DOES THE USE OF AN ORTHO-GLIDE DEVICE IMPROVE PATIENT OUTCOMES FOLLOWING A TOTAL KNEE REPLACEMENT?

Robyn Jones

BSc (Hons) Physiotherapy

A thesis submitted in partial fulfilment of the requirements for the MSc by Research at the University of Central Lancashire

March 2020

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Type of Award **MSc by Research**

School **Health Sciences**

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DECLARATION OF INTERESTS

The following outlines the affiliations and involvements with organisations with a financial or non-financial interest in the subject matter and materials discussed in this manuscript.

Funding for tuition fees associated with this MSc by Research was provided by Medical Devices Technology International, manufacturers of the Ortho-Glide device.

Robyn Jones (the author) is a Chartered Physiotherapist employed by Blackpool Teaching Hospitals NHS Foundation Trust based at Blackpool Victoria Hospital, the study centre used in this project.

R. Jones

20/03/2020

ABSTRACT

Physiotherapy is routinely provided following Total Knee Replacement (TKR) surgery however, despite the rising prevalence of osteoarthritis and subsequent TKR rates, no formal guidelines outline the optimal modality of post-TKR exercise. This study aimed to evaluate the effectiveness of utilising an assistive device, known as the Ortho-Glide, for completing the prescribed Physiotherapy exercises following TKR.

The study design was a randomised controlled trial and a total of 31 participants were recruited and randomised into two groups. The Standard Physiotherapy group (n=16) were prescribed routine post-operative exercises, the Ortho-Glide group (n=15) undertook the same routine exercises but were issued with the Ortho-Glide assistive device to facilitate their completion. The primary outcome measure was the Knee Osteoarthritis Outcome Score (KOOS). Secondary outcome measures were the Numerical Pain Rating Scale (NPRS), with pain scores reported for both at rest and during exercise, and the Exercise Adherence Rating Scale (EARS). Outcome scores were collected at a pre-operative baseline, then at six weeks post-operatively, with the final data collected at 12-weeks following the TKR procedure.

A mixed methods analysis of variance was performed on the data. Mean scores for the KOOS and NPRS in both groups demonstrated statistical and clinically significant improvements from baseline to six weeks, and baseline to 12-weeks following TKR. No statistically significant difference was noted between groups at any time-point, however clinically significant differences were noted in a number of the KOOS subscales, favouring the Ortho-Glide group.

This study represents the first use of an Ortho-Glide device in clinical research. Despite economic and clinical motivations to optimise post-operative recovery, a lack of clarity exists regarding best practice in the prescription of Physiotherapy exercises post-TKR. The use of an Ortho-Glide appeared to offer greater clinically significant improvements in function compared to standard-care, although further research to investigate this is suggested.

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ACKNOWLEDGEMENTS

Since beginning this project I have been incredibly fortunate to have guidenace and support from a number of people, to whom I owe a debt of gratitude.

Professor James Richards and Dr Ambreen Chohan, my academic supervisors, have provided ongoing advice and encouragement throughout the entirity of the project, without their support none of this would have been possible.

When initially discussing the feasibility of this project, and throughout its duration, I have been given support and encouragment from Nick Lane, Anneka Curdling-Edmondson and Charlotte Stubbs, the senior leadership team for Physiotherapy at Blackpool Victoria Hospital. The level of encouragement and support offered from senior leadership demonstrates their commitment to personal development as well as patient centred-care, and this ethos makes me proud to work with this fantastic team.

I was fortunate to be able to conduct this study with the endorsement of Mr. Javed, senior Orthopaedic Consultant at Blackpool Victoria Hospital, to whom I am very greatful. Implementation of the project would not have been possible without the help of Catherine Bennett, Gemma Livingston, Jo Emery and the rest of the Orthopaedic Physiotherapy team at Blackpool Victoria Hospital. Particular thanks must also be extended to Karen Croft and Emma Whiston for their help with the recruitment process, both of whom went above and beyond their duties in the support they offered, for which I am extremely greatful.

Lastly, a number of my colleagues have been a source of ongoing support, encouragement and advice, occasionally unknowingly! I would therefore like to extend my thanks to Kirsty Philpott, Jane Jackson, David Seddon, Leanne McCarthy and Simon Hayward, your support has meant a great deal.

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LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
BMI	Body Mass Index
CPM	Continuous Passive Motion
EARS	Exercise Adherence Rating Scale
ERAS	Enhanced Recovery After Surgery
KOOS	Knee Osteoarthritis Outcome Score
MCID	Minimal Clinical Important Difference
MSK	Musculoskeletal
NICE	National Institute for Health and Care Excellence
NJR	National Joint Registry
NPRS	Numerical Pain Rating Scale
QoL	Quality of Life
ROM	Range of Movement
SCB	Substantial Clinical Benefit
TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
VAS	Visual Analogue Scale
WOMAC	Western Ontario and McMasters Universities Artiritis Index

1 CHAPTER 1: INTRODUCTION

1.1 Total Knee Replacement

A total-knee replacement (TKR), also known as a total-knee arthroplasty (TKA), is a surgical procedure to replace all the articulating condylar surfaces of the femur and tibia in order to reduce pain, correct deformity and allow the patient to return to normal daily activities (American Academy of Orthopaedic Surgeons [AAOS], 2015).

Although accounts vary, the earliest documented evidence of a total knee replacement being performed dates back to the 1890's when Theophilus Gluck performed a total-knee arthroplasty using a rudimentary design of hinged ivory and plaster of Paris (Ranawat & Ranawat, 2012). This hinge design remained in use until the 1970's however advancements in materials were seen with the introduction of acrylic (Walldius, 1953) and later cobalt chrome prostheses (Walldius, 1957).

Whilst early designs for knee prostheses were based on a simple hinge design, modern designs recognise the complexities of the knee joint and address the requirement for rolling and gliding between the condylar surfaces as well as the requirement for a slight amount of rotation. Currently, over 150 different designs of TKR are available with variations between the ligaments retained, materials used to secure the prosthetic components to the bone (cement or cementless), and most recently gender specific designs addressing anatomical differences between male and female patients (AAOS, 2016). Although numerous variations exist, an example of a TKR is shown in Figure 1.1 (United States Library of Medicine, 2019).

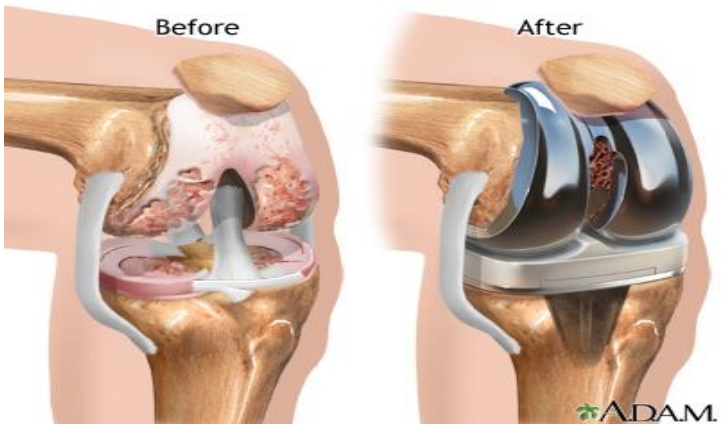


Figure 1.1 Example of TKR (United States Library of Medicine, 2019).

1.2 Rationale for TKR

A TKR may be performed for a variety of reasons, including presence of congenital deformities or avascular necrosis. However, the overwhelming majority of TKR procedures are performed to alleviate the symptoms of either idiopathic or post-traumatic osteoarthritis (Mahomed et al., 2005, Van Manen et al., 2012, Lespasio et al., 2017). As a major loadbearing joint, the knee is the area most commonly affected by osteoarthritis (Heidari, 2011), with large scale literature reviews suggesting it may account for up to 80% of all cases of the disease (Global Burden of Disease Study, 2012).

Arthritis Research UK in partnership with Imperial College London developed a musculoskeletal (MSK) calculator to estimate arthritis prevalence across different local authorities and clinical commissioning group regions in the UK (Arthritis Research UK, 2018). The most recent data from the MSK Calculator estimates that 8.75 million people in the UK have sought treatment for some form of osteoarthritis, with osteoarthritis of the knee affecting 4.11 million (18.2%) of adults over 45-years of age in England (Arthritis Research UK, 2018). The Global Burden of Disease Study (2017) estimated direct treatment costs for osteoarthritis and rheumatoid arthritis in the UK to be £10.2 billion per year.

As a progressive degenerative disease osteoarthritis is likely to be initially managed with pharmacological intervention to limit pain (Yu & Hunter, 2015). Exercise interventions are recommended to improve pain and function (Zhang et al., 2010) whilst obesity has been identified as the most significant modifiable risk factor for the disease (Lementowski & Zelicof, 2008). In addition to exercise prescription, Physiotherapeutic intervention for lower limb osteoarthritis management may include provision of walking aids and orthoses (van Raaij et al., 2010, Jones et al., 2012). However, depending on progression of symptoms, surgical intervention may eventually be required (Katz et al., 2013). Whilst once widely used, knee arthroscopy procedures have now been shown to be ineffective for managing osteoarthritis symptoms (Felson, 2010). The National Institute for Health and Care Excellence (NICE) indicate that TKR may be considered if non-surgical treatment modalities such as exercise prescription, weight loss, orthoses and pharmacological input have proven insufficient (NICE, 2014).

Information reported on the UK's National Joint Registry (NJR) in 2019 shows that a total of 308,961 total knee replacements were performed in the UK between 2016 and 2019 by 1937 consultant surgeons working across 408 centres. The majority of these were performed on females (56.7%) with osteoarthritis being listed as the reason for surgery in 97.4% of cases (NJR, 2019). Concerningly, due to projected increases in life expectancy and obesity rates by 2030 (NCD Risk Factor Collaboration, 2016, Kontis et al., 2017) osteoarthritis rates are also predicted to significantly increase. It has been estimated that by 2032, an additional 26,000 individuals per million over the age of 45 are expected to present with osteoarthritis globally (Turkiewicz et al., 2014). With the increase in risk factors, TKR procedures are projected to rise globally by 2030 (Sloan et al., 2018, Ackerman et al., 2019) with rates in the UK predicted to be as high as 1.2 million procedures performed per year by 2035 (Culliford et al., 2015).

1.3 The Management of TKR

Total knee replacements are considered to have high success rates, both in terms of patient reported outcomes as well as revision rates. Patients report an overall reduction in pain, increased function and an overall improvement in quality of life (da Silva et al., 2014, Lee et al., 2017, Canovas & Dagneaux 2018). Whilst direct comparison between different patients reported outcome measures used to assess pain, function and quality of life changes may be challenging, a recent meta-analysis by Shan et al., (2015) reported an overall 'satisfaction' rate of approximately 75% five years post-operatively. As well as patient reported outcomes, total knee replacements hold a relatively low rate of early revisions with cumulative data from worldwide joint registries showing approximately 6% of prostheses needing revision surgery after five-years and 12% after 10-years (Labek et al., 2011). Despite the generally high success rates of TKR procedures, some studies have shown that up to 36% of patients report ongoing pain and no functional improvements at 12-months post-operatively (Franklin et al., 2008, Beswick et al., 2012). Positive long term TKR outcomes have been strongly linked with early post-operative improvements in function and pain during the first 12-weeks of surgery (Davis et al., 2018), emphasising the importance of rehabilitation during this period.

Post-operative Physiotherapy input is routinely offered, however the exact implementation and content of this has been noted to vary widely during the immediate post-operative (acute) period as well as the post-discharge (sub-acute) period, making conclusions regarding optimal programme design unclear (Artz et al., 2015, Sattler et al., 2019). The Department of Health (2011) suggested implementation of Enhanced Recovery After Surgery (ERAS) pathways to improve clinical efficiency, cost savings and reduce length of hospital stay with these pathways now widely utilised within the NHS (NHS, 2019). ERAS is a multidisciplinary approach to optimising pharmaceutical, dietetic, medical and therapy management which, for TKR patients, involves early

mobilisation within 24-hours of surgery and multiple therapeutic sessions per day until discharge home (Wainwright et al., 2019).

1.4 Role of Physiotherapy for TKR

Physiotherapy provided during the immediate post-operative inpatient period is generally aimed at improving joint mobility, aiding ambulation, reducing post-operative complications and returning to function in order to safely return home (NHS, 2019). This period of reduced mobility following joint arthroplasty is recognised as a significant risk to developing venous thromboembolism (VTE) or deep vein thrombosis (DVT) in more severe cases (Colwell et al., 2010). Incidences of VTE or DVT have been noted to be as high as 60% in post-operative orthopaedic patients without the implementation of prophylactic exercise therapy (Geerts et al., 2008). Performing routine joint mobility exercises following TKR has been shown to reduce the likelihood of developing VTE or DVT by improving maximal venous outflow and maximal venous capacity therefore reducing blood rheology (Huang, 2016, Li et al., 2016). In addition to reducing the risks of developing VTE or DVT, post-operative mobility exercises also aim to improve the range of movement (ROM) of the joint. Following TKR, knee joint ROM at discharge from hospital has been shown as a predictor of long-term ROM, as well as patient reported knee pain and function (Naylor et al., 2012). Investigating longer term outcomes following TKR, limited ROM was found to significantly reduce patient satisfaction levels due to its effect on functional ability and activities of daily living (Matsuda et al., 2013, Matsuzaki et al., 2017). Following discharge from hospital, Physiotherapy aims to further increase lower limb strength and ROM with an aim of improving pain and function (DeJong et al., 2009, Wesby et al., 2014) although, similarly to the immediate post-operative phase, the content and format of this Physiotherapy provision varies widely (Blom et al., 2016, Henderson et al., 2018).

Despite the routine provision of Physiotherapy following TKR, at the time of writing, no formal clinical guidelines were available in the UK that address specific rehabilitation exercises to be included post-TKR. However, NICE are due to publish guidelines covering joint replacement rehabilitation on March 25th 2020 (NICE, 2019), although the level of specificity to be included was, at the time of writing, unclear. Given projected rates of TKR, and the positive effect of joint mobilisation exercises on post-operative complications, function and patient satisfaction, improving means of delivering Physiotherapy input may further enhance long-term outcomes.

1.5 Barriers to Physiotherapy following TKR

Several factors may be considered barriers to performing post-operative joint mobilisation exercises. A significant stress-response including inflammation and lack of muscular strength have been noted (Desborough, 2000, Bautmans et al., 2010, Welvaart et al., 2011) which can lead to significant impaired knee ROM, particularly in flexion (Chiu et al., 2002, Schulz et al., 2018). Due to the importance of joint mobilisation, Physiotherapists encourage knee flexion exercises following a TKR, an example of this is shown in Figure 1.2 (AAOS, 2017). This same form of 'knee-slide' exercise is present in post-TKR information leaflets from multiple NHS organisations, including regional Centres of Excellence such as Wrightington, Wigan and Leigh NHS Foundation Trust (NHS, 2018, NHS Wales, 2014), suggesting it is common practice post-TKR.

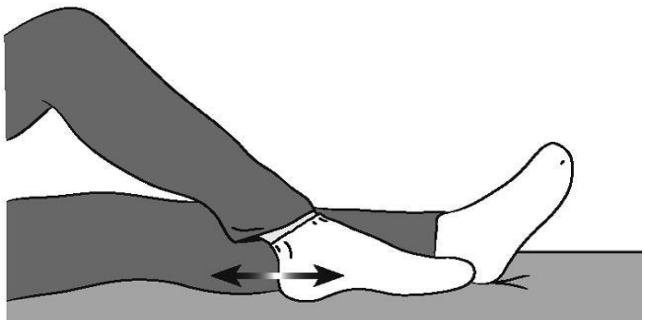


Figure 1.2 Bed Supported Knee-slide (AAOS, 2017).

With several potential post-operative limitations the use of assistive devices or techniques to facilitate ROM may be required (Schultz et al., 2018). However, as with other aspects of post-operative Physiotherapy protocols, the exact implementation of these assistive devices is often poorly documented in literature, making it challenging to draw conclusions about optimal post-TKR rehabilitation (Oatis et al., 2018). Whilst significant improvements in clinical and economic effectiveness have been noted, research to further optimise the recovery and rehabilitation of TKR patients has been suggested (Jorgensen et al., 2016). Recognising the lack of formal best practice guidelines, Bandholm et al., (2018) reviewed contemporary rehabilitation practices, concluding that further examination of specific postoperative rehabilitation interventions is required.

1.6 Introduction Summary

The increasing prevalence of TKR procedures places greater emphasis on further optimising recovery protocols. As discussed, Physiotherapy provision is a key component in achieving this goal, although a current lack of clinical guidelines in the UK means optimal methods of implementation may be unclear. A literature review was undertaken to establish understanding of current evidence surrounding Physiotherapy provision for TKR with a view to investigate the effectiveness of issuing patient with an assistive device, the Ortho-Glide, to aid completion of post-operative exercises.

2 CHAPTER 2: LITERATURE REVIEW

2.1 Search Strategy

Prior to undertaking any research, a literature search was undertaken to establish the current evidence regarding TKR rehabilitation and Physiotherapy provision. AMED, CINAHL Complete, EMBASE, Medline, Nursing & Allied Health Database, Proquest, Science Direct, SportDiscus and Wiley Online Library were accessed via the UCLan computer network, as well as a further search of Google Scholar, to identify relevant literature. Search terms used were 'Total knee replacement' or 'Total knee arthroscopy', rehabilitation, recovery, Physiotherapy and exercise. The Boolean operator 'AND' was used to ensure relevance of results. Further parameters imposed during the search included the literature being in English, availability of the full-text and being sourced from an academic journal. Despite these refining techniques, some databases returned several hundred results. Articles included in these results were reviewed and irrelevant ones discarded based on the title or abstract content. Review articles, meta-analyses and commentaries were considered for relevant conclusions, and their reference lists were utilised to identify any further appropriate literature. A total of 77 primary research studies were selected for review, ranging in publication date from 1990 to 2019.

Literature was reviewed with the goal of identifying current practices in TKR rehabilitation, including exercise protocols and the use of assistive devices. The World Medical Association's (WMA) Declaration of Helsinki (DoH) states that, for ethical purposes, effectiveness of a new intervention should be tested against those of the current best proven intervention (WMA, 2013). It was therefore considered an ethical duty to establish an overview of evidence regarding optimal rehabilitation for TKR patients, ensuring any proposed study methodology did not contradict this. Additionally, research methodology used in the literature was reviewed, with commonly utilised outcome measures, duration of interventions and data collection time points noted for

consideration in any proposed further research. For purposes of clarity, this review is therefore broken down into two sections, one discussing Physiotherapy input at various phases of the TKR journey and the other discussing the outcome measures used in the TKR literature.

2.2 Literature Review by Phase of TKR Journey

At the time of writing, no formal clinical guidelines were available in the UK that address Physiotherapy for TKR, with the National Institute for Health and Care Excellence (NICE) due to publish guidelines covering joint replacement rehabilitation in March 2020 (NICE, 2019). Given the lack of formal guidelines the literature was reviewed to establish common themes and differences in the Physiotherapy provision for TKR patients, particularly any evidence surrounding the use, or provision, of assistive devices. The literature highlighted that various forms of Physiotherapy, or equivalent, was provided for patients in three distinct stages of the TKR journey - before the procedure, immediately following the procedure and after hospital discharge. For the purposes of this review these will be referred to as the pre-operative, acute and sub-acute phases of rehabilitation with the literature focussed on each phase discussed in the following subsections.

2.2.1 Pre-operative Physiotherapy

Of the papers identified, six considered pre-operative Physiotherapy. Wide variations were noted in its implementation, such as the duration of intervention, with little information provided regarding aspects of Physiotherapy prescription, such as the specific exercises issued. Mitchell et al., (2005) conducted a randomised controlled trial (RCT) of 160 participants to investigate the effectiveness of pre and post-operative home-based physiotherapy on patients undergoing a TKR. The Western Ontario and McMaster Universities Arthritis Index (WOMAC), a patient reported questionnaire, was used as the primary outcome score. Comparable WOMAC scores demonstrated that

home-based physiotherapy was equally as effective as visiting an out-patient clinic, but that pre-operative physiotherapy had no impact on results. However, on manually reviewing the protocol it was noted the pre-operative input only involved a total of three home visits for gait re-education. No further information was provided regarding the specific exercises or devices used in either pre-operative or post-operative therapy sessions. Conversely, another RCT, by Evgeniadis et al., (2008), found that a three-week pre-operative physiotherapy programme improved the sample of 53 patient's mental health, confidence and post-operative recovery times, facilitating quicker discharges and reducing treatment costs. The Physiotherapy intervention utilised by Evgeniadis et al., (2008) included trunk and upper extremity strengthening exercises utilising resistance bands conducted three times per week, although no more specific details were provided.

Three studies directly compared the results of participants who received pre and post-TKR Physiotherapy with those who received only post-operative input in randomised trials (Alghadir et al., 2016, Cavill et al., 2016 and Calatayud et al., 2017). A variety of outcome scores were used including the Lower Extremity Functional Scale (Alghadir et al., 2016), WOMAC (Calatayud et al., 2017) and the EQ5D3L, a patient reported health-related quality of life questionnaire (Cavill et al., 2016). All 3 studies also used a visual analogue scale (VAS) to measure pain, with pre-operative exercise appearing to have a positive effect on post-operative pain in each of the studies. However, Alghadir et al., (2016) noted that this was not significantly higher than the group who received post-operative exercise only. Pre-TKR exercise improved post-operative range of movement (ROM) in each of the papers, although only Calatayud et al., (2017) found that these improvements in pain and ROM translated into significantly higher functional improvements compared to post-operative exercise only. Direct comparability between the studies was limited as the duration of pre-TKR Physiotherapy intervention ranged from several days (Alghadir et al., 2016) to eight weeks (Calatayud et al., 2017). Details regarding the exercises, and the modalities used, were generally vague, being

described simply as strengthening exercises (Calatayud et al., 2017), or strength and mobility practice (Alghadir et al., 2016). However, a comprehensive breakdown of the prescribed exercises was offered by Cavill et al., (2016), including knee flexion exercises completed in supine, although the use of an assistive device was not mentioned. None of the studies considered participant adherence to the prescribed exercises although Evgeniadis et al., (2008) noted a high drop-out rate with participants, citing an inability to fulfil the programme requirements as the primary reason.

Unlike the above studies, an RCT by Skoffer et al., (2016) did not find pre-operative exercise to elicit any benefit to patient reported outcomes in the sample of 59 participants. However, a significant improvement was noted in objective scores at 12 weeks post-TKR for a timed up and go (TUG) test and knee flexor/extensor strength in the pre-operative exercise group. The Physiotherapy intervention used by Skoffer et al., (2016) was a four-week resistance training programme, focussed on developing knee flexor and extensor muscle strength, with no assistive device, such as an Ortho-Glide, used.

Given the differences in intervention duration, exercise dosage and general lack of detail surrounding specific exercises used, a direct comparison between any of the papers utilising pre-operative Physiotherapy was challenging. As noted, none of the papers reviewed made use of the Ortho-Glide, or similar assistive devices, with the focus of interventions appearing to be to increase strength prior to TKR. Although a common goal of increasing strength was noted, evidence has also linked higher pre-operative ROM with improved post-operative functional outcomes (Bade et al., 2014, Garg, 2018). Unfortunately, variations in methodology, including small sample sizes, in literature relating to Physiotherapy provision at this stage of the TKR means the evidence of its effect on post-operative outcomes is unclear, as suggested by the systematic review by Kwok et al., (2015).

2.2.2 Acute Post-Operative Physiotherapy

For this review, acute post-TKR Physiotherapy was considered as any rehabilitation input provided during the immediate hospital-based period following surgery, up to the point of discharge home, although the duration of this varied between papers. The purpose of exercise provision in the immediate post-TKR phase is to increase the strength and range of movement in the operated limb, aiming to return to an acceptable level of function to enable a safe and timely discharge home (DeJong et al., 2009, Artz et al., 2015, Sattler et al., 2019). In addition to improving function post-operative mobilisation of the lower limbs, as well as early ambulation, is key to reduce the risk of developing thromboembolism (Li et al., 2016, Ghosh & Chatterji, 2019).

Although the purpose of acute post-TKR rehabilitation may be clear, significant variation in provision of the Physiotherapeutic interventions makes conclusions regarding best practice challenging to reach, as noted in other literature (Oatis et al., 2014, Sattler et al., 2019). The literature search returned a total of 37 studies which included details of acute Physiotherapy interventions. Twenty-five of those specifically investigated variations in the Physiotherapy and exercise provision during the acute-phase, whilst the other 12 simply included details of the acute-phase Physiotherapy treatment provided. As previously described, variations in provision, timing and the specific exercises used during acute post-operative Physiotherapy sessions were noted in the reviewed literature, as documented below.

Following the TKR procedure, the presence of severe post-operative pain, as experienced by up to 60% of patients, may act as a barrier to engagement with rehabilitation and completion of Physiotherapy exercises (Aso et al., 2019). The impact of reduced engagement with initial rehabilitation input negatively impacts clinical outcomes as well as patient reported satisfaction (Li et al., 2019).

The effect of different acute post-operative pain relief strategies on rehabilitation outcomes were compared in two RCT's by Aveline et al., (2008) and Bech et al., (2015). The use of ketamine was found to have a greater impact on pain compared to

nefopam or a saline placebo during the initial post-operative period (48 hours), leading to decreased pain and improved range of movement (ROM) scores (Aveline et al., 2008). Unfortunately, limited information of the specific Physiotherapy input was provided by Aveline et al., (2008), only stating that active knee flexion and extension exercises were completed by all participants in addition to receiving intravenous doses of pain relief. Bech et al., (2015) also studied post-TKR pain relief in the form of cryotherapy. The intervention group received continuous ice therapy by means of a cooling device, with additional compressive properties. Meanwhile, intermittent cryotherapy, in the form of patient-applied ice bags, was allocated to the control group, with both pain relief interventions lasting for 48-hours post-TKR. A numerical pain rating scale (NPRS) was used to measure pain intensity after 48-hours and the WOMAC was used to measure changes in function six weeks post-operatively. Although Bech et al., (2015) failed to document any details of the Physiotherapy exercises given to the patients, it was assumed there were no differences in post-operative care other than the cryotherapy intervention used. No statistically significant difference was shown in either the NPRS or the WOMAC scores between the intermittent and continuous cryotherapy groups, although some potentially clinically significant differences were seen in patient satisfaction, favouring the continuous cooling device. An earlier Cochrane review supported this conclusion stating that cryotherapy in any form may have a small but not clinically significant effect on pain or range of movement and that its use may not be justified from a time and inconvenience perspective (Adie et al., 2012).

A third pain-related study, by Holm et al., (2010) utilised a well-documented exercise and cryotherapy regime as part of an established fast-track patient pathway following TKR. It was concluded that beyond the initial 24-hour post-operative period, pain as measured using a VAS, had minimal influence over functional outcomes or active range of movement (AROM). Holm et al., (2010) also suggested that, due to this minimal influence of pain, early Physiotherapy input should include intense active

exercises for the lower limb to improve functional recovery. Limitations to this study were recognised by Holm et al., (2010) as being a lack of repeat measures during the immediate post-operative period. Additionally, no post-discharge follow-up data was collected by Holm et al., (2010), limiting conclusions regarding the longer-term recovery trajectory and comparison to Aveline et al., (2008) and Bech et al., (2015).

Despite inconsistencies between the reviewed literature, ensuring patients are capable of completing post-TKR Physiotherapy exercises without significant pain appears to allow for improved outcomes and patient satisfaction scores. Reducing the pain experienced post-operatively may be considered primarily a Pharmaceutical management concern (Li et al., 2019). However, due to the nature of the TKR procedure, and associated soft tissue disturbances, the pain experienced during Physiotherapy input may partially be influenced by the nature of the exercises being prescribed.

With a lack of evidence surrounding best practice for specific exercise prescription following TKR, research continues to explore the effectiveness of rehabilitation devices and alternative means of exercise and Physiotherapy input. The literature search identified fourteen studies utilising additional devices or non-conventional therapeutic interventions in the acute post-operative rehabilitation phase. A cohort study was conducted by Bedekar et al., (2012) assigning 51 participants to either receive a well described standard post-TKR Physiotherapy regime, or the standard post-TKR Physiotherapy plus additional yoga exercises. The yoga exercises commenced on the third post-operative day, along with collection of baseline WOMAC scores. Both groups demonstrated statistically significant improvements ($P<0.05$) upon re-testing at six and 12-weeks post-operatively. However, the yoga intervention group demonstrated greater improvements compared to the Physiotherapy-only group in the pain and stiffness WOMAC categories, suggesting the inclusion of yoga exercises has a positive influence on these outcomes. Unfortunately, Bedekar et al., (2012) did not collect any pre-operative outcome scores, a factor which Judge et al., (2012) found to be a reliable

predictor of post-operative outcomes and would have allowed the research team to ensure pre-operative equivalence between groups.

Twelve of the studies reviewed utilised continuous passive motion (CPM) devices in the acute phase of TKR rehabilitation, the most frequently cited device in the available literature. Considered an adjunct to post-operative Physiotherapy, CPM involves continuous passive flexion/extension of the knee joint, facilitated by the motorised device (Rex, 2018). An example of a CPM device is pictured in Figure 2.1.

Figure 2.1. An example of a CPM device (Kinetic Medical Products, 2016).

Seven of the studies reviewed utilised CPM as part of the standard post-operative regime, whilst the remaining papers specifically studied the difference between CPM regimes or CPM and other forms of exercise. Evgeniadis et al., (2008), Ebert et al., (2013), Buker et al., (2014), Castorina et al., (2017) and DeFine (2017) each specified that CPM was used although further details varied. Evgeniadis et al., (2008) provided between 12 and 14-days of acute rehabilitation for participants, stating that CPM was used in the early post-operative days, although no further details were given. Similarly, Castorina et al., (2017) state that a CPM device was used on the first day post-TKR, but again no additional details were listed. Only Buker et al., (2014) outlined the specific ROM settings on the CPM device starting at 45° of flexion on day one and

progressively increased this to 110° by day four to five. Ebert et al., (2013) and De Fine et al., (2017) initiated CPM use on day one post-TKR, although different details are provided. De Fine et al., (2017) set the device at 40° of flexion on day one, providing no further details regarding frequency or duration, whilst Ebert et al., (2013) stated that they utilised the device for one hour, twice daily, but provided no further details regarding ROM.

Leonard et al., (2007) investigated differences in ROM between 60 participants assigned to groups receiving early CPM from six hours and those receiving later CPM from 52 hours post-TKR. All participants used CPM devices for a two-hour period, twice daily. A statistically significant increase in knee ROM was noted in participants receiving CPM from six hours post-operation to those receiving it later in rehabilitation. It was not made clear in the article if it was passive or active ROM being studied. Both groups also completed a well-documented rehabilitation protocol including active and passive knee mobilisation and strengthening exercises. Liao et al., (2016) retrospectively reviewed 354 TKR patients who had received CPM as a component of their rehabilitation, noting that an earlier introduction of the device post-operatively, in conjunction with higher ROM settings, elicited greater functional outcomes measured using the WOMAC at six-months. Liao et al., (2016) did not document any of the other exercises prescribed to participants and, as with Leonard et al., (2007), did not include a non-CPM control group, a limitation and suggestion for further research recognised in their conclusion.

Mau Moeller et al., (2014) randomised 125 participants to either receive a CPM or a sling device during the acute post-TKR hospital stay, with both interventions beginning on the first post-operative day and ceasing prior to discharge home. In contrast to the pre-set, passive nature of CPM, the sling device was designed to facilitate active ROM of the knee joint by reducing gravitational and frictional forces, with participants encouraged to increase the range achieved as pain allowed. Passive ROM was the primary outcome measure in addition to active ROM, pain (VAS) and the WOMAC with

scores taken pre-test, on day of discharge from hospital and at 12-weeks post-operation. Despite demonstrating a statistically significant difference in mean passive ROM (6°) in favour of the sling training group no differences were noted between the sling and CPM for any outcomes at 12-weeks post-TKR with the authors citing early cessation of the exercises as a potential reason.

Whilst specific details regarding CPM use varied between literatures, the rationale for using CPM is always to increase the joint ROM, as suggested by (Harvey et al., 2014). However, the effectiveness of CPM in improving post-TKR ROM has long been questioned in literature. Lake et al., (1990) retrospectively reviewed ROM achieved in patients who received CPM and those who received only standard post-operative exercises. No significant difference was noted in ROM at discharge or length of hospital stay in those who received CPM and those who did not, although the study did not include follow-up beyond the acute in-patient stay and no patient reported or functional outcomes were used. Additional limitations were recognised as potential variation in the post-operative exercises given to patients over the three-year trial period, as well as the CPM group having a significantly higher mean age.

Beaupre et al., (2001), Bruun Olsen et al., (2009) and Herbold et al., (2012) also investigated the efficacy of CPM compared to no-CPM in acute post-operative Physiotherapy treatment. Beaupre et al., (2001) and Bruun Olsen et al., (2009) both conducted RCTs with 40 and 33 participants respectively assigned to receive CPM post-TKR, however no significant difference was noted in ROM or functional outcomes, WOMAC and TUG, on follow-up. Interestingly, the Physiotherapy regime used in the study by Beaupre et al., (2001) did not start until the third post-operative day, which is comparatively late compared to the majority of studies reviewed, including Bruun Olsen et al., (2009), which generally start on the first post-operative day. Neither paper gave detailed descriptions of the standard exercise protocols utilised, Beaupre et al., (2001) describing them as active knee ROM and strengthening exercises lasting for 30-minutes daily, including use of a slider board device. Similarly, Bruun Olsen et al.,

(2009) described the exercise regime as including assisted, and active, exercises for the knee and hip as well as isometric contractions of the quadriceps, again for 30-minutes daily. Beaupre et al., (2001) included an additional study group who completed 10 minutes twice daily of slider board exercises as well as the standard exercises. However, as with the use of CPM, Beaupre et al., (2001) noted no additional benefit in ROM or WOMAC scores to those who completed the standard exercise regime alone, which was also noted to include the use of a slider board. Herbold et al., (2012) recognised this lack of consistency in exercise prescription as a limitation in their matched cohort study of 122 participants, noting that despite departmental protocols CPM and exercise prescription often varied significantly from these guidelines. Similarly to Beaupre et al., (2001) and Bruun Olsen et al., (2009), Herbold et al., (2012) did not find that CPM use improved active knee ROM, or functional independence, compared to standard exercise use alone, although scores were only taken pre-operatively and on discharge from hospital.

