of pain and less knee flexion post knee surgery (Brown et al., 2016) with high kinesiophobia being correlated with post-operative pain and recovery after surgery for up to 1 year (Filardo et al., 2015). Therefore, the need to reduce kinesiophobia prior to surgery would enhance the recovery phase, this potentially could be reduced by implementing a pre-operative questionnaire that would highlight individuals with high kinesiophobia, and they would be sign-posted to a specialist physiotherapist who would use motivational strategies.

5.10. Limitations of the study

As with any study, there are limitations. Individuals who participated in the study were not blinded to the exercise programme; furthermore, investigator blinding was not present due to the study participants being recruited, assessed and data being collected by the investigator. Standard practices were included to reduce the bias, improve credibility and transferability such as any grade of knee OA being included, age 45 and above, same testing environment with the investigator completing all data collection and data analysis. Validated and reliable outcome measures were used, with the application of standardised statistical tests also being used within the final analysis to provide positive epistemology and repeatability. Further bias from the investigator was present with motivation and persuasion during the assessment and exercise programme, which could increase participation loyalty to the investigator.

Diversity of the participants could further limit the study, with a varied age range (47 to 79 years of age), physical and mental expectations of the exercises programme with 21 participants being employed, and 33 non-workers. Participants who were working could have had different expectations and thoughts throughout the study, examples being worried about time off work, worried about the cost of having time off work, worried about if the pain will decreased the risk of working and cost of parking.

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The exercise programme was designed to utilise the gym equipment available in the physiotherapy department, most of the equipment is out-dated, and therefore a basic programme was designed to promote ease of developing an exercise programme for the participants to self-manage. In addition, gym availability provided major issues with 2 hours on a Tuesday and Thursday being issued, due to other health services using the gym. Individuals who started the programme on a Tuesday were disadvantaged as they received less time to recover (1.5 days) compared to those who started on a Thursday (4.5 days). Ideally, the exercise programme would be completed 3-times per week with individuals commencing the class on a certain day. Further issues with the gym availability was the time of day allocated with midafternoon for both days, which increased barriers on participants to have time off work to exercise and also struggling to park at the clinic at this time was mentioned by the participants. Ideal equipment such as a leg press machine or a squat machine to increase lower limb strength would benefit individuals, as it would make the progression of loading as per ACSM guidelines easier to complete. In addition, the use of an anti-gravity treadmill to reduce forces through the lower limb and could provide valuable information in relation to specific forces and walking speed throughout the programme (Patil et al., 2013). However, a thorough review of the literature would be required to purchase this equipment, as they are very costly.

Multiple variables are associated with kinesiophobia and is a further limitation to the study. Kinesiophobia is considered a psychological behavioural factor with sociological, lack of confidence and previous experience being as important as the physical characteristics. We have assumed that the exercise programme had a positive impact on kinesiophobia, however, the patient/therapist interaction, the hawthorne effect and the simple education provided by the physiotherapist could have changed the participant's beliefs and behaviours regarding knee OA and exercise, which could have influenced the results and reduced kinesiophobia. Further limitations highlight non-significant changes in activity avoidance using the tampa scale of kinesiophobia. Although the scores reduced throughout the exercise programme the p-value does not change, which highlights that the measurement may not powered effectively and that the sample size may be too small. Understanding individual exercise behaviours and habits should be established as

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part of the routine examination and treatment for knee OA especially in relation to physical activity and will be further investigated by Hinman et al., 2017.

Pre and post testing for the activPAL[™] is a limitation due to 20% of the participants not having complete data. Genuine reasons for not wearing the monitor were given by the participants and were accepted by the investigator. Seven days analyses was completed for the activPAL[™], an appreciation of weekday and weekend activity was completed, as data can be similar for Monday to Friday, but significantly different on Saturdays/Sundays, which can highlight sedentary behaviour and light-lifestyle activity (Kocherginsky et al., 2017). In addition older people are more likely to be retired, which may decrease the variability of weekday-weekend pattern (Kocherginsky et al., 2017). Further variables such as the weather (individuals walking or sitting more when it is sunny) or ill health (individuals could have developed a cold and stayed in bed) could have influenced the results. To reduce these variables, the chief investigator and the exercise class physiotherapist asked the individuals if they had any problems between sessions, as this is routine practice.

Patient choice was adhered to with two participants did not want to complete the semi-structured interview; no reason other than they did not want to complete it was given.

Finally, the major limitation of the study is that it is not a randomised control trial and that the effect of the exercise programme could have been seen if the individuals did not complete the exercise programme. A control was not chosen, as we wanted to fully investigate the pragmatic effects of an NHS delivered exercise programme to specific outcomes during the programme.

5.11. Conclusion

The aim of the thesis was to investigate the relationship of a lower limb exercise programme on kinesiophobia in individuals with knee osteoarthritis and other clinical outcomes. Kinesiophobia was measured by using the Tampa scale of kinesiophobia questionnaire with physical activity being measured subjectively using the PASE questionnaire and objectively using the activPAL[™]. Pain, symptoms, function, activities of daily living, quality of life and sport and recreation was measured using the KOOS questionnaire, with tests such as the 6MWT, 30-second chair stand test

and the Y balance test were used for functional outcomes. The VAS and Borg scale measured pain and perceived exertion.

This is the first study, to the author's knowledge to demonstrate that kinesiophobia and pain significantly reduces after completing an exercise programme in individuals with knee OA. Reducing kinesiophobia in a primary care setting is an essential aspect of treatment so that physiotherapists or other health professionals can prescribe exercise that will positively influence the outcome of rehabilitation

Further significant findings demonstrate that the exercise programme increases objectively measured physical activity attributes and mobility in individuals with OA. This is the first study to the author's knowledge to objectively measure data using an activPAL [™] monitor to investigate pre- and post- changes in individuals with knee OA after completing an exercise programme. ActivPAL[™] data highlighted improvements throughout the study, with significant findings for 7-day stepping and transitions, weekday walking, weekday stepping and weekday energy expenditure. This gives some indication that individuals diagnosed with knee OA complete more weekday activity than at weekends. Cadence was significant for both 7-day and weekday analysis at 110-120 steps per minute, which supports that the individuals in the study were moderately active, this was supported subjectively by the Borg scale, as individuals who were completing the exercise programme reported that they were exerting themselves within a moderate level of scoring.