The fact that CPM was the most commonly utilised device in acute TKR rehabilitation was surprising given that its efficacy, when compared to standard exercises alone, has long been questioned. The goal of CPM in all the reviewed papers was to improve ROM, an outcome correlated with improved post-TKR function and patient satisfaction (Noble et al., 2006, Matsuda et al., 2013). The passive nature by which CPM attempts to improve ROM has been directly questioned by Stevens-Lapsley et al., (2012) who suggest that active ROM exercises encourage greater patient engagement and offer greater long-term benefits to ROM, strength and function. More contemporary research by Schulz et al., (2018) investigated the effects of CPM compared to active ROM exercises performed using the exact same device. Both groups, with a total of 50 participants, reported significant improvements in KOOS scores post-TKR. However, the active ROM group had greater improvements in pain and quality of life scores, as well as knee joint ROM after 30-days of outpatient Physiotherapy, suggesting this to be a more effective method of rehabilitation post-TKR. Unlike other studies, the work by

Schulz et al., (2018) used an identical device for both study groups, with only the level of assistance altered between CPM and active ROM groups. This limitation in variables between groups enhances the validity of the conclusion by Schulz et al., (2018) that active ROM exercises were superior to passive ROM in post-TKR patients.

In addition to pain and reduced ROM, several other post-operative symptoms result from the extensive tissue damage inflicted during the TKR procedure. These may include swelling, or fluid retention, and reduced strength (Judd et al., 2012), and may be considered barriers for post-operative Physiotherapy to overcome (Pellegrini et al., 2018). Attempting to address these barriers, Ebert et al., (2013) prescribed manual lymphatic drainage, or massage, to reduce the volume of fluid retention around the joint to increase the available ROM. Improvements in knee ROM at six weeks following TKR were reported, however, Ebert et al., (2013) noted this increased knee ROM did not translate into functional improvements, as measured using the KOOS.

Aiming to improve both active ROM and strength post-TKR, Petterson et al., (2009) and Stevens-Lapsley et al., (2012) conducted RCTs investigating the use of neuro-muscular electrical stimulation (NMES) devices. Both noted improvements in function using several outcome measures including the WOMAC, TUG and six-minute walk test (6MWT) at various intervals up to 12-months post-TKR. However, only Stevens-Lapsley et al., (2012) noted any improvement in active ROM, although Petterson et al., (2009) did note the standard care group received significantly more Physiotherapy sessions post-operatively, potentially influencing the results. Petterson et al., (2009) also included an additional group, receiving progressive strengthening exercises without the NMES device, demonstrating improvements in all outcomes compared to the NMES-only group at all study intervals. Muscle inhibition post-TKR, and subsequent muscle atrophy, was cited as a key limitation to recovery by Mizner et al., (2005), who suggested rehabilitation programmes should encourage voluntary muscle contractions to counter these effects.

Eight further studies focussed on rehabilitation in the acute post-operative phase. Five of the papers utilised what may be described as an enhanced recovery after surgery (ERAS) protocol, involving early mobilisation and at least two Physiotherapy sessions per day until discharge. Each of these found significant improvements to mortality rates, length of stay and functional outcome measures at all post-operative intervals with ERAS protocols, compared to those previously used (Cook et al., 2008, Malviya et al., 2011, Sanchez-Labraca et al., 2011, Gnanakumaran et al., 2017, Harikesavan et al., 2019). Despite all utilising an ERAS protocol there were variations in the exact Physiotherapy input between studies. However, all involved early mobilisation of the patient between four hours (Gnanakumaran et al., 2017) and 24-hours (Sanchez-Labraca et al., 2011) after surgery. Further details of exact exercises utilised varied, Sanchez-Labraca et al., (2011) describe the provision of active and passive flexion/extension exercises, whilst Harikesavan et al., (2019) and Gnanakumaran et al., (2017) only state that routine post-operative exercises were prescribed.

Unlike the literature implementing an ERAS protocol, the RCT by Akbaba et al., (2016) involved Physiotherapy only once per day, lasting 30-minutes, from the first day post-TKR. Deviating further from the modern ERAS protocol, participants in the study by Maruyama et al., (2011) did not receive Physiotherapy input until the second or third post-operative day, potentially explaining a longer mean length of stay of 28-days. Details regarding the specific Physiotherapy methods and any assistive devices utilised were limited for both Akbaba et al., (2016) and Maruyama et al., (2011).

Unfortunately, inconsistencies in Physiotherapy protocols implemented, devices used, and exercises prescribed in the available literature make conclusions regarding optimal acute post-operative rehabilitation difficult to reach. This wide variation in exercise dosing, timing, frequency and content was recognised in a cross-sectional observation study by Oatis et al., (2014), suggesting further research is needed to clarify optimal post-operative Physiotherapy input. Although best practice for acute post-TKR rehabilitation is not clear, the reviewed literature identified several consistent themes.

As mentioned, the goal of this phase of rehabilitation is to improve joint mobility, reduce the risk of thromboembolism, facilitate ambulation and a return to function in order to return home safely. Post-operative pain may present as a barrier to engagement with Physiotherapy and should be addressed with appropriate Pharmaceutical management. Although intended to reduce pain, cryotherapy appears to be of limited clinical benefit to post-operative outcomes and its use may not be justified. The optimal post-operative protocol appears to include early Physiotherapy input, within the first 24-hours after surgery, and multiple sessions per day, as with the ERAS protocol. Whilst potentially minimising discomfort, passive ROM exercises such as CPM, may not elicit the same benefits as active ROM exercises, and activities encouraging voluntary muscle contractions should be prioritised.

2.2.3 Sub-Acute Post-Operative Physiotherapy

Following the acute post-operative phase, the sub-acute phase was considered to be any rehabilitation that occurred after discharge home from hospital. Twenty-seven papers were identified during the literature search that included elements of sub-acute TKR rehabilitation. As with the pre-operative and acute phase Physiotherapy/exercise prescription, there were wide variations in the protocols used in the sub-acute phase papers reviewed. Following a review of the literature, several themes were identified, including level of supervision during Physiotherapy sessions, format of exercise prescription, the use of devices to facilitate exercise, and the duration of sub-acute rehabilitation provided. Unfortunately, as with the other phases of the TKR patient journey, the level of detail provided regarding the exercise prescription, and any assistive devices used, varied.

Six papers compared supervised to un-supervised exercise programmes lasting various lengths of time during the sub-acute phase of post-TKR recovery. Two papers, an RCT by Akbaba et al., (2016) and a pilot study by Sindhu et al., (2013), found that outcomes were improved following supervised compared to un-supervised exercise programmes, on overall sample sizes of 60 and 20 respectively. The remaining four

papers investigating differences between supervised and un-supervised exercise programmes found no significant differences between groups across a variety of outcomes. Madsen et al., (2013) and Han et al., (2015) conducted RCT's lasting six weeks and found no significant differences in patient reported functional outcome scores. No significant difference between supervised and un-supervised exercise groups was noted using the WOMAC score and VAS by Lopez-Liria et al., (2015) in a non-randomised trial investigating the effectiveness of a home rehabilitation service. However, methodological inconsistencies were noted as the un-supervised/home group had occasional check-ins by a visiting Physiotherapist. The trial period also varied as participants were discharged once they achieved certain functional goals, rather than completing a set period of exercise (Lopez-Liria et al., 2015). Alongside ROM, the VAS was also used by Buker et al., (2014) as a primary outcome measure in a prospective study of 34 participants allocated to receive 4 weeks of unsupervised home exercise or supervised exercise. Unlike the relatively low frequency of twice weekly sessions implemented by Akbaba et al., (2016) and Madsen et al., (2013), the exercise frequency for participants in both groups by Buker et al., (2014) was five times weekly. Both groups were prescribed the same strength, ROM and mobilisation exercise programme as the home-rehabilitation group. However, the supervised group in the prospective study by Buker et al., (2014) also utilised heat and transcutaneous electrical nerve stimulation (TENS) to reduce pain and improve performance during the programme. Despite the access to additional pain relief techniques and devices, no significant difference was noted in ROM or VAS between the supervised or home-exercise groups after the trial period of four weeks.

The efficacy of remote supervision using telerehabilitation during home-based exercise programme was investigated in an RCT by Tousignant et al., (2011). Based on WOMAC scores, this method of supervision was shown to be equally as effective as conventionally supervised outpatient Physiotherapy post-TKR. Interestingly, the remotely supervised, telerehabilitation group continued to demonstrate functional

improvements eight-weeks after the intervention had ceased (Tousignant et al., 2011). Although limited, the available research generally appears to suggest that in the sub-acute phase of post-TKR rehabilitation, prescribed exercises are equally as effective in an unsupervised environment as they are when being supervised. As demonstrated by Tousignant et al., (2011), depending on the level of engagement, patients may continue to functionally improve following the completion of sub-acute rehabilitation.

Based on the information given regarding the exercise programmes used during sub-acute Physiotherapy, two other papers utilised additional devices for rehabilitation purposes. For example, Buker et al., (2014) and Alghadir et al., (2016) included the use of TENS for participants in an RCT, however this was issued to all participants regardless of group allocation. Fernando Dias et al., (2018) provided a bio-feedback device to the study group for both the acute and sub-acute post-operative phases of rehabilitation.

The bio-feedback device involved motion trackers which provided real-time feedback on performance during the home rehabilitation sessions as well as enabling the clinical team to monitor and progress the exercises as needed. Fernando Dias et al., (2018) demonstrated significant improvements in the bio-feedback group using the KOOS outcome score when compared to the standard exercise group.

In contrast to the number of studies utilising CPM in the acute post-operative phase, only one paper, an RCT by Lenssen et al., (2008), mentioned the use of CPM in the sub-acute phase. In addition to the standard Physiotherapy input, Lenssen et al., (2008) assigned the experimental group to receive two further weeks of CPM use in the sub-acute phase but detected no significant difference in ROM or WOMAC scores at six or 12-weeks post-op.

Several other papers stated that sub-acute TKR rehabilitation was utilised. Based on the details provided, notable variations included duration of the intervention, which varied from 10 days (Kauppila et al., 2010) to four weeks (Akbaba et al., 2016, Buker et

al., 2014 and Cavill et al., 2016). Lengthier sub-acute rehabilitation intervention periods were reported, lasting from 12-weeks (Naili et al., 2017) up to a maximum of six-months post-operatively (Monticone et al., 2013). Unfortunately, the detail provided regarding the specific exercise programmes used was insufficient for meaningful comparison of results between papers. Although the specific details of Physiotherapy provision significantly varied, the goal of strengthening, improving ROM and function was noted as the aim of all papers which included a sub-acute phase of TKR rehabilitation.

As with the pre-operative and acute post-operative phase papers, there was very limited discussion regarding exercise adherence of individual participants. Following the implementation of a 24-week circuit training programme, starting at 12-weeks post-TKR, Hsu et al., (2017) concluded that circuit-training has the potential to facilitate exercise adherence of up to 80% due to the social interaction provided by the group environment. However, no specific outcome measure was used to measure exercise adherence in this retrospective cohort study of 34 participants. Unfortunately, the sample of only 16 assigned to the circuit-training group also meant insufficient power to demonstrate statistical significance in the KOOS score improvements shown by the control group at all time points. Madsen et al., (2013) and Han et al., (2015) both noted marginally, but not significantly, lower drop-out rates in the supervised groups compared to unsupervised which could be interpreted as exercise-adherence related. However, as with Hsu et al., (2017) no specific outcome measure was used to quantify this metric. The RCT by Piva et al., (2010) quantified exercise adherence as simply participant attendance at supervised sessions, whilst adherence to prescribed home-exercises was calculated as the number of exercises completed out of those prescribed. Aside from numbers of participants who did not complete the studies, exercise adherence to the Physiotherapy interventions was not recorded.

2.2.4 Summary of Physiotherapy Provision for TKR

A wide range of Physiotherapy interventions appeared to be implemented in the reviewed literature making direct comparison between papers challenging at all stages of the TKR journey. A common theme in many of the studies was the poor level of detail surrounding the specific content of the Physiotherapy provided. Despite this lack of detail, and the lack of any formal guidelines to direct best practice, the literature reviewed provided a general overview of the TKR journey and provision of Physiotherapy at each stage, as summarised below.

At the pre-operative stage, Physiotherapeutic exercise may influence post-operative outcomes, but in order to allow a physiological response the patient may need to commence this at an appropriate length of time before the procedure. To optimise mortality rates, length of stay and functional outcomes an ERAS pathway should be implemented, including early mobilisation within 24-hours and multiple Physiotherapy sessions per day post-TKR until discharge home. Pharmacological management of pain relief in the acute post-operative period may influence the ability to engage with Physiotherapy exercises, although the relevance of pain intensity to functional outcome during the initial post-operative period has been questioned. Although previously provided as an adjunct to pain relief, continuous or intermittent cryotherapy is unlikely to yield clinically or statistically significant improvements in functional outcomes post-TKR.

The specific exercise regimes prescribed in the acute post-operative phase were poorly documented, although of those documented a form of flexion/extension of the knee joint was consistently mentioned. CPM machines were the most common device used to facilitate knee flexion/extension in the acute post-operative period. However, the passive nature of CPM has been questioned and there is limited evidence that its use improves ROM or function compared to standard exercises alone. Furthermore, it has been suggested that muscle inhibition and weakness post-TKR is a primary limiting factor in recovery, and that Physiotherapy regimes should address this with active,

rather than passive, exercises. Several non-conventional therapeutic techniques and devices were used in the available literature, with variable results, however there is limited data to support, or refute, their efficacy. During the sub-acute rehabilitation phase, unsupervised, or home based, Physiotherapy appears to be equally as effective as supervised Physiotherapy, although once again wide variation was noted in the specific details of its provision.

In addition to the level of detail provided, a consistent limitation noted in the reviewed literature was the lack of consideration for patient adherence to the prescribed Physiotherapy exercise regime. Adherence to Physiotherapist- prescribed exercise may have a significant effect on treatment outcomes, having been shown to positively influence factors such as pain and physical function (Van Gool et al., 2005, Pisters et al., 2010). Given the potential influence of exercise to improve pain and physical function, it is likely that some of the data reported in the papers reviewed may be skewed by none, or partial, compliance to the interventions used. Future research should address this and attempt to objectively quantify adherence to the prescribed intervention in order to enhance comparability between groups.

2.3 Literature Review by Outcome Measure

In addition to the methodological differences discussed in the preceding section, a significant variation in the reviewed literature was the outcome measures selected, occasionally limiting the direct comparability of results between studies. A common theme across the literature reviewed was the use of patient reported outcome measures to monitor improvements in factors such as pain and function during the TKR journey. Patient reported outcomes are gaining increasing recognition as methods of gathering valuable patient-centred data, and ultimately contribute to quantifying the success of a TKR procedure (Price et al., 2010, Merciecca-Bebber et al., 2018). Multiple outcome measures were implemented in the available literature, with varying

degrees of validity, reliability and responsiveness. This variation was noted by Ramkumar et al., (2015), who concluded that a single outcome measure optimally addressing these requirements in TKR patients was difficult to identify. The outcome measures used were noted during the literature review with those most frequently employed, their key features, and variations in their implementation discussed in this section. The most commonly used measures used were the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) and the Knee Osteoarthritis Outcome Score (KOOS), both to assess overall patient function, with 16 and 14 uses respectively. Many of the papers reviewed also used secondary outcome scores to specifically assess factors such as patient pain or discomfort levels. The most commonly used outcome score for this was the Visual Analogue Scale (VAS), with 15 uses, followed by the Numerical Pain Rating Scale (NPRS) with four uses.

This review of outcomes was undertaken to establish common methodological features, as well as strengths and limitations to be avoided in any research undertaken into the Ortho-Glide. Additionally, whilst methodological variations impacted the ease of direct comparison between the literature this section of the review aimed to establish a recovery trajectory for patient reported outcomes post-TKR.

2.3.1 Review of Patient Reported Functional Outcome Measures

The WOMAC is a patient reported outcome measure initially developed in 1982, and later validated, by Bellamy et al., (1988) for use in cases of osteoarthritis of the hip or knee. The WOMAC consists of 24 questions over three sub-sections; pain, stiffness and function. Each question is scored on a five-point Likert scale from 0 (none) to 4 (extreme) and can be totalled to give an overall WOMAC score, with higher scores indicating worse pain, stiffness and function. Since its inception the WOMAC has been widely used in clinical trials of osteoarthritis in the knee and hip, as well as for a variety of other purposes, including as a Physiotherapy outcome measure, providing valid and reliable data as shown in a review of its use in 43 studies by McConnell et al., (2001). First developed in 1998, the KOOS is another patient reported outcome measure

expanding on the three subscales offered by the WOMAC. The KOOS comprises of 42 questions across five subscales; symptoms, pain, function in activities of daily living (ADL), function in sports & recreation and knee related quality of life (Roos et al., 1998). A five-point Likert scale (0-4) for each question is used to calculate the score for each subscale as a percentage, although unlike the WOMAC, higher KOOS scores represent fewer problems. It is recommended each KOOS subscale be considered for analysis separately. However, a composite score may be calculated to give an overall KOOS Total score, although this is only recommended for use as a primary outcome measure in an RCT (Roos et al., 2011). As an outcome measure for TKR, the KOOS has been shown to be reliable and responsive, as well as showing a higher level of validity when compared to the WOMAC (Roos & Toksvig-Larsen, 2003).

The wide variations in interventions being studied meant comparison of outcome score data reported in the available literature would be of little value. However, for the purposes of comparison to data generated by this study, the scores reported in the reviewed studies were noted (Appendix 1). For additional comparative purposes, WOMAC and KOOS scores for healthy individuals, stratified by age range, gender and body mass index (BMI) may be found in (Appendix 2), as reported in the cross-sectional, international study conducted by Marot et al., (2019).

Pre-operative baseline scores were compared to scores taken at various post-operative time points by thirteen of the papers using the WOMAC outcome measure, and 10 using the KOOS. The earliest post-operative use of a functional outcome measure was two weeks post-TKR by Lin et al., (2018), where mean KOOS scores had worsened for both control and intervention group compared to the pre-operative baseline. However, these scores improved by the four-week post-operative stage (Lin et al., 2018). All other papers utilised data collection phases ranging from as little as six weeks post-operatively for Bech et al., (2015), Han et al., (2015) and Ebert et al., (2013) up to three years post-operatively in the study by Aunan et al., (2016). Despite studying different interventions, both Bech et al., (2015) and Han et al., (2015)

demonstrated an improvement in mean pre-operative to post-operative WOMAC scores at the six week post-operative point. Bech et al., (2015) and Han et al., (2015) found no significant differences in WOMAC scores between the intervention and control groups. These results suggest that patients may experience an initial period of increased pain, stiffness and decreased function before a subsequent improvement as early as four to six weeks post-TKR.

The most commonly used final data collection point was 12-weeks post-TKR, with six of the papers reviewed using the WOMAC but only two papers using the KOOS up to this time point. All six papers using the WOMAC score at 12-weeks post-TKR demonstrated mean improvements from pre-operative baseline scores for both intervention and control groups. Bedekar et al., (2012), Mau Moeller et al., (2014) and Calatayud et al., (2017) each demonstrated greater WOMAC improvements in their intervention groups, whilst Mitchell et al., (2005), Lenssen et al., (2008) and Piqueras et al., (2013) found no significant difference between intervention and control group WOMAC scores. Investigating the influence of a pre-operative lower limb strength regime, Lin et al., (2018) collected the final KOOS outcome scores at 12-weeks post-TKR. Both intervention and control groups showed significant improvements at the 12-week stage, although the ADL and quality of life (QOL) subscales for the intervention group were significantly better than the control group (Lin et al., 2018). Significant improvements in KOOS scores at 12-weeks post-TKR were also reported by Harikesavan et al., (2019) using an early mobilisation protocol, however no control group was included to allow direct comparison.

It has previously been observed that the greatest improvements in outcome scores post-TKR may occur during the first 12-weeks (Shields et al., 1999). This was used as the rationale for this length of data-collection phase by Mitchell et al., (2005) and was also demonstrated in the WOMAC scores collected by Kramer et al., (2003).

Four papers used the six-month post-operative point for the final WOMAC scoring with significant variations in intervention and study methodology limiting direct comparison.

However, only Liao et al., (2016) demonstrated significantly improved WOMAC scores in the study group, utilising higher frequency and intensity of CPM use, compared to the control group, using normal CPM application. All studies citing a pre-operative baseline, reported improvements in mean WOMAC scores at the six-months post-TKR. Harmer et al., (2009) found that whilst the WOMAC pain-subscale improved most significantly in the initial 12-weeks post-TKR, the WOMAC stiffness scores continued to improve up to the six month post-operative stage, indicating that different aspects of TKR recovery may progress at different rates. Unlike the other literature utilising the WOMAC score, Harmer et al., (2009) recorded baseline scores at two-weeks post-operatively in the randomised, single-blind trial of water vs land based post-TKR exercise. Only Monticone et al., (2013) used the KOOS score at six-months post-TKR as their final re-test point when comparing the effects of a home-based exercise programme to general exercise advice post-TKR. At six-months the mean improvements in KOOS scores of the home-exercise group were greater than those of the control group, however unlike the majority of other papers baseline scores were taken post-operatively instead of pre-operatively.

Several papers using either the WOMAC or KOOS cited longer post-operative periods before collecting the final data from participants. Investigating variations in sub-acute rehabilitation, Kramer et al., (2003) and Kaupilla et al., (2010) found no significant difference between WOMAC scores of intervention and control groups at 12-months post-TKR. Conversely, the pilot RCT by Minns Lowe et al., (2011) reported differences in the KOOS scores between groups investigating the provision of additional home-based Physiotherapy in the sub-acute rehabilitation phase. Interestingly, the standard-care control group utilised by Minns Lowe et al., (2011) reported greater improvements in some KOOS subscales. However, the long period between completion of the intervention and final data collection at 12-months post-TKR reduced the validity of conclusions drawn about the effect of the treatment variables. All papers which collected outcomes at 12-months reported significant improvements in scores

compared to baseline. However, investigating post-TKR functional deficits, Naili et al., (2017) concluded that improvements in KOOS scores at 12-months remained below those reported by the age-matched, healthy control group.

Aiming to establish the effect of various interventions, a number of the studies reviewed utilised data collection periods extending beyond 12-months post-TKR. Parallel RCT's by Skou et al., (2018) compared TKR followed by non-surgical treatment, including Physiotherapy, to non-surgical treatment alone. KOOS scores were only taken pre-operatively and two-years post-operatively. At the two-year point the TKR followed by non-surgical treatment group showed significantly greater mean improvements in all KOOS subscales compared to the non-surgical treatment-only group. This was the only study reviewed to directly compare TKR to non-surgical treatment for osteoarthritis, with the result demonstrating the benefits of undergoing the procedure for osteoarthritis patients. Unfortunately, considering the prolonged trial duration, the lack of mid-way KOOS scoring made it challenging to accurately map the trajectory of improvement post-TKR (Skou et al., 2018). Conversely, despite the same trial duration as Skou et al., (2018), mid-way data collection was implemented by Buker et al., (2014), with WOMAC scores collected pre-operatively as well as at regular intervals post-TKR. Unlike Skou et al., (2018), no significant difference could be demonstrated in WOMAC scores between the supervised Physiotherapy group and the unsupervised, home-based Physiotherapy group.

The longest data collection phase utilised in the available literature was by Aunan et al., (2016) who collected data from 129 participants pre-TKR and up to three years post-operatively. This RCT compared KOOS, Oxford Knee Score and patient satisfaction measured using a visual analogue scale (VAS) of patients undergoing TKR with or without patellar resurfacing. Greater KOOS scores were shown at one-year and three-years post-operatively in the TKR with patellar resurfacing group, although the secondary outcome measures, the Oxford Knee Score and VAS, showed no significant difference between groups. As with the other studies cited, both groups in this trial

showed significant improvements in KOOS scores from pre-operative baseline to post-operatively. Minimal differences in mean KOOS scores were noted by Aunan et al., (2016) between one-year and three-years post-TKR, again suggesting that optimal improvements may occur within the initial 12-months post-TKR.

2.3.2 Review of Patient Reported Pain Scores

Originally introduced by Freyd (1923) as the Graphic Rating Scale, the VAS is an instrument used to measure an individual's perception of a specific characteristic, such as pain. The VAS consists of a horizontal line, 100mm in length, with word descriptors at each end, generally 'no pain' on the left, and 'severe pain' on the right, although additional wording may also be present along the scale (Gould et al., 2001). Participants then mark on the scale the point at which they feel represents their current pain level. The VAS has been found to be a valid and reliable outcome measure for chronic and experimental pain changes (Price et al., 1983) as well as pain specifically in TKR patients (Boeckstyns & Backer, 1989). The NPRS is the numerical version of the VAS where instead of marking a pain level on the scale participants verbally give a number from 0 (no pain) to 10 (severe pain). The NPRS has been shown to be highly correlated with the VAS, with good test–retest reliability, for both literate and illiterate patients (Hawker et al., 2011).

In addition to being significantly quicker to administer, taking less than 60 seconds, the VAS and NPRS have been shown to be more reliable methods of scoring pain than question based outcome measures alone (Boeckstyns & Backer, 1989). Nine papers used the VAS or NPRS as additional outcome measures to WOMAC or KOOS scores with the ease of administration allowing for pain scores to easily be taken at additional time points to the primary outcome measures. This versatility and ease of administration allowed Bech et al., (2015) to record NPRS scores every four-hours between 24 and 48-hours post-TKR, in addition to their use of the WOMAC at pre-operative and six weeks post-operative time points. Ebert et al., (2013) collected NPRS scores on day two, three, and four post-TKR finding that, as with pre-operative and six

week post-TKR KOOS scores, there was no difference between participants conducting manual lymphatic drainage and those not.

Frequent data collection time points were also utilised in the RCT by Bathis et al., (2005) who collected VAS scores on day one, two, three, eight and 15 post-TKR, citing the speed of administration as rationale for its use. Analysis of the VAS scores led to the conclusion that a mid-vastus surgical approach correlated with improved pain scores both at rest and during movement during the initial post-operative period (Bathis et al., 2005). Several other papers noted the ease and speed of administration of the VAS and NPRS in gather pain scores during different levels of activity for each participant. Aveline et al., (2008) took VAS scores of participants at two, 12 and 48-hours post-TKR, both during rest and with the knee flexed to 40°, concluding that ketamine has a greater analgesic effect that nefopam in facilitating mobilisation post-TKR.

In contrast to the acute post-operative use of the VAS, Buker et al., (2014) recorded VAS scores at rest and during activity pre-operatively and three, six, 12 and 24-months post-operatively. Unlike the WOMAC scores, which showed no significant difference at any of the time points, a significant difference was noted between VAS scores of the supervised-Physiotherapy and standard-care group at the two-years post-TKR. Of note in the data reported by Buker et al., (2014) was the consistently higher (worse) VAS scores during activity compared to rest, suggesting that activity continues to be more painful for the knee than rest, even two-years post-TKR.

Similar to the results of WOMAC and KOOS scores, the literature reviewed demonstrated overall improvements in mean pain scores between baseline, either pre-operative or pre-intervention, and the final post-operative data collection point. Unsurprisingly, scores taken at rest were consistently better than those taken during any form or activity, mobilisation or flexion of the knee, suggesting that activity continues to cause discomfort to the knee following TKR.

2.3.3 Summary of Patient Reported Outcome Measures used for TKR

The best outcome measure to quantify patient reported improvements post-TKR is not clear, with a wide variety of outcomes being utilised in the literature reviewed. With the increasing recognition of its value, patient reported function was most frequently measured using the WOMAC and KOOS outcomes measures. High validity and reliability have been noted for both the WOMAC and KOOS outcomes, although the KOOS may be superior for use in TKR patients. The VAS and NPRS were the most frequently cited outcome scores used to measure pain. Following TKR, the mean pain and functional outcome scores significantly improved for all participants, partially as a result of the TKR procedure itself. Optimal improvement has been suggested to occur within the first three to six-months. Despite significant improvements compared to pre-operatively, the pain experienced post-TKR during activity, or exercise, is likely to continue being worse that at rest. Additionally, patient reported function, despite significant improvement, may not reach the same level as age-matched, healthy individuals. As previously discussed, despite the likely influence on function, no outcome measures appear to have been used to quantify adherence to the prescribed Physiotherapy intervention.

2.4 Literature Review Summary

A wide variation in post-operative exercise protocols was seen in the reviewed literature, although in many cases there was little, or no, detail about the specific exercises prescribed, or how these were carried out. As previously noted, best practice surrounding post-TKR exercise prescription remains unclear, however the importance of regain active knee ROM is recognised. With no evidence of its use in previous literature, a study was designed to investigate the effectiveness of an assistive device, the Ortho-Glide, with patients completing exercises following TKR. The methodology and design of this study is documented in the following chapter.

3 CHAPTER 3: METHODOLOGY

3.1 Aims and Objectives

The aim of this study was to investigate the effectiveness of providing patients with an assistive device, the Ortho-Glide, to aid completion of joint mobilisation exercises following total knee replacement. The objectives were:

- To determine any benefits between the use of an Ortho-Glide device or the currently utilised method of completing Physiotherapy exercises post-TKR.
- To determine if use of the Ortho-Glide device influenced exercise adherence following TKR.
- To determine any benefit of using the Ortho-Glide on the trajectory of recovery following TKR.
- To consider providing recommendations for clinical practice based on the results of the study.
- To provide recommendations for future research to further enhance the evidence surrounding Physiotherapy provision for TKR patients.

The Orthoglide (Figure 3.1) is a rehabilitation device manufactured by Medical Devices Technology International (MDTi) designed to facilitate lower limb ROM by reducing the frictional forces created by the foot rubbing against a surface (MDTi, 2017), in the case of acute post-TKR patients the bedding.

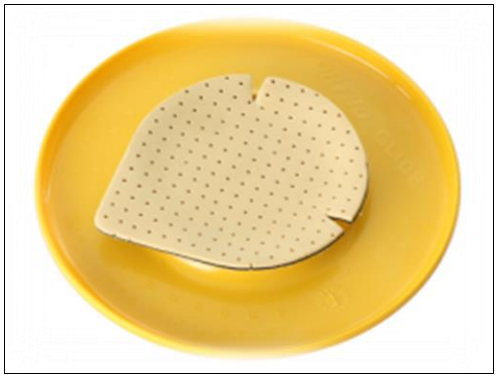


Figure 3.1 The Ortho-Glide device.

This project aimed to investigate the effects of using the Ortho-Glide to aid completion of post-operative Physiotherapy exercises as part of an ERAS pathway at Blackpool Victoria Hospital.

3.2 Rationale

As noted in the literature review, evidence surrounding specific aspects of Physiotherapy provision for TKR is limited, primarily due to methodological inconsistencies and limited detail regarding specific exercise prescription. The majority of evidence regarding the provision of assistive devices post-TKR focussed on CPM machines, and relatively little research has been undertaken into the effects of other rehabilitation devices. At the time of writing no research had been undertaken into the effectiveness of the Ortho-Glide device.

Considering the lack of evidence surrounding rehabilitation devices, the experimental hypothesis for this project was that the use of the Ortho-Glide device would elicit a significant difference in rehabilitation outcomes compared to current standard Physiotherapy exercises alone. The null hypothesis was therefore no significant difference would be demonstrated between use of the Ortho-Glide device and standard Physiotherapy exercises alone.

3.3 Variables

3.3.1 Independent Variables

Issuing the Ortho-Glide device to assist with standard Physiotherapy exercises, and issuing standard Physiotherapy exercises alone.

3.3.2 Dependent Variables

Pain, Function, and adherence to prescribed exercise.

3.3.3 Controlled Variables

This study will consider rehabilitation following unilateral total knee replacement performed at Blackpool Victoria Hospital. Post-operative rehabilitation pathways will include a standardised exercise protocol which is detailed in Appendix 3 and Appendix 4. The number of inpatient Physiotherapy sessions per day was standardised at a minimum of two per day (Appendix 4), along with exercise recommendations following discharge home (Appendix 3).

3.4 Study design

Due to the lack of previous literature exploring use of the Ortho-Glide the design selected for this project was a pilot randomised control trial (RCT), considered the most effective, and safest, way to study new treatments in clinical settings (Stang, 2011). The RCT study design helps to reduce potential researcher bias through randomised allocation of participants to different groups (Zwarenstein et al., 2008). This reduction in potential bias allows a more rigorous examination of cause-effect relationships between the intervention being tested and outcomes seen (Hariton & Locascio, 2018).

3.5 Setting

Participant recruitment, TKR procedure and provision of post-operative Physiotherapy exercises was undertaken at a single centre, Blackpool Victoria Hospital, a large acute hospital serving residents of the Fylde Coast health economy. Blackpool Victoria Hospital provides acute orthopaedic services for residents from three boroughs – Blackpool, Fylde and Wyre (NHS, 2020).

Based on the MSK calculator, designed by Arthritis UK (2018), rates of severe osteoarthritis in individuals over the age of 45 requiring treatment across Blackpool,

Fylde and Wyre are approximately 11,018, representing 7% of the population, higher than the national average of 6.1%.

3.6 Ethics

3.6.1 Considerations and Approval

Prior to commencing recruitment of participants ethical approval was sought from the relevant authorities. An application for ethical approval was made using the Integrated Research Application System (IRAS), IRAS project ID 235931. Ethical approval was obtained from the Health Research Authority (HRA) and Yorkshire & Humber – Bradford Leeds Research Ethics Committee (18/YH/0401). Further ethical approval was gained from the Clinical Research Centre, Research and Development department at Blackpool Victoria Hospital and the UCLan ethics committee (STEMH 952). All documents confirming ethical approval are available in Appendix 5. This project was submitted for registration as a clinical trial and at the time of writing is awaiting a trial registration number.

As with current standard Physiotherapy interventions post-TKR, patients were likely to experience some discomfort as they mobilised the affected joint, although this was likely to be the same level of discomfort within both groups. Post-operative mobilisation is vital to ensure the joint is able to return to baseline, or better than-baseline, levels of mobility and function. Patients were offered the standard variety of pain relief options following the procedure which was not affected as a result of their participation in the study, as shown in the patients guide to TKR (Appendix 3). No adverse reactions to the use of the Ortho-Glide device were anticipated, however if any such event occurred participants were encouraged to contact the research team using the contact details provided on the patient information sheet (Appendix 6). Any adverse events were to be recorded and, if deemed to be a potential hazard to other participants, the study would be ceased.

3.6.2 Data Protection and Confidentiality

Participant contact details were held on record for the duration of the trial and for a three-month period following completion, allowing contact with them in case of any adverse results or emerging concerns. Data generated by the study is to be held for a five-year period following completion under the custody of Professor James Richards, the initial lead academic supervisor, at the University of Central Lancashire. If information during the data collection phase became available that was relevant to their continued participation then they were informed by an appropriate means depending on the urgency, and relevant guidance/advice given by the research team.

As employees of the NHS all clinicians involved in this study were bound by the HCPC codes of conduct (HCPC, 2020), as well as local policies governing confidentiality (Blackpool Teaching Hospitals NHS Foundation Trust, 2020). All those involved were reminded of these policies and their duty to uphold them during the pre-trial briefing. The information accessed for recruiting potential participants is routinely required for the pre-op clinic nurses to fulfil their role, no additional information was needed to be accessed. Confidentiality and breaches of data protection are also governed by European Union law, specifically the General Data Protection Regulations (GDPR) brought into force in 2018, and this was expressed to participants in the patient information sheet and consent form (Appendix 6, Appendix 7). All stakeholders in this research, including the participants, were made aware of their duty to maintain patient/participant confidentiality and the consequences for any breaches.

All identifiable participant information, and the results of telephone interview outcome scoring, was initially stored on a Microsoft Word document before being transferred to a Microsoft Excel spreadsheet, all stored on a password protected NHS computer. Participants were at all times anonymised using an encryption key known only to the research team, with no identifiable participant information being included in subsequent reports or publications.

3.7 Participant Recruitment

Participants were recruited from patients already identified as requiring a total-knee replacement at Blackpool Victoria Hospital, a flow chart of the participant journey from recruitment to completion of the study is shown in Figure 3.2. All orthopaedic surgery patients are required to attend a pre-operative assessment clinic with an Advanced Clinical Practitioner (ACP), and it was during this appointment that potential participants were issued with a patient information pack by the ACP (Appendix 6). This included an invitation to participate, information regarding confidentiality, FAQ's, contact information as well as a consent form to be taken away and considered at home (Appendix 7). The pre-operative assessment clinics were attended no longer than 12-weeks prior to the date of surgery.

Following the pre-operative assessment, a home visit is routinely undertaken by the Homeward team as part of normal protocol for all elective orthopaedic surgery patients. During this visit the attending clinician further discussed the study and, if the patient consented to take part, the signed consent forms were collected and returned to Blackpool Victoria Hospital. A copy of this consent was placed in the patient's medical notes and they retained a copy for their own records, a third copy was retained by the research team for record keeping purposes.

No additional safety concerns surrounding these processes were identified by the research team. All home visit/lone-working scenarios which were involved in the study were part of standard protocol for pre-operative care of orthopaedic patients and any safety concerns were already accounted for by the relevant staff.

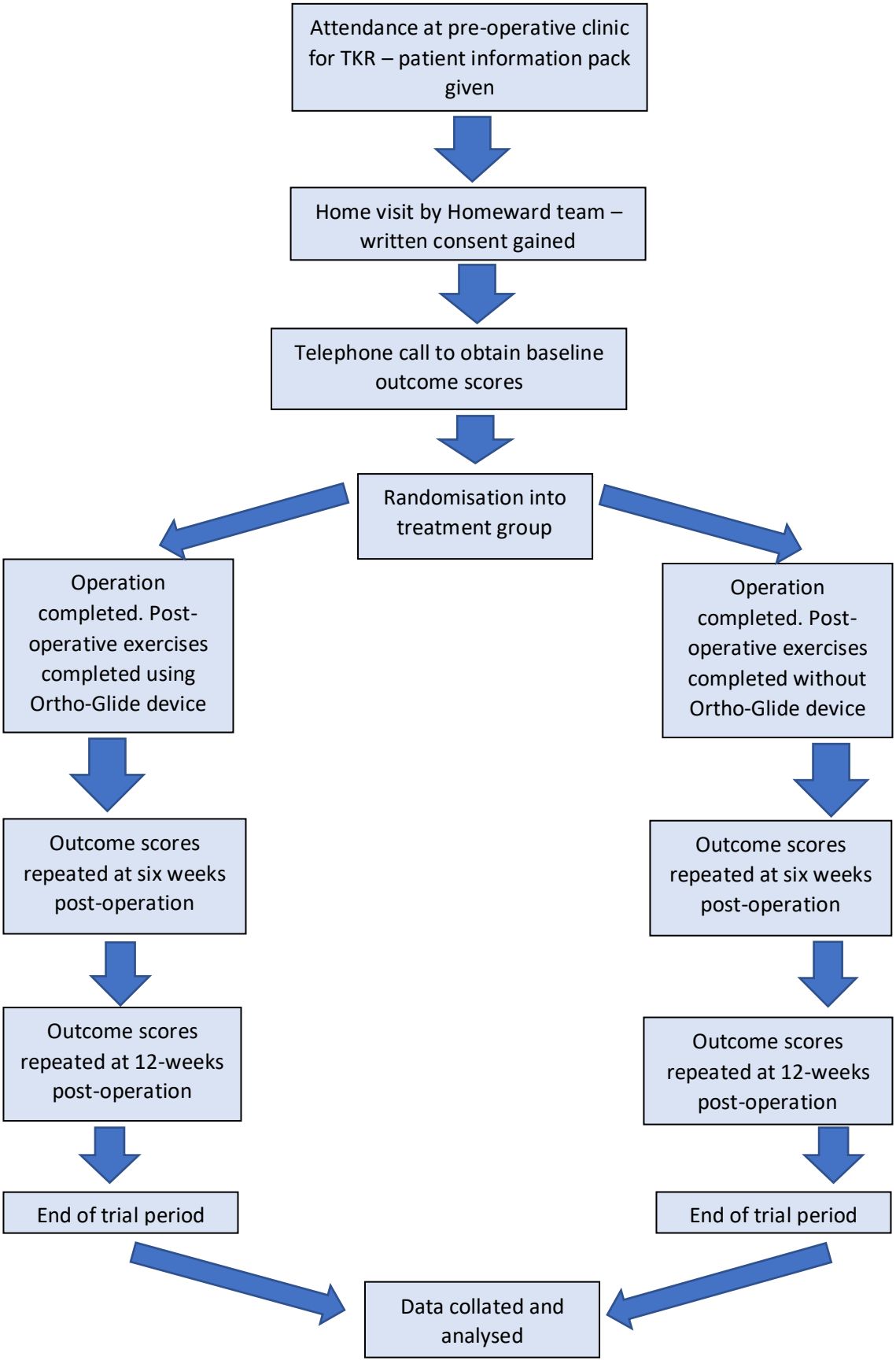


Figure 3.2 Participant recruitment chart.

3.8 Eligibility Criteria

3.8.1 Inclusion criteria

Patients planned to undergo a unilateral total knee replacement at Blackpool Victoria Hospital were aged between 45 to 75 years and independently mobile, with or without a walking aid. The mean age of TKR patients generally falls within this range (Artz et al., 2015) and is the age range of most potential participants attending pre-operative clinics at Blackpool Victoria Hospital. Gathering data from participants within this age range allowed results to be more easily compared to other studies on TKR rehabilitation.

3.8.2 Exclusion criteria

Patient safety, wellbeing and ability to engage in the post-TKR rehabilitation process were the primary factors considered in the selection of exclusion criteria. Therefore, patients were excluded from participation if they had undergone previous lower limb orthopaedic surgery within the last six-months, or if further lower limb orthopaedic surgery was anticipated within the next 12-months. Additional exclusion criteria were the presence of rheumatoid arthritis, any neurological condition affecting lower limb function and any co-morbidity, or cognitive impairment, which would act as a contraindication to engaging with prescribed exercise. Patients participating in other clinical trials which may impact rehabilitation outcomes following TKR were also considered ineligible to participate.

3.9 Outcome Measures

This study used the following patient reported outcome measures to determine the effectiveness of the treatments within and between the groups. A template of the scoring sheet used to record participant responses for each outcome score question is included in Appendix 8.

3.9.1 The Knee Injury and Osteoarthritis Outcome Score

The Knee Injury and Osteoarthritis Score (KOOS) is a quantitative instrument to assess the patient's opinion about their knee and associated problems. It is a patient reported questionnaire which takes approximately 10-minutes to complete. The KOOS may be used in clinical trials to assess a number of areas, specifically pain, stiffness and function (Roos et al., 1998) and is considered a valid, reliable, and responsive outcome measure in total joint replacement (Roos & Toksvig-Larsen, 2003).

The questionnaire itself is broken down into five sub-sections; symptoms & stiffness, pain, activities of daily living (ADL), sports & recreation and quality of life (QoL). Each sub-section contains several questions scored on a 5-point Likert scale, giving a sub-section percentage score from 0% (worst score) to 100% (best score). An aggregate score for the combined sub-sections may also be calculated (Roos et al., 2011). The minimal clinically important change has been estimated as 8% to 10% for the KOOS (Roos & Lohmander, 2003), however it is noted that this range may vary significantly based on the patient group.

In studies of patients with knee injury, Collins et al., (2011) suggested minimally detectable change (MDC) ranges of 6% to 6.1% for KOOS Pain, 5% to 8.5% for KOOS Symptoms, 7% to 8% for KOOS ADL, 5.8% to 12% for KOOS Sport & Recreation, and 7% to 7.2% for KOOS QoL. However, despite its frequent use in literature, Collins et al., (2011) noted that the minimal clinically important difference (MCID) of the KOOS for specific patient populations, such as post-TKR, had yet to be accurately calculated.

Lyman et al., (2018) later conducted work to estimate the minimal detectable change (MDC), the minimal clinically important difference (MCID) and what difference in KOOS score represents a substantial clinical benefit following knee joint replacement. Based on KOOS Scores of 2630 TKR patients Lyman et al., (2018) found a MDC of 15% for pain, 16% for symptoms, 15% for ADL and 14% for QoL were accurate (CI 95%), the Sport and Recreation subscale was excluded from the analysis. Lyman et al., (2018)

also found a MCID was represented by a change of 8% for pain, 9% for symptoms, 9% for ADL and 8% for QoL scores. Finally, it was concluded that patients may feel a substantial clinical benefit with a change in KOOS score of 22% for pain, 21% for symptoms, 15% for ADL and 23% for QoL (Lyman et al., 2018). Unfortunately, Lyman et al., (2018) excluded the Sport and Recreation subscale when analysing MCID's of TKR patients due to differences in post-operative exercise recommendations in the sample. Based on a sample of 2630 TKR patients Lyman et al., (2018) calculated a minimal detectable change of 15% per sub-section (95% confidence interval) as well as a minimally clinically important change of 14.5% per sub-section, whilst a difference of 20.25% indicated a substantial clinical benefit in the post-operative sample. The thresholds used for MCID and SCB for the KOOS outcome score are shown in Table 3.1 below. Despite no telephone interview version being available, the KOOS was selected as the primary outcome measure for this study due to its ease of administration, validity, reliability and frequent use in research allowing comparison of the results generated. Responses to each question were recorded on the outcome score reporting sheet (Appendix 8) and KOOS Scores were then calculated using an online KOOS calculation tool (Orthopaedicscore.com, 2018).

3.9.2 The Exercise Adherence Rating Scale

The Exercise Adherence Rating Scale (EARS) was developed by Newman-Beinart et al., (2017) as the first validated questionnaire to assess adherence to prescribed home-exercise. The EARS is a patient reported questionnaire designed to quantitatively measure the adherence to the prescribed exercises given to patients prior to, and following, the total knee replacement. This test takes approximately five minutes to administer (Newman-Beinart et al., 2017). The EARS consists of six questions scored on a 5-point Likert scale, with positively worded questions reverse scored, giving a final rating from 0 (lowest adherence) to 24 (highest adherence). As a newly designed outcome measure the EARS is yet to be validated specifically for use in telephone

interviews, and unfortunately no literature could be found outlining the minimally clinically important changes using this score.

3.9.3 The Numerical Pain Rating Scale

The Numerical Pain Rating Scale (NPRS) is an 11-point scale which assesses participants pain levels. The scale ranges from 0 indicating no pain, to 10 which indicates severe pain. This measure is quick to administer and has been validated for use in telephone interviews (Von Korff et al., 2000, Williamson & Hoggart, 2005). Pain scores were collected 'at rest' and 'during exercise', with the post-operative scoring being specifically related to the rehabilitation exercises prescribed. A minimally clinically important difference of two points (or 30%) has been estimated by several papers (Childs et al., 2005, Michener et al., 2011), including specifically on osteoarthritis patients (Farrar et al., 2001). The minimal clinically important difference for the NPRS outcome score is shown in Table 3.1 below.

Outcome Score	**MCID**	**SCB**	**Suggested by**
KOOS Aggregate	10	N/A	Roos & Lohmander (2003)
KOOS Symptoms	9%	21%	Lyman et al., (2018)
KOOS Pain	8%	22%	Lyman et al., (2018)
KOOS ADL	9%	15%	Lyman et al., (2018)
KOOS Sport & Recreation	10%	N/A	Roos & Lohmander, (2003)
KOOS QoL	8%	N/A	Lyman et al., (2018)
EARS	N/A	N/A	
NPRS at Rest	2	N/A	Farrar et al., (2001)
NPRS during Exercise	2	N/A	Farrar et al., (2001)

Table 3.1 Minimally Clinically Important Difference and Substantial Clinical Benefit Thresholds for KOOS and NPRS outcome scores.

3.10 Sample Size, Data Collection and Randomisation

3.10.1 Sample Size

Following the literature review it was determined that a total sample of 60 participants split into two groups would be adequate to generate the required data for comparison. The participant numbers utilised in the papers reviewed ranged from 17 (Levine et al., 2009) to 4500 (Malviya et al., 2011), however 34 of the relevant papers recruited between 20 (Sindhu et al., 2013) and 100 (Holm et al., 2010) participants with eight of these studies utilising data from between 51 and 69 participants. It was also felt that given the method of recruitment, academic time constraints and limited human resources to conduct data collection that this would be a realistic participant target.

3.10.2 Data Collection and Randomisation

Once participant consent forms were received by the research team, the individuals were contacted by telephone and baseline measurements were taken using the KOOS, EARS and NPRS outcome measures listed above. Due to the wide geographical area from which patients came to attend surgery it was determined that gathering data in-person, particularly post-operatively, would not be feasible. Scores were taken pre-operatively, at six weeks post-operatively and finally at 12-weeks post-operatively. Outcome scores were collected by telephone call at each time point with verbal consent to partake/continue to partake in the study gained on each occasion.

Participants were then randomised into one of two groups, either to receive standard post-operative Physiotherapy exercises as per current practice or to receive standard Physiotherapy exercises with addition of the Ortho-Glide device. The participants were randomised to the Ortho-Glide or standard Physiotherapy treatment group by an online randomisation tool (Appendix 9) using a block randomisation method - six blocks of 10 patients (Appendix 9). This randomisation method was selected due to the timescales involved - participants recruited early in the trial will have potentially had their procedure before later participants have even attended pre-operative assessment

clinics. Using the block randomisation method meant that for every 10 participants recruited, five were equally allocated into the intervention and control group. This ensured that data was collected for both the Ortho-Glide and Standard Physiotherapy groups at a relatively similar rate, accounting for the contingency that data collection may suddenly be unable to continue for any reason.

Participants were allocated a number based on completing the baseline outcome measures over the telephone, for example the first participant contacted was allocated as participant number 1, the second number 2, and so on. These numbers were then cross referenced with the participant group allocations as provided by the randomisation tool and they were assigned to the relevant group. Participants were not informed which group they had been allocated to and were therefore blinded, however due to the nature of the intervention they were aware of the device they were using to complete post-operative exercises once post-operative Physiotherapy had begun. It was also not possible to blind the Orthopaedic Physiotherapy team as they were responsible for issuing the Ortho-Glide device or standard Physiotherapy-only to participants on the first post-operative contact.

Following the date of surgery participants were scheduled to be contacted after six weeks and again after 12-weeks, with the same outcome measure questions being asked on each telephone interview. If participants were unavailable on the intended contact date, they were telephoned at the next possible opportunity.

3.11 Intervention

At the end of each week during the data collection-phase, the clinical research team identified participants due to undergo surgery the following week and liaised with the Orthopaedic Physiotherapy team to highlight who had been assigned to the Ortho-Glide or Standard Physiotherapy groups. The Physiotherapists and Physiotherapy

Assistants working on the elective orthopaedic ward were briefed on the Ortho-Glide device and its use prior to the study commencing.

Following an elective total knee replacement, it is standard protocol for the Orthopaedic Physiotherapy team to engage with the patient within 24-hours; either in the afternoon on the day of surgery for morning operations, or the following morning for surgeries undertaken in the afternoon. All total knee replacement patients at Blackpool Victoria Hospital are seen under the same protocol referred to as the Enhanced Recovery After Surgery (ERAS) pathway (Appendix 3). As previously discussed, the Orthopaedic Physiotherapy team aimed to see all TKR patients twice daily during their inpatient stay (Appendix 4). During the initial Physiotherapy input patients are issued with exercises designed to accelerate the process of regaining mobility and strength in the operated joint. One such exercise involves the patient lying in a semi-recumbent position and flexing and extending the knee by sliding their foot up and down the bed, this exercise is often referred to as knee-slides. Although the exercises prescribed will progress as the patient advances through their rehabilitation journey, knee-slides remain an exercise encouraged after discharge. A list of the standard exercises prescribed may be seen in Appendix 3.

3.11.1 Standard Physiotherapy Group

Participants randomised into the Standard Physiotherapy group were seen twice daily and issued with Teflon slide boards to facilitate knee-slide exercises during their inpatient hospital stay. On discharge home patients were encouraged to continue completing knee-slide exercises, as well as all other exercises prescribed, although they were not permitted to take the Teflon slide-boards home. The patients TKR guide booklet (Appendix 3) suggests that a wooden board or plastic bag may be used to facilitate these knee-slide exercises and this recommendation is verbally discussed with the patient prior to discharge home.

3.11.2 Ortho-Glide Group

Participants randomised into the intervention group were also seen twice daily but issued with an Ortho-Glide device to complete the knee-slide exercises. As with the Standard Physiotherapy group, they were encouraged to complete the exercises for the exact same sets and repetitions as normally prescribed, the only difference being the device used. For hygiene purposes, patients were allowed to keep the Ortho-Glide on discharge and were encouraged to continue to use it for knee-slide exercises at home.

3.11.3 Physiotherapy Protocol at Blackpool Victoria Hospital

Despite lack of clarity surrounding best-practice for Physiotherapy provision for TKR patients, the current protocol offered by the Orthopaedic team at Blackpool Victoria Hospital was based on best-available evidence. As shown in Appendix 3 and Appendix 4, the Physiotherapy protocol initially involved the provision of basic joint mobilisation and strengthening exercises pre-operatively as part of the ERAS pathway for TKR patients. Post-operatively, patients were seen by a Physiotherapist within 24-hours, mobilised fully weight bearing and given joint mobilisation exercises which are comprehensively outlined in Appendix 3. As part of the ERAS pathway patients were seen at least twice daily following TKR and aimed to achieve a minimum of 80° active ROM in flexion prior to discharge home, as outlined in Appendix 4.

3.12 Statistical Analysis

Descriptive statistics including the means and standard deviations of the two groups for; age, KOOS, EARS and NPRS for the three time points, pre-surgery, six weeks and 12-weeks post-surgery, were reported. Shapiro-Wilks tests of normality were performed, and all data were found suitable for parametric statistical testing. A 2 x 3 mixed methods ANOVA was performed to explore the differences between the two groups over the three time points. Further Least Significant Difference Pairwise

comparisons were performed to explore the differences between time points. If an interaction was seen between groups and time points, each group was explored separately using Repeated Measures ANOVA tests. Based on the literature reviewed in Chapter 2, it was considered likely that participants would report significant, but unpredictable, improvements in outcome measure scores between pre-operative baseline and post-TKR time points. To avoid inaccurate representation of these improvements in the data, no attempt was made to predict missing outcome scores based on those reported at previous time points, such as the use of a last-observation-carried-forward technique. Therefore, any missing data from participants lost to follow-up, or who did not undergo the TKR procedure, was disregarded from the data analysis. All analyses were performed in SPSS v26, with the significance level set at $p=0.05$.

4 CHAPTER 4: RESULTS

4.1 Recruitment

Prior to commencing recruitment, a target of 60 participants was set. Recruitment commenced in January 2019, although during this period Blackpool Victoria Hospital was experiencing an increase in medical admissions leading to greater pressure for hospital beds. As a result, the elective orthopaedic ward was reduced to 50% capacity, and elective procedures, including TKR's, were limited. This period, known as winter pressures, was in place until April 2019 when available orthopaedic bed spaces and elective procedures performed increased back to normal levels. Due to the limited number of TKR's being performed during the initial recruitment period, and the length of the follow-up period, a total of 31 participants were recruited to this study. Pre-operative data was collected for all 31 participants recruited. Following the block randomisation allocation 15 participants were allocated to the Ortho-Glide group and 16 to the Standard Physiotherapy group. Of those allocated to the Ortho-Glide group, two did not receive the TKR due to medical reasons and a further two were unavailable for data collection at the six week follow up. Of those allocated to the Standard Physiotherapy group three did not receive the TKR due to medical reasons, two were unavailable for data collection at the six week follow up and an additional participant was excluded due to repeated non-adherence to post-operative Physiotherapy and medical input. No further participants were lost during the study although the two participants allocated to the Ortho-Glide group who were unavailable for data collection at the six week point did re-engage with the study and were available for data collection at 12-weeks post-operation. Of the 31 recruited, a total of 23 participants provided follow-up data at the 12-week point, 13 participants allocated to the Ortho-Glide group and 10 allocated to the Standard Physiotherapy group, as shown in Figure 4.1.

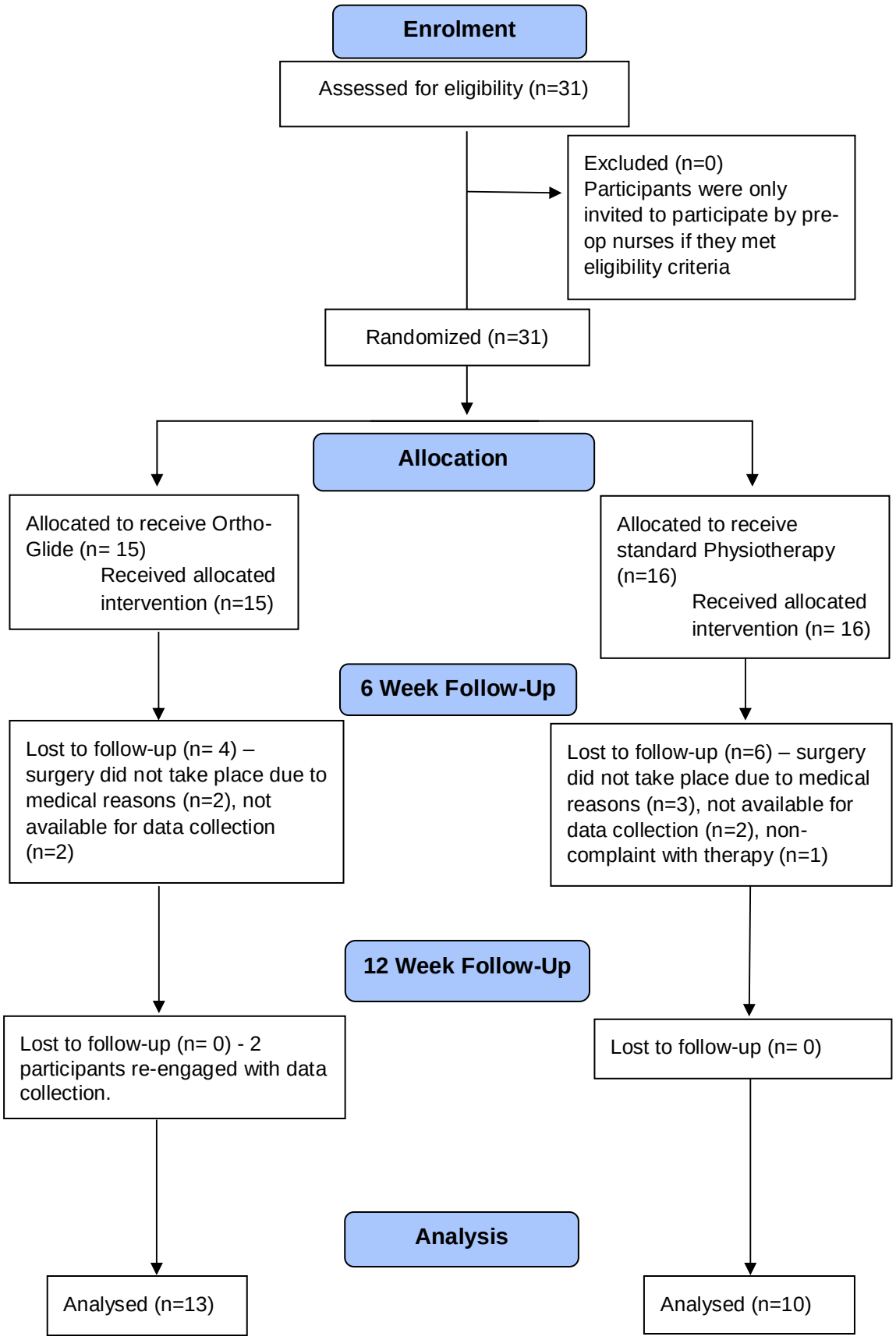


Figure 4.1 Consort diagram showing participant flow through the study.

4.2 Participant Characteristics

As planned, nursing staff involved in the pre-operative clinics used the inclusion and exclusion criteria to screen patients, only inviting those that met these criteria, meaning none had to be excluded at this stage. The mean age of the sample at collection of baseline data was 65.23 years old (SD 5.33). The sample of 31 consisted of 11 males (35.48%) and 20 females (64.52%). Upon randomisation to the Ortho-Glide (n=15) or Standard Physiotherapy (n=16) groups the participant characteristics and pre-operative outcome measure scores are detailed in Table 4.1. At the second data collection point, six weeks post-TKR, four participants from the Ortho-Glide group and six from the Standard Physiotherapy group had been lost to follow up for reasons discussed in section 4.1. The mean age of the 21 remaining participants was 64.69 years old, the characteristics of those remaining in each group are detailed in Table 4.1. At the final data collection point, 12-weeks post-TKR, two participants from the Ortho-Glide group had re-engaged with the trial whilst the number of participants in the Standard Physiotherapy group remained the same. Therefore, final data was collected from 13 and 10 participants respectively. The mean age from the combined study groups at this stage was 64.76 with further characteristics of each group again detailed in Table 4.1.

	Baseline		Six weeks post-TKR		12-weeks post-TKR	
	Ortho-Glide (n=15)	**Standard Physiotherapy (n=16)**	**Ortho-Glide (n=15)**	**Standard Physiotherapy (n=16)**	**Ortho-Glide (n=11)**	**Standard Physiotherapy (n=10)**
Mean Age (SD)	65.27 (4.73)	63.25 (5.66)	65.27 (4.73)	63.25 (5.66)	64.18 (5.22)	65.2 (5.06)
Age Range	60-72yrs	53-75yrs	60-72yrs	53-75yrs	60-72yrs	59-75yrs
Male n (%)	6 (40%)	5 (31.25%)	6 (40%)	5 (31.25%)	3 (27.27%)	3 (30%)
Female n (%)	9 (60%)	11 (68.75%)	9 (60%)	11 (68.75%)	8 (72.73%)	7 (70%)
Mean KOOS Aggregate (SD)	40.04 (11.80)	36.34 (18.46)	40.04 (11.80)	36.34 (18.46)	64.45 (18.60)	58.76 (21.99)
Mean KOOS Symptoms (SD)	42.62 (16.78)	41.07 (19.95)	42.62 (16.78)	41.07 (19.95)	63.96 (15.27)	67.50 (15.10)
Mean KOOS Pain (SD)	43.59 (15.96)	41.15 (22.55)	43.59 (15.96)	41.15 (22.55)	69.44 (19.12)	69.72 (26.11)
Mean KOOS ADL(SD)	49.51 (14.27)	44.48 (21.78)	49.51 (14.27)	44.48 (21.78)	74.33 (22.39)	64.41 (27.09)
Mean KOOS Sport & Recreation (SD)	10.00 (9.06)	8.44 (13.87)	10.00 (9.06)	8.44 (13.87)	28.64 (21.34)	18.50 (21.35)
Mean KOOS Quality of Life (SD)	22.08 (15.28)	15.23 (16.13)	22.08 (15.28)	15.23 (16.13)	55.11 (23.35)	45.00 (22.59)
Mean EARS (SD)	17.73 (4.99)	17.94 (4.68)	17.73 (4.99)	17.94 (4.68)	20.18 (4.05)	18.30 (5.25)
Mean NPRS at Rest (SD)	3.87 (2.36)	4.56 (2.50)	3.87 (2.36)	4.56 (2.50)	1.82 (2.48)	1.70 (1.70)
Mean NPRS during Exercise (SD)	6.33 (2.19)	6.88 (1.89)	6.33 (2.19)	6.88 (1.89)	4.45 (2.46)	4.30 (2.91)

Table 4.1 Participant Characteristics for Ortho-Glide and Standard Physiotherapy Group at Baseline, six weeks and 12-weeks post-TKR.

4.3 Data Analysis

All available data was inputted to SPSS and mean scores calculated for each outcome measure for the baseline, six week and 12-week post-operative points. Mixed model analyses were performed using SPSS for each outcome measure across the three time points to determine if any differences were present between the Ortho-Glide and the Standard Physiotherapy groups. Missing data was treated as missing due to the likelihood of significant but unpredictable improvements being made during the recovery period, as shown in multiple previous studies reviewed in Chapter 2. Data were analysed for any statistically significant differences between groups as well as the presence of minimally clinically important differences (MCID) or differences implying a significant clinical benefit (SCB). A table summarising mean outcome scores and significance of differences between mean outcome scores between groups at each time point can be found in Appendix 9.

4.3.1 Analysis of Primary Outcome Measure (KOOS Aggregate) Scores

Mean KOOS Aggregate scores for the two groups for pre-operative baseline, six week follow up and 12-week follow up are shown in Figure 4.2. The Standard Physiotherapy group had a slightly lower mean KOOS Aggregate at baseline (36.34) compared to the Ortho-Glide group (40.04), although this was not found to be significant ($p=0.136$). The estimated marginal means showed the Ortho-Glide group to have a greater mean difference of 59.89 compared to 55.79 of the Standard Physiotherapy group (Appendix 10). Both groups surpassed the MCID of 8-10 (Roos & Lohmander, 2003) from baseline to six weeks and baseline to 12-weeks, as well as between six weeks and 12-weeks post-TKR. At 12-weeks post-op the Ortho-Glide group had the higher mean KOOS Aggregate score (75.19) compared to the Standard Physiotherapy group (72.28) although no significant difference was noted between groups ($p>0.05$).

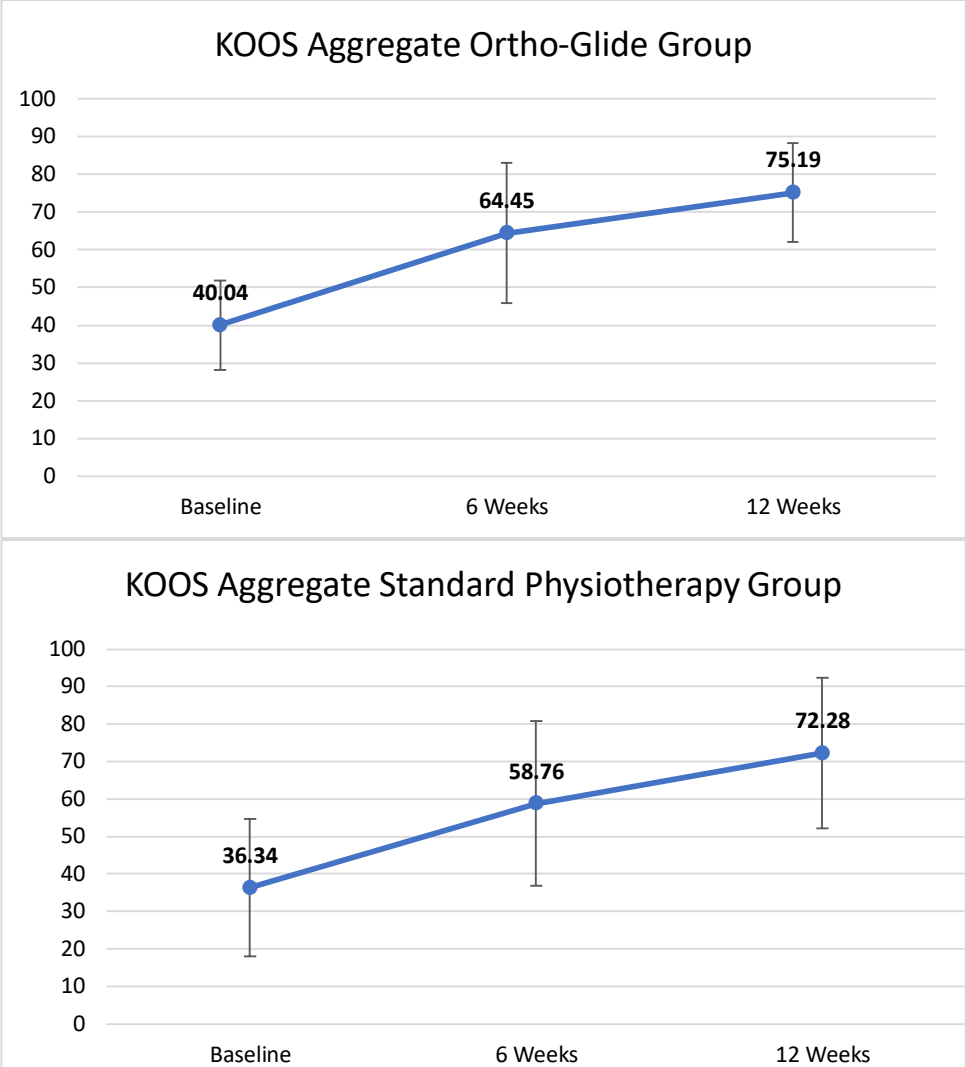


Figure 4.2 Mean KOOS Aggregate Scores for both groups at baseline, six week and 12-week follow up, including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.963$). No significant difference was found between treatment groups ($p=0.315$), as shown in Table 4.2, however a significant difference between time intervals was shown ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks ($p<0.001$), baseline and 12-weeks ($p<0.001$) and six week to 12-week time points ($p<0.05$), as shown in Table 4.2. The mean difference of 4.2 between groups did not meet the MCID of 8 as outlined by Roos & Lohmander (2003).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean KOOS Aggregate Score	4.10	4.05	0.32	-3.98	-12.98
Baseline vs. 6 Weeks	-23.41	5.24	<0.001	-33.14	-13.68
Baseline vs. 12 Weeks	-35.55	4.77	<0.001	-45.06	-26.03
6 Weeks vs. 12 Weeks	-12.13	5.23	<0.05	-22.57	-1.70

Table 4.2 Pairwise comparison of mean KOOS Aggregate scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2 Analysis of Secondary Outcome Measures

Although the KOOS Aggregate score is viable for use as a primary outcome measure in RCT's, it is also suggested to analyse each subscale separately (Roos et al., 2011). As with the aggregate KOOS Aggregate score, results of the data analysis for the separate KOOS subscales, EARS as well as NPRS at Rest and NPRS during Exercise scores are detailed in the following subsections. These results, and differences between groups, are summarised in Appendix 10.1 - 10.4.