Balance, aerobic fitness and strength significantly improved throughout the exercise programme. One reason for this could have been the variety of exercises, which included cardio-vascular activity, single leg activity, and strength based activity. Given the improvement in the outcome measurements, this study supports research that exercise is beneficial in the treatment of knee OA.

Further work should asses specific exercise prescription utilising the ACSM guidelines for strength training or similar principles, so that individualized exercise programmes can be developed to enable individuals to self-manage the condition, which potentially enhances exercise adherence (Jordan et al., 2010; Miles et al., 2011). In conjunction with an exercise programme, the use of an education programme such as the ESCAPE pain programme would further enhance the treatment of knee OA.

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Locally, liaising with the local council and government to reduce the price of gym membership and one-off gym sessions could potentially motivate individuals to exercise and increase adherence, as currently a membership is £31 per month or £3.50 per session. In addition, the potential use of activity monitors to monitor activities could be positive and could be used a physical activity quality and innovation indicator (CQUIN). An example of this from the NHS perspective would be financial rewards for successfully promoting physical activity similar to that of smoking and obesity and from a patient perspective, rewards may be issued if you reach the set target of activity.

Research is core business for the NHS (NHS Constitution, 2012) and the opportunity to embed research as front line clinicians will only improve the quality of care, improve health outcomes, and further enhance the profession in the future (CSP, 2010; Elzinga, 1990). Equally important is the engagement of health care staff who are required to conduct research to improve the current and future health and care of the population. NHS staff should be supported to undertake research to fulfil their potential to deliver high quality care to the current population and enhancing care for the future health of the population (NHS constitution, 2012).

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Appendices

Appendix 1

University Ethics



Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team G0.3 Joule House University of Salford M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

30 October 2015

Dear James,

<u>RE: ETHICS APPLICATION HSCR 15-80</u> – Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement with lower limb exercises in Knee Osteoarthritis.

Based on the information you provided, I am pleased to inform you that application HSCR15-80 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting <u>Health-ResearchEthics@salford.ac.uk</u>

Yours sincerely,

day An.

Sue McAndrew Chair of the Research Ethics Panel

Health Research Authority South West - Cornwall & Plymouth Research Ethics Committee

Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT

08 February 2016

Mr James Molyneux Clinical Lead Physiotherapist Bridgewater Community Foundation Trust Physiotherapy Department, Leigh Health Centre The Avenue Leigh WN7 1HS

Dear Mr MOLYNEUX

Study title:	Mixed methods study to evaluate pain, function,
	postural stabilisation, and fear of movement following a
	lower limb exercise programme for Knee Osteoarthritis
REC reference:	16/SW/0036
IRAS project ID:	154227

Thank you for your letter of 04 February 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Georgina Castledine,

nrescommittee.southwest-cornwall-plymouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study. Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, <u>www.hra.nhs.uk</u> or at <u>http://www.rdforum.nhs.uk</u>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact <u>hra.studyregistration@nhs.net</u>. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

A Research Ethics Committee established by the Health Research Authority

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance or Indemnity]	1	10 November 2015
GP/consultant information sheets or letters	1	18 January 2016
Interview schedules or topic guides for participants [interview schedule]	1	18 January 2016
Interview schedules or topic guides for participants [Interview Questions]	1	18 January 2016
IRAS Checklist XML [Checklist_25012016]		25 January 2016
IRAS Checklist XML [Checklist_06022016]		06 February 2016
Letters of invitation to participant	1	18 January 2016
Other [University Ethics]	1	10 November 2015
Other [Insurance]	1	10 November 2015
Other [RJ CV]	1	18 January 2016
Other [Exercise Leaflet]	1	18 January 2016
Other [ActivePal instructions]	1	18 January 2016
Other [VAS]	1	18 January 2016
Other		
Other [Response to ethics]	1	04 February 2016
Participant consent form	2	04 February 2016
Participant information sheet (PIS)	2	04 February 2016
REC Application Form [REC_Form_25012016]		25 January 2016
Research protocol or project proposal	1	18 January 2016
Summary CV for Chief Investigator (CI)	1	17 November 2014
Summary CV for student	1	21 December 2015
Summary CV for supervisor (student research) [LH CV]	1	18 January 2016
Validated questionnaire [KOOS]	1	18 January 2016
Validated questionnaire [TKS]	1	18 January 2016
Validated questionnaire [PASE]	1	18 January 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- · Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of

A Research Ethics Committee established by the Health Research Authority

changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <u>http://www.hra.nhs.uk/hra-training/</u>

16/SW/0036 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

L Roberts. pp.

Canon Ian Ainsworth-Smith Chair

Email: nrescommittee.southwest-cornwall-plymouth@nhs.net

Copy to:

Kay Hack Dr Rachel Hall, Bridgewater Community Healthcare Foundation trust

Bridgewater Community Healthcare INHS



NHS Foundation Trust

Research Department Medical Directorate Spencer House 1st floor, 89 Dewhurst Road Birchwood Warrington WA3 7PG

Tel: 01925 867718 clincialaudit.research@bridgewater.nhs.uk Twitter: @BridgewaterRes www.bridgewater.nhs.uk

9th February 2016

Mr James Molyneux Clinical Lead Physiotherapist Bridgewater Community Healthcare NHS Foundation Trust Physiotherapy Dept. Leigh Health Centre The Avenue Leigh WN7 1HS

Local Study Ref: BCHC201605 REC Ref: 16/SW/0036 Study Sponsor: University of Salford Approval Until: 01/03/2017

Dear Jimmy,

Study Title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for knee osteoarthritis.

I confirm that the above study has been granted R&D approval to be undertaken in Bridgewater Community Healthcare NHS Foundation Trust. You now have permission to proceed on the basis that you are the Chief Investigator. Approval is granted until 1st March 2017, unless terminated earlier.

Permission for this study has been granted on the understanding that where necessary a favourable opinion from a Research Ethics Committee and authorisation by the Medicines and Healthcare products Research Agency (MHRA) has been obtained.