4.3.2.1 Analysis of KOOS Symptoms Scores

Mean scores for the symptoms subscale of the KOOS for pre-operative baseline, six week follow up and 12-week follow up are shown in Figure 4.3. The Standard Physiotherapy group had a slightly lower mean KOOS Symptoms score at baseline (41.07) compared to the Ortho-Glide group (42.62), although this was not found to be significant ($p>0.05$). The estimated marginal means showed the Standard Physiotherapy group to have a greater mean difference of 62.38 compared to 61.08 in the Ortho-Glide group (Appendix 11). Both groups exceeded a change of 21, indicating a substantial clinical benefit from baseline to six weeks, and a further MCID of over 9 was also seen for both groups between the six and 12-week follow ups (Lyman et al.,

2018). At 12-weeks post-op the Standard Physiotherapy group had the higher mean KOOS Symptoms score (78.57) compared to the Ortho-Glide group (76.65).

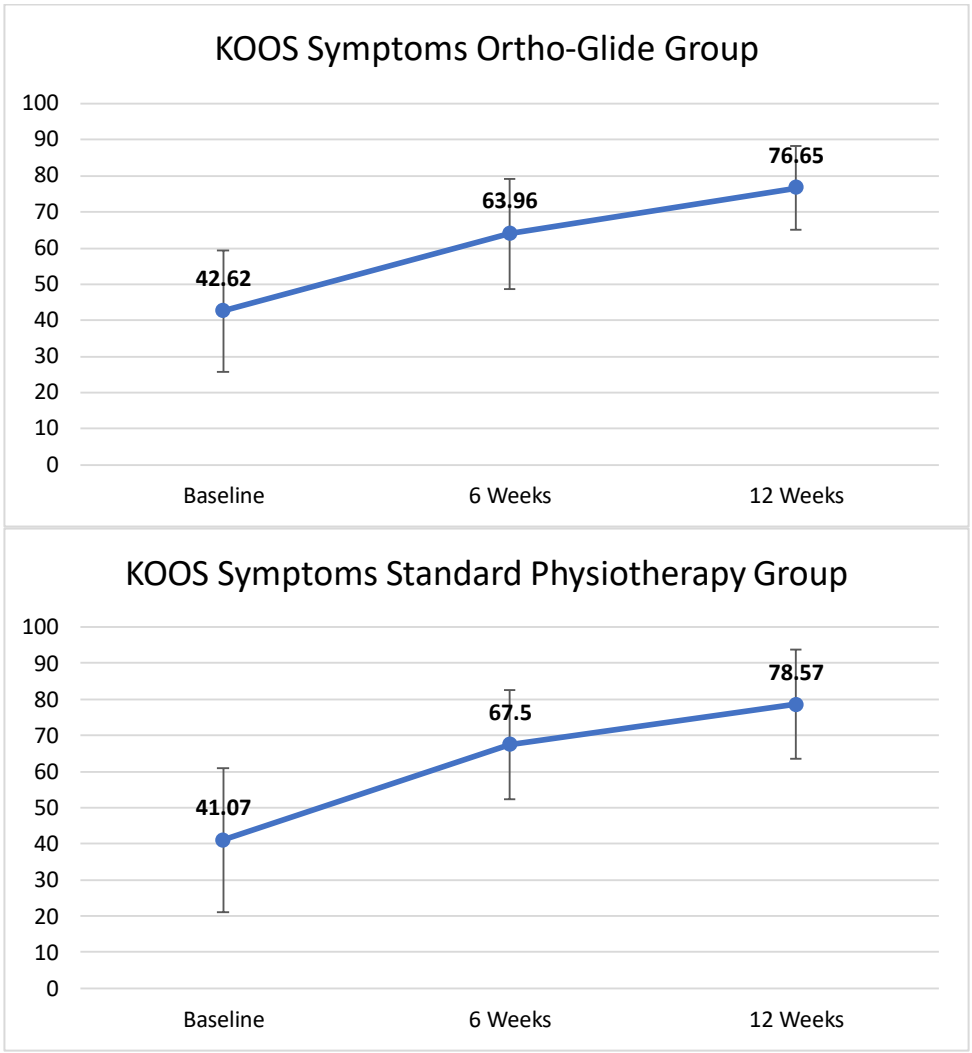


Figure 4.3 Mean KOOS Symptom scores for baseline, six week and 12-week post-TKR including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.844$). No significant difference was found between treatment groups ($p=0.732$), as shown in Table 4.3, however a significant difference between time intervals was shown ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks ($p<0.001$), baseline and 12-weeks ($p<0.001$) and six week to 12-week time points ($p<0.05$), as shown in

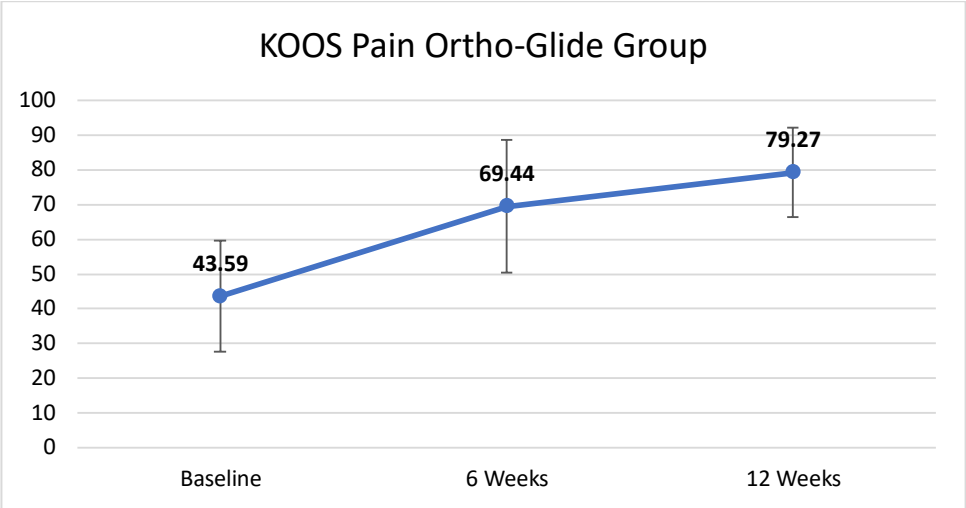
Table 4.3. The mean difference between groups of 1.305 did not meet the MCID of 8-9 (Roos & Lohmander, 2003, Lyman et al., 2018).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide group vs. Standard Physiotherapy group mean KOOS Symptoms score	-1.31	3.79	0.73	-8.87	6.26
Baseline vs. 6 Weeks	-23.89	4.56	<0.001	-32.99	-14.78
Baseline vs. 12 Weeks	-35.77	4.46	<0.001	-44.67	-26.86
6 Weeks vs. 12 Weeks	-11.88	4.89	0.02	-21.64	-2.12

Table 4.3 Pairwise comparison of mean KOOS Symptoms scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.2 Analysis of KOOS Pain Scores

Mean scores for the KOOS Pain subscale at baseline, six week and 12-week time points are detailed in Figure 4.4. The Standard Physiotherapy group showed a slightly lower baseline mean KOOS Score (41.15) compared to the Ortho-Glide group (43.59), although this was not found to be significant (p=0.445). The estimated marginal means showed the Ortho-Glide group to have a greater mean difference of 64.10 compared to 63.64 in the Standard Physiotherapy group (Appendix 11). Both groups exceeded a change of 22, indicating a substantial clinical benefit from baseline to six weeks, and a further MCID of over 8 was also seen for both groups between the six week and 12-week follow ups (Lyman et al., 2018). At 12-weeks post-op the Standard Physiotherapy group had the higher mean KOOS Symptoms score (80.04) compared to the Ortho-Glide group (79.27).



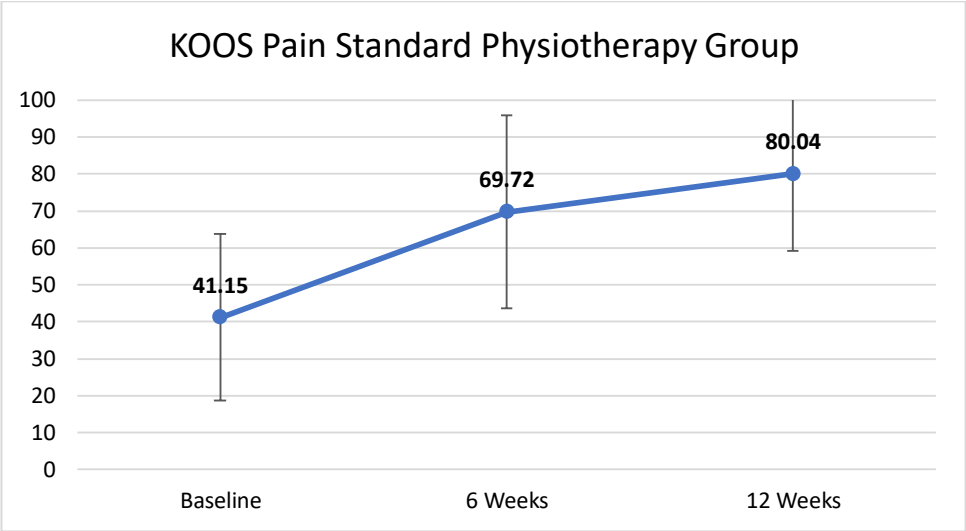


Figure 4.4 Mean KOOS Pain scores for baseline, six week and 12-week post-TKR including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.949$). No significant difference was found between treatment groups ($p=0.920$), as shown in Table 4.4, however a significant difference between time intervals was shown ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks ($p<0.001$) and baseline to 12-weeks ($p<0.001$). The difference from six weeks to 12-weeks was not found to be statistically significant ($p=0.097$). The results of these pairwise comparisons can be seen in Table 4.4. The mean difference between groups of 0.465 did not meet the MCID of 8-9 (Roos & Lohmander, 2003, Lyman et al., 2018).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean KOOS Pain score	0.47	4.64	0.92	-8.79	9.71
Baseline vs. 6 Weeks	-27.22	5.58	<0.001	-38.35	-16.08
Baseline vs. 12 Weeks	-37.29	5.46	<0.001	-48.18	-26.40
6 Weeks vs. 12 Weeks	-10.07	5.98	0.01	-22.01	1.86

Table 4.4 Pairwise comparison of mean KOOS Pain scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.3 Analysis of KOOS Activities of Daily Living Scores

Mean scores for the KOOS Activities of Daily Living (ADL) subscale at baseline, six week and 12-week time points are detailed in Figure 4.5. The Standard Physiotherapy group had a lower mean KOOS ADL scores at baseline (44.48) compared to the Ortho-Glide group (49.51) although this was not significant (p=0.104). The estimated marginal means showed the Ortho-Glide group to have a mean of 70.01, compared to 62.89 of the Standard Physiotherapy group (Appendix 11).

Mean KOOS ADL scores for both groups exceeded a change of 15, indicating a substantial clinical benefit from baseline to six weeks (Lyman et al., 2018), and the Standard Physiotherapy group showed a further difference of >15 between the six and 12-week time points. A MCID of >9 was noted for the Ortho-Glide group between six and 12-weeks post-op finishing on a higher mean KOOS ADL score (86.2) compared to the Standard Physiotherapy group (79.77). As seen in Figure 4.5, at the six week time point the mean score for the Ortho-Glide group was 74.33, a difference of >9 compared to the Standard Physiotherapy group score of 64.41, again indicating a potential clinically important difference (Lyman et al., 2018).

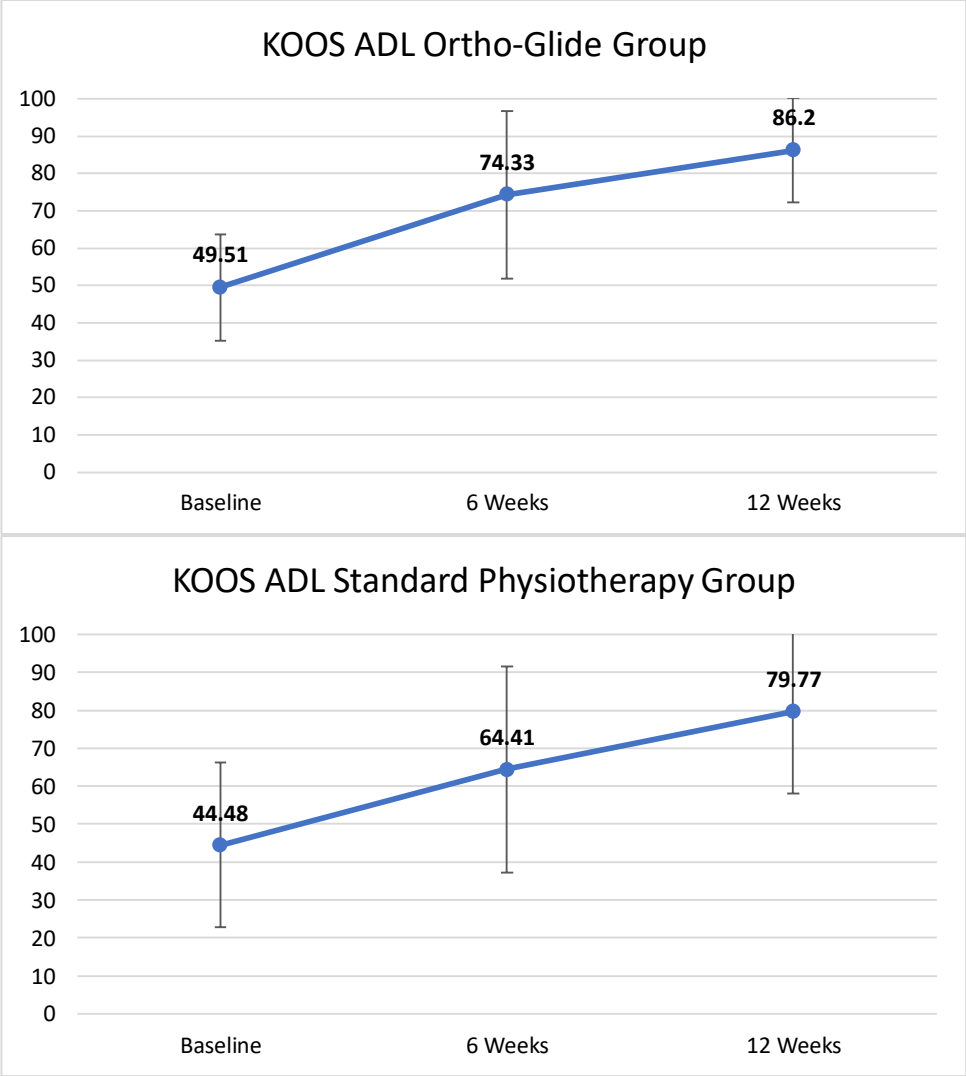


Figure 4.5 Mean KOOS ADL scores for baseline, six week and 12-week post-TKR including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.911$). No significant difference was found between treatment groups ($p=0.138$), as shown in Table 4.5, however a significant difference between time intervals was shown ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks ($p<0.001$), baseline and 12-weeks ($p<0.001$) and for six weeks to 12-weeks ($p<0.05$). The results of this

can be seen in Table 4.5. The mean difference between groups of 7.124 did not meet the MCID of 8-9 (Roos & Lohmander, 2003, Lyman et al., 2018), despite being close.

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean KOOS ADL score	7.12	4.75	0.14	-2.35	16.59
Baseline vs. 6 Weeks	-22.38	5.71	<0.001	-33.77	-10.98
Baseline vs. 12 Weeks	-35.99	5.59	<0.001	-47.13	-24.84
6 Weeks vs. 12 Weeks	-13.61	6.12	0.03	-25.83	-1.40

Table 4.5 Pairwise comparison of mean KOOS ADL scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.4 Analysis of KOOS Sport and Recreation Scores

Mean scores for the KOOS Sport and Recreation subscale at baseline, six week and 12-week time points are detailed in Figure 4.6. The Standard Physiotherapy group had slightly lower mean KOOS Sport and Recreation scores at baseline (8.44) compared to the Ortho-Glide group (10) although this difference was not shown to be significant (p=0.251). The estimated marginal means showed the Ortho-Glide group to have a greater mean difference of 25.83 compared to 21.82 of the Standard Physiotherapy group (Appendix 11).

Changes in mean KOOS Sport and Recreation scores for both groups exceeded the MCID of 8 (Roos & Lohmanded, 2003) at both the six week and 12-week time points. At 6 weeks post-op the mean score for the Ortho-Glide group was 28.64, compared to 18.5 for the Standard Physiotherapy group, a difference of >8 indicating a possible clinically important difference (Roos & Lohmander, 2003). At 12-weeks post-op the Ortho-Glide group finished with a slightly higher mean score (38.85) compared to the Standard Physiotherapy group (38.54).

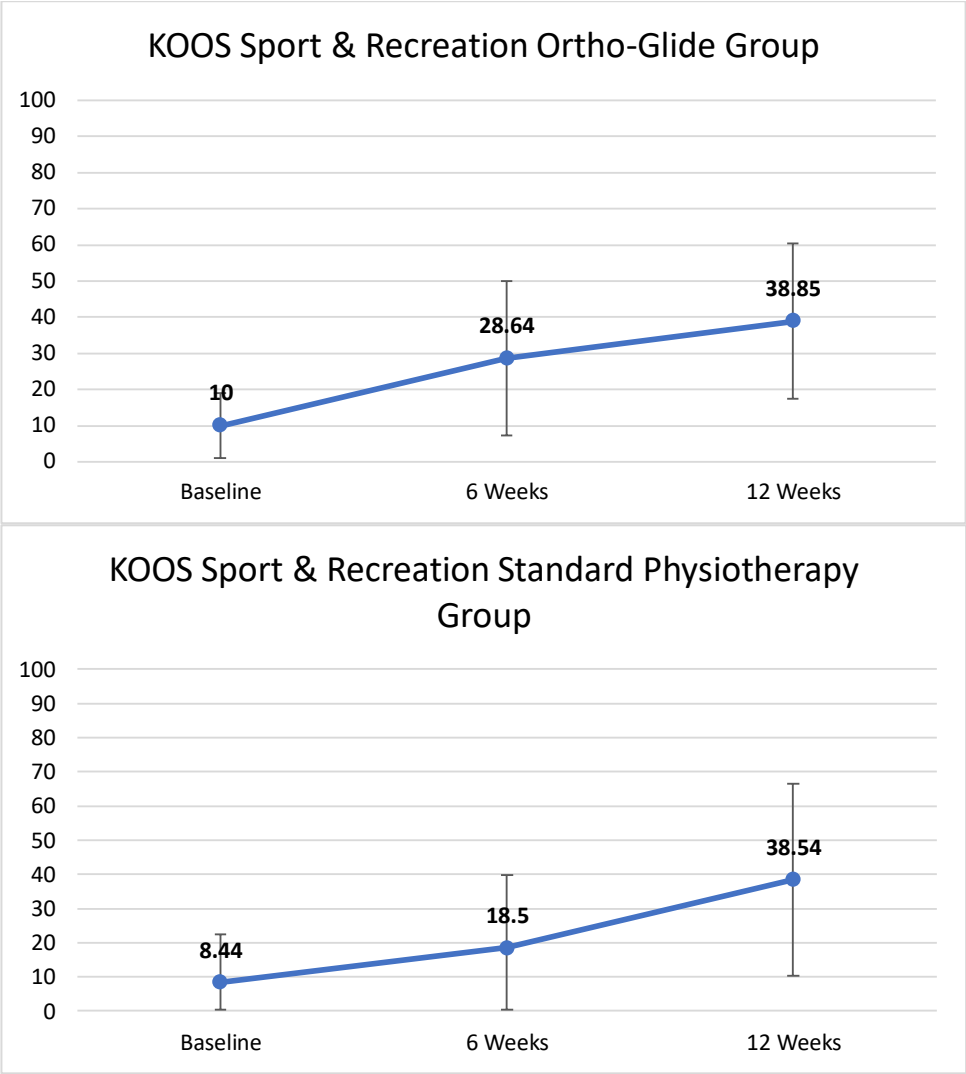


Figure 4.6 Mean KOOS Sport and Recreation scores for baseline, six week and 12-week post-TKR including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.651$). No significant difference was found between treatment groups ($p=0.377$), as shown in Table 4.6, however a significant difference between time intervals was shown ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks ($p<0.05$), baseline and 12-weeks ($p<0.001$) and for six weeks to 12-weeks ($p<0.05$), the results of which can be seen in Table 4.6. The mean difference of 4.003 did not meet the MCID of 8 as outlined by Roos and Lohmander (2003).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy mean KOOS Sport & Recreation score	4.00	4.51	0.38	-4.98	12.99
Baseline vs. 6 Weeks	-14.45	5.42	0.01	-25.17	-3.53
Baseline vs. 12 Weeks	-29.47	5.30	<0.001	-40.05	-18.89
6 Weeks vs. 12 Weeks	-15.12	5.81	0.01	-26.72	-3.52

Table 4.6 Pairwise comparison of mean KOOS Sport & Recreation scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.5 Analysis of KOOS Quality of Life

Mean scores for the KOOS Quality of Life (QoL) subscale at baseline, six week and 12-week time points are detailed in Figure 4.7. The Standard Physiotherapy group had a lower mean KOOS QoL score at baseline (15.23) compared to the Ortho-Glide group (22.08) although this was not significant (p=0.790). The estimated marginal means showed the Ortho-Glide group to have a greater mean difference of 46.41 compared to 37.79 of the Standard Physiotherapy group (Appendix 11).

Changes in mean KOOS QoL scores for both groups exceeded 23, indicating a substantial clinical benefit between the pre-op and six week post-op scores (Lyman et al., 2018). Between the six and 12-week time points both groups demonstrated a change in mean KOOS QoL scores of >8, indicating a clinically important difference. At six weeks post-op the mean score for the Ortho-Glide group was 55.11, compared to 45 for the Standard Physiotherapy group, a difference of >8 indicating a possible clinically important difference between the groups (Lyman et al., 2018). At 12-weeks post-op the Ortho-Glide group finished with a higher mean score (62.02) compared to the Standard Physiotherapy group (53.13), again a difference of >8 signifying a potential clinically important difference (Lyman et al., 2018).

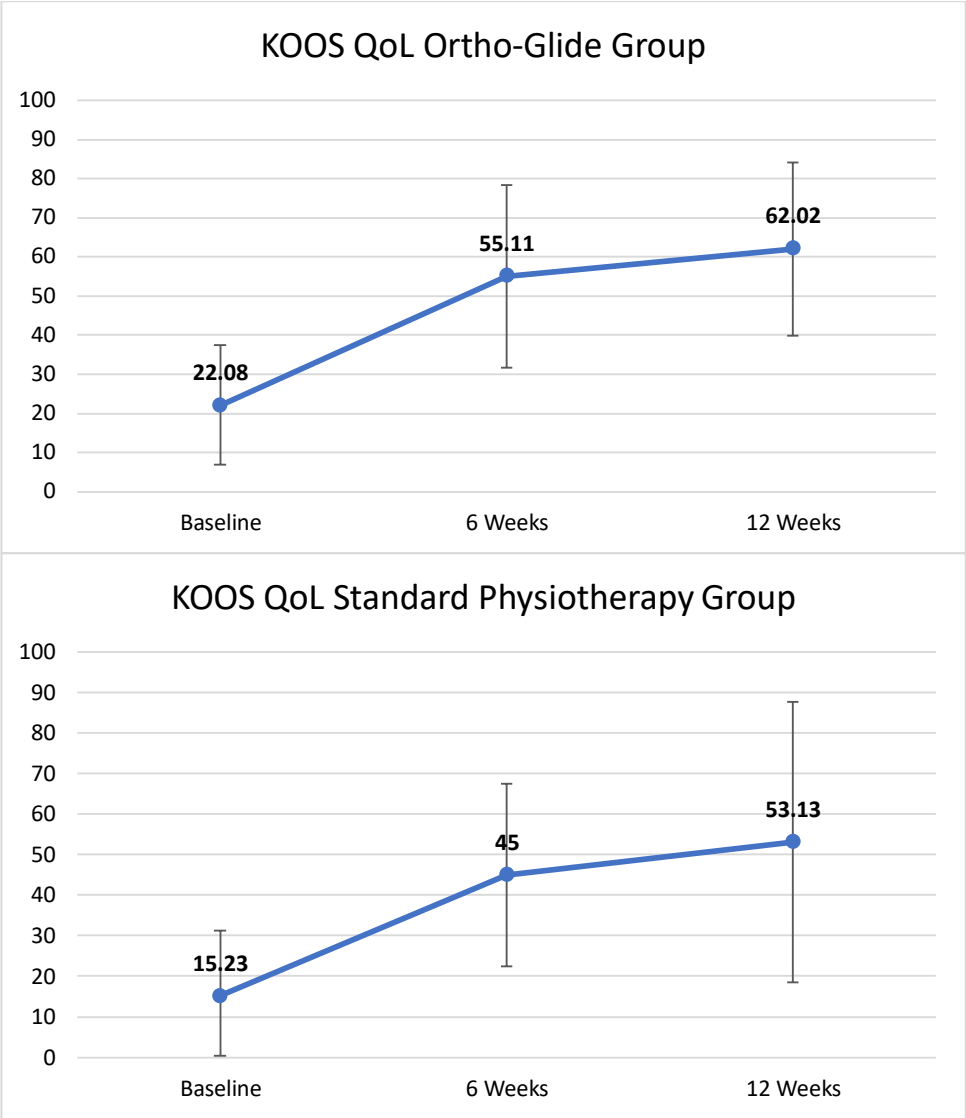


Figure 4.7 Mean KOOS QoL scores for baseline, six week and 12-week post-TKR including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time (p=0.965). No significant difference was found between treatment groups (p=0.103), as shown in Table 4.7, however a significant difference between time intervals was shown (p<0.001). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks (p<0.001) and baseline and 12-weeks (p<0.001). No significant difference was noted for the six week to 12-week time point (p=0.268). The results of ths pairwise comparison can be seen in Table 4.7. The mean difference of 8.619 exceeded the MDC of 8 suggested by Roos

and Lohmander (2003) and the MDC of 7-7.2 suggested by Collins et al., (2011) as well as exceeding the MCID of 8 suggested by Lyman et al., (2018) suggesting a clinically significant difference.

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean KOOS QoL score	8.62	5.21	0.10	-1.78	19.01
Baseline vs. 6 Weeks	-31.40	6.27	<0.001	-43.91	-18.89
Baseline vs. 12 Weeks	-38.91	6.13	<0.001	-51.15	-26.68
6 Weeks vs. 12 Weeks	-7.52	6.72	0.27	-20.93	5.90

Table 4.7 Pairwise comparison of mean KOOS QoL scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups

4.3.2.6 Analysis of Exercise Adherence Rating Scale Scores

Mean scores for the Exercise Adherence Rating Scale (EARS) outcome measure at baseline, six week and 12-week time points are detailed in Figure 4.8. The Ortho-Glide group had a slightly lower mean EARS Score at baseline (17.73) compared to the Standard Physiotherapy group (17.94) although this was not significant (p=0.812). The estimated marginal means showed the Standard Physiotherapy group to have a greater mean difference of 20.48 compared to 19.23 in the Ortho-Glide group, (Appendix 11).

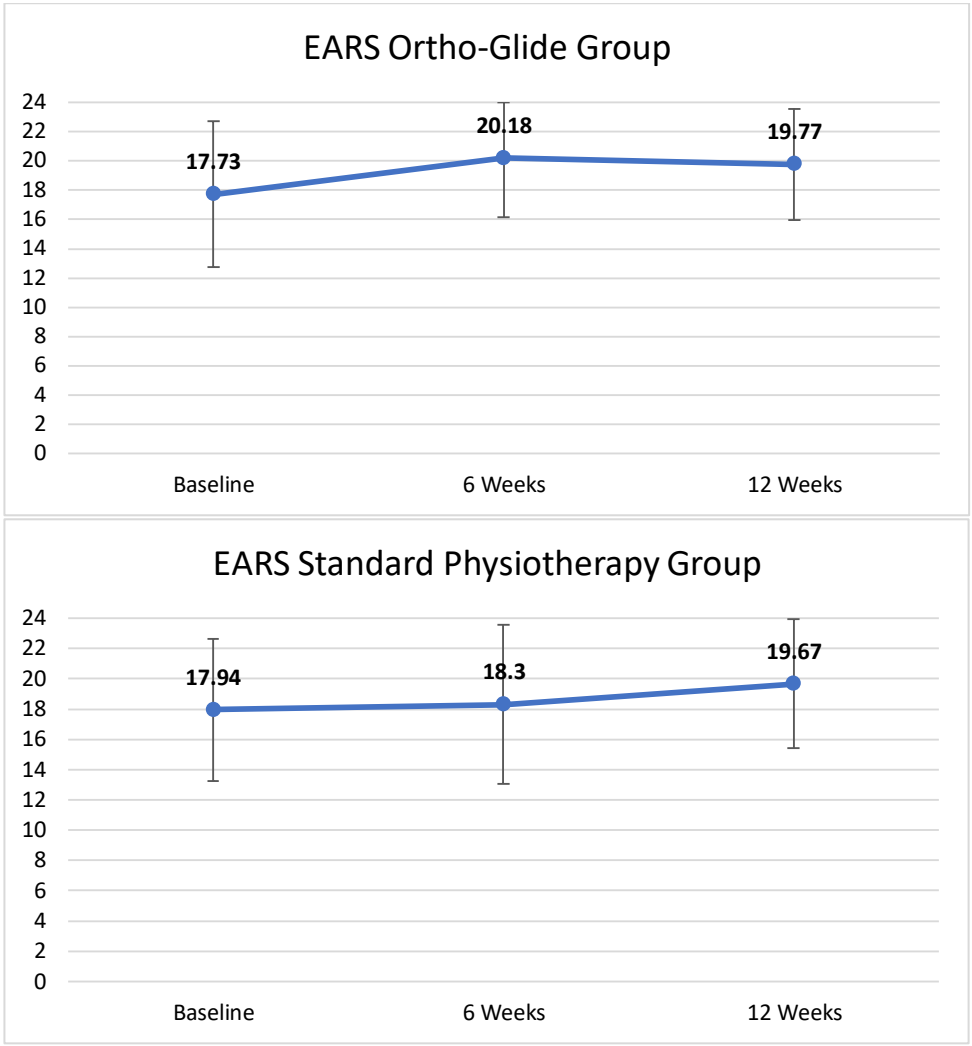


Figure 4.8 Mean EARS scores for baseline, six week and 12-week post TKR, including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.277$). No significant difference was found between treatment groups ($p=0.496$), as shown in Table 4.8, and no significant difference was found between time intervals ($p=0.101$). Further pairwise comparisons between time points showed no significant difference between baseline and six weeks ($p=0.526$), although baseline and 12-weeks did show a significant difference ($p<0.05$). No significant difference was noted between six and 12-weeks ($p=0.174$). The results of ths pairwise comparison can be seen in Table 4.8. Unfortunately, at the time of writing no MCID information was available for the EARS.

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy mean EARS score	0.949	1.501	0.528	-2.009	3.907
Baseline vs. 6 Weeks	-1.405	1.822	0.441	-4.994	2.183
Baseline vs. 12 Weeks	-1.349	1.800	0.454	-4.895	2.197
6 Weeks vs. 12 Weeks	0.056	1.893	0.976	-3.675	3.788

Table 4.8 Pairwise comparison of mean EARS scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.7 Analysis of Numerical Pain Rating Scale at Rest Scores

Mean scores for the Numerical Pain Rating Scale (NPRS) at rest for baseline, six week and 12-week time-points are detailed in Figure 4.9. The Ortho-Glide group had a slightly lower mean NPRS at Rest score at baseline (3.87) compared to the Standard Physiotherapy group (4.56), a difference shown to be insignificant (p=0.828). The estimated marginal means showed the Standard Physiotherapy group to have a greater mean difference of 2.32 compared to 2.28 in the Ortho-Glide group (Appendix 11).The mean NPRS scores for both groups demonstrated a change of >2, indicating a MCID (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011), between baseline and six weeks post-op. The difference in mean NPRS scores between six and 12-weeks post-op were below the MCID of 2 for each group with the Standard Physiotherapy group finishing on a slightly lower mean NPRS score (0.7) compared to the Ortho-Glide group (1.15).

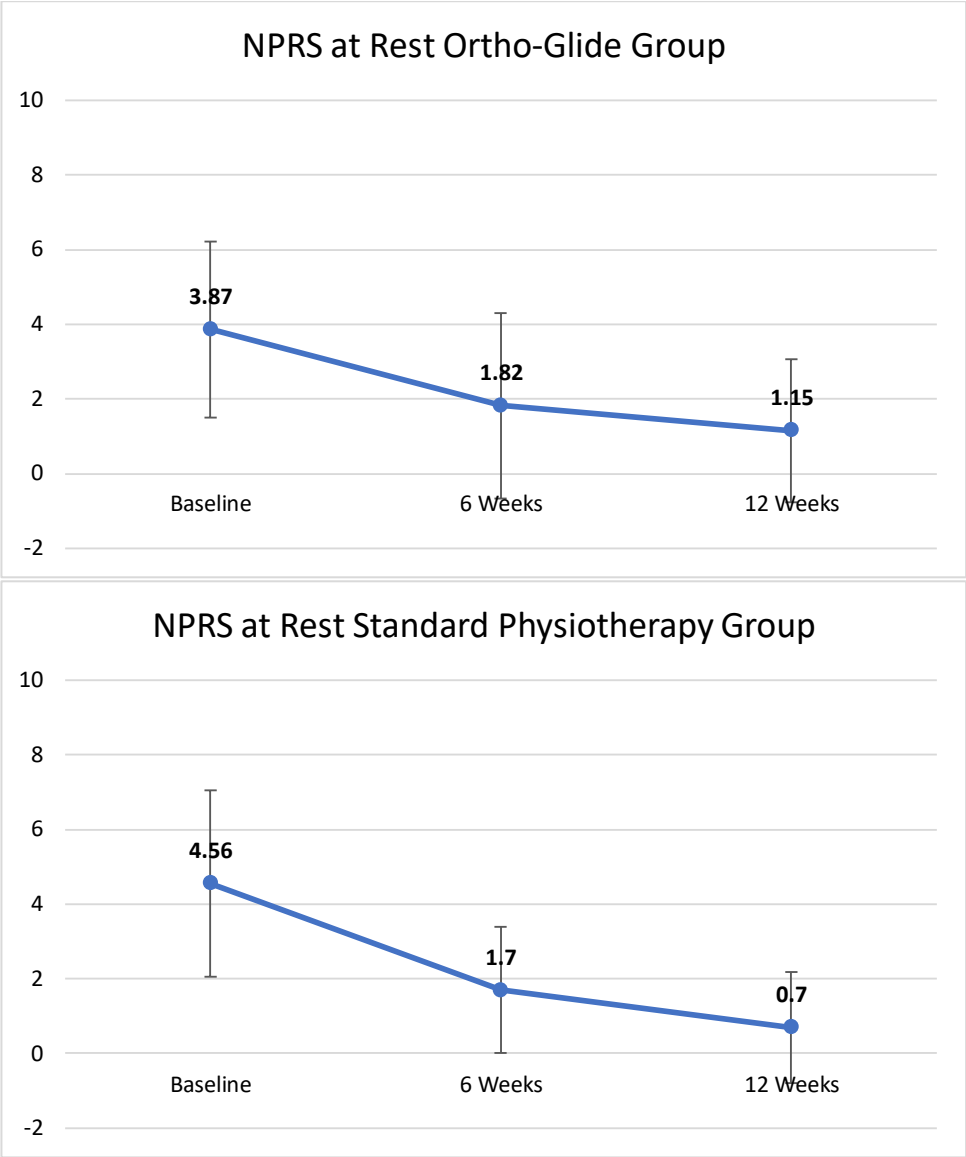


Figure 4.9 Mean NPRS at Rest scores for baseline, six week and 12-week post-TKR, including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.606$). No significant difference was found between treatment groups ($p=0.936$), as shown in Table 4.9, although a significant difference was found between time intervals ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks scores ($p<0.001$) and baseline and 12-weeks scores ($p<0.001$). No significant difference was found between the six weeks and 12-weeks scores ($p=0.209$). The results of this pairwise comparison can be

seen in Table 4.9. The mean difference of 0.041 between groups did not meet the MCID of 2 suggested in the literature (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean NPRS at Rest score	-0.04	0.51	0.94	-1.06	0.97
Baseline vs. 6 Weeks	2.46	0.61	<0.001	1.23	3.68
Baseline vs. 12 Weeks	3.29	0.6	<0.001	2.09	4.48
6 Weeks vs. 12 Weeks	0.83	0.66	0.21	-0.48	-2.09

Table 4.9 Pairwise comparison of mean NPRS at Rest scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.3.2.8 Analysis of Numerical Pain Rating Scale during Exercise Scores

Mean scores for the Numerical Pain Rating Scale (NPRS) during exercise for baseline, six week and 12-week time-points are detailed in Figure 4.10. The Ortho-Glide group showed slightly lower mean NPRS during exercise scores at baseline (6.33) compared to the Standard Physiotherapy group (6.88), although this was not shown to be significant (p=0.798). The estimated marginal means showed the Ortho-Glide group to have a greater mean difference of 4.75 compared to 4.59 of the Standard Physiotherapy group (Appendix 10). The mean NPRS scores for both groups demonstrated a change of >2, indicating a MCID (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011), between baseline and six weeks post-op. Further improvement was seen in mean scores of both groups at the 12-week post-TKR time point, however this only exceeded the MCID of 2 for the Standard Physiotherapy group (Table 4.10).

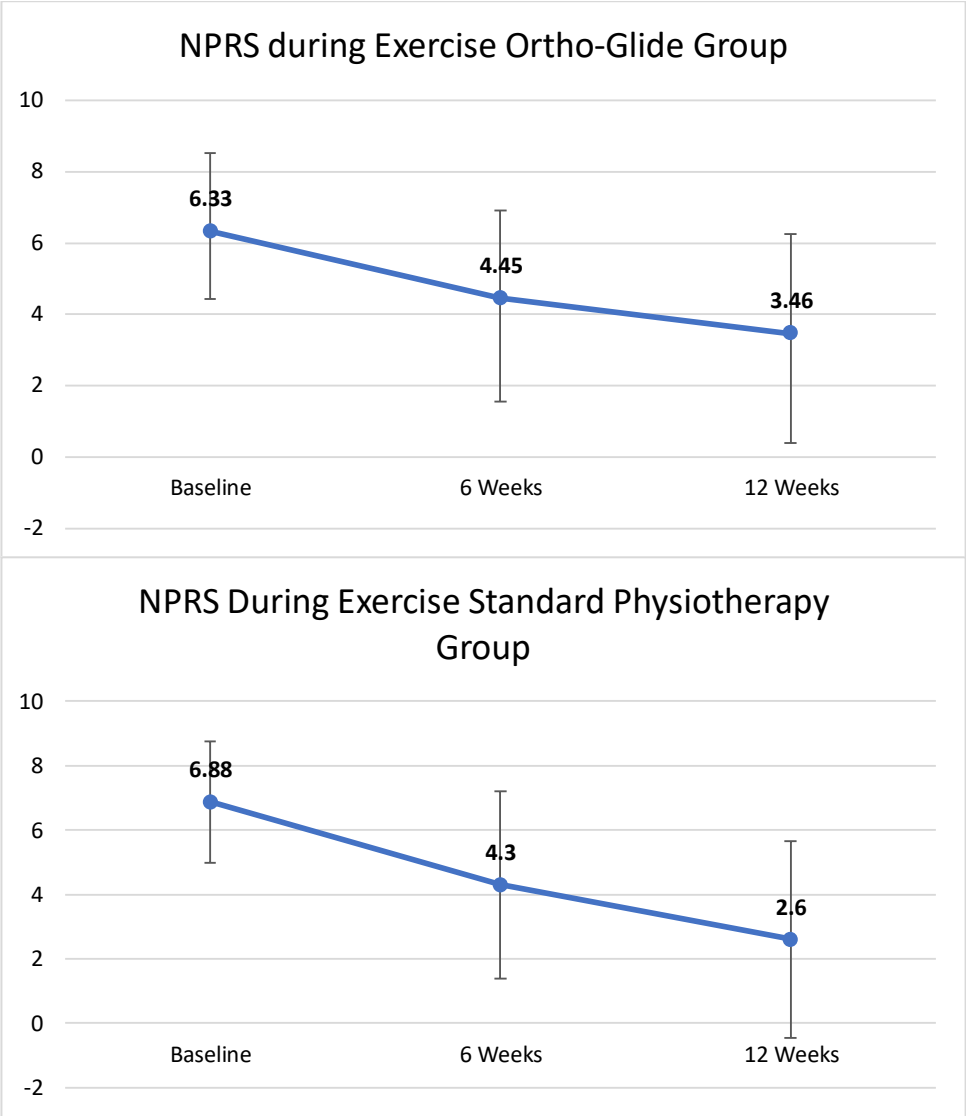


Figure 4.10 Mean NPRS during Exercise scores for baseline, six week and 12-week post-TKR, including standard deviations.

The mixed methods ANOVA did not show a significant interaction between group and time ($p=0.601$). No significant difference was found between treatment groups ($p=0.790$), as shown in Table 4.10, although a significant difference was found between time intervals ($p<0.001$). Further pairwise comparisons between time points showed a significant difference between baseline and six weeks scores ($p<0.005$) and baseline and 12-weeks scores ($p<0.001$). No significant difference was found between the six weeks and 12-weeks scores ($p=0.82$). The results of this pairwise comparison can be seen in Table 4.10. The mean difference of 0.041 between groups did not meet

the MCID of 2 suggested in the literature (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011).

Pairwise Comparison	Mean Difference	Standard Error	P Value	Lower Bound	Upper Bound
Ortho-Glide vs. Standard Physiotherapy group mean NPRS during Exercise score	0.16	0.59	0.79	-1.02	1.34
Baseline vs. 6 Weeks	2.23	0.71	0.003	0.81	3.65
Baseline vs. 12 Weeks	3.57	0.7	<0.001	2.19	4.96
6 Weeks vs. 12 Weeks	1.35	0.76	0.08	-0.17	2.87

Table 4.10 Pairwise comparison of mean NPRS during Exercise scores and differences between time points for Ortho-Glide and Standard Physiotherapy groups.

4.4 Summary of Results

The data analysis revealed a significant improvement in all outcome measures, except the EARS, from baseline to 12-weeks post-operatively. This overall improvement appears to signify that patients report a general improvement in functional status and reduction in levels of pain, both at rest and during exercise, following TKR. Further discussion, interpretation of the results, and comparison of the data to other literature for each outcome measure, and subscales, may be seen in the following chapter.

5 CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter will discuss the results generated from the analysis of data outlined in Chapter 4. Scores for each outcome measure will be discussed with consideration given to the presence of any statistically or clinical important differences. Strengths and limitations of the methodology as well as other issues encountered during the implementation of the research will also be discussed. Factors influencing the results will be considered with comparisons drawn to existing literature where relevant. Implications for clinical practice and suggestions for further research will be made as well as a statement regarding the experimental hypothesis.

5.2 Participant Characteristics

5.2.1 Male to Female Ratio

At baseline, the Ortho-Glide group comprised of 60% female to 40% male participants (Table 4.1). With three males and one female lost at the six week post-TKR stage this ratio became 72.73% female to 27.27% male (Table 4.1), again changing at the 12-week post-operative stage to 69.23% female to 30.77% male following the re-inclusion of two participants. Although the Standard Physiotherapy group lost a total of six participants to follow up at the six week post-operative time point, the ratio of female to male patients remained relatively consistent. The baseline split of 68.75% female to 31.25% male (Table 4.1) was altered to 60% female to 40% male at 6-weeks post-TKR, remaining the same at the 12-week stage (Table 4.1). Despite gender-ratio not being a factor considered during the randomisation process, conveniently, the ratio of male to female participants was similar to that noted in other literature. Ritter et al., (2008) and Parsley et al., (2010) both reported ratios of approximately 60% female to 40% male patients undergoing TKR, utilising significantly larger sample sizes of 7327 and 698 participants respectively. Although the percentage of female to male

participants appears to deviate slightly from the previously reported normal ratio, due to the small sample sizes this deviation represents a difference of a single participant.

The higher number of female patients undergoing TKR may be related to the increased incidence of osteoarthritis in females compared to males, a difference well established in literature (Felson et al., 1987, Srikanth et al., 2005, Blagojevic et al., 2010). The cause of this difference in osteoarthritis presentation is believed to be multifactorial and likely to include bio-mechanical and kinematic differences as well as genetic and hormonal variations (Hame & Alexander, 2013). An important consideration in research surrounding TKR is that female patients often seek treatment for osteoarthritis at a later stage in its development, and at lower functional abilities than male counterparts (Macdonald et al., 2008, Lim et al., 2015). Female TKR patients have also been reported to achieve worse post-operative pain and functional outcomes than male patients (Ritter et al., 2008, Dalury et al., 2009). However, more recent studies have suggested a comparative level of improvement is seen in outcomes post-TKR for both male and female patients, with the lower overall scores noted in females due to the lower (worse) pre-operative scores (Lim et al., 2015, Mehta et al., 2015). Given the differences in presentation and recovery, a sample with a greater number of male participants may generate higher mean baseline and post-operative outcome scores, making the data non-comparable to the normal patient population undergoing TKR.

The approximate ratio of 60% female to 40% male participants in both Ortho-Glide and Standard Physiotherapy groups also ensured that the mean outcome scores generated were comparable between groups. As noted above, the greatest variation in female to male ratio between groups was seen at baseline, with a difference of 8.75% noted between the Ortho-Glide group and Standard Physiotherapy group. As mentioned, this difference represented a single additional female participant leading to a 68.75% female to 31.25% male ratio in the Standard Physiotherapy group, compared to 60% female to 40% male ratio in the Ortho-Glide group. Due to participant drop-out, this

difference reduced at the six week and 12-week post-operative time points with a variation of <3% noted between groups at either.

5.2.2 Participant Age

The age range of 45-75 years was used for this study as this has previously been cited as the most common age range for patients to undergo a TKR (Artz et al., 2015). As seen in Table 4.1 the age range for participants recruited was 53 to 75 years of age at baseline, with the greater age range seen in the Standard Physiotherapy group. Despite the variation in age range between groups, the mean age of participants was relatively similar at baseline, with a difference of only 2.02 years between the mean age of 65.27 for the Ortho-Glide group, and 63.25 for the Standard Physiotherapy group. At the six and 12-week post-TKR time points, the age range for both groups, as well as the difference between mean ages, was reduced, as shown in Table 4.1.

The influence of age on outcomes post-TKR is a topic of debate in orthopaedic literature. A more advanced age has previously been linked with increased length of hospital stay, higher incidence of post-operative complications and worse functional outcomes post-TKR (Kennedy et al., 2013, Kuperman et al., 2016). Conversely, differences in functional outcomes between younger and older patients have been found to be non-clinically significant (Murphy et al., 2018), with age being reported to have no influence on functional or clinical outcomes (Venkatesh & Maheswaran, 2019). Although the influence of the age on recovery post-TKR is unclear, a significant difference in mean age between groups could be considered an influential variable that may have affected the mean scores of the functional outcome measures used. However, a similar mean age was reported in each group at baseline, six week and 12-week time points meaning a high level of comparability between groups was maintained throughout the study period.

Robust data generated from NHS England, The National Joint Registry and hospital statistics suggest that the mean age of patients undergoing TKR is 69 (Edwards et al., 2018), similar, although slightly higher, to the mean age of participants in either the

Ortho-Glide or Standard Physiotherapy groups at any time point (Table 4.1, Table 4.2, Table 4.3). Based on a large population of 66,769 TKR patients, Edwards et al., (2018) reported that the most common age ranges to undergo TKR were 51 to 65 years (29.7%) and 66 to 75 years (40%). As previously discussed, the overall age range of participants was 63 to 75 years, falling within the most common age ranges to undergo TKR. Therefore, the age of participants included in this study fell within the same age range as 69.7% of all patients undergoing TKR and is likely to be representative of the wider population.

Due to limitations in study methodology, stratification of the participants recruited by gender and by age was not feasible. However, based on data reported in other literature, it appears the mean age and gender ratio of participants offers a high degree of comparability to the wider TKR population. Additionally, the lack of stratification did not result in a notable difference between the mean ages and gender ratios seen in each group, allowing a high degree of intergroup comparability.

5.3 Interpretation of Results by Outcome Measure

As shown in Chapter 4, no statistically significant difference was seen between the Ortho-Glide group and Standard Physiotherapy group for any of the outcome measures used at any of the time points. Statistical significance is used to gauge the likelihood of the results occurring due to the null hypothesis, however it has been considered restrictive (Ranganathan et al., 2015) and may not account for changes in outcome that are considered valuable to the patient (Cook, 2008). Sole reliance on statistical significance has also been criticized for its dependence on the sample size (Ranganathan et al., 2015), with larger scale studies generating statistically significant results despite clinically inconsequential results being reported (Halsey et al., 2015, Van Calster et al., 2018). Outcome measure scores were also considered for minimally clinically important differences (MCID) established in previous literature. Unlike

statistical significance, the presence of MCID may indicate whether the observed improvement has value and represents meaningful change for the patient (Cook, 2008, Katz et al., 2015). The use of the MCID metric has been recommended in studies utilising patient reported outcome measures where clinically relevant differences may not be obvious (McGlothlin & Lewis, 2014).

5.3.1 KOOS Aggregate and KOOS Subscale Results

No statistical or clinically significant differences were noted between groups in the KOOS Total or any subscale scores at baseline, indicating that both groups had a similar functional status pre-TKR. A significant difference at baseline would have potentially led to reduced validity in the results as a high correlation has been shown between higher pre-operative outcome scores, such as the KOOS, and positive post-operative results following TKR (Dunbar and Haddad, 2014, Tilbury et al., 2018). Given the eventual sample size, the increased sensitivity of the KOOS will have allowed any functional changes to be more easily detected and represented in mean scores, despite the small sample size, a benefit of the KOOS over the WOMAC (Roos & Lohmander, 2003). Although at the time of writing no validated telephone version of the KOOS was available this was the only feasible method of administration. However, the consistent administration of the KOOS over the telephone at all time points means reliability should not be impacted (Pollard et al., 1976, Peer & Lane, 2013). The KOOS Total and individual KOOS subscale scores will be discussed in the following sections.

5.3.1.1 KOOS Aggregate

The Ortho-Glide group had the higher mean KOOS Aggregate score at 12-week post-TKR (75.19), however the baseline score for this group was also higher (40.04) than the Standard Physiotherapy group (36.34). Based on the mean KOOS Aggregate scores shown in Figure 4.2 the Ortho-Glide group demonstrated the greater improvement between mean scores at baseline and six weeks, however the Standard Physiotherapy group demonstrated the greater improvement between baseline and 12-weeks and six weeks to 12-weeks post-TKR. Both groups had statistically significant

($p<0.05$) improvements between each time point, as well as exceeding the minimal clinically important difference (MCID) of 10 suggested by Roos and Lohmander (2003). Analysis of the estimated marginal means resulted in the Ortho-Glide group having a higher score of 59.89 compared to 55.79 for the Standard Physiotherapy group. No statistically significant or clinically important difference was shown between the KOOS Aggregate scores of the Ortho-Glide and Standard Physiotherapy groups at six weeks or 12-weeks post-TKR.

As discovered during the literature review in Chapter 2, the KOOS Aggregate score has limited use in other available literature. Whilst the KOOS Aggregate score is considered appropriate for use in statistical analysis as a primary outcome measure (Roos et al., 2011) the majority of papers focus on the analysis of the separate KOOS subscales.

Hsu et al., (2017) did report the KOOS Aggregate in their paper, noting higher mean scores at pre-operative baseline compared to both the Ortho-Glide and Standard Physiotherapy group. Despite the higher pre-operative scores, indicating a higher level of function, both groups in the Ortho-Glide study had greater improvements at the 12-week post-operative time point although minimal detail regarding the acute post-operative rehabilitation phase was given, making direct comparison challenging.

KOOS Aggregate scores were also reported by Skou et al., (2018) at a pre-operative baseline, with mean scores at this time point again being higher than those in both Ortho-Glide and Standard Physiotherapy groups. Despite starting on higher scores, 2 years post-TKR a mean improvement of 34.6 was noted in the KOOS Aggregate score by Skou et al., (2018). Participants in both the Ortho-Glide and Standard Physiotherapy groups exceeded this score by the 12-week post-operative time point with differences from baseline of 35.15 and 35.94 respectively.

The KOOS Aggregate is calculated from the scores of each KOOS subscale and therefore, as a stand-alone measure, it gives little insight into the improvements made

in specific aspects of function. Despite this limitation, based on the data analysis, the Ortho-Glide did not make a significant difference to KOOS Aggregate scores from baseline to 12-weeks post TKR compared to standard Physiotherapy provision. However, both groups demonstrated a statistically significant improvement is KOOS Total score from pre-operative baseline up to 12-weeks post-operatively, with a greater clinically important difference seen in the Ortho-Glide group from baseline to six weeks post-TKR.

5.3.1.2 KOOS Symptoms

No significant difference was shown between the mean KOOS Symptom scores of the two groups at any of the time points indicating a similar manifestation of osteoarthritis symptoms in both groups. At the 12-week time point the Standard Physiotherapy group had the higher (better) mean KOOS Symptoms score (78.57) compared to the Ortho-Glide group (76.65), despite starting from a slightly lower (worse) baseline mean of 41.07 compared to 42.62. The estimated marginal means also demonstrated a slightly higher mean of 62.38 for the Standard Physiotherapy group compared to 61.08 for the Ortho-Glide group. The difference between mean KOOS Symptom scores between each time interval exceeded the MCID of 9 as suggested by Lyman et al., (2018), indicating an important improvement in patient symptoms (Beaton et al., 2002).

Changes in mean KOOS symptoms scores for both groups between baseline to six weeks and baseline to 12-weeks also exceeded the score of 21 suggested by Lyman et al., (2018) as indicating a substantial clinical benefit (SCB). As defined by Glassman et al., (2008), the SCB indicates the lower bound for defining optimal patient benefit, in this case to the symptoms of knee osteoarthritis. Although a SCB was noted, mean KOOS Symptom scores in either group did not meet those suggested by Marot et al., (2018) of age matched, healthy adults (Appendix 2).

The trajectory of clinical improvements noted above indicates that the greatest change in symptoms occur in the initial six weeks post-TKR with smaller, but still clinically important, differences occurring up to the 12-week time point. This improvement in

scores is similar to that in other literature, although only one of the papers reviewed presented pre-operative and six week post-operative data. Participants in the study by Ebert et al., (2013) noted improvements to mean KOOS Symptom scores of 20.98 and 13.25, for manual lymphatic drainage and non-manual lymphatic drainage groups respectively, from pre-op baseline to six weeks post-TKR. Interestingly, Ebert et al., (2013) offered participants no assistive device to facilitate exercises in the acute post-TKR phase, possibly contributing to the lower differences seen in mean KOOS Symptom scores compared to both Ortho-Glide and Standard Physiotherapy groups. Despite a higher mean KOOS Symptom score of 51.2 at pre-operative baseline, participants mobilised <7 hours after surgery by Harikesavan et al., (2019) reported an improvement of only 9.8 at four-weeks post-TKR, then further improvement of 10.8 up to 12-weeks post-TKR. Whilst not clearly explained, the use of a knee immobilisation device by Haikesavan et al., (2019) may account for the smaller improvements seen in KOOS Symptoms scores in the weeks following TKR when compared to the active knee mobilisation used in this current Ortho-Glide study. The smaller difference in mean KOOS Symptom score noted for both groups between the six and 12-week time points is similar to the mean difference of 9.5 noted by Bruun Olsen et al., (2013). Encouragingly, Bruun Olsen et al., (2013) and Hsu et al., (2017) noted further mean improvements in KOOS Symptoms of 12 and 13.05 respectively from 12-weeks to 36-weeks post-TKR, suggesting all participants recruited may also continue to see improvements in symptoms beyond the 12-week post-TKR time point.

Based on the data analysis, the Ortho-Glide device did not make a significant difference on KOOS Symptom scores compared to standard Physiotherapy input post-TKR. However, both groups reported substantial improvements in symptoms compared to pre-operative baseline.

5.3.1.3 KOOS Pain

No statistically significant or clinically important difference was noted between KOOS Pain scores of the Ortho-Glide and Standard Physiotherapy group at baseline,

indicating that participants across both groups had comparable pain levels pre-TKR. Despite starting on the slightly lower (worse) mean KOOS Pain score at baseline, the Standard Physiotherapy group demonstrated slightly higher (better) mean scores post-operatively, although only marginal differences of 0.28 and 0.77 were recorded between groups at six and 12-week time points respectively. The baseline KOOS Pain scores for the Ortho-Glide (43.59) and Standard Physiotherapy (41.15) groups were relatively low when compared to the literature reviewed in Chapter 2. Whilst scores >63 seen in some papers (Lin et al., 2018) only Fernando Dias et al., (2008), Minns Low et al., (2011), Aunan et al., (2016) and Harikesavan et al., (2019) reporting slightly lower mean KOOS Pain scores of <40.5 pre-TKR. Despite starting at a relatively low KOOS Pain score, both groups demonstrated differences of >22 indicating a substantial clinical benefit (Lyman et al., 2018) between baseline and six weeks and baseline to 12-weeks post-TKR. The Standard Physiotherapy group showed the greater difference in mean KOOS Pain scores between each time point. However, given the very marginal difference (<1) between groups at six and 12-week time points, this appears to be due to the higher (better) mean score the Ortho-Glide group demonstrated at baseline (Appendix 9.1). Conversely, the estimated marginal means favoured the Ortho-Glide group showing a mean of 64.10 compared to 63.63 for the Standard Physiotherapy group.

At six weeks post-TKR the Standard Physiotherapy group had a higher mean KOOS Pain score of 69.72 compared to 69.44 in the Ortho-Glide group, both higher than the mean scores reported by Ebert et al., (2013), despite starting at a clinically important greater mean baseline score of 50.805 (Lyman et al., 2018). At 12-weeks post-TKR the KOOS Pain scores for the Ortho-Glide group (79.27) and Standard Physiotherapy group (80.04) are amongst the highest when compared to scores in other literature. Mean KOOS Pain scores for both groups in the Ortho-Glide study demonstrated greater differences from baseline to 12-weeks post-TKR than the majority of other papers reviewed, including Minns Lowe et al., (2011), Hsu et al., (2017) and

Harikesavan et al., (2019), with an MCID of >8 present in each case (Lyman et al., 2018). Only Lin et al., (2018) listed a higher mean KOOS Pain score of 88.5-95.1 for participants at 12-weeks post-TKR, although these scores may be considered anomalous given that they are close to the expected KOOS Pain scores of age matched non-osteoarthritis, healthy individuals (Marot et al., 2018). Available literature has demonstrated continued clinically important improvements in KOOS Pain scores from 12 to 36-weeks post-TKR (Bruun Olsen et al., 2013, Hsu et al., 2017) and up to 12-months post-TKR (Minns Lowe et al., 2011), indicating participants in this study are likely to continue to see improvements in pain.

Given the available data use of the Ortho-Glide did not make a significant difference to the KOOS Pain scores when compared to standard Physiotherapy input post-TKR. Both groups reported substantial improvements in pain levels post-TKR as demonstrated by the substantial clinical benefit seen up to the 12-week time point. The trajectory of mean KOOS Pain scores suggests the greatest improvement is seen between pre-TKR and six weeks post-op, however small improvements were seen up to the 12-week time point. Although available literature suggests further improvements may be seen up to 12-months post-TKR this was outside the scope of this current study.

5.3.1.4 KOOS ADL

As with the other KOOS subscales, no statistically significant or clinically important difference was noted between the Ortho-Glide and Standard Physiotherapy groups at baseline, indicating a similar level of function during activities of daily living pre-TKR. The KOOS ADL subscale has a higher number of questions that the other KOOS subscales and demonstrates high content validity and responsiveness to change in older patients with the greatest relevance in post-TKR cases (Collins et al., 2016).

At six weeks post-TKR the Ortho-Glide group had a higher KOOS ADL score of 74.33, compared to 64.41 in the Standard Physiotherapy group, with a difference of >9 indicating a clinically important difference in function during ADL for those who used

the Ortho-glide (Lyman et al., 2018). The Ortho-Glide group also showed a higher mean KOOS ADL score at the 12-week time point, although the difference between groups at this stage was not clinically important. Both groups demonstrated changes of >9 in scores, indicating a MCID (Lyman et al., 2018), between each time point, with the Ortho-Glide group finishing on the higher (better) KOOS ADL score of 86.2 compared to 79.77 for the Standard Physiotherapy group. A substantial clinical benefit (SCB) of >15 (Lyman et al., 2018) was seen for both groups from baseline to six weeks, and baseline to 12-weeks post-TKR, although only the Standard Physiotherapy group noted a SCB between six and 12-weeks post-TKR. Based on the questions for this subscale, this may be interpreted as a significant improvement in the ability to perform daily tasks, such as toileting, dressing and mobilising.

Once again, the trajectory of scores for the Ortho-Glide and Standard Physiotherapy group indicate the greatest improvement in KOOS ADL between baseline and 6 weeks post-TKR with ongoing, but smaller, improvements seen up to the 12-week time point. The Ortho-Glide group finished on the higher (better) KOOS ADL score as well as showing the greatest overall improvement from baseline (Table 4.26).

Compared to previous studies, the baseline mean KOOS ADL scores for the Ortho-Glide group (49.51) and Standard Physiotherapy group (44.48) fell somewhere between the lowest score of 34, reported by Schulz et al., (2018), and the highest score of 57.2, reported by Naili et al., (2017). Despite the moderate pre-TKR scores, the improvements in mean KOOS ADL scores for both groups exceeded those seen in all papers reviewed, more closely resembling the mean improvements of 42.65, noted at 12-months post-TKR by Minns Lowe et al., (2011), and 30.4 recorded two-years post-TKR by Skou et al., (2018). Despite the SCB seen in mean KOOS ADL scores at 12-weeks post-TKR they still remain below those reported by age and gender matched scores of healthy individuals. However, the ongoing improvements noted in other literature suggest participants in the Ortho-Glide study may see continued

improvements at 36 weeks (Bruun Olsen et al., 2013, Hsu et al., 2017) and 12-months post-TKR (Minns Lowe et al., 2011).

Interestingly, as suggested by Collins et al., (2016), improvements in KOOS ADL for the Ortho-Glide group were alongside the Pain and QoL subscales as showing the greatest change from pre-op to 12-weeks post-TKR. Conversely, the overall improvement reported by the Standard Physiotherapy group was only greater than the Sport & Recreation subscale, commonly the lowest improved subscale post-TKR (Sidhu, 2018). This suggests that the whilst the Ortho-Glide group conformed to conventional recovery patterns, the Standard Physiotherapy group may have under-reported potential improvements, or the data may have again suffered due to the small sample sizes used. Based on the data generated by the participants in this study, use of the Ortho-Glide device elicited a clinically important difference in improvement, compared to standard Physiotherapy, at six weeks post-TKR. However, both groups reported significant clinical improvements in completing functional activities 12-weeks post-TKR.

5.3.1.5 KOOS Sport & Recreation

The relevance and appropriateness of utilising the KOOS Sport & Recreation subscale in post-TKR patients has been questioned. Peer & Lane (2013) suggested that due to the post-operative recovery process, including reduced mobility and overall function, sport and recreational activities may not be undertaken during normal daily routines, or may be contraindicated by clinicians. The value of the Sports & Recreation subscale is further questioned as undertaking sporting activities was been found to be of value to only 50% or TKR patients (Roos & Toksvig-Larsen, 2003), with variations in post-TKR scores suggested to reflect differences in patient lifestyles as well as recovery trajectories (Gandek & Ware, 2017). Although this study did not include a measure to quantify the value placed on improving function in sport and recreational activities, pre-operative scores for the KOOS Sport & Recreation subscale showed no statistically significant or clinically important difference between groups. This indicates a

comparable level of physical difficulty was perceived by participants in the Ortho-Glide and Standard Physiotherapy group at baseline and allows greater validity in the comparison of post-operative scores. The lack of statistical or clinically significant difference for the EARS score reinforces the likelihood that no differences in exercise engagement were seen between groups. The mean scores generated for this subscale were the lowest (worst) of all KOOS subscales at baseline, although both groups showed substantial improvement at the six and 12-week post-TKR time points, with the Ortho-Glide showing higher (better) scores on each occasion (Appendix 9.1). No statistically significant difference was noted between mean scores of the groups at any time point. However, a clinically important difference was noted at six weeks post-TKR with a MCID seen in the Ortho-Glide group over the Standard Physiotherapy group. The MCID of >10, suggested by Roos & Lohmander (2003), was used as the Sport & Recreation subscale was not assessed by Lyman et al., (2018) for MCID or SCB in TKR patients.

A marginal difference of only 0.31 was noted between groups at the 12-week time point, the lowest difference between groups for any of the KOOS subscales, indicating that at this post-operative stage both groups had very similar perceptions of their physical function when performing sport or recreational activities. As seen in Table 4.26, the changes in mean scores of each group between each time point suggest the Ortho-Glide group had a faster rate of improvement with a clinically important higher score at the six week time point. However, the mean scores of Standard Physiotherapy group indicated that they had the greater improvements between baseline and 12-weeks, as well as between six and 12-week time points, allowing for a comparative, albeit marginally lower, mean score at 12-weeks post-TKR.

As demonstrated in the mean Ortho-Glide and Standard Physiotherapy group scores, the Sport & Recreation subscale often demonstrates the lowest rate of improvement post-TKR (Sidhu, 2018). It has been suggested these relatively low improvements may

be attributed to a data collection period too short to assess change during recovery of these specific activities (Peer & Lane, 2013).

The mean KOOS Sport & Recreation scores were amongst the lowest when compared to those reported in the other literature, with pre-operative scores ranging from 10 (Minns Lowe et al., 2011) to 28.6 (Hsu et al., 2017). The only other paper utilising the six week post-operative time point was Ebert et al., (2013) who, unlike participants in the Ortho-Glide Study, noted a decrease in KOOS Sport & Recreation scores, despite an improvement being seen in all other subscales. The majority of papers reviewed reported relatively low improvements in Sport & Recreation subscale, with improvements of only 5.7 and 6.4 to 11.4 noted by Harikesavan et al., (2019) and Lin et al., (2018).

Despite comparatively low baseline scores the improvements seen in the Ortho-Glide (28.85) and Standard Physiotherapy (30.10) groups were amongst the highest in the reviewed literature, only lower than Hsu et al., (2017), who showed an improvement of 34.2 at 12-weeks post-TKR. Encouragingly, continued improvements were noted up to 12-months (Minns Lowe et al., ,2011, Aunan et al., 2016), with these improvements appearing to be maintained up to three-years post-TKR (Aunan et al., 2016), suggesting all study participants may see ongoing improvements. However, despite improvements noted, mean KOOS Sport & Recreation scores for both groups, as well as all literature reviewed, remained substantially below the estimated scores for age matched, non-osteoarthritic, individuals (Marot et al., 2018)

In summary, both groups demonstrated clinically, but not statistically, significant differences between each time point. Participants utilising the Ortho-Glide device reported faster improvements in ability to perform sport and recreation activities, as seen at 6 weeks post-TKR, as well as higher scores at the 12-week time point. Other literature suggests KOOS Sport & Recreation scores may continue to improve up to three-years post-TKR, indicating further reduced difficulty in physical activities may be achieved but may never reach the same level as age matched, healthy individuals.

5.3.1.6 KOOS QoL

The KOOS QOL subscale broadly conceptualizes the perceived impact of knee problems, including awareness of any knee problems, the difficulty caused by any knee problem, lifestyle modification due to the knee and overall difficulty with knee (Gandek and Ware, 2017). This subscale is considered highly responsive (Collins et al., 2016) and the strongest at detecting change in post-TKR patient's ability to engage in physical activity and work (Gandek & Ware, 2017).

No clinically significant or statistically important difference was noted in mean scores between groups at baseline. This suggests participants in both groups had a similar perception of the impact of knee problems, both pre-and post-operative, on their lifestyle and quality of life. Both groups demonstrated SCB (>23) from baseline to six weeks, and from baseline to 12-weeks, post-TKR and the Standard Physiotherapy group also demonstrated a MCID of >8 (Lyman et al., 2018) in mean scores between the six and 12-week time points (Appendix 9.1). The Ortho-Glide group reported the higher (better) mean KOOS QoL scores at both the six and 12-week time points, with a clinically important difference (MCID) of >8 noted over the Standard Physiotherapy group on each occasion (Appendix 9.2).