As the Chief Investigator you will take responsibility for the conduct of the research, and are accountable for this to the Trust and the research sponsor. On completion of your study, you are required to send a final report and a lay summary to the Trust within three months of the completion date. In addition, you must notify the Trust's Head of Research of the following:

- Commencement and completion of the study; ٠
- Numbers of Trust patients/participants recruited;
- Any significant changes to the study design, including amendments;
- Any further decisions made by a Research Ethics Committee and/or regulatory body regarding this study, including copies of relevant correspondence;
- Any serious adverse events on Trust participants or staff;
- Any suspension or abandonment of the study;
- Supply copies of publications relating to the study.

The study must be conducted in accordance with the Department of Health Research Governance Framework for Health and Social Care, Trust policies and procedures, and all relevant and applicable legislation/regulatory requirements, including International Conference on Harmonisation – Good Clinical Practice guidelines (ICH GCP).

All queries should be directed to the Head of Research via 01925 867718 or rachel.hall@bridgewater.nhs.uk.

Yours sincerely,

Dr Rachel Hall

Head of Research

Appendix 4

Written informed consent form



NHS Foundation Trust

Informed consent form

Chief Investigator: Jimmy Molyneux Physiotherapy Department Leigh Health Centre The Avenue WN7 1HS

Tel: 01942 483413 Email: jimmy.molyneux@bridgewater.nhs.uk

INFORMED CONSENT FORM

Study title: Mixed methods study to evaluate pain, function, postural stabilisation, and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Principal Investigator: Jimmy Molyneux

I confirm that I have read and understand the participant information sheet Version 2, 04/02/2016 for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal right being affected.

I understand that if I agree to participate, members of the research team from the University of Salford, from regulatory bodies, or from the NHS trust, may view relevant sections of my medical notes and data collected during this study. I give permission for these individuals to have access to my records.

I understand that the information about me and the data generated from the study is to be kept.

I consent to your team informing my GP or other health care provider of my participation in the study.

Please initial each box







Continued on next page

Should I withdraw I understand that the data acquired from my participation would still be used unless I specify otherwise in writing.					
I consent to be contacted by the university about other studies.					
I agree to take part in the above stud	he above study.				
Name of Participant	Date	Signature			
Name of person taking consent (If different from Researcher)	Date	Signature			
Researcher	Date	Signature			



Chief Investigator: Jimmy Molyneux Physiotherapy Department

Leigh Health Centre

The Avenue WN7 1HS

Tel: 01942 483413 Email:jimmy.molyneux@bridgewater.nhs.uk

PARTICIPANT INFORMATION SHEET

Study title: Mixed methods study to evaluate pain, function, postural stabilisation, and fear of movement following a lower limb exercise programme for Knee Osteoarthritis.

Study Subjects

We would like to invite you to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being completed and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. This information sheet is divided into two parts:

- **Part 1** tells you the purpose of this study and what will happen to you if you participate.
- Part 2 gives you more information about the study.

Please ask if you would like more information, or if there is anything that is not clear. Take time to decide whether you wish to take part in the study.

Part 1.

What is the aim of the study?

The aim of the study is to improve our understanding of the management of knee osteoarthritis and the effect that an exercise programme has on your beliefs and experiences within physiotherapy. Once you have completed the exercise programme we will ask you questions to gain a better understanding of your exercise participation and beliefs. This will help us understand what has the best results.

Why have I been asked to take part?

You have been assessed in the orthopaedic/clinical assessment/GP/physiotherapy clinic within the borough and have been diagnosed with having osteoarthritis of the knee joint that (at present) does not require an operation. Therefore, you have been identified as someone who may be interested in taking part in a study looking at how exercises may help with your knee osteoarthritis.

Do I have to take part in the study?

You do not have to take part if you do not want to. The principal researcher will contact you in 24 hours to answer any further questions. You are free to withdraw from the study at any time. You do not have to give any reason and this will not affect the care you receive, either now or in the future

What will happen to me if I take part?

If you decide to take part in the study, the principal researcher will arrange a suitable appointment time for you. On attendance at the physiotherapy department, the study will be explained in detail and any questions answered before you will be asked to complete a written informed consent form. You will then complete some questionnaires that will help us to determine the way osteoarthritis has affected your everyday life. These will take around 20 minutes to complete. Following this, you will complete some simple tests, which include walking for 6 minutes and a balance test. The whole testing session will take approximately 60 minutes to complete. You will

also be issued with an activity monitor and should be worn throughout the day for 7 days except when swimming.

Once the testing has been completed, you will be required to attend eight exercise sessions within a group class environment that will last for 1 hour. Exercise is best practice for the management of knee osteoarthritis and is standard physiotherapy care. Please dress in comfortable clothing and trainers. Exercises such as walking, cycling, and stepping will be included in the group class. During the hour, you will be asked to score your pain at the beginning and at the end of the session.

Following completion of a 5-minute warm up, exercises specific to strengthening your legs will commence. Each exercise will be timed for two minutes and you will count the number of repetitions and score how difficult the exercise was to complete. At the end of the class, a cool down will be completed. After each exercise class, you will be advised to have a recovery day to rest.

At the end of the 8 sessions, we will refer you to a local health centre so that you can continue to exercise and you will be given a follow up appointment in six weeks. At the 6-week appointment, you will complete the questionnaires and tests again and answer some further questions in relation to exercise and your symptoms.

What are the potential benefits of taking part?

Exercise is a core treatment for knee osteoarthritis and has been proven to reduce pain and improve your ability to perform activities. We would like to understand how you feel about exercise as a treatment intervention and in exploring this, it is hoped new knowledge and theory will be generated to understand this better.

What are the potential risks, discomforts, and inconveniences from taking part?

Exercise may cause some slight discomfort during and after the exercise class. However, you can discuss any problems (face to face or over the phone) with the specialist physiotherapist or principal investigator at any time during the study.

THIS COMPLETES PART 1 OF THE INFORMATION SHEET

<u>Part 2</u>

What will happen if I do not want to carry on with the study?

You can **stop the testing** at any time without giving a reason and without it affecting your healthcare in any way. If you do decide to withdraw, any data we have collected will be retained and used as part of the study, unless you specifically wish for it to be deleted.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with your physiotherapist (01942 483413 or face to face) who will do their best to answer your questions or you can contact the Principal Researcher (Jimmy Molyneux Tel: 01942 483417 or email: jimmy.molyneux@bridgewater.nhs.uk or face to face). If you are unhappy and wish to make a formal complaint, this can be done by contacting Anish Kurien, Research and Innovation Manager on 0161 295 5276 or a.kurien@salford.ac.uk. In the event that something does go wrong and you are harmed during the research study, there are no special compensation arrangements.

What if something goes wrong?

This is very unlikely. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the NHS but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?

Any information obtained in connection with this study will be treated as privileged and confidential. All information will be anonymised so that you cannot be identified, except by a single paper form that will be stored on your electronic record. The research team, their colleagues, the University of Salford, and people who need to audit the conduct of our research will have access to the identifiable forms. The data will be analysed to complete the study as outlined above. We will also keep the data for at least five years and may use it in future studies to improve our understanding of managing knee osteoarthritis. For example, we may wish to combine the data from this study with that of future studies to enable us to use more powerful analysis techniques. Ethical approval will not normally be sought for these studies. If you do not wish to be contacted for future studies please highlight on the consent form or discuss this with a member of the research team.

What will happen to the results of the study?

The results of the study will form part of the researcher's doctoral thesis and may be published anonymously in professional journals and/or as conference presentations. If you wish, we can send you a summary of the findings when the study has been completed.

Who is organising and funding the study?

The study is being led and organised by Jimmy Molyneux (Musculoskeletal Team Lead Physiotherapist) based at Leigh Health Centre. The study is part of a doctoral training programme supervised at the University of Salford and is being supported by Bridgewater Community Foundation Trust Research and Development department.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will be informed that you have taken part in the study but this will not affect your healthcare, well-being, or lifestyle.

Thank you for taking time to read this information and considering your possible participation.

Appendix 6

Arthritis exercise leaflet

Simple exercises



Sit on the floor with your legs stretched out in front. Keeping your foot to the floor, slowly bend one knee until you feel it being comfortably stretched. Hold for 5 seconds. Straighten your leg as far as you can and hold for 5 seconds. Repeat 10 times with each leg.

Leg cross

Leg stretch

Sit on the edge of a table or bed. Cross your ankles over. Push your front leg backwards and back leg forwards against each other until the thigh muscles become tense. Hold for 10 seconds, then relax. Switch legs and repeat. Do 4 sets with each leg.



Sit/stands

Sit on a chair. Without using your hands for support, stand up and then sit back down. Make sure each movement is slow and controlled. Repeat for 1 minute. As you improve, try to increase the number of sit/stands you can do in 1 minute and try the exercise from lower chairs or the bottom two steps of a staircase.



Step ups Step onto the bottom step of stairs with the right foot. Bring up the left foot, then step down with the right foot, followed by the left foot. Repeat with each leg until you get short of breath. Hold on to the bannister if necessary. As you improve, try to increase the number of steps you can do in 1 minute and the height of the step.

Knee squats



Hold onto a chair or work surface for support. Squat down until your kneecap covers your big toe. Return to standing. Repeat at least 10 times. As you improve, try to squat a little further. Don't bend your knees beyond a right angle.

2304/P-KNEE/12-9

Summary

- Knee pain can be caused by a number of different things. Whatever the cause, exercise and keeping to a healthy weight can reduce symptoms.
- You can take painkillers to ease pain. Taking them before exercise can help you stay active without causing extra pain.
- Try the exercises suggested here to help ease pain and prevent future symptoms.

ww.arthritisresearchuk.org

rthritis Research UK

Knee pain

This leaflet provides general information about knee pain and simple exercises that may help.



SOCIETY OF PHYSIQTHERAPY

Appendix 7 **Exercise sheet**

Lower Limb Rehabilitation Class Worksheet

Name _____ Physiotherapist _____

Please count the number of repetitions and record them in the box Please use the Borg scale (situated in the gym) for perceived rate of exertion

Please record your progress in the boxes.

Exercises to be completed in a clockwise direction

Date								
VAS score (pre session)								
VAS SCOLE (pre session)								
Exercise 2 mins each	1	2	3	4	5	6	7	8
Hip Extension over plinth								
Wobble Board								
Single leg balance with ball throw (1 mins/leg)								
Squats with exercise band around knee								
X-Trainer								
Stepper								
Exercise Bike								
Wall squat with ball								
Trampet – hop balance (single leg)								
Heel Raises								
Crab Walking – side stepping with theraband								
Step up with hand weights								
Monster Walks								
Treadmill								
VAS score (post session)								
Borg score (post session)								

Subject No:___

Date |__|_//__|__|/20|__|_|

Study title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Chief Investigator – Jimmy Molyneux

KOOS LK 1.0

KNEE INJURY AND OSTEOARTHRITIS SCORE

INSTRUCTIONS TO PATIENTS				
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.				
Please answer every question by putting an "X" in one of the boxes, only one box for each question.				
EXAMPLE:				
Never	Rarely	Sometimes	Often	Always
		\square		
If you are unsure 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 <u>last</u> week.

S1.	Do you have swellin	g in your kne	e?		
	Never	Rarely	Sometimes	Often	Always
S2. mov	Do you feel grinding res?	, hear clickir	g or any other typ	e of noise wh	en your knee
	Never	Rarely	Sometimes	Often	Always
S3.	Does your knee cate	h or hang u	o when moving?		
	Never	Rarely	Sometimes	Often	Always
S4.	Can you straighten y	our knee fu	ly?		
	Never	Rarely	Sometimes	Often	Always
S5.	Can you bend your l Never	nee fully? Rarely	Sometimes	Often	Always

Stiffness

Then following questions concern the amount of joint stiffness you have experienced during the <u>last week</u> in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

6. How se	evere is your sti	ffness after f	irst wakening in th	ne morning?	
	Never	Rarely	Sometimes	Often	Always
7. How se	evere is your sti Never	ffness after s Rarely	itting, lying or res Sometimes	ting later in the Often	e day? Always

Pain

P1. How often of	do vou exper	ience knee	nain?		
			Sometimes	Often	Always
What amount of following active	-	have you o	experienced the I	ast week durir	າg the
P2. Twisting/pi Ne	• •		Sometimes	Often	Always
P3. Straighteni Ne			Sometimes	Often	Always
P4. Bending kr Ne		Rarely	Sometimes	Often	Always
P5. Walking or Ne			Sometimes	Often	Always
P6. Going up o N			Sometimes	Often	Always
P7. At night wh Ne		Rarely	Sometimes	Often	Always
P8. Sitting or ly Ne		Rarely	Sometimes	Often	Always
P9. Standing u Ne		Rarely	Sometimes	Often	Always

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 difficultly you have experienced in the last week due to your knee.