Pre-operative KOOS QoL scores for other literature reviewed ranged from 13 (Fernando Dias et al., 2018) to 40.2 (Hsu et al., 2017). The improvements reported by both groups from baseline to six weeks post-TKR were higher than those reported by Ebert et al., (2013), the only other paper to use the six week post-op time point. The improvements noted in the Ortho-Glide (39.94) and Standard Physiotherapy (37.90) groups at 12-weeks post-TKR were higher than those reported in other literature, the closest being 33.4 by Harikesavan et al., (2019). Beyond the 12-week post-TKR time point improvements in KOOS QoL scores varied, further improvements were reported at 36-weeks (Hsu et al., 2017) and at 12-months (Minns Lowe et al., 2011) although a slight decrease in scores was seen at two-years post-TKR (Aunan et al., 2016). Once again, despite substantial improvements, mean scores for this subscale did not reach

those of age matched healthy individuals as outlined by Marot et al., (2018), as shown in Appendix 2.

The mean KOOS QoL scores indicate the Ortho-Glide group had the greater trajectory of improvement, as well as the higher (better) scores, with clinically significant differences seen at six and 12-weeks post-TKR compared to the Standard Physiotherapy group. For this KOOS subscale, use of the Ortho-Glide device appeared to make a clinically significant difference to patient improvements post-TKR. Although both groups appeared to report higher levels of improvement than other literature, further improvements in KOOS QoL for participants in both groups may be varied and may not achieve the level reported by healthy individuals.

5.3.1.7 KOOS Summary

Despite no validated telephone format being available KOOS scores were taken over telephone interview at all time points, a consistent approach unlikely to have effected reliability. Having demonstrated no significant differences between groups at baseline, all KOOS scores for both groups showed a substantial clinical improvement, if known, by six weeks, with further improvements seen at 12-weeks post-TKR. No statistically significant differences were noted between the Ortho-Glide and Standard Physiotherapy groups scores at six or 12-weeks post-TKR in any of the KOOS subscales. However, clinically important differences were noted between the mean ADL, Sport & Recreation and QoL subscale scores at six weeks and mean QoL scores at 12-weeks post-TKR, favouring the Ortho-Glide group over Standard Physiotherapy. Based on the changes in mean KOOS scores between each time point it appears the Ortho-Glide group progressed faster to the six week post-op point in all subscales apart from KOOS Symptoms and Pain. The Standard Physiotherapy group recorded the higher (better) overall scores in the KOOS Symptom and KOOS Pain subscales at six and 12-week time points, however the Ortho-Glide group reported higher mean scores for all other subscales.

As an objective measure, the KOOS scores offer no explanation or insight into why the participants reported improvements in function following TKR. However it may be speculated that, given the purpose-specific nature of the Ortho-Glide, patients found it more user friendly to complete the prescribed exercises compared to the standard Physiotherapy provision during the early phase of TKR recovery. Any perceived ease-of-use offered by the Ortho-Glide may have translated into greater exercise adherence during the acute post-TKR stage, leading to early improvements in knee ROM, which have been correlated with improved functional status (Naylor et al., 2012). As mentioned, this improved function appears to be represented by the clinically important differences seen in favour of the Ortho-Glide group KOOS ADL, Sport & Recreation and QoL sub scales at six weeks post-TKR.

The trajectory of improvement in KOOS scores seen in other literature suggests participants are likely to see further improvements beyond the 12-week time point, although not to the level of age-matched healthy individuals. Further research into the use of the Ortho-Glide device should consider extending the data collection beyond 12-weeks post-TKR to allow any further differences to manifest, particularly regarding the Sport & Recreation subscale.

5.3.2 EARS

Both groups demonstrated statistically significant changes from the pre-operative baseline scores to the six and 12-week time points in all outcome measures, except for the EARS. This signifies that exercise adherence during the study period likely remained relatively consistent for participants in both groups. No significant difference was noted between the groups at any of the time points, with the Ortho-Glide group reporting higher mean EARS scores at six and 12-weeks post-TKR, indicating greater adherence. Interestingly the mean EARS score in the Ortho-Glide group at 12-weeks was slightly lower than the mean score recorded at the six week time point. Conversely, the Standard Physiotherapy group demonstrated a steady improvement in mean EARS scores over the three time points, although slightly lower that those

reported by the Ortho-Glide group. As shown in Chapter 4, the largest change in mean EARS score for either group was between baseline and six weeks post-op for the Ortho-Glide group, despite starting on a slightly lower score initially. This improvement of 2.45 is notable compared to the improvement of 0.36 for the Standard Physiotherapy group. Unfortunately, at the time of writing no information was available regarding what signifies a MCID or SCB for the EARS score, although 2.45 represents a change of 10.2% towards the maximal possible score of 24, which may be considered noteworthy if not clinically important.

At the time of writing the EARS had not yet been utilised in any other available literature and the normal method of determining adherence from exercise diaries would not have been feasible to use for this study. The lack of statistical significance between EARS scores at any of the time points for either group, in addition to the lack of directly comparable data in other literature, means any conclusions regarding its relevance are speculative.

Despite the lack of comparable data to the EARS scores generated during this study, literature has previously examined the link between adherence to prescribed exercise and long-term outcomes. Several papers have found a correlation between post-operative outcomes and dose, intensity, frequency and participation in exercise (Franklin et al., 2006, Rosal et al., 2011, Artz et al., 2015). In addition to general participation, low adherence would also compromise intensity, volume and frequency of exercise undertaken during the overall rehabilitation period, therefore jeopardising achieving optimal outcomes. The effect of exercise adherence on hip/knee osteoarthritis as a general condition has also been studied and correlated with long-term improvements in levels of pain and function (Van Gool et al., 2005, Pisters et al., 2010). Suggestions have also been made for future research to explore methods of, and barriers to, stimulating and maintaining exercise behaviours in osteoarthritis patients to facilitate further optimisation of exercise protocols (Pisters et al., 2010).

Barriers to exercise adherence in osteoarthritis patients are varied and, like other chronic conditions, may be considered complex (Bennell et al., 2014). Participation in this study may have positively influenced adherence to the prescribed exercise as it may be considered as reinforcement by a healthcare professional, as suggested by Roddy et al., (2005). However, as all participants were contacted at the same time points and any discussion regarding exercise adherence was only for data collection purposes, therefore any effect is likely to have been consistent across both groups.

Previous studies have cited a lack of access to appropriate equipment or resources as a perceived barrier to commencing, and adhering to, prescribed exercise in the general population (Bautista et al., 2011, Herazo-Beltran et al., 2017), as well as specifically in osteoarthritis patients (Petursdottir et al., 2010, Bennell et al., 2014).

During the immediate post-operative inpatient stay all patients in this study had access to purpose-specific equipment to perform knee-slide exercises, either the Ortho-glide or a Teflon board, as used with current standard Physiotherapy. Upon discharge from the hospital the Standard Physiotherapy group were given advice on how to perform the knee-slide exercises using make-shift equipment, such as a plastic bag or a dinner tray, whilst the Ortho-Glide group took the Ortho-glide device home with them. Qualitative research would be needed to determine if the lack of provision of purpose-specific equipment is a barrier to exercise adherence following discharge.

The initial period following TKR is when exercise devices such as the Ortho-glide may be most beneficial as their friction reducing qualities aid performing knee flexion as the patient recovers from the trauma of the procedure and subsequent reduced strength (Bautmans et al., 2010, Welvaart et al., 2011, Schulz et al., 2018). Therefore, the provision of the purpose-specific exercise aid (the Ortho-glide) may have contributed to the mean difference in EARS score from baseline to six weeks post-op of 2.45 compared to 0.36 for the Ortho-Glide and Standard Physiotherapy groups respectively.

In addition to lack of comparable studies using the EARS, other limitations of this outcome measure are potential recall bias, perceived social desirability of high exercise adherence and misreporting due to memory lapses, as recognised during its initial validation (Newman-Beinart et al., 2017).

Whilst no statistically significant difference was noted, and clinical significance is unknown, the data shows that use of an Ortho-glide is at least equal to standard Physiotherapy in facilitating exercise adherence post-TKR. Exercise adherence post-TKR has been correlated with improved functional outcomes, however, despite this well documented correlation, few papers implement formal outcome measures to quantify exercise adherence. At the time of writing the Ortho-Glide study appeared to be the first research study to utilise the EARS score to quantify the adherence of participants to prescribed exercise post-TKR. The improvements in exercise adherence from baseline to 12-weeks post-TKR in both groups may account for the reported functional improvements, beyond those noted in comparable literature, as indicated by the KOOS. Provision of assistive devices such as the Ortho-glide may reduce potential barriers to exercise adherence in the early post-operative stages by allowing easier completion of exercises, despite reduced strength. Further research should consider adding a measurement to record perceived barriers to exercise adherence in post-TKR patients, for example the provision, or lack of, an assistive device.

5.3.3 NPRS at Rest and NPRS during Exercise

As with the other outcome measures used, no statistically significant or clinically important differences were seen between groups for either NPRS score at baseline, indicating a similar level of pain was perceived by both groups at rest and when completing the prescribed knee-slide exercises.

Given the pathogenesis of osteoarthritis, unsurprisingly, both groups reported higher (worse) NPRS during exercise than NPRS at rest scores at each time point, including baseline, a feature of the disease well documented in the literature (Cecchi et al., 2009, Hunter et al., 2009, Alkan et al., 2014). Despite this known difference in pain levels,

only two of the papers reviewed monitored pain at rest as well as during exercise (Bathis et al., 2005, Buker et al., 2014), with only Buker et al., (2014) recording these scores pre-operatively.

As documented in Chapter 2, only four of the papers reviewed utilised the NPRS scale, with the majority of other papers utilising the VAS, which has shown high correlation with the NPRS (Hawker et al., 2011, Rosas et al., 2017, Cheatham et al., 2018). Therefore, comparison to pain scores reported in other literature will, unless stated, be based on the NPRS at rest scores but may be compared to VAS scores reported in other papers.

Baseline NPRS at rest scores for the Ortho-Glide group (3.87) and Standard Physiotherapy group (4.56) were lower (better) than the majority of other papers reviewed with only Aveline et al., (2008) reporting lower scores of 1.9 to 2 at the pre-operative time point. Pre-operative NPRS and VAS scores reported in other literature suggest that participants in the Ortho-Glide study had comparably lower pain levels at rest, with pain scores >7.0 reported by Sanchez Labraca et al., (2011), Alghadir et al., (2016) and Harikesavan et al., (2019). The pre-operative NPRS during exercise scores in both the Ortho-Glide group (6.33) and Standard Physiotherapy group (6.88) were also lower than those documented by Buker et al., (2014) who reported scores of 9.25 for participants during activity.

Both groups reported improvements in NPRS at rest and NPRS during exercise scores at the six and 12-week time points, with the Standard Physiotherapy group showing lower (better) mean scores at each post-operative time point, despite starting on slightly higher (worse) baseline scores. The significance of improvements noted at each time point varied, although both groups reported improvements of >2, in both NPRS at rest and during exercise, signifying a clinically important improvement from baseline to 12-weeks post-TKR (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011). Statistical significance ($p<0.05$) was also seen in NPRS at rest and NPRS

during exercise scores from baseline to six weeks and from baseline to 12-weeks post-TKR, as seen in Table 4.9 and table 4.10.

The improvements reported in mean NPRS at rest by both groups from baseline to 6 weeks post-TKR were lower than those documented in other papers utilising this time point (Alghadir et al., 2016, Gnanakumaran et al., 2017), with only the control group in Ebert et al., (2013) reporting a lower improvement of 1.71 in NPRS score. Similarly, the improvements in both groups mean NPRS scores from baseline to 12-weeks post-TKR were generally lower than those reported in other literature, only greater than a mean improvement of 2.4 reported by Bruun Olsen et al., (2009).

At 12-weeks post-TKR the improvements in mean NPRS during exercise scores of 2.87 and 4.28 for the Ortho-Glide and Standard Physiotherapy groups respectively were significantly lower than the mean improvement of 7.42 reported by Buker et al., (2014). Unfortunately the only other paper using a pain scale during exercise, Bathis et al., (2005), did not utilise a pre-operative baseline and used eight and 15-day time points to retest VAS scores, meaning the results are not comparable to those generated by this current Ortho-Glide study.

Improvement in symptoms of pain relating to osteoarthritis of the knee have previously been shown as a key factor in determining patient satisfaction following TKR (Baker et al., 2007, Scott et al., 2010), and has been shown to limit rehabilitation activities (Ramlall et al., 2019). Whilst the mean NPRS scores suggest improved levels of pain, during data collection a number of the individuals expressed ongoing or worse pain, particularly during exercise, a phenomenon estimated to occur in approximately 20% of TKR patients (Wylde et al., 2013). The underlying reason for higher levels of pain post-TKR is not currently fully understood, but is though to be a combination of biological, surgical and psychosocial factors, not specifically related to the form of rehabilitation used (Wylde et al., 2018). Unfortunately, this study did not account for biological differences, variations in surgical procedure or psychosocial aspects which may have influenced improvement in pain post-TKR. Future research may consider including

outcomes to assess these holistic factors in an attempt to further optimise post-operative outcomes. To ensure fair comparison of groups, future research could also include consideration of post-operative analgesia use as this will influence the level of pain experienced at different time points.

Improvements in pain have been predicted to plateau between 12-weeks and six months post-TKR (Halket et al., 2010, Lenguarrand et al., 2016). Whilst 12-weeks post-TKR was the final data collection point for participants in this study, data reported in other literature suggests further improvements in pain levels may be seen at 26-weeks (Harmer et al., 2009) and 12-months post-operatively (Monticone et al., 2013).

Given the small sample sizes, individuals expressing worsening pain, or lack of any improvement, may have had a significant impact on the mean NPRS scores. However, although a larger sample size may give the results greater levels of generalisability the proportion of participants experiencing ongoing, or worse, pain may be the same, leading to the generation of a similar mean score.

Despite the clinically important improvements in mean NPRS scores, no statistical significant or clinically important difference was shown between groups at six or 12-weeks post-TKR. This suggests that participants using the Ortho-Glide device, and those who engaged in standard Physiotherapy, perceived similar levels of discomfort, both at rest and during exercise. Consistent with the trajectory seen in other outcome scores used, the improvements noted in mean NPRS at rest and NPRS during exercise scores suggest the greatest improvement in pain is seen between baseline and six weeks post-TKR, with a smaller improvement seen up to 12-weeks post-operatively. Based on the data reported, use of the Ortho-Glide device did not influence improvements in pain compared to engaging in standard Physiotherapy exercises.

5.4 Limitations of the Study

5.4.1 Limitations of the Sample Size

The primary limitation of this study was the sample size. As highlighted in section 4.1, a sample size of 60 was initially targeted, however this was not achieved due to reduced TKR procedures being conducted during the recruitment phase. Eventually a total of 31 participants were recruited to this study, a relatively small sample size compared to other literature exploring recovery post-TKR. As a pilot study investigating the effects of a device previously not studied no formal power analysis was conducted and it was unclear if this number would be adequate to generalise any effect demonstrated in the data. At the final data analysis stage 23 participants were analysed, 13 in the Ortho-Glide group and 10 in the Standard Physiotherapy-only group, a number lower than the majority of studies reviewed in Chapter 2.

The importance of sample size on generalising conclusions from data generated has been well documented in literature from various disciplines in the scientific community. Small sample sizes can lead to the data from 'outlier' participants who score particularly high, or low, on an outcome measure having a large effect on the mean score for the treatment group as a whole. In studies with larger sample sizes this effect would be less pronounced than in studies with a smaller sample size. One limitation of a small sample size is the possibility of it producing a Type 1, or false-positive, error. A Type 1 error occurs when the magnitude of an association is over-estimated (Hackshaw, 2008). For this study that would potentially mean that the effect of the Ortho-Glide was under-estimated, and had the sample been larger a statistically significant benefit over the Standard Physiotherapy-only group may have been shown. Likewise, a small sample size also increases the chances of a Type 2 error, or false-negative, being present. For this study that would mean the effect of the Ortho-Glide device being over-estimated due to a small number of the sample showing far greater outcome score results than the rest of the group. Whilst small sample sizes risk

skewing the overall mean scores, the Ortho-Glide and Standard Physiotherapy groups both showed a normal distribution with no obvious outliers.

Whilst small sample sizes may present ethical issues due to the risk of the results misrepresenting the effect of a device, overly large sample sizes may also present ethical issues (Faber & Fonseca, 2014). A sample with more participants required would mean more people were exposed to a study variable, in this case the Ortho-Glide, which may be sub-optimal to their recovery. Likewise, if the Ortho-Glide demonstrated significantly greater results then more participants than were necessary would have been exposed to the sub-optimal treatment provided in the standard care group. Future research could address this issue by utilising a prolonged recruitment phase, or strategically commencing recruitment to avoid the likelihood of caseload pressures limiting the number of TKR procedures being undertaken, allowing adequate participants to be recruited.

5.4.2 Limitations of the Outcome Measures

Whilst the KOOS has been shown to be more responsive that the WOMAC in post-TKR populations (Roos & Toksvig-Larsen, 2003, Gandek & Ware, 2017), there were some inconsistencies noted during its administration. Particularly, the Sport and Exercise subscale includes questions relating to twisting one the knee, jumping and kneeling, which some participants reported they had been prohibited to perform whilst others did not mention these were prohibited and gave responses indicating they had attempted these actions. Post-operative advice regarding specific activities may be down to the preferences of the performing surgeon, advice given by a Physiotherapist or misinterpretation of the prohibited movements by either of the above. Unfortunately, the performing consultant surgeon and specific recommendations given post-discharge for each participant were not factors taken into account as part of this study, therefore the homogeneity of advice for contraindicated exercises is unclear. The KOOS Sport & Recreation subscale has previously been shown to have greater content validity for younger patients (Collins et al., 2016), whilst the mean age for participants at the 12-

weeks post-TKR for this study was 64.31 for the Ortho-Glide group and 65.2 for the Standard Physiotherapy-only group, meaning a lower level of validity may be present. Several post-TKR studies utilising the KOOS did not include the Sport & Recreation subscale at all. It has been suggested by Gandek and Ware (2017) that due to validity issues this subscale should be further developed to include more specific activities for post-TKR patients.

The primary limitation of utilising the Exercise Adherence Rating Scale (EARS) was the lack of comparable data in other literature, as well as the lack of a known clinically important difference threshold. However, as discussed, no other validated means of quantifying exercise adherence was available that could be administered over telephone interview in a quick and effective manner. Whilst the reported EARS scores were unable to be compared to any other literature, they did allow for accurate intergroup comparisons to be drawn.

The Numerical Pain Rating Scale (NPRS) was utilised for its high levels of validity and versatility of administration (Ferraz et al., 1990, Hawker et al., 2011). However, the NPRS has been previously criticized for not adequately accounting for complexities and idiosyncrasies associated with osteoarthritic pain (Hawker et al., 2008, Hush et al., 2010). As discussed, unlike the majority of other papers utilising pain rating scales, participant pain levels were assessed both at rest as well as during exercise. Only assessing pain at two distinct levels of activity may have been inadequate to comprehensively capture improvements in the complex manifestation of pain in patients post-TKR. Due to the ease and speed of administration, future research could utilise the NPRS to measure pain levels during additional activities, offering a more comprehensive overview of the recovery process.

A limitation of the outcome measures used was the lack of any objective measure of recovery, such as knee range of movement (ROM). As previously discussed, increased knee ROM at hospital discharge and in the sub-acute phase post-TKR has been associated with improved patient reported outcomes (Naylor et al., 2011). Research

into recovery post-TKR generally utilises a combination of functional and clinical outcome measures, such as ROM (Blasco et al., 2019). Given that the Ortho-Glide device is designed to facilitate patients to perform active ROM, inclusion of an objective measure of the ROM achieved between participants at each time point may have added valuable data for comparison. Unfortunately, due to feasibility issues, inclusion of an objective outcome measure would have posed a significant challenge to implement, particularly in ensuring data was collected in a timely manner at the six and 12-week time points.

5.4.3 General limitations

Several potential limitations were noted during the study period which may have influenced participant recovery and could be considered variables to standardise during any future research.

Although significant co-morbidities of patients were considered in the exclusion criteria, it was not possible to screen participants for Body Mass Index (BMI), which has a debatable effect on post-operative recovery. Available literature has reported higher BMI to have a negative impact on recovery (Collins et al., 2012, Waimann et al., 2016), particularly within the first six weeks post-TKR (Correa-Valderrama et al., 2019). Conversely, based on a systematic review of 50 primary research papers, BMI was considered to have no significant influence on outcome post-TKR (Dere et al., 2014), a conclusion also reached in more contemporary primary research (Burke et al., 2019). Whilst the role of BMI on recovery post-TKR is unclear, future research may consider recording participants pre-operative BMI to ensure no significant variation between groups is noted, further reducing variables which may potentially influence the mean outcome scores reported.

Whilst all participants underwent TKR at a single centre, Blackpool Victoria Hospital, specifics regarding the surgical procedure were not considered in analysis, including performing surgeon, peri-operative complications and type of prosthesis used. Complications such as surgical wound issues, haemodynamic derangement and

undesirable response to anaesthetic, such as prolonged confusion, have been cited as delaying hospital discharge and impacting initial post-operative rehabilitation (Zhang et al., 2018). Variations in the surgical procedure, such as the approach and the inclusion of patellar resurfacing have also been shown to influence post-operative recovery and patient reported outcome measures (Bathis et al., 2005, Aunan et al., 2016). Additionally, the type of prosthesis utilised, whilst not considered in this study, may have an influence on patient reported outcomes post-TKR, with clinically important, but not statistically significant, differences noted by Hamilton et al., (2015). Future research into the effectiveness of the Ortho-Glide device should aim to consider variations in influential co-morbidities as well as variations in the surgical procedure and prosthesis used.

Due to being undertaken by the Physiotherapy team at the single surgical centre, the pre-operative and acute-post-operative Physiotherapy input was consistent. All participants received the same pre-operative exercise advice and consistent post-operative input commenced within 24 hours, continuing until the day of discharge. Post-discharge exercise advice was also consistent in its content, including mode, frequency and technique to complete rehabilitation exercises. Following discharge home, all patients were offered out-patient Physiotherapy appointments to further progress rehabilitation. Unfortunately, these outpatient appointments varied significantly in terms of geographical location meaning it was not reasonably possible to track how soon after the procedure the patient attended. Although exercises prescribed at out-patient Physiotherapy appointments have a common goal to further improve ROM and enhance patient's functional capabilities, the exact exercises may vary based on the attending Physiotherapist. Again, due to feasibility limitations it was not possible to track the exact exercises prescribed therefore their potential influence on the reported outcome measure scores is unclear. To ensure consistency in variables outside of the post-operative device issues, it may be beneficial for future

research to track the surgical variations, as well as any differences in post-discharge Physiotherapy exercises and advice issued.

5.5 Implications for Clinical Practice

The purpose of this project was to determine if use of the Ortho-Glide device offered patients a greater benefit compared to standard Physiotherapy provision following TKR. Encouragingly, participants in both groups demonstrated substantial clinical benefits in mean outcome scores between pre-operative baseline and the end of data collection at 12-weeks post-operatively. This overall improvement in patient reported outcomes likely represents a high level of satisfaction with the procedure as improvements in functional outcome measures, such as the KOOS, have previously been shown as paramount for indicating patient satisfaction (Kahlenberg et al., 2018).

Whilst no statistically significant differences were noted between groups in any of the outcome measures utilised, clinically important differences were noted for the KOOS ADL, Sport & Recreation and QoL subscales, favouring the Ortho-Glide group on each occasion. Of note was that these clinically important differences were all present at the six weeks post-operative time point although, with the exception of the KOOS QoL, no difference was noted at 12-week time point. This suggests that use of the Ortho-Glide device offered a significantly greater clinical benefit in the initial weeks post-TKR when compared to standard Physiotherapy provision. Whilst a smaller sample size than expected was utilised, the participant characteristics at baseline, including age, gender and mean outcome scores, were similar, allowing for reasonable intergroup comparability. The mean age and gender ratio of the groups also appeared to be representative of the wider TKR population, allowing for greater generalisability of results. Additionally, as previously discussed, despite the lack of national clinical guidelines Physiotherapy provision at Blackpool Victoria Hospital appears to comply

with current best practice, including early mobilisation and the provision of joint mobility exercises.

Based on the data generated by this study it is reasonable to state that provision of the Ortho-Glide to patients following a TKR appears be beneficial in eliciting greater outcomes over standard Physiotherapy in patient reported ADL, Sport & Recreation and QoL scores. Furthermore, the data suggests that, although only a small refinement to current Physiotherapy practice, use of the Ortho-Glide offered participants an accelerated improvement in ADL, Sport & Recreation and QoL. Although further research is needed, clinicians should consider providing participants with an Ortho-Glide device to facilitate post-TKR active joint mobilisation and reduce barriers to continued adherence to prescribed exercises upon discharge home.

5.6 Recommendations for Future Research

As demonstrated by participants used for this study, future research should ensure any sample used is representative of the age range, 50 to 75 years, and gender ratio, 60% female to 40% male, of the wider TKR population, allowing high levels of generalisability. Future research should also aim to address the limitations discussed throughout this chapter which, based on the following recommendations, may add to the evidence supporting use of the Ortho-Glide device post-TKR

The primary limitation of this study was the relatively small sample size, which should be addressed by any future research. Ensuring the recruitment of an adequate sample size will potentially allow any differences between an Ortho-Glide and control group to be expressed with statistical significance, enhancing the validity of any result. A larger sample size will also reduce the impact any statistical outliers, such as non-responders, have on the mean outcome scores.

Future research may also consider making alterations to the methodology implemented for this study. Whilst the KOOS has been shown to be one of the most valid and

responsive outcome measures for patients undergoing TKR (Gandek & Ware, 2017) inclusion of the Sport & Recreation subscale may be reconsidered. Many of the activities encompassed in this subscale are potentially contraindicated in post-TKR exercise recommendations, depending on the performing surgeon or Physiotherapists advice. Returning to sport and exercise-based activities was also only found to be of value to 50% of TKR patients (Roos & Toksvig-Larsen, 2003). Therefore, results generated by use of this subscale may be skewed by the individual psychosocial properties of the participants, hindering the validity of intergroup comparisons. To allow accurate intergroup comparison of this subscale future research may consider including an additional quantitative, or qualitative, outcome to measure participants aspiration to, or value placed on, return to sport and exercise activity.

A further additional outcome to consider including would be the ease participants found in completing the post-operative knee flexion exercises, as this is part of the rationale behind the design of the Ortho-glide device. Data to assess these potential differences may be particularly beneficial in the acute post-operative hospital-based stage where, due to its design, use of the Ortho-glide device may provide the most benefit. Therefore, additional data collection time points to gather this information during the initial days following the TKR would need to be included. As well as including additional data collection time points to more accurately map differences in recovery trajectory, future research may also consider expanding the time period which participants are enrolled in the study. Based on the literature reviewed, ongoing improvements in recovery continue to occur beyond 12-weeks post-TKR.

A prolonged participation period would especially benefit use of the KOOS Sport & Exercise subscale, if included, which has previously shown the slowest rate of improvement post-TKR due to the more advanced nature of the factors it encompasses (Sidhu, 2018). Future research may consider extending the study period beyond pre-operative to 12-weeks post-operative to allow differences in sport and exercise activities between users of the Ortho-glide device and a control group to be expressed.

Whilst results from this study suggest the Ortho-glide device was most beneficial during the first six weeks post-TKR, analysing this initially greater trajectory over a longer period will provide more comprehensive, possibly clinically important, data.

In addition to the comorbidities considered in the exclusion criteria, future research may consider stratification of participants by BMI, as this potentially influences outcomes post-TKR. Additional factors that potentially influence outcomes should also be considered, including the performing surgeon, variations in surgical procedure and type of prosthesis used. Variations in engagement-with and content-of outpatient Physiotherapy during the sub-acute phase may also influence outcomes, particularly at later post-operative time-points. Therefore, for the highest level of intergroup comparability to exist, these variables should be accounted for in future research, potentially also providing valuable data to optimise the provision of local Physiotherapy services.

Surprisingly, despite its significant contribution to the effectiveness of rehabilitation post-TKR, exercise adherence was rarely considered in the data analysis of the available literature, as noted in Chapter 2. As with this study, future research should implement a method of quantifying adherence to the prescribed exercises, such as the EARS. Analysis of this variable would allow stratification of participants based on levels of adherence, or enhance the accuracy of intergroup comparisons, if consistent adherence was noted between groups. Alternatively, assuming comparable baseline scores, correlations may be drawn between any differences in post-operative adherence between groups and the use of the Ortho-glide. Although a complex and multi-faceted topic, exercise adherence appears to the largest gap in current literature surrounding recovery following TKR but given its importance on optimising recovery merits inclusion in future research.

6 CHAPTER 6: CONCLUSION

Many advances have been made in total knee replacement procedures since its introduction over 130 years ago and it is currently considered one of the most consistently successful joint replacement procedures performed. With an ageing population, and increasing rates of obesity, cases of osteoarthritis are set to rise, with a predicted increase in the number of total knee replacements performed annually. With these increasing caseload pressures, health care providers should seek to further optimise patient's post-operative recovery, for both economic and patient satisfaction purposes.

Surprisingly, despite its increasingly prevalent role, conclusive evidence surrounding optimal post-operative Physiotherapy appears to be lacking. A review of the available literature revealed significant variations in post-operative exercise prescription, particularly following discharge from hospital. A lack of clarity in the provision of exercises during the early, hospital based, post-operative period was also noted in the literature, with many studies simply stating that Physiotherapy was provided, without specifying its content. None of the studies reviewed appeared to utilise the Ortho-Glide device in total knee replacement patients, or any other orthopaedic patient population. The lack of conclusive evidence regarding Physiotherapeutic exercise, including the use of assistive devices such as the Ortho-Glide, represents a gap in the literature which may further optimise outcomes following total knee replacement.

This study considered the benefit of issuing patients with an Ortho-Glide device following total knee replacement, in addition to standard Physiotherapy, compared to receiving standard Physiotherapy input alone, at a single surgical centre. Based on the age and gender ratio of participants in each group, although small, the sample appeared to be representative of the wider total knee replacement population, allowing for cautious generalisability of the results. The validity of any intergroup comparisons was also enhanced by statistically, and clinically, similar mean outcome scores

reported at pre-operative baseline. Post-operative outcome scores reported by participants in both groups indicated a substantial benefit following total knee replacement. However, based on the mean post-operative outcome scores, participants issued with the Ortho-Glide device reported a clinically important greater benefit to function during Activities of Daily Living, Sport and Recreation activities and to their Quality of Life.

Given the results reported in this study it is reasonable to state that use of the Ortho-Glide device provided some clinical benefit, but no detriment, when compared to the current standard Physiotherapy provision at Blackpool Victoria Hospital. Therefore, in a bid to optimise post-operative patient outcomes, clinicians should consider issuing, or recommending use of, the Ortho-Glide to facilitate standard post-operative knee flexion exercises following a total knee replacement. This study represents the first clinical research into the effectiveness of the Ortho-Glide device in total knee replacement patients. Although encouraging results were generated, methodological limitations, including sample size, were identified, limiting the power of any conclusions. Further research is warranted to provide more robust evidence of the effectiveness of the Ortho-Glide device in enhancing outcomes for patients following total knee replacement.

When compared to other literature, the current provision of Physiotherapy at Blackpool Victoria Hospital appears to contribute to greater functional improvements post-TKR. Given the lack of clinical guidelines this may be considered best known practice. However, despite appearing to offer higher than average functional improvements, it appeared this provision was further enhanced by the utilisation of the Ortho-Glide device.