A1.	Descending Stairs. Never	Rarely	Sometimes	Often	Always
A2.	Ascending Stairs. Never	Rarely	Sometimes	Often	Always
A3.	Rising from Sitting. Never	Rarely	Sometimes	Often	Always
A4.	Standing. Never	Rarely	Sometimes	Often	Always
A5.	Bending to floor. Never	Rarely	Sometimes	Often	Always
A6.	Walking on flat. Never	Rarely	Sometimes	Often	Always
A7.	Getting in/out of Car. Never	Rarely	Sometimes	Often	Always
A8.	Going shopping. Never	Rarely	Sometimes	Often	Always

	on socks/stock Never	tings. Rarely	Sometimes	Often	Always
A10. Rising	from bed. Never	Rarely	Sometimes	Often	Always
A11. Taking	off socks/stocl Never	kings. Rarely	Sometimes	Often	Always
A12. Lying ir	n bed. Never	Rarely	Sometimes	Often	Always
	in/out of the b Never	ath. Rarely	Sometimes	Often	Always
A14. Sitting.					
	Never	Rarely	Sometimes	Often	Always
A15. Getting	on/off the toile		O a ma a time a a	04.5	A
	Never	Rarely	Sometimes	Often	Always
A16. Heavy	domestic dutie Never	s (moving he Rarely	eavy boxes, scrubl Sometimes	bing floors, etc) Often	Always
A17. Light d	omestic duties Never	(cooking, du Rarely	isting, etc). Sometimes	Often	Always

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 have you experienced during the <u>last week</u> due to your knee

SP1. Squatt	ing. Never	Rarely	Sometimes	Often	Always
SP2. Runnir					
SF2. Ruilli	Never	Rarely	Sometimes	Often	Always
SP3. Jumpi	ng. Never	Rarely	Sometimes	Often	Always
SP4. Twistir	ng/pivoting on y Never	our injured k Rarely	nee? Sometimes	Often	Always
SP5. Kneeli	ng? Never	Rarely	Sometimes	Often	Always
Quality of L		<i>,</i>			
Q1. How off	en are you awa Never	Rarely	Sometimes	Often	Always
Q2. Have yo knee?	ou modified you	r life style to	avoid potentially	damaging activ	ities to your
	Never	Rarely	Sometimes	Often	Always
Q3. How mu	uch are you trou Never	ibled with la Rarely	ck of confidence ir Sometimes	n your knee? Often	Always
Q4. In gene	ral, how much o Never	difficulty do y Rarely	ou have with your Sometimes	knee? Often	Always

Subject No:_____

Date |__|_/|__|__|/20|__|_|

Study title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Chief Investigator – Jimmy Molyneux

(PASE) PHYSICAL ACTIVITY SCALE FOR THE ELDERLY

INSTRUCTIONS TO PATIENTS

Please complete the questionnaire by either circling the correct response or filling in the blank. Example:

During the past 7 days, how often have you seen the sun?

0-NEVER

1- SELDOM (1-2 DAYS)

2- SOMETIMES (3-4 DAYS) 3- OFTEN (5-7 DAYS)

If you are unsure how to answer a question please give the best answer you can.

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0] NEVER	GO TO Q.2	[1] SELDOM (1-2 DAYS)
[2] SOMETIMES	(3-4 DAYS)	[3] OFTEN (5-7 DAYS)

1a.	What were these activities?	
1b.	On average, how many hours per day d sitting activities?	lid you engage in these
[1] LE	SS THAN 1 HOUR	[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4	4 HOURS	[4] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0] NEVER GO TO Q.3 [1] SELDOM (1-2 DAYS)

[2] SOMETIMES (3-4 DAYS) [3] OFTEN(5-7 DAYS)

2a. On average, how many hours per da	ay did you spend walking?
[1] LESS THAN 1 HOUR	[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS	[4] MORE THAN 4 HOURS

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[2] SOMETIMES (3-4 DAYS) [3] OFTEN (5-7 DAYS)

За.	What were these activities?	
3b.	On average, how many hours pe light sport or recreational activitie	
[1] LESS THAN 1 HOUR [2] 1		[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS		[4] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0] NEVER	GO TO Q.5	[1] SELDOM (1-2 DAYS)

[2] SOMETIMES (3-4 DAYS) [3] OFTEN (5-7 DAYS)

4a.	What were these activities?	
4b.	On average, how many hours pe moderate sport and recreational	
[1] LESS THAN 1 HOUR		[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS		[4] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0] NEVER	GO TO Q.6	[1] SELDOM (1-2 DAYS)
[2] SOMETIMES	(3-4 DAYS)	[3] OFTEN (5-7 DAYS)

5a.	What were these activities?	
5b.	On average, how many hours pe strenuous sport and recreational	
[1] LESS THAN 1 HOUR [2] 1 BUT LESS THAN 2 HOURS		[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS		[4] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0] NEVER	GO TO Q.7	[1] SELDOM (1-2 DAYS)
[2] SOMETIMES	(3-4 DAYS)	[3] OFTEN (5-7 DAYS)

6a.	What were these activities?	
6b.	On average, how many hours p increase muscle strength and e	er day did you engage in exercises to ndurance?
[1] LE	[1] LESS THAN 1 HOUR [2] 1 BUT LESS THAN 2 HOURS	
[3] 2-4 HOURS		[4] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

[1] NO [2] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

[1] NO [2] YES

9. During the past 7 days, did you engage in any of the following activities?

Please answer <u>YES</u> or <u>NO</u> for each item.

		<u>NO</u>	<u>YES</u>
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2
b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
C.	Outdoor gardening	1	2
d.	Caring for an other person, such as children, dependent 1 2 spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1] NO

[2] YES

10a.	How many hours per week did you work for pay and/or as a volunteer?
	HOURS
10b.	Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?
	[1] Mainly sitting with slight arm movements. [Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.]
	[2] Sitting or standing with some walking. [Examples: cashier, general office worker, light tool and machinery worker.]
	 [3] Walking, with some handling of materials generally weighing less than 50 pounds. [Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]
	 [4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds. [Examples: lumberjack, stone mason, farm or general laborer.] NK YOU FOR TAKING THE TIME AND EFFORT OMPLETE THIS QUESTIONNAIRE

Subject No:____

Date |__|_/|__|__|/20|__|_|

Study title: Mixed methods study to evaluate pain, function, postural stabilisation, and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Chief Investigator – Jimmy Molyneux

Tampa Scale for Kinesiophobia

INSTRUCTIONS TO PATIENTS

Please answer every question by scoring them 1 to 4, only one number for each question.

1-strongly disagree

2-disagree

3- agree

4-strongly agree

If you are unsure how to answer a question please give the best answer you can.

1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
1	2	3	4
	1 1	1 2 1 2	123

Appendix 11	Standard Physiotherapy Questions		
	Subject No:		
	Date _/ _ /20 _		

Study title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Chief Investigator – Jimmy Molyneux

How is the condition affecting you? Pain, Function (Hobbies/Work)

Is the intensity/variability the same? AM/PM

What are the aggravating and easing factors?

Is it preventing you from doing something you like or have to do?

Did you feel the exercises eased your pain?

What do you feel eases the pain?

Appendix 12 Appointment Letter



NHS Foundation Trust

Appointment confirmation letter

Chief Investigator: Jimmy Molyneux Physiotherapy Department Leigh Health Centre The Avenue WN7 1HS

Tel: 01942 483413 Email: jimmy.molyneux@bridgewater.nhs.uk

Study title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Dear (enter patients name)

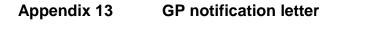
I am writing to confirm your appointment for the above study at Leigh Health Centre, on *(enter date)* at *(enter time)*. You will find directions and car park information attached to this letter.

If you are unable to attend your appointment for any reason, please contact the research team as soon as possible to arrange an alternative appointment,

Please bring this letter with you to your appointment and report to reception on arrival. We look forward to seeing you, if you have any questions please do not hesitate to contact myself or a member of the research team.

Yours sincerely,

Jimmy Molyneux- Chief Investigator Physiotherapy Musculoskeletal Clinical Lead





General Practitioner Notification letter

Chief Investigator: Jimmy Molyneux Physiotherapy Department Leigh Health Centre The Avenue WN7 1HS

Tel: 01942 483413 Email: jimmy.molyneux@bridgewater.nhs.uk

Study title: Mixed methods study to evaluate pain, function, postural stabilisation and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Re:

DOB:

NHS No:

Dear (GP)

I am writing to inform you that *(insert patient's name)* has consented to take part in the above study. Please find attached a copy of the patient information sheet for your reference.

If you should have any further questions or concerns please do not hesitate to contact myself or a member of the research team.

Yours sincerely,

Jimmy Molyneux- Chief Investigator Physiotherapy Musculoskeletal Clinical Lead



Bridgewater Community Healthcare NHS

NHS Foundation Trust

Letter of Invitation

Chief Investigator: Jimmy Molyneux

Physiotherapy Department Leigh Health Centre The Avenue WN7 1HS

Tel: 01942 483413 Email: jimmy.molyneux@bridgewater.nhs.uk

Study title: Mixed methods study to evaluate pain, function, postural stabilisation, and fear of movement following a lower limb exercise programme for Knee Osteoarthritis

Dear (enter patients name)

My name is Jimmy Molyneux and I am a clinical lead physiotherapist. I would like to invite you to participate in the above osteoarthritis research study taking place at Leigh Health Centre. This study is looking at exercises as a treatment for osteoarthritis of the knee and is part of a Professional Doctorate degree, at the University of Salford.

Please find enclosed a Participant Information Sheet outlining details of the research. Please take your time to read the information sheet and if you have, any questions do not hesitate to contact a member of the research team.

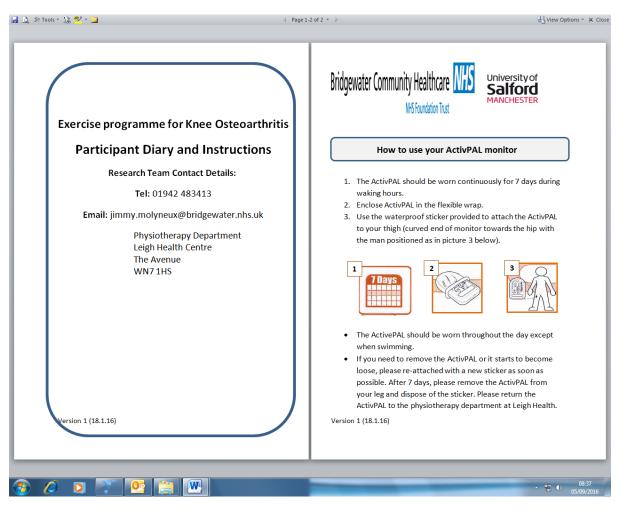
Remember you are under no obligation to take part.

Yours sincerely,

Jimmy Molyneux- Chief Investigator Physiotherapy Musculoskeletal Clinical Lead

Enc: Patient Information Sheet

Appendix 15 ActivPAL leaflet



Appendix 16 TIDieR guidelines

ITEM NUMBER	EXPLANATION	PAGE
		NUMBER OR APPENDIX NUMBER
1. BRIEF NAME	Exercise, Kinesiophobia, Knee Osteoarthritis.	
2. WHY	Osteoarthritis (OA) is one of the leading causes of pain and disability. Exercise has been recommended as a core treatment for OA. Exercise behaviour is an essential factor of physical inactivity with kinesiophobia/fear of movement being a major clinical implication. Knowledge of the psychological and functional relationships in exercise behaviour may provide a more comprehensive rehabilitation programme for individuals with knee osteoarthritis. Therefore, the purpose of the study was to investigate the relationship between kinesiophobia and outcomes of a lower limb exercise programme in knee osteoarthritis.	Page 1
3. WHAT (Materials)	Individuals with clinical and/or radiographic knee OA) completed a 4-week, 8-session lower limb exercise programme. Tampa scale of kinesiophobia (TSK), physical activity scale for the elderly (PASE), Knee injury and osteoarthritis outcome score (KOOS), Y balance test, 6-minute walk test (6MWT) and the 30-second chair stand test with an activPAL [™] activity monitor were used with six standard physiotherapy questions asked. Following written informed consent, study participants opted into the study and were issued with an educational arthritis research leaflet and a patient information sheet. The patient information sheet includes a brief description, contact telephone numbers (Appendix 5), and an advice sheet supported by the Chartered Society of Physiotherapy and the Arthritis Research Campaign (Appendix 6).	Page 65-73 Appendix 5 Appendix 6
4. WHAT	Referrals came from orthopaedic consultants,	Page 59