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8 APPENDIX

Appendix 1

Outcome Score Review Table for KOOS, WOMAC, NPRS and VAS

Appendix 1.1 KOOS Outcome Score Review Table

Study	Outcome Score	Outcome Intervals	Score Information
Aunan et al., 2016 TKR with (63) vs without (66) Patella resurfacing Resurfacing = statistically better KOOS	KOOS	Pre-op, 1 year post-op, 3 year post-op	Mean Pre-op; 1 year; 3 year post-op scores: Symptoms: 51 84 88 Pain: 41 87 88 ADL: 45 86.5 86 Sport: 13 59.5 62 QoL: 24 81.5 81
Bruun Olsen et al., 2013 RCT Walking skill programme (29) vs usual Physio (28) post TKR No difference between groups in KOOS, however 6MWT was better post-intervention in walking skill group.	KOOS	6 weeks post-operatively Post-intervention 9 months post-intervention	Pre-intervention mean (6 weeks post-op): Symptoms: 56 Pain: 58 ADL: 62 Sport: 30.5 Qol: 47

Cook et al., 2008 Descriptive study: a comprehensive joint replacement programme for TKR (63)	KOOS	Preoperative only	Pre-op KOOS: Symptoms: 57.1 Pain: 44.5 ADL: 52.9 QoL: 25 (KOOS Sport & Rec was omitted)
Ebert et al., 2013 Randomized trial Manual lymphatic drainage (24) vs no drainage (26) post-TKR Manual lymphatic drainage improved knee flexion scores but not KOOS	KOOS	Pre-operative 6 week post-operative	Mean Pre; 6 week post-operative: Symptoms: 56 73 Pain: 51 68 ADL: 55 74 Sport: 16 10 QoL: 27 51
Fernando Dias et al., 2018 Biofeedback system(38) vs normal in-person physio (31) post-TKR Biofeedback superior to conventional	KOOS	Pre-operative Pre-intervention 8 weeks following commencement of intervention	Mean Pre-operative; pre-intervention; 8 weeks: (conventional/ bio-feedback) Symptoms: 39 50/34 71/81 Pain: 39 47/33 78/90.5 ADL: 38 41/34 76/90.5

Physio			Sport: 0 5/0 15/20 QoL: 13 25/13 56/69
Harikesavan et al., 2019 Early mobilisation efficacy No control group	KOOS	Pre-operative 1 month post-op 3 months post-op	Mean pre-op; 1 month post; 3 months post: Symptoms: 51.2 61 71.8 Pain: 40.4 55.5 67.7 ADL: 45.9 47.5 71.3 Sport: 17.2 22.3 22.9 Qol: 29.5 49.3 62.9
Hsu et al., 2017 Circuit training post-op (16) vs no circuit training post-op (18) Circuit training facilitated improved scores, needs further investigation.	KOOS	Pre-op Pre-exercise (12 weeks post-TKR) Mid exercise (24 weeks post-TKR) Post-exercise (36 weeks post-TKR)	Pre-op; Pre-exercise; Mid exercise; Post-exercise: Control/circuit Symptoms: 49/46 67/62 71/73 72/83 Pain: 47/47 71/72 78/76 74/84 ADL: 49/49 71/73 74/77 71/85 Sport: 29/17 39/51 35/39 34/48 Qol: 40/38 48/54 62/64 61/68
Hutchinson et al., 2018 Inpatient rehab (29) vs home based rehab (27)	KOOS	Pre-op 6 months post-op	Mean Pre-op; 6 months post-op Symptoms: 42 Pain: 42 ADL: 52

No significant difference			Sport: N/A QoL: 31
Lin et al., 2018 Randomised Lower limb strength training pre-op (100) vs normal care (100) All participants initially decreased KOOS scores 2 weeks post-TKR but then improved. Significant improvements in ADL and QoL in training group	KOOS	Pre-op 2 weeks post-op 4 weeks post-op 8 weeks post-op 12 weeks post-op	Mean Pre-op; 8 weeks post-op/ 12 weeks post op: Non-strength control/strength training Symptoms: 64/62 81/87 87/92 Pain: 64/64 84/90 89/95 ADL: 50/51 62/74 69/81 Sport: 15/16 16/22 21/27 QoL: 31/31 44/53 48/59
Minns Lowe et al., 2011 Pilot RCT 2 x Additional Physio visits (56) vs normal care (51)	KOOS	Pre-op 3 months 6 months 12 months	Mean pre-op; 3 month; 12 month post-op: Control/additional visits: Symptoms: 39 71/68 79/82 Pain: 40 72/69 90/81

			ADL: 45 75/70 89/85 Sport: 11.5 32/42 50/60 QoL: 23.5 56/53 63/63
Monticone et al., 2013 RCT Home based exercise programme (55) vs general exercise advice (55)	KOOS	Within 15 days Post-op 6 months post-op	Mean <15 days post-op; 6 months post-op: Control/home exercise programme: Symptoms: 20/33 21/32 Pain: 27/37 34/43 ADL: 25/40 33/45 Sport: 22/35 30/41 QoL: 22/31 30/42
Naili et al., 2017 Prospective cohort of knee kinematics/gait in TKR patients (28) vs age matched healthy control group (25) Patients improve post-TKR but do not reach the level of their healthy, age matched peers.	KOOS	Pre-op 12 months post	Mean pre-op; 12 months post-op: OA-TKR/Healthy control: Symptoms: 41 76 95 Pain: 45 78 97 ADL: 57 81 96 Sport: 22 39 90

			QoL: 28 62 91
Skou et al., 2018 TKR then non-surgical Rx (100) vs non-surgical Rx alone (100) 2 separate RCT's – 1 did not include any TKR procedure due to ineligibility	KOOS	Pre-operative 2 years later	Pre-op; 2 years post-op TKR + non-surgical RX vs non-sugical RX only RCT: Symptoms: 54/58.3 +29/12.8 Pain: 49/50 +36/19 ADL: 55/54 +30/15 Sport: 18/17 +39/20 QoL: 32/33 +42/18 Raw KOOS scores at 2 years not listed, only average improvements

Appendix 1.2 WOMAC Outcome Score Review Table

Study	Outcome Score	Outcome Intervals	Score Information
Akbaba et al., 2016 RCT Intense supervision for 1 month (20) vs normal care (20) post TKR vs healthy control group (20) Intense supervision improved WOMAC at 2 months post-op	WOMAC	Pre-op 1 month post 2 months post	Mean Pre-op/1 month/2 months post-op Healthy control/ Standard exercise/ intense supervision: Pain: 0.8/6.7/7.0 3.3/3.3 2.6/1.4 Stiffness: 0.5/1.9/3.9 5.2/5.8 4.0/2.5 Function: 0.9/8.4/8.3 6.2/4.7 4.0/1.9
Beaupre et al., 2001 Slider board and exercises (40) vs CPM and exercises (40) vs exercises alone (40) Exercises alone were equal to slider board or CPM groups at 6 months withy ROM and WOMAC the first RCT comparing effectiveness of CPM and SB therapy added to routine Rx post-TKR	WOMAC	Pre-op On discharge 3 months post-op 6 months post-op	Unable to interpret

Bech et al., 2015 Consistent cooling (37) vs intermittent cooling – standard therapy (34) post-TKR No additional benefit of consistent cryotherapy using the icing device over intermittent ice bags	WOMAC	Pre-op 6 weeks post-op	Pre-op score/6 weeks post-op mean difference Standard/continuous cooling Pain: 1.8/1.6 -0.7/-0.4 Stiffness: 2.0/1.9 -0.8/-0.3 Function: 1.9/1.8 -0.6/-0.6
Bedekar et al., 2012 Yoga + normal care vs normal care alone post-op Yoga showed improved scores at 6 weeks and 3 months post-op	WOMAC	3 days post-op (pain & stiffness only) 6 weeks post-op 3 months post-op	% improvement standard care/yoga group: **6 weeks:** Pain and stiffness: 17.15%/ 23.86% **3 months:** Pain and stiffness: 12.9% 28.1% Function: 14.55%/26.45%
Calatayud et al., 2017 High intensity pre-op training (22) vs normal pre-op care (22) Pre-op Rx group had improved WOMAC	WOMAC	Baseline (pre-Rx) After 8 weeks Rx (pre-op) 1 month post-op 3 months post-op	Pre-Rx/Pre-op/1 month post-op/3 months post-op: Rx group/normal care Pain: 10.5/10.6 6.8/10.3 4.0/5.1 2.9/3.8 Stiffness: 4.0/4.1 3.5/4.7 2.8/4.2 2.2/3.2 Function: 37.2/36.7 29/40.3 20.5/31.6 18.8/22.7
Han et al., 2015	WOMAC	baseline	**Baseline/6 weeks post-op**

RCT Home exercise (194) vs outpatient Physio (196)		6 weeks	HEP/ OP Physio: Pain: 11.1/10.8 7.2/7.4 Function: 35.8/36.6 22.4/22.5
Harmer et al., 2009 Land (49) vs water (43) based exercise post-TKR: 1hr x 2 weekly for 6 weeks Comparable outcomes up to 26 weeks post-op	WOMAC	2 weeks post-op (baseline) 8 weeks post-op 26 weeks post-op	WOMAC pain scores improved by 8 weeks post-op but then no significant improvements or between group-differences after that. WOMAC stiffness reduced up to 26 weeks post-op with land-based group showing greater improvements. No data-table given in paper.
Kaupilla et al., 2010 RCT Normal physio + 10 day MDT input 2-4 months post TKR (36) vs normal physio (39) No difference noted between groups	WOMAC	Pre-op 8 weeks post-op 6 months post-op 12 months post-op	Shown in graph form, both showed equal improvements up to the 12 month point – greatest improvements generally seen from 0-6 months.
Kramer et al., 2003 Clinic (80) vs Home based Rx (80) post-TKR	WOMAC	Pre-op 3 months post-op	Shown in graph form

No difference between groups at any time-point		1 year post-op	Comparable improvements in all aspects. Greatest difference seen in first 3 months post-op
Lenssn et al., 2008 RCT 17 days CPM + physio (30) vs 4 days CPM + physio (30) Short term benefit of CPM but no long-term carry-over	WOMAC	Pre-op 17 days post-op 6 weeks post-op 12 weeks post-op	Pre-op/day 17/6 week/3 month Normal care vs prolonged CPM: Pain: 10.5/10.6 15.3/15.8 16.6/16.0 17.5/17.3 Stiffness: 3.8/4.0 4.8/5.0 4.8/5.4 5.3/5.5 Function: 36.9/40.2 45.3/49.1 52.7/53.0 58.6/57.6
Liao et al., 2016 Higher levels of CPM application, including a greater initial angle and accelerated progress in the applied flexion motion arc, independently predicted greater recovery in knee flexion at discharge and improved long-term WOMAC functional outcomes 6 months after TKA Only passive flexion scored and no control	WOMAC	Pre-op At discharge 3 month 6 month	Steady progression of WOMAC scores in all groups up to 6 months post-op

group.			
Lopez-Liria et al., 2015 Home based (32) vs Hospital rehab (39) post-TKR. Both equally effective at improving WOMAC	WOMAC	5 days post-op 2nd time point unclear – appears to be once rehab allocation had finished.	
Mau Moeller et al., 2014 Sling training vs CPM Sling training is better	WOMAC	Pre-op Hospital discharge 3 months post-op	**Pre-op/discharge/3 months post-op:** Sling/CPM: Pain: 8.9/9.5 15.2/14.9 15.2/14.7 Stiffness: 4.6/4.0 6.0/6.4 5.5/5.1 Function: 32.3/34.7 44.9/43.7 49.4/47.2
Mitchell et al., 2005 RCT Home visits pre+ post TKR vs normal care in hospital No difference in WOMAC scores	WOMAC	Pre-op 12 weeks (optimal time for improvements – Shields et al., 1999)	Pre-op/12 weeks Hospital group/Home group Pain: 12/12.4 6.9/6.8 Stiffness: 5.2/5.4 3.6/3.5 Function: 40.6/40 26.4/24.9
Piva et al., 2010 RCT - Pilot study 6 weeks/12 sessions of functional training +	WOMAC	Baseline 2 months 6 months Intervention started 2 to 6 months post-TKR (9-23	Poorly documented/ difficult to interpret

balance vs functional training alone. Followed by 4 months home exercise		weeks)	
Tousignant et al., 2011 2 months of tele-rehabilitation post-TKR Equally as effective as conventional outpatient Physio	WOMAC	1 week post-op Post-intervention 2 months post-intervention	No difference between experimental and control group

Appendix 1.3 NPRS Outcome Score Review Table

Study	Outcome Score	Outcome Intervals	Score Information
Bech et al.,, 2015 Consistent cooling (37)/intermittent cooling (34)	NPRS	24-48hrs post-op	**24-48hrs post-op** 3.6/3.8
Ebert et al.,, 2013 Manual lymphatic drainage (24)/no manual lymphatic dranage (26)	NPRS	Pre-op, 6 weeks post-op	**Pre-op/ 6 weeks post-op** 4.67 4.71 1.5/3
Harikesavan et al.,, 2019 Early mobilisation <7hrs post-TKR (75)	NPRS	Pre-op, 4 weeks post-op, 12 weeks post-op	**Pre/4 weeks / 12 weeks** 7.35 4.3 1.68 **Mean change** **Baseline-12 weeks =** 5.6 **Mean change** **Baseline-4 weeks =** 3
Monticone et al.,, 2013 Home based exercise (55)/Standard care (55)	NPRS	7-10 days post-op, 6 months post-op, 12 months post-op	**7-10 days post-op =** 4.65/4.75 **Mean changes up to 6 months** = -3.5/-3.5 **Mean Changes to 12 months =** -2/-2.5

Appendix 1.4 VAS Outcome Score Review Table

Paper	Outcome	Outcome Intervals	Score Information
Alghadir et al.,, 2016 Pre+post op PT (25)/post-op PT alone (25)	VAS	Pre-op, 3 weeks post-op, 6 weeks post op	**Pre-op** 8.9/8.7 **3 weeks** 4.7/4.1 **6 weeks** 1.9/2.4
Aveline et al.,, 2008 Early mobilisation with ketamine (24)/Nefopam (24)	VAS	Pre-op, 48hrs post-op	**Pre-op** 1.9/2.0 **48hrs post-op** 3.5/4.0
Bathis et al.,, 2005 Mid-vastus (25)/parapatellar (25) approach to TKR	VAS	Day 1 post-op, Day 8 post-op, Day 15 post-op At rest and during activity	**Day 1 post-op at rest =** 3/3.5 **Day 1 post-op activity =** 5/6 **Day 8 post-op at rest =** 1/3 **Day 8 post-op activity =** 3.5/4 **Day 15 post-op at rest =** 1/2 **Day 15 post-op activity =** 3/3
Bruun Olsen et al.,, 2009 CPM+exercises (30)/exercises alone (33)	VAS	Pre-op, 1 week post-op, 12 weeks post-op	**Pre-op =** 5.2/4.7 **1 week post-op =** 4.0/4.0 **12 weeks post-op =** 2.9/2.2

Buker et al.,, 2014 Supervised (18)/standard home PT (16) post-TKR	VAS	Pre-op, 12 weeks post-op, 2 years post-op At rest and during activity	**Pre-op at rest =** 5.3 **Pre-op activity =** 9.25 **12 weeks post-op rest =** 0.33 **12 weeks post-op activity =** 1.83 **2 years post-op rest =** 1.11 **2 years post-op activity =** 0.83
Calatayud et al.,, 2017 High intensity pre-op training (25)/ standard care (25)	VAS	Pre-intervention, 4 weeks post-op, 12 weeks post-op	**Pre-intervention =** 6.1/5.9 **4 weeks post-op =** 2.5/4.2 **12 weeks post-op =** 1.4/2.9
Gnanakumaran et al.,, 2017 Mobilised <6 hours (20)/mobilised <24 hours post-TKR	VAS	Pre-op, pre-discharge, 6 weeks post-op	**Pre-op =** 6.85/6.75 **Pre-discharge =** 4.82/4.45 **6 weeks post-op =** 3.6/3.29
Harmer et al.,, 2009 Land based(49)/ water based(53) rehab post-TKR	VAS	2 weeks post-op, 8 weeks post-op, 26 weeks post-op	**2 weeks post-op =** 3.5/4.2 **8 weeks post-op =** 1/2 **26 weeks post-op =** 0.8/1
Holm et al.,, 2010 Pain in early rehab post-TKR (100) Bed transfers/ sit to stand/ walking	VAS	Day 1 post-op, Day 2 post-op, Day of discharge	**Day 1 post-op =** 4/4/5 **Day 2 post-op =** 3/3/4 **Day of discharge =** 3/3/2

Lopez-Liria et al.,, 2015 Home (32)/hospital (39) based rehabilitation	VAS	5 days post-op Unclear 2nd collection	**5 days post-op =** 7.03/2.75 **Unclear 2nd collection =** 7.13/2.38
Mau Moeller et al.,, 2014 Sling training (19)/CPM (19) post-TKR	VAS	Pre-discharge	**Pre-discharge =** 1.22/1.78
Piqueras et al.,, 2013 Interactive telerehabilitation (90)/ converntional rehab (91) post-TKR	VAS	1st day of rehab, 12 week follow-up	**1st day of rehab =** 3.8/4.3 **12 week follow-up =** -2.3/-1.79
Sanchez Labraca et al.,, 2011 Rehab starting <24 hours (153)/ 48-72hours post-TKR	VAS	Pre-op, Post-rehabilitation period	**Pre-op =** 6.46/7.08 **Post-rehabilitation period =** 3.01/5.36
Schulz et al.,, 2018 Continuous Active Movement (25)/Continuous Passive Movement (25) post-TKR	VAS	4-5 days post-op, >30 days post-op	**4-5 days post-op =** 3.2/3.5 **>30 days post-op =** 1.0/1.9
Sindhu et al.,, 2013 Supervised ()/home based rehabilitation post-TKR	VAS mentioned in methods, but no results displayed or discussed.		

Appendix 2

Predicted KOOS and WOMAC scores for healthy individuals by BMI, age range and gender

Appendix 2.1 Predicted KOOS and WOMAC scores for healthy individuals with BMI under 25 by age range and gender

Predicted KOOS and WOMAC Scores for healthy males with BMI <25kg/m^2 by age range								
Age Range (years)	KOOS Symptoms	KOOS Pain	KOOS ADL's	KOOS Sport & Recreation	KOOS QoL	WOMAC Pain	WOMAC Stiffness	WOMAC Function
15-24	92	95	98	92	91	96	93	98
25-34	94.6	96.1	100	95.5	94.3	97.3	97.4	100
35-44	93.4	95.5	98.7	94	91.5	96.9	98.5	98.7
45-54	89.8	91.4	92.1	82.6	86.8	92.4	90.1	91.9
55-64	91.4	91	92.9	82.4	86.2	91.9	92.4	92.9
65-74	96.8	95.1	97.1	89.9	93.1	94.7	97.9	97.2
75-84	97.4	98.4	97.8	83.4	99.6	96.8	96.2	97.4
≥85	93.4	92.1	92.9	83	88.3	92.8	92.2	92.8
Predicted KOOS and WOMAC Scores for healthy females with BMI <25kg/m^2 by age range								
Age Range (years)	KOOS Symptoms	KOOS Pain	KOOS ADL's	KOOS Sport & Recreation	KOOS QoL	WOMAC Pain	WOMAC Stiffness	WOMAC Function
15-24	88.8	93	95.7	85.2	88.9	93.6	90	95.6
25-34	91.4	94.1	97.7	88.7	92.2	94.9	94.4	97.6
35-44	90.2	93.5	96.4	87.2	89.4	94.5	95.5	96.3
45-54	86.6	89.4	89.8	75.8	84.7	90	87.1	89.5
55-64	88.2	89	90.6	75.6	84.1	89.5	89.4	90.5
65-74	93.6	93.1	94.8	83.1	91	92.3	94.9	94.8
75-84	94.2	96.4	95.5	76.6	97.5	94.4	93.2	95
≥85	90.2	90.1	90.6	76.2	86.2	90.4	89.2	90.4

Appendix 2.1 Predicted KOOS and WOMAC scores for healthy individuals with BMI under 25 by age range and gender

Predicted KOOS and WOMAC Scores for healthy males with BMI >25kg/m^2 by age range								
Age Range (years)	KOOS Symptoms	KOOS Pain	KOOS ADL's	KOOS Sport & Recreation	KOOS QoL	WOMAC Pain	WOMAC Stiffness	WOMAC Function
15-24	89	93	95.7	88.9	87.5	94.5	88.1	95.8
25-34	91.6	94.1	97.7	92.4	90.8	95.8	92.5	97.8
35-44	90.4	93.5	96.4	90.9	88	95.4	93.6	96.5
45-54	86.8	89.4	89.8	79.5	83.3	90.9	85.2	89.7
55-64	88.4	89	90.6	79.3	82.7	90.4	87.5	90.7
65-74	93.8	93.1	94.8	86.8	89.6	93.2	93	95
75-84	94.4	96.4	95.5	80.3	96.1	95.3	91.3	95.2
≥85	90.4	90.1	90.6	79.9	84.8	91.3	87.3	90.6
Predicted KOOS and WOMAC Scores for healthy females with BMI >25kg/m^2 by age range								
Age Range (years)	KOOS Symptoms	KOOS Pain	KOOS ADL's	KOOS Sport & Recreation	KOOS QoL	WOMAC Pain	WOMAC Stiffness	WOMAC Function
15-24	85.8	91	93.4	82.1	85.4	92.1	85.1	93.4
25-34	88.4	92.1	95.4	85.6	88.7	93.4	89.5	95.4
35-44	87.2	91.5	94.1	84.1	85.9	93	90.6	94.1
45-54	83.6	87.4	87.5	72.7	81.2	88.5	82.2	87.3
55-64	85.2	87	88.3	72.5	80.6	88	84.5	88.3
65-74	90.6	91.1	92.5	80	87.5	90.8	90	92.6
75-84	91.2	94.4	93.2	73.5	94	92.9	88.3	92.8
≥85	87.2	88.1	88.3	73.1	82.7	88.9	84.3	88.2

Appendix 3

Blackpool Victoria Hospital Enhanced Recovery Guide to TKR

NHS
Blackpool Teaching Hospitals
NHS Foundation Trust

A Patient's Enhanced Recovery Guide to having a Knee Replacement

Patient Information

Your Planned Journey and Goals, from Pre op to Discharge Home

People Centred | Positive | Together we care | Compassion | Excellence

Contents

Enhanced Recovery;

At Blackpool Teaching Hospitals NHS Foundation Trust we aim to provide high standards of care based on current recommendations and protocols. Enhanced Recovery After Surgery (ERAS) is part of this and ensures that all members of the hospital and primary care staff work together to improve the patient experience throughout their stay in hospital. Recent research has recognized that patients who are maintaining a healthy lifestyle before surgery recover much better after surgery.

By identifying any problems after surgery early such as pain control or post operative nausea and vomiting we can ensure that patients are able to move around early after surgery, take on the necessary calories needed to recover and therefore ensure a timely discharge from hospital.

What Enhanced Recovery Means for You

- Taking an active role in your recovery – following the advice of the clinical team.
- Being positive about your recovery.
- Starting normal activities eg, eating, drinking, toileting, walking (with supervision initially), as soon as possible after surgery.
- Making sure that before you come into hospital for your surgery, that you have organised any help that you will need at home after you are discharged home.
- Being aware of your discharge date prior to coming in for surgery.
- Knowing your estimated length of stay. This will be two days following your surgery, in some cases patients can go home the following day if they manage to move around the ward independently on crutches.

How Will this Benefit You?

Patients who actively participate in their recovery;

- Feel better, sooner.
- Leave hospital sooner.
- Return to normal living sooner.

How can you prepare for your admission?

- Ensure you have help in place ready for discharge and relatives / friends are aware of the estimated date of discharge.
- Ensure that you follow a healthy diet on the weeks prior to your surgery in order to prepare your body for surgery and aid with recovery.
- Bring loose fitting clothes, you will be encouraged to move around the ward within 24 hours, often on the day of your surgery. You will also be encouraged to walk on the first day after your surgery (depending on your consultants advice).
- It is important to look after yourself before coming in for surgery. This includes keeping your skin clean and dry and reporting any rashes or breaks in your skin a week prior to coming in for surgery to the Orthopaedic Nurse Practitioner (the telephone number can be found in the contact information at the end of this booklet).
- You need to complete your exercise programme as recommended.

Pre Admission Discharge Planning

Prior to coming into hospital you need to think carefully about any adaptations to your lifestyle or possible assistance that you may require when you return home.

These could be such things as;

- Preparing meals in advance, to keep ready in the freezer.
- Using microwaveable pre prepared meals.
- Having plenty of supplies in store including long life milk for emergencies.
- Internet shopping.
- Recruiting friends and family to help with shopping/housework/looking after pets.
- Removal of any clutter that may impede you walking with walking aids.
- Removing any loose rugs, that you could catch with your walking aids.
- Plan your transport to and from the hospital.

It is important to eat and drink before surgery. Please make sure you eat a good meal the evening before surgery and have a light supper at 10pm before you go to bed. If you are on the afternoon list you will be able to eat breakfast on the day of surgery. You will be told if you are able to eat breakfast.
You will be able to drink water on the day of surgery up until the time you are admitted. Once at the hospital the preadmission nurses will tell you when you need to stop drinking.

To ensure a safe and timely discharge home, we will ensure that:

- Your blood count (HB) is checked to see that it is at an acceptable level.
- You can walk independently with walking aids.
- You are able to walk up and down steps (where applicable).
- Your pain relief is sufficient.
- A routine check x-ray of your knee has been performed.

Pre-operative Assessment

In preparation for surgery, you will be asked to attend a pre-operative assessment clinic where blood tests, x-rays, infection screening and a check of your general health may be performed by the health care team. If you have a long term illness, heart, lung or a metabolic (diabetes, thyroid) condition, a consultant anaesthetist may see you in an anaesthetic clinic to make sure you are medically fit for an anaesthetic. The anaesthetist will discuss with you the different types of anaesthesia and pain management methods available to you. It may be necessary for you to be seen by a specialist if you have a more serious health problem. If you are not considered fit for anaesthetic and surgery your operation will be cancelled. You will receive an out-patient department appointment with your consultant surgeon who will discuss alternative treatment options. This may include the following:

- medication.
- injection.
- physiotherapy.
- an appliance.
- arthroscopy (key hole surgery)

It is important that you inform the nursing staff if you take any form of medication. If you are on blood thinning tablets e.g. aspirin, warfarin, clopidogrel or dipyridamole please inform the nursing staff as you may have to stop taking this medication before the operation. This would only be under the direction of a doctor or nurse practitioner.

It is also important to let the staff know if you have ever experienced any problems such as allergies or stomach upsets, when you have previously taken pain relief. You should also advise the pre op staff if you are already taking regular pain relief.

In some cases, you may need to have some of your investigations repeated 2 -3 days prior to your surgery. The pre op nurses will provide you with the necessary completed forms if this is the case.

If you need to have a repeat blood test, you will need to attend the Pathology Lab with your completed blood test form. The Pathology Lab is open between the hours of 8.30am and 4.30 pm Monday to Friday and is located at the far end of the main hospital corridor in the older part of the hospital.

If you need to have a repeat X ray, you will need to attend X ray **North** with your completed X ray card. X ray North is open between the hours of 8.30am and 4.30 pm Monday to Friday. X ray North is located near to Orange Reception, where you will have been on another occasion to visit the Orthopaedic doctors. Following your x ray, you may be given a blue slip. Please discard this and DO NOT attend the Outpatient Department as stated on the blue slip. The blue slip is routinely handed out to all patients after their X ray to advise the clinic staff that they have had their X ray, however you are NOT attending clinic that day, therefore please discard the blue slip.

Pre Op Exercises;

In the weeks before your operation, it is important that you maintain the mobility of your knee joint and the soft tissues around it. You also need to strengthen the muscles around the knee.

By strengthening the muscles around the knee, you will help to support your new joint, improve your posture and walking pattern, as well as greatly aiding your progress after your operation.
A member of the Pre Op Physiotherapy, 'Homeward' team will arrange to visit you at home prior to your surgery to assess your mobility and to give you some pre op exercises to start doing.

Start these exercises as soon as you have been given them.
You should not feel too much pain or discomfort with them.

Please do all of the exercises on BOTH legs
Exercise 1

Lie on your back or sit up with your legs out straight in front of you on your bed.

Bend your ankle up and push your knee down firmly against the bed. Hold for 5 seconds.

Repeat 6 times, 3 times a day.

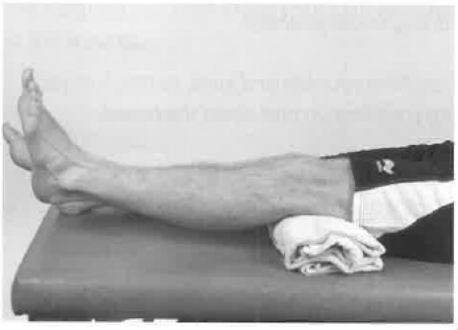
Please do all exercises on BOTH legs
Exercise 2

Lie on your back, or sit up with your legs out straight on your bed.

Exercise your knee by pulling your toes up, straighten your knee and lift your leg 10cm off the bed. Hold for approx 5 seconds, then slowly relax.

Repeat 6 times, 3 times a day.
Increase to more than 10 repetitions each time if you are able.

Please do all exercises on BOTH legs
Exercise 3



Sit or lie as shown. Put a rolled up towel or block under your knee.

Exercise your knee by pulling your foot up, tightening your thigh muscle and straightening your knee. (Keep the back of of your knee on the towel or block). To make the exercise harder put a small weight on your ankle.

Hold for 5 seconds. Slowly release. Repeat 6 times, 3 times a day. Increase to 10 or more repetitions, as it feels easier.

Please do all exercises on BOTH legs
Exercise 4

Sit on a chair.

Pull your toes up, tighten the front of your thigh muscle and straighten your knee slowly. Hold for approx 5 seconds. Slowly release.

To make the exercise harder put a small weight on your ankle.

Repeat 6 times, 3 times a day.
Increase to 10 repetitions each time if you are able.

Please do all exercises on BOTH legs
Exercise 5

Sit on a chair with your feet flat on the floor.

Slowly bend your knee as much as possible. Hold for 5 seconds. Then straighten your knee as fully as you can.

Repeat 6 times, 3 times a day.
Increase to 10 repetitions each time if you are able.

Please do all exercises on BOTH legs
Exercise 6

Lie on your back or sit semi reclined on your bed with a plastic board/bag under your leg.

Bend and straighten your hip and knee, as much as you can, by sliding your foot up and down the board.

Repeat 6 times, 3 times a day.
Increase to 10 repetitions each time if you are able.

After the operation

You will spend a short time in the recovery area of the operating theatres before you are taken t ward. You will be offered drinks in the recovery area and you should be able to eat and drink nc when you go to the ward. You will have a cannula in your hand which will be used to give you s antibiotics after the operation which help to reduce the risk of post operative infections.

Some discomfort will be experienced following the operation so pain relief medication will be g to help ease the discomfort. You may have an intravenous drip in your hand to give you fluids a antibiotics after the operation. An antibiotic is given before the operation and sometimes for 24 after the operation to help reduce the risk of post-operative infection. The drip will be removed hours after surgery.

Post-operative pain relief

All operations which involve cutting the skin or muscle result in some pain. We work very hard t the amount of discomfort that you will feel after any procedure. It is rare to be able to complete remove all postoperative pain but we strive to reduce it to a level that is easily bearable.
We have a number of methods of achieving this, together with a team of specialist staff whose r help in the management of acute pain should it be needed.
An operation will inevitably result in some pain, however, pain can be a very different experienc person and the best way to treat it can be different as well. What you experience may not be th your family or friends.

The different types of pain relief include:

- **Tablets or syrup/liquid**
  You will need to be able to drink and not feel sick before taking these pain relief medicines. take 30-45 minutes to work and it is important that you take the medication before the pain too bad.

- **Injections**
  These can be used if you are not eating and drinking properly. They are given either into you or through a small needle just under the skin in your arm or thigh. These usually take 20 mir work.

- **Local anaesthesia**
  A one off dose of local anaesthetic medicine as an injection may be given in the anaesthetic before the operation starts, it may be done whilst you are awake or asleep. This will be discu with you by the anaesthetist prior to the operation. It will numb the area which is being ope on and will stay numb for a few hours after the operation ends. Other forms of pain relief de above will be used in addition to the local anaesthetic medication.

Post-operative exercises ;

It is essential that you commence the following exercises as soon as you can after your operation. These exercises replace the previous exercises that you were doing before your operation.

Exercise 1

After your operation it is very important that whilst you are not as mobile as usual, that you do deep breathing exercises, to try to prevent the occurrence of any chest infections. You can start this exercise yourself after your operation.

Sit upright in bed or your chair. Take a normal breath in through your nose, allowing the air to flow to the bottom of your lungs, so that your abdomen rises slightly on inhalation. Breathe out through your mouth. Repeat 5 times.

Follow this with 3 deep breaths, allowing your lungs to fully expand to their maximum capacity.
If you hear any secretions in your chest or throat, when doing your deep breaths then try to cough them up.
Repeat another 2 times. Do for 10 seconds every hour.

Continue this exercise daily until you are up and about as normal and your chest is normal 'for you'.

Please do this exercise on BOTH legs
Exercise 2

Start this exercise yourself, as soon as you can after your surgery. This exercise is very important as it can reduce your risk of getting a DVT. (Deep vein thrombosis).

Lie on your back or sit on your bed or chair.

Slowly move your toes and ankles away from you so that you are pointing your toes, then pull your toes and ankles up towards you – as far as you can.

Moving your ankles up and down like this is more effective at preventing a DVT than moving ankles round in circles. Do for 10 seconds every hour.

Please do this exercise on BOTH legs
Exercise 3

You can start this exercise yourself straight after your operation.

Lie on your back or sit up with your legs out straight in front of you on your bed.

Bend your ankle up and push your operated knee down firmly against the bed. Hold for 5 seconds.

Repeat 4 times, slowly every hour.

Exercise 4

This exercise is important as it helps to provide support to your new knee by strengthening your quadriceps (at the front of your thigh) muscles.

Lie on your back, or sit up with your legs out straight.

Exercise your operated knee by pulling your toes up, straighten your knee and lift your leg 10cm off the bed. Hold for approx 5 seconds, then slowly relax.

Repeat 2 times, every hour, until you can easily do this and then reduce to 2 every other hour.

Exercise 5

This exercise is very important as you need to ensure that your operated knee can go as straight as possible, to support you whilst you are walking.

Lie on your back, or sit up on your bed, with your legs out straight in front of you.

Place a rolled up towel or an exercise block under your ankle.

Relax your operated leg and try to allow the back of your knee to rest on the bed.

Rest in this position for 2 - 3 minutes every hour.
It will be quite uncomfortable, but getting a straight knee will help to prevent it from giving way whilst you are walking.

Exercise 6

This exercise is important as it helps to get your operated knee moving after your operation.

During your operation, your knee will have been in a flexed, (bent) position throughout most of the procedure. The surgeon will have checked that your knee does fully bend and straighten before the end of your operation. You now need to work hard to ensure that you can fully bend your knee yourself.

Sit with the heel of your operated leg on a plastic or wooden board or plastic bag.

Bend your knee as far as you can, by sliding your foot towards your bottom, along the slippery surface.

When you cannot bend your knee any further with your muscles, place your hands under your thigh to assist you to bend your knee further.

Hold your knee at the peak of the bend for a couple of seconds. This will feel painful.

Take your hands away and slowly straighten your knee. Repeat 6 times, slowly every 4 hours.

This exercise will be very painful. It will be less painful if you try to relax as much as possible whilst trying to bend your knee.

Please do this exercise on BOTH legs
Exercise 7

From the SECOND day after your operation, you can practice this exercise whilst you are sitting in your chair.

Pull your toes up, tighten the front of your thigh muscle on the operated leg and straighten your knee slowly. Hold for approx 5 seconds. Slowly release.

Repeat 6 times, every 4 hours.

When you are sat in your chair, you MUST ensure that your operated leg is placed up on a stool, fully straight at all times, unless you are doing these exercises.

Elevation will help to ease the swelling, which will make your exercises more difficult and could delay wound healing.

Exercise 8
You should also make sure that you massage your knee and thigh firmly in an upwards direction for a few minutes every hour. Do not massage directly over your dressing.

Mobility

If you normally use a stick/walking frame/elbow-crutches, please bring these with you to hospital as this will allow the physiotherapist to check them for safety and possible use after surgery. You will be assessed by the physiotherapist or physiotherapy assistant for a suitable aid to use after your surgery. This will normally be elbow-crutches and you will be provided with these.

As a general rule you will be allowed to walk on the day after your operation. Some patients will be able to get up out of bed to stand on the day of their operation. The staff will do this with you. Do not worry if this is not the case for you. You will be told as soon as possible when you will be able to get up. Do not attempt to get up after your surgery without the assistance of the staff.

At first, the physiotherapy team or nurses will help you to get yourself out of bed. You will be instructed on the use of crutches/walking aid and the correct way to walk. Once assessed by the physiotherapy team, you should then be able to walk as frequently as possible with the staff. The aim is to help you regain your independence with the crutches/walking aid as quickly as possible, allowing you to walk with minimum supervision or independently as soon as you are able to do so. The staff will tell you when you are safe to walk on your own. However, it is important to understand that you are all individuals and that the appropriate amount of help is given to you. 'Little and often' in walking and changing position is important. If your walking distance has been limited, it is best to gradually increase your distance and speed. Try to have a little walk every hour or so during the day.

Do NOT walk on your own until you have been advised that you are safe to do so, by a member of staff.

Exercise 9

Make sure that you try and have a short walk with your frame or crutches every hour during the day and the evening.

This will help to promote your mobility and strength and greatly reduces the risk of you developing a DVT. It will also help to reduce the risk of chest infections and pressure sores.

Do NOT walk on your own until you have been advised that you can do so, by the physiotherapists or nurses.

You should also continue to have short hourly walks around your house when you go home.