(Proceduree)	general practitioners musculaskalatel disise]
(Procedures)	general practitioners, musculoskeletal clinical assessment unit, other allied health professionals such as podiatrists and self-referral. A specialised physiotherapist triaged the referral and then the administration staff sent out appointment letters for an initial assessment (Appendix 12), with individuals contacting the department via telephone for an appointment time. Equally, if the individual walks into the department and requests an appointment, an appointment was issued. Individuals either choose to attend, decline the appointment or do not attend (DNA) without contact. Individuals who were deemed eligible were issued with the information leaflets and were encouraged to discuss their potential participation with a specialist physiotherapist and relatives/visitors. The individual's national health number was then passed to the chief investigator and the patient was given 24 hours to consent to be assessed for inclusion into the study. Individuals had the option to be included in the study, decline participation, and choose 1:1 treatment with a physiotherapist. After 24 hours, the chief investigator telephoned potential individuals to answer any further questions they may have. If they were willing to participate, an appointment (Appendix 4) and was stored in the study at any time during the programme and consider other physiotherapeutic treatment options. Other forms of interventions during the study were not permitted such as the provision of injections or orthotics; on the other hand, analgesic and anti- inflammatory medication was	Appendix 4 Appendix 12
	permitted and documented. The chief investigator assessed all the participants entering. No remuneration or expenses were issued to the individuals.	
5. WHO	A specialised physiotherapist triaged the referral.	Page 59
PROVIDED	Administration staff sent out appointment letters for an initial assessment (Appendix 12)	Page 61 Appendix 12
	A specialist physiotherapist, who received three hours training by the chief investigator, which consisted of reviewing each exercise station,	

6. HOW	outcome measurements, and documentation, supervised the group class. In addition to the training, the specialist physiotherapist did have the authority to alter the exercise programme as some exercises may be pain provoking than others and may potentially pose further risks such as falls. Both the chief investigator and specialist physiotherapist offered telephone support to any of the participants during department open times. Chief investigator completed all outcome measurements. The chief investigator completed a 60-minute initial assessment, which included range of movement and muscle strength of the hip, knee and ankle. In participants with bilateral symptoms, the symptomatic knee was assessed. Participants attended the exercise class, twice per week for four weeks. During the hour, participants completed a 5-minute warm up. The exercise class commenced with 14 exercises (Appendix 7). Participants recorded the number of repetitions and progression of exercises was patient led. Each exercise was timed for 2-minutes with approximately 1-minute in between each exercise. After seven exercises, a 5-minute hydration break was completed. After each exercise class, a cool down was completed. Both the chief investigator and specialist physiotherapist offered telephone support to any of the participants during department open times.	
7. WHERE	The assessment and treatment work was completed in the Physiotherapy Department within Leigh Health Centre. The group class was operated from the physiotherapy department gymnasium in Leigh Health Centre.	Page 61
8. WHEN and HOW MUCH	Participants were asked to attend eight exercise sessions within a group class environment that lasted for 1 hour and each individual was asked to dress in comfortable clothing and trainers. Participants attended the class, twice per week for four weeks. Questionnaires and physical outcome measurements were completed at baseline, session 4, session 8, and 6-weeks after the exercise programme (Appendix 8, 9, 10). An activPAL [™] monitor was attached to the right thigh at baseline and 6-weeks after the exercise	Page 47-53 Page 61 Page 65-73 Appendix 8 Appendix 9 Appendix 10 Appendix 15

	programme and participants were asked to keep this on for 7-days (Appendix 15).	
9. TAILORING	Participants recorded the number of repetitions and progression of exercises were patient led (Appendix 7). Following the exercise programme, a content analytical approach was used to listen to the participant's voice by completing a short set of standard questions, which was written so that the patient's voice can be heard and themes extracted from the answers. Specific themes were extracted to investigate this as the main aspect of analysis.	Page 54 Page 61 Appendix 7 Appendix 11

Appendix 17

Poster presented at Osteoarthritis Research Society International (OARSI 2017) World congress. Caesar's Palace, Las Vegas, Nevada, United States of America. April 27-30,2017.



An investigation into the effect of a lower limb exercise programme on kinesiophobia in individuals with knee osteoarthritis.

1967-2017 50 YEARS

Jimmy Molyneux^{1,1}, Lee Herrington¹, Richard Jones¹ ¹School of Health Sciences, The University of Salford, Greater Manchester, United Kingdom, M6 6PU. idgewater Community Healthcare NHS Foundation Trust, Physiotherapy Service, Leigh, United Kingdo WN7 1HS

BACKGROUND

Osteoarthritis (OA) is one of the leading causes of pain and disability with the knee joint being most commonly affected. Exercise has been recommended as a core treatment for knee osteoarthritis, however only 5% of knee OA sufferers are achieving the recommended level of activity.

An essential factor on physical inactivity is exercise behaviour, with kinesiophobia being a potential major barrier. Whilst studies have highlighted kinesiophobia is prevalent in knee OA, no studies have assessed kinesiophobia before, during, and after a lower limb exercise programme in individuals with knee OA.

Therefore, the purpose of this study was to investigate kinesiophobia and the effects of a lower limb exercise programme in patients diagnosed with knee OA

ClinicalTrials.gov: NCT02734342

METHOD

Forty-four participants were recruited; all diagnosed with knee OA confirmed diagnosed with knee OA confirmed radiologically via the Kellgren and Lawrence scale (KL), and with the American College of Rheumatology criteria (ACR). Participants completed an 8-session lower limb exercise programme, which consisted of 14 exercises. Each individual completed two questionnaires, the Tampa kinesiophobia scale (TKS) and the knee injury and osteoarthritis outcome score (KOOS). Each measurement was completed at the baseline assessment, at session 4 of the programme, at session 8 of the programme, and 6 weeks after the exercise programme. Physical activity intensity levels were measured after each exercise session using the modified Borg scale to rate perceived exertion (RPE) and the visual analogue scale (VAS) was measured at the start and end of each session. A repeated analysis of variance was used for the KOOS and the Friedman test was used for the TKS to compare results at baseline, session 4, session 8 and 6 weeks after the exercise programme. Correlational data analysis for KOOS pain and the TKS was completed using a spearman's rank correlational coefficient.

RESULTS

Forty- four participants (23 male: 21 female) completed the programme with a mean age of 64.36 (SD 8.92), (16 KL 2; 13 KL 3, 8 KL 4 and 7 ARC criteria). Twenty-eight (52%) participants recorded high kinesiophobia (>37) at baseline , at session 4, 19 (35%), at session 8, 13 (24%) and 14 (25.9%) 6 weeks after the exercise programme

Kinesiophobia decreased throughout the exercise programme from baseline assessment (median 37, IRQ 9.3), at session 4 (median 33.5, IRQ 11), at session 8 (32, IRQ 8.5) and a minimal increase at 6 weeks after the exercise programme (33, IRQ 12), with the overall reduction in kinesiophobia after the exercise progra significant (p=<0.01) (Figure 1). programme being

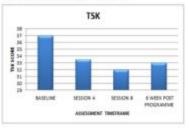


Figure 1: Median score for the Tampa Kinesiophobia Scale

KOOS symptoms and quality of life increased with significant comparisons seen between baseline and session 4 (p = <0.01, p=<0.01), between session 4 and session 8 (p= 0.05, p=<0.01), and session 8 and 6 weeks after the programme (p=0.01, p=<0.01) with the overall reduction in symptoms after the exercise programme being clinically significant (p=<0.01, p=<0.01) (Figure 2.Figure 3)

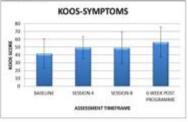


Figure 2: Mean score for KOOS symptoms



However, KOOS pain only increased between session 4 and session 8 (p= 0.019) and session 8 and 6 weeks after the programme (p=0.017).

Although the overall reduction in pain after the exercise programme being clinically significant (p=0.013). (Figure 4). Incidentally, the KOOS activities of daily living was not significant (p=0.1).

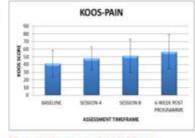


Figure 4: Mean score for KOOS pain

VAS for pain was also significant after completing the full programme (p=0.028), with the greatest mean score being recorded after session 2 (mean 4.1, SD 2.6) and lowest being recorded 6 weeks after the exercise programme (mean 2.1, SD 2.3), KOOS pain and kinesiophobia have a moderate negative correlation at 6 weeks after the exercise programme (coefficient -0.44: p= 0.01).

CONCLUSIONS

Our findings demonstrate that kinesiophobia and pain reduces after completing an exercise programme in participants with knee OA. Therefore, understanding an individual's kinesiophobia level before an exercise programme is important for future prognosis of changes in pain. The next stage of the analysis is to determine the changes in physical activity.

Correspondence: J.Molyneux1@edu.salford.ac.uk





Appendix 18

Poster presented at International Society for the Measurement of Physical Behaviour World Congress. National Institutes of Health (NIH), Bethesda, Maryland. United States of America. June 22 -23, 2017.



An investigation into the effect of a lower limb exercise programme on objectively measured physical activity in individuals with knee osteoarthritis Jimmy Molyneux^{1,2}, <u>Alex Clarke-Cornwell¹</u>, Lee Herrington¹, Richard Jones¹

³Bridgewater Community Healthcare NHS Foundation Trust, Physiotherapy Service, UK, WN7 1HS

Bridgewater Community Healthcare NRS Foundation Trust

1967-2017 50 YEARS

Background

- Osteoarthritis (OA) is one of the leading causes of pain and disability, with the knee joint being most commonly affected
- Exercise has been recommended as a core treatment for knee osteoarthritis; however, only 5% of knee OA sufferers achieve the recommended level of physical activity
- Previous studies have shown that adults with symptomatic knee OA take between 4000-8700 steps per day, which is fewer than the recommended 7000 steps a day for developing and maintaining function
- The purpose of this study was to investigate whether an exercise programme changed activity attributes such as length of time walking, standing, stepping, sitting, and upright transitions, in individuals diagnosed with knee OA

Methods

- Individuals radiologically and clinically diagnosed (American College of Rheumatology (ACR)) with knee OA were recruited (ClinicalTrials.gov: NCT02734342)
- Participants completed an 8-session lower limb exercise programme over a 4-week period
- Activity data were collected using an activPAL^{TN} activity monitor for seven days at baseline, and again 6-weeks after the programme. Measurements included sitting time, standing time, walking time, stepping, and transitions
- Data were analysed using paired sample t-tests

Results

- Forty-three participants (19 male; 24 female) completed the programme with a mean age of 64.38 (SD 8.62) years
- 14 Kelgren-Lawrence (KL) grade 2; 14 KL grade 3; 10 KL grade 4 and 5 ACR ontena)

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 Weekday walking times significantly increased on average from 8.07 hours. (SD 2.62) to 8.71 hours. (SD 3.02). (p+0.03) (Figure 1). Seven-day and weekend walking times did not differ significantly (p=0.81; p=0.77)

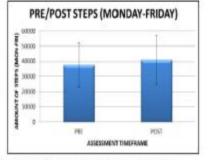


Figure 2: Mean pre-post weekday stepping times

- Weekday stepping time significantly increased on average from 37.457, (SD 14505) to 40.834, (SD 16299), (p=0.03) (Figure 2). Seven-day stepping was also significantly higher (p=0.04) with weekend walking times not (p=0.62)
- Average steps per day increased from 7491 to 8166

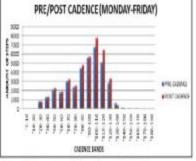


Figure 3: Pre-post weekday cadence distribution

- Post-exercise programme, a higher proportion of steps occurred in cadence bands greater than 100 steps/min (Figure 3)
- Seven-day transitions significantly increased on average from 319 (SD 81.04) to 365.3 (SD 104.8), (pr <0.01) (Figure 4)



Figure 4: Mean pre-post 7-day transitions

Conclusions

 A lower limb exercise programme increases objectively measured physical activity attributes and mobility in OA patients, therefore having a greater impact on developing and maintaining function

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