Getting ready for home

Your hospital stay may last about 2 days. Before you are able to go home you will need to meet several goals:

- Walk independently with your crutches/ frame.
- Bend your knee.
- Extend (straighten) your knee fully.
- Get in/out of bed and on/off the chair and toilet by yourself. The aim is to be able to get on/off. ordinary heights of furniture as this encourages you to strengthen your muscles and bend your knee.
- Be able to get up/down stairs if you need to be able to manage this at home.
- Do the prescribed home exercises regularly and independently.
- Have had a routine check x-ray of your new joint.

You will NOT be seen routinely by the occupational therapist. A referral to the ward occupational therapist can be made before you go home if a need is identified. The occupational therapist will then assess your needs.

The ward physiotherapist will arrange for you to attend your local hospital for further out patient physiotherapy. Your local hospital will contact you. The ward physiotherapist will give you more information on this when you are due to be discharged home.

The Surgeon, Physiotherapist or GP can advise you when it is safe to return to normal activities.

Medication

Pharmacy will supply you with any new medication that you have commenced whilst you have been in hospital. This will include any pain relief. Please ensure that this is what you have been taking whist in hospital. The nursing staff will check your medication with you.

- **DVT Prophylaxis** – whilst in hospital you will have commenced on medication to assist in the prevention of blood clots. This will be by tablet or injection. If you are on injectable medication the nursing staff will have assessed your ability to self inject. If you are unable to do so, they should have taught a relative or organised a District Nurse. If you were previously on, or have been started on warfarin you should have an anti-coagulant appointment booked prior to discharge. The ward staff will arrange this for you.
- **Antibiotics** – If you have an infection you may be discharged with a course of antibiotics. You will be informed of the course length on discharge. All antibiotics have side effects. If you feel you are unable to cope with these side effects please contact your GP.
- **Pain relief** – You will be sent home with a small supply of the pain relief that you have been taking in hospital. If you run out of pain relief, contact your GP prior to them running out.

Wound care

- Keep your wound area clean and dry. A dressing will be applied in the hospital and usually does not need changing. If it does the ward staff will tell you how to arrange this.
- The dressings are water resistant so you may have a quick shower but do not bathe until until your wound is dry and the sutures or staples have been removed, usually two weeks after your surgery. You will be referred to the district nurse for removal of your sutures or staples. The district nurse at your local practice may phone you to discuss your suitability to visit the treatment room,

rather than visit you at home. The nurses on the ward will give you a paper copy of the referral; thi will include a date your first appointment is required. The nurses on the ward should also provide you with any equipment the district nurse will need.

- Notify your doctor/ district nurse if your wound appears red, begins to drain fluid or you have an increased temperature.
- Swelling is normal for the first three to six months after your surgery. Continue with your exercises elevate your leg slightly. If you are concerned about the amount of swelling that you have, then speak to your GP or Out-Patient Physiotherapist.
- Your stitches or clips will be removed by the GP or practice nurse approximately 12 -14 days after your operation.

Once at home

Please remember you have undergone major surgery and your recovery can take up to 12 months. It i very important that you follow these guidelines when you return home:

- Continue to take the pain relievers or anti-inflammatories as prescribed to you once you go home to enable you to exercise effectively and manage your pain and swelling. It is common for other joints in your operated leg such as your ankle, hip and even your lower back to become a little ach due to the changes in your overall posture. If in doubt, please speak to your physiotherapist for advice, or your contact your GP.
- Keep your operated leg elevated whilst sitting, to help reduce the swelling and minimize the amount of time spent in one position.
- Make sure that you continue to have short hourly walks.
- Gradually try to increase your walking distance. Walk a little and often throughout the day.
- Try to walk at least once every hour but be guided by your own limitations
- Your Physiotherapist will advise you on how long you need to use your crutches for. They will progress you onto a stick when you ready. Continue to use the stick – in the opposite hand for as long as you continue to have a limp. When you no longer walk with a limp, you can start to wean yourself off your stick, by walking without it for short distances.
- It will initially be difficult to carry items if using two crutches. You may be able to slide items along surface or use an over the body bag to carry items
- Wear sensible footwear.
- You must continue to do the exercises that you have been taught when you get home. Your operated leg may feel stiff each morning when you wake up. Do not worry about this; the stiffness should wear off, given time. Always exercise to achieve the bend that you had the previous day an then add a little bit more.
- Avoid crossing your legs as this may hinder your circulation and could predispose towards DVT.s
- Check with the ward prior to your discharge, regarding how long you need to continue to wear the compression stockings. Most consultants prefer that their patients wear them for up to 2 weeks post op. Some patients may have to wear them for longer. You need to wear them both night and d (except for up to an hour for washing). You will need assistance from another person to put them d
- Avoid sleeping with a pillow/cushion under your knee as this will cause extra stiffness in your knee and make it more difficult for you to straighten it.

- Observe your calves for any unusual symptoms such as swelling, pain, redness and heat. These symptoms may indicate a DVT. Report any of these symptoms immediately to your G.P.
- Most consultants do not allow their patients to drive until 3 months after the operation. Prior to driving for the first time, you need to ensure that you are no longer on strong pain relievers. You should be relatively painfree in your knee. You should also try sitting in your unstarted car and pressing on the appropriate foot pedal firmly to see if that causes any pain. If so, this is too soon for you. You are advised to contact your insurance company after your operation before you start driving.
- There are post op restrictions on sporting activities. These include no contact sport for 12 months, no jogging for 6 months, no light sport for 3 months and no swimming for 6 weeks.
- A healthy diet and not smoking will help to promote wound healing and overall recovery.

Out-patient Appointments

Your out-patient appointments are all from the date of surgery. Your follow-up appointment may be carried out by a specialist nurse, registrar or your consultant. Please note that all follow up appointments will take place at the Orange Reception, Blackpool Victoria Hospital.

If your appointment is not given on discharge, you should receive it within two weeks. If for any reason you do not receive an appointment through the post, please contact ward 15A, Monday to Friday, between the hours of 8am and 4pm.

Your ward physiotherapist will also arrange for you to attend outpatient physiotherapy. The physiotherapy staff will discuss this with you prior to your discharge home.

Useful Websites;

Other useful information can be found at the following websites;
www.nhs.uk/
www.nice.org.uk/guidance
www.arthritisresearchuk.org/
www.helpdirect.org.uk/
www.ageuk.org.uk/
www.gov.uk/government/publications/the-eatwell-guide
www.bda.uk.com/foodfacts

Research

Research is undertaken to add to the existing scientific knowledge on a particular subject. There are a number of staff within the Trust who conduct Research studies. It is possible that during the course of your treatment you may be asked to take part in a research study, however, you do have the right to refuse, and this will not affect the care that you receive.

Useful contact details

Hospital Switchboard: **01253 300000**

Patient Relations Department

The Patient Relations Department offer impartial advice and deal with any concerns or complaints the Trust receives. You can contact them via:

Tel: **01253 955589** or by Email: **bfwh.PALS@nhs.net**

You can also write to us at: **Patient Relations Department, Blackpool Victoria Hospital, Whinney Heys Road, Blackpool FY3 8NR**

Further information is available on our website: **www.bfwh.nhs.uk**

References

This leaflet is evidence based wherever the appropriate evidence is available, and represents an accumulation of expert opinion and professional interpretation.

Details of the references used in writing this leaflet are available on request from: **Procedural Document and Leaflet Coordinator 01253 953397**

Options available

If you'd like a large print, audio, Braille or a translated version of this booklet then please call: **01253 955588**

Together we care

Our Four Values:

People Centred	Positive
Compassion	Excellence

Health & care information you can trust

The Information Standard

NHS Blackpool Teaching Hospitals NHS Foundation Trust

Author: Catherine Bennett **Approved by:** Orthopaedic Directorate Meeting
Reference No: BTH315 - PL/434 (V3) **Date of Publication:** 07/09/2018 **Review Date:** 01/09/2021

Appendix 4

Blackpool Victoria Hospital Total Knee Replacement Physiotherapy Protocol

Total Knee Replacement Physiotherapy Protocol
All Consultants

Day of Surgery; (POD0)

- Plan to mobilise out of bed on afternoon of op day (POD0) –if on the morning theatre list.
- Check op notes for clarification of procedure.
- Pre part- fill in the out patient referral card, including phone no, GP etc in anticipation of their D/C.
- Check anaesthetic notes – to denote type of anaesthetic – (usually spinal with no diamorphine).
- Do post anaesthetic , pre mob mobility checks, to ensure that the spinal has worn off sufficiently to mobilise.

Post Anaesthetic, Pre Mobility Checks

1. Power in lower limbs and pelvis – include bridging and trans abs.
2. Sensation of lower limbs and pelvis.
3. Observations – esp BP

- Mobilise out of bed, usually fully weight bearing. Allow the pt to flex their knee over the edge of the bed when getting up, but do not encourage excessive repeated flexion on PODO.
- Sit out into chair, with leg elevated in full knee extension on stool. Advise to always use foot stool.
- Check pt can SLR – advise not to do excessively on PODO.
- Advise can mobilise independently if safe – and not to mobilise independently if not safe.
- Refer to OT if elderly and live alone.
- Complete Tracker and book.

POD1;

- Mobilise FWB as able, aiming for the patient to be safe independently on ECs by the end of the day. – or independently on RF if not ready for ECs – the majority of patients should be on ECs by the end of POD1.
- Aim for the patient to be out of bed for about 8 hours. (if the patient goes back to bed for some reason, they need to get back up later again, if medically fit)
- Practise chair/bed exercises and deep breathing exercises – refer to the exercises and goals in the TKR booklet.
- Aim for independent SLR – or minimal assistance.
- Aim for active flexion > 65 – 70’ – with minimal new, wound ooze
- Aim for extension with heel hangs, < -10’
- Skin test for ice and apply if appropriate.
- Check the patient’s social and pre op situation.

- Ensure that patient understands short term and long term goals and aiming for LOS of 2 – 3 days where possible.
- Ensure that all patients are marked 'in progress' on the ward tracker'.
- See 2 -3 times/day – if fully staffed.
- Complete Tracker and book.

POD2 onwards;

Aim for home, if patient achieves the following goals;

- Medically fit for discharge.
- Independent with SLR or controlled Quads through ROM – especially terminal extension.
- Active flexion > 80'
- Extension as close to 0 as possible. D/W Drs if exn > -10'
- Mobilising safely independently with ECs or RF – as appropriate to home circumstances.
- Practised step/stairs if required and can manage safely – alone or with assistance, as appropriate to home circumstances.
- Continue to see 2 – 3 times a day until patient achieves the above.
- Complete Tracker and book.

On D/C;

- Send out patient physio referral to BTH physio reception – and date in the book.
- Ensure that patient is aware of their physiotherapy out patient appointment and where it will be.
- Provide with Physiotherapy patient satisfaction survey.
- Discharge from ward tracker.

Note;

- Patients can be D/C home on POD 1 if they meet al.,l the criteria above on POD1 and their doctors are aware and happy for D/C.
- Patients will not be referred to 'rehab', simply because they live alone! Patients will be assessed on an individual basis and may be D/C directly home with earlier community support where possible.

Driving;

- Right TKR; At least 8 weeks
- Left TKR, Clutch controlled car; Six weeks
- Left TKR; Automatic car; As soon as sutures are out, pt is not on strong analgesia and can comfortably get in and out of the car.

Permitted Activities after 3 months;

(Check with senior medical team on an individual basis)

- Walking

- Hiking
- Golf
- Ballroom dancing & light modern
- Swimming - crawl for legs rather than breast stroke
- Cycling
- Elliptical machines
- Low resistance weight training
- Doubles tennis
- Rowing
- Bowling
- Cross country skiing

Activities NOT Recommended;

(Check with senior medical team on an individual basis)

- High impact sports/dancing/aerobics/jumping.
- Aerobics
- Football
- Running
- Squash
- Rock climbing
- Singles tennis
- Downhill skiing
- Weight lifting
- Vibration/power plates in the gym

Staffing Levels;

- Full staffing for our 12 bedded elective ward, is 2 members of staff/day – about 15 - 16hrs / day.
- Most days there is cover until 5pm/5.30pm, (depending on which staff are covering each day).
- Safe staffing levels allow all patients to be seen 2 – 3 times/day, if fully staffed and for the first two theatre patients of the day to be assessed for mobilisation on PODO.

Appendix 5

Ethics Documents

Appendix 5.1 Health Research Authority Acknowledgement Letter

NHS
Health Research Authority

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8081

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

13 November 2018

Professor James Richards
University of Central Lancashire
School of Health Sciences
Brook Building
PR1 2HE

Dear Professor Richards

Study title:	**Does the use of an Ortho-Glide device improve patient reported outcomes following total knee replacement?**
REC reference:	**18/YH/0401**
Protocol number:	**N/A**
IRAS project ID:	**235931**

Thank you for your letter of 12th November. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 November 2018

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Orthoglide Covering Letter]		12 November 2018

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Orthoglide Covering Letter]		12 November 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCLan Insurance Doc]		11 September 2018
GP/consultant information sheets or letters [Letter to GP]	1.0	02 May 2018
Instructions for use of medical device [Ortho-Glide Product Instructions]	unknown	01 August 2018
IRAS Application Form [IRAS_Form_19092018]		19 September 2018
Letter from funder [MDTi Letter of Support]	1.0	29 August 2018
Non-validated questionnaire [Numerical Pain Rating Scale]	1.0	31 July 2018
Non-validated questionnaire [Exercise Adherence Rating Scale]	1.0	31 July 2018
Other [Orthoglide IPA]		11 April 2018
Participant consent form [Orthoglide Consent Form 4.0]	4.0	07 November 2018
Participant information sheet (PIS) [Orthoglide PIS 4.0]	4.0	07 November 2018
Research protocol or project proposal [Orthoglide Protocol 2.0]	2.0	20 October 2018
Response to Additional Conditions Met		
Summary CV for Chief Investigator (CI) [Jim Richards CV]	1.0	29 August 2018
Summary CV for student [Robyn Jones Research CV]	1.0	04 June 2018
Summary CV for supervisor (student research) [Dr Ambreen Chohan CV]		11 September 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Orthoglide Protocol 2.0]	2.0	20 October 2018
Validated questionnaire [Knee Injury and Osteoarthritis Outcome Score]	unknown	31 July 2018

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/YH/0401	Please quote this number on all correspondence

Yours sincerely

Katy Cassidy

E-mail: nrescommittee.yorkandhumber-bradfordleeds@nhs.net

A Research Ethics Committee established by the Health Research Authority

Appendix 5.2 Health Research Authority Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor James Richards
University of Central Lancashire
School of Health Sciences
Brook Building
PR1 2HE

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

13 November 2018

Dear Professor Richards

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Does the use of an Ortho-Glide device improve patient reported outcomes following total knee replacement?**
IRAS project ID:	**235931**
Protocol number:	**N/A**
REC reference:	**18/YH/0401**
Sponsor	**University of Central Lancashire**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Prof. StJohn Crean
E-mail irassponsor@uclan.ac.uk
Telephone 01772 89 2735

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **235931**. Please quote this on all correspondence.

Yours sincerely

Catherine Adams
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Prof. StJohn Crean*
Ms Helen Spickett, Blackpool Teaching Hospitals
Robyn Jones, Blackpool *Teaching Hospitals*

Appendix 5.3 UCLan Ethics Approval

27 November 2018

Jim Richards / Robyn Jones
School of
University of Central Lancashire

Dear Jim /Robyn

Re: STEMH Ethics Committee Application
Unique reference Number: STEM 952

The STEMH ethics committee has granted approval of your proposal application 'The Orthoglide Study - Does the use of an Ortho-Glide device improve patient reported outcomes following total knee replacement?'. Approval is granted up to the end of project date*. It is your responsibility to ensure that

- the project is carried out in line with the information provided in the forms you have submitted
- you regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify EthicsInfo@uclan.ac.uk if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use e-Ethics Closure Report Proforma).

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely

Karen A. Rouse

Karen Rouse
Chair
STEMH Ethics Committee

* for research degree students this will be the final lapse date

NB - Ethical approval is contingent on any health and safety checklists having been completed, and necessary approvals as a result of gained.

Appendix 5.4 Email Confirmation of Approval from Blackpool Teaching Hospitals Clinical research Centre

From: FINCH, Amanda (BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST)
Sent: 15 November 2018 10:40
To: JONES, Robyn (BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST)
Cc: SPICKETT, Helen (BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST); jrichards@uclan.ac.uk
Subject: IRAS 235931. Confirmation of Capacity and Capability at Blackpool Teaching Hospitals NHS Foundation Trust

Dear Robyn,
Full Study Title: The Orthoglide Study; does the use of an Ortho-Glide device improve patient reported outcomes following total knee replacement?
This email confirms that Blackpool Teaching Hospitals NHS Foundation Trust has the capacity and capability to deliver the above referenced study. Please find attached our agreed Statement of Activities as confirmation.

We agree to start this study as previously discussed.

Please inform the R&D department when your study has finished recruitment.
Kind Regards
Amanda
Amanda Finch
Senior Clinical Trials Coordinator *(R&D)*
Clinical Research Centre
2nd Floor, Area 5, Blackpool Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool
Lancashire
FY3 8NR
☎ 01253 (9)51508 7 01253 (95)3038
✉amanda.finch2@nhs.net

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RESEARCH & DEVELOPMENT
TODAY'S RESEARCH | TOMORROW'S CARE

Appendix 6

Patient Information Sheet

Blackpool Victoria Hospital
Whinney Heys Rd
Blackpool
FY3 8NR
Tel: 01253 953512
Email: robyn.jones4@nhs.net
IRAS Project ID: **235931**

PATIENT INFORMATION SHEET

VERSION 4.0 – 07/11/2018

Study Title: Orthoglide Study – investigating patient reported outcomes of different rehabilitation devices following total-knee replacements.

A research project to investigate knee rehabilitation devices has been designed by Robyn Jones, a Chartered Physiotherapist working at Blackpool Victoria Hospital. The project is being undertaken as part of an MSc (by research) through the University of Central Lancashire with funding provided by Medical Devices Technology International (MDTi), a company who manufacture orthopaedic rehabilitation devices.

An Invitation to participate

We would like to invite you to participate in the Orthoglide Study.

You are being invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what is involved. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that you are unclear about or if you would like more information – the contact details of the research team can be found at the end of this document.

What is the purpose of the study?

This study aims to investigate the effectiveness of devices used to assist rehabilitation exercises following a total knee replacement. In particular we are going to investigate whether the use of one type of device shows improved results compared to another.

Why have I been asked to take part in the study?

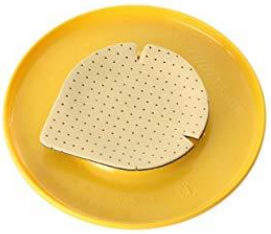
You have been invited to take part in this study because you have been identified as requiring a total knee replacement which will be performed at Blackpool Victoria Hospital.

Do I have to take part in the study?

It is up to you to decide whether to take part or not. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or the treatment that you are receiving.

What do I have to do as part of this study?
If you decide to participate in this study you will first be asked to sign a consent form. Once your consent has been gained you will be contacted by a member of the study team to answer some simple survey-style questions over the telephone, this should take approximately 25 minutes, a SMS text message may be sent to your phone as a reminder prior to us calling. These questions are related to how painful your knee is, how you manage with it during normal daily activities and how you manage with exercise.
Following this, participants will be split into 2 groups at random (randomisation) to determine which device you will be given to assist with exercises after surgery. You will not be required to do anything during this process and you will not be informed of which group you have been allocated into.
Following your procedure you will be seen by the Physiotherapy team on the ward and prescribed a number of standardised exercises to complete - these form part of standard protocol for knee-replacement rehabilitation and are not being altered for this study. One of these exercises is to bend and straighten your knee to help improve the range of movement in your new joint. Depending on which group you were allocated to during the randomisation process you will be issued with a different device to assist with this exercise, both devices perform the same function – making it easier to bend and straighten your knee by providing a low friction surface to slide your heel back and forth on. You will be seen by the Physiotherapy team atleast twice daily during your stay in the hospital and will be asked to continue with these exercises once you have gone home, this is the same for all patients, regardless of your participation in this study. Further instruction on the correct technique and number of repetitions to use during the exercises will be provided by the Physiotherapy team following your surgery.

The two devices that may be used are pictured below:



Please note that although the assistive device issued will vary between groups, the type of exercises you will complete and amount of times you will be seen by Physiotherapists will not vary – you will receive the same care as any other patient aside from the device used to facilitate the knee exercises.

Once you have been discharged home you will be contacted after 6 weeks and again at 12 weeks to answer the same survey-style questions as before the operation, as before it should take approximately 25 minutes to answer these questions and you may be sent a SMS text message as a reminder prior to us

calling. Once the telephone conversation at 12 weeks post-operation is complete we will have gathered all the required information and you will not be contacted again as part of the study aside from receiving a copy of the results by email or post (please see the relevant section below).

What are the possible benefits of taking part?
The purpose of this study is to investigate knee rehabilitation methods, it is therefore possible that you will experience some direct benefit from taking part in it.
The information gathered will also help in the treatment of future patients undergoing similar procedures.

What are the potential risks of taking part in the study?
There are no additional risks through participating in this study. Your personal data such as name, address and telephone number will not be passed on to any other parties and any information gathered will be made anonymous.

Will the study team access my medical records?
Yes, the study team will need to access your medical records. Primarily this will be to document your consent to take part in the study. Your medical records may also be accessed to determine the planned date of your surgery, hospital discharge date, your GP's address and relevant contact information. Access to this information will be for the purposes of the study only and confidentiality will be maintained at all times. This information will not be passed on to any other organisation or used for any purpose other than for this research project.

Will my taking part in the study be kept confidential?
Yes, any information about you that is shared with the Sponsor as part of this study will be anonymous. Your name and address will be removed from all information so that you cannot be recognized from it. The answers you give to questions will only be identifiable to the study team through use of an encryption key and on completion of the study all data will be made fully anonymous – it will then be impossible to identify you from it. All information about you will be handled in confidence. The study will also be carried out in accordance to Ethical and Research Governance Guidelines that are followed when completing any type of research within the NHS. If you decide to take part in the study your medical records and the data collected for the study will only be looked at by authorised persons from within the research team. In addition, your records may also be viewed by employees of the regulatory authorities to ensure that the study is being carried out correctly. Your GP will be informed of your involvement with the study by letter; however, no additional data will be shared with them. Please see the relevant section for information on data protection.

What will happen if I want to withdraw from the study?
You may withdraw from the study at any point up to the final follow-up call at 12 weeks post-surgery. If you choose to withdraw we will continue to use any anonymised data collected up to your withdrawal but will not contact you about the study from this point forward.
A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or the treatment that you are receiving.

Data Protection
The University of Central Lancashire (UCLan) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCLan will not keep identifiable information about you once the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting Robyn Jones (Chartered Physiotherapist, Blackpool Victoria Hospital) on 01253 953512 or robyn.jones4@nhs.net.

Blackpool Teaching Hospitals NHS Foundation Trust will collect information from you and your medical records for this research study in accordance with our instructions.

Blackpool Teaching Hospitals NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to UCLan. Blackpool Teaching Hospitals NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from UCLan and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UCLan will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Blackpool Teaching Hospitals NHS Foundation Trust will keep identifiable information about you from this study for no more than 3 months after this study has finished (estimated to be March 2020).

What if there is a problem?
If you are concerned at any point about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can contact the Orthoglide Study Team at the hospital on 01253 953512 or the supervisory team at UCLAN on 01772 89 4575.

If you remain unhappy and wish to complain formally through the NHS complaints procedure, you can contact the **Patient Advice and Liaison Service (PALS) at the hospital on 01253 955588**. Complaints may also be lodged with the UCLan officer for ethics on 01772 892735.

If you have been harmed or injured as a result of taking part in this study, or due to someone's negligence relating to this study, then you may be entitled to take legal action and/or claim compensation. UCLan has taken out an insurance policy for study related injuries in patients participating in the study. Insurance is provided
Allianz Insurance plc, policy number SZ21703420.

What will happen to the results of the study?
Once the results of the study have been reviewed and analysed by the research team a written summary of the project will be made available to all participants and other stakeholders.

It is possible for a copy of the research results to be sent to you by email or post once the information gathered has been formally written up. On the consent form there is a section to state your preferred method of receiving the results. Alternatively, a copy may be requested by emailing Robyn.Jones4@nhs.net. Please note that the written summary of the results is not expected to be available until April 2020.

On completion of the trial the results of the research will be the property of the Sponsor. They may choose to present the results at a medical conference or publish the research results in a medical journal - As previously mentioned all data will be anonymous and it will be impossible to identify you from any published or presented literature.

Who can I contact for further information?
For further information regarding the study you can contact:

- Robyn Jones (Chartered Physiotherapist, Blackpool Victoria Hospital)
  Telephone: 01253 953512
  Email: robyn.jones4@nhs.net

Thank you for taking the time to read this information

Appendix 7

Participant Consent Form

Blackpool Teaching Hospitals NHS
NHS Foundation Trust

INFORMED CONSENT FORM

Version 4.0 – 07/11/2018

Patient Research Identification Number:

Name of Researcher: Robyn Jones

Title of Research: **Orthoglide Study (**IRAS Project ID: **235931)**

Please Initial b

I confirm that I have read and understand the information sheet dated the 07/11/2018 (version 4.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, sponsor (UCLan), regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

I understand that the research team and all other individuals involved in this project are bound by strict confidentiality and data protection laws including the General Data Protection Regulations (2018) and will only access information required for this study from my medical records, specifically the date of my planned surgery, my GP and contact details. ☐

I agree to take part in the above study which includes being contacted by telephone before my surgery, 6 weeks afterwards and again at 12 weeks, with each conversation taking around 25 minutes. ☐

I agree that I will adhere to the rehabilitation exercises prescribed to me by the Physiotherapy team. ☐

Once analysed and written would you like to receive a copy of the results of this study? Please select the appropriate box below:

Yes ☐ No ☐

If you selected 'yes' how would you like the results to be sent to you? Please select from the options below:

By Email ☐

By Post ☐

Please provide the email/postal address you would like the results sent to:

……

……

……

Name of Patient	Date	Signature

Preferred contact number of patient

……..

Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 8

Outcome Measure Scoring Sheet

EARS Score				
		Pre-op Scores	6 Week Post-op	12 Week Post-op
1	I do my exercises as often as recommended	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
2	I don't get around to doing my exercises	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
3	I do most, or all of my exercises	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
4	I do less exercise than recommended by my healthcare professional	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
5	I fit my exercises into my regular routine	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
6	I forget to do my exercises	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree	0 - completely agree 1 2 3 4 - completely disagree
	Total:			

Scored using a 5-point Likert scale (0 = completely agree to 4 = completely disagree) with a possible summed score range from 0 to 24.

KOOS Score				
Symptoms - These questions should be answered thinking of your knee symptoms during the **last week**				
		Pre-op Scores	6 Week Post-op	12 Week Post-op
1	Do you have swelling in your knee?	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always
2	Do you feel grinding, hear clicking or any other type of noise when your knee moves?	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always
3	Does your knee catch or hang up when moving?	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always
4	Can you straighten your knee fully?	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always
5	Can you bend your knee fully?	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always	Never Rarely Sometime Often Always
Stiffness - The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.				
		Pre-op Scores	6 Week Post-op	12 Week Post-op
6	How severe is your knee joint stiffness after first wakening in the morning?	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
7	How severe is your knee stiffness after sitting, lying or resting **later in the day**?	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Pain				
		Pre-op Scores	6 Week Post-op	12 Week Post-op
8	How often do you experience knee pain?	Never Monthly Weekly Daily Always	Never Monthly Weekly Daily Always	Never Monthly Weekly Daily Always
What amount of knee pain have you experienced the **last week** during the following activities?				
9	Twisting/pivoting on your knee	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
10	Straightening knee fully	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme

11	Bending knee fully	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
12	Walking on flat surface	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
13	Going up or down stairs	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
14	At night while in bed	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
15	Sitting or lying	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
16	Standing upright	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Function, daily living The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.				
17	Descending stairs	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
18	Ascending stairs	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.				
19	Rising from sitting	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
20	Standing	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
21	Bending to floor/pick up an object	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
22	Walking on flat surface	None Mild Moderate Severe	None Mild Moderate Severe	None Mild Moderate Severe

		Extreme	Extreme	Extreme
23	Getting in/out of car	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
24	Going shopping	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
25	Putting on socks/stockings	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
26	Rising from bed	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
27	Taking off socks/stockings	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
28	Lying in bed (turning over, maintaining knee position)	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
29	Getting in/out of bath	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
30	Sitting	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
31	Getting on/off toilet	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.				
32	Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
33	Light domestic duties (cooking, dusting, etc)	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Function, sports and recreational activities The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.				
34	Squatting	None Mild Moderate	None Mild Moderate	None Mild Moderate

		Severe Extreme	Severe Extreme	Severe Extreme
35	Running	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
36	Jumping	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
37	Twisting/pivoting on your injured knee	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
38	Kneeling	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Quality of Life				
39	How often are you aware of your knee problem?	Never Monthly Weekly Daily Constantly	Never Monthly Weekly Daily Constantly	Never Monthly Weekly Daily Constantly
40	Have you modified your life style to avoid potentially damaging activities to your knee?	Not at all Mildly Moderately Severely Totally	Not at all Mildly Moderately Severely Totally	Not at all Mildly Moderately Severely Totally
41	How much are you troubled with lack of confidence in your knee?	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
42	In general, how much difficulty do you have with your knee?	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Total:				

NPRS	
How would you describe your pain on a scale from 0 to 10, with 0 being no pain and 10 being the most severe pain possible, whilst at rest?	
And whilst completing the knee bending exercises given to you by the Physiotherapist? On a scale from 0 to 10, with 0 being no pain and 10 being the most severe pain possible?	

Appendix 9

Participant Randomisation List

A Randomization Plan

from

http://www.randomization.com

1. Physiotherapy_____
2. Orthoglide_____
3. Orthoglide_____
4. Physiotherapy_____
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60. Orthoglide_____

60 subjects randomized into 6 blocks
To reproduce this plan, use the seed 1216
along with the number of subjects per block/number of blocks
and (case-sensitive) treatment labels as entered originally.
Randomization plan created on 22/11/2018, 13:20:31

Appendix 10

Mean Outcome Measure Scores and Differences between Groups at Baseline, Six weeks and 12-weeks post-TKR

Appendix 10.1 Summary of Outcome Measure Scores and Differences Between Groups at Each Data Collection Point

Outcome Score	Pre-operative			Six weeks post-op			12 weeks post-op		
	Ortho-Glide	Standard Physiotherapy	Difference	Ortho-Glide	Standard Physiotherapy	Difference	Ortho-Glide	Standard Physiotherapy	Difference
KOOS Aggregate	**40.04**	**36.34**	**3.7**	**64.45**	**58.76**	**5.69**	**75.19**	**72.28**	**2.91**
Significance of difference	**N/A**			**N/A**			**N/A**		
KOOS Symptoms	**42.62**	**41.07**	**1.55**	**63.96**	**67.5**	**3.54**	**76.65**	**78.57**	**1.92**
Significance of difference	**N/A**			**N/A**			**N/A**		
KOOS Pain	**43.59**	**41.15**	**2.44**	**69.44**	**69.72**	**0.28**	**79.27**	**80.04**	**0.77**
Significance of difference	**N/A**			**N/A**			**N/A**		
KOOS ADL	**49.51**	**44.48**	**5.03**	**74.33**	**64.41**	**9.92**	**86.2**	**79.77**	**6.43**
Significance of difference	**N/A**			**MCID (Lyman et al., 2018)**			**N/A**		
KOOS Sport & Recreation	**10**	**8.44**	**1.56**	**28.64**	**18.5**	**10.14**	**38.85**	**38.54**	**0.31**
Significance of difference	**N/A**			**MCID (Roos & Lohmander, 2003)**			**N/A**		
KOOS QoL	**22.08**	**15.23**	**6.85**	**55.11**	**45**	**10.11**	**62.02**	**53.13**	**8.89**
Significance of difference	**N/A**			**MCID (Lyman et al., 2018)**			**MCID (Lyman et al., 2018)**		
EARS	**17.73**	**17.94**	**0.21**	**20.18**	**18.3**	**1.88**	**19.77**	**18.6**	**1.77**
Significance of difference	**N/A**			**N/A**			**N/A**		
NPRS at Rest	**3.87**	**4.56**	**0.69**	**1.82**	**1.7**	**0.12**	**1.15**	**0.7**	**0.45**
Significance of difference	**N/A**			**N/A**			**N/A**		
NPRS during Exercise	**6.33**	**6.88**	**0.55**	**4.45**	**4.3**	**0.15**	**3.46**	**2.6**	**0.86**
Significance of difference	**N/A**			**N/A**			**N/A**		
			Key:	**Better Score**					
				Worse Score					

Appendix 10.2 Summary of Differences, and Significance of Difference, of KOOS Scores between Each Data Collection Point

	Baseline – 6 Weeks Post-op		Baseline – 12 Weeks Post-op		6 Weeks to 12 Weeks post-op	
	Ortho-Glide	Standard Physiotherapy	Ortho-Glide	Standard Physiotherapy	Ortho-Glide	Standard Physiotherapy
KOOS Aggregate	**24.41**	**22.42**	**35.15**	**35.94**	**10.74**	**13.52**
Significance of Difference	**MCID**	**MCID**	**MCID**	**MCID**	**MCID**	**MCID**
KOOS Symptoms	**21.34**	**26.43**	**34.03**	**37.5**	**12.69**	**11.07**
Significance of Difference	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID**	**MCID**
KOOS Pain	**25.85**	**28.57**	**35.68**	**38.89**	**9.83**	**10.32**
Significance of Difference	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID**	**MCID**
KOOS ADL	**24.82**	**19.93**	**36.69**	**35.29**	**11.87**	**15.36**
Significance of Difference	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID**	**MCID, SCB**
KOOS Sport & Recreation	**18.64**	**10.06**	**28.85**	**30.10**	**10.21**	**20.04**
Significance of Difference	**MCID**	**MCID**	**MCID**	**MCID**	**MCID**	**MCID**
KOOS QoL	**33.03**	**29.77**	**39.94**	**37.90**	**6.91**	**8.13**
Significance of Difference	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**MCID, SCB**	**N/A**	**MCID**
Key:	MCID/SCB: KOOS Aggregate = >10/ N/A (Roos & Lohmander, 2003) KOOS Symptoms = >9/ >21 (Lyman et al., 2018) KOOS Pain = >8/ >22 (Lyman et al., 2018) KOOS ADL = >9/ >15 (Lyman et al., 2018) KOOS Sport & Recreation = >10/ N/A (Roos & Lohmander, 2003) KOOS QoL = >8/ >23 (Lyman et al., 2018)		Greater Difference		Lesser Difference	

Appendix 10.3 Summary of Differences, and Significance of Difference, of NPRS at Rest and NPRS during Exercise Scores between Each Data Collection Point

	Baseline – 6 Weeks Post-op		Baseline – 12 Weeks Post-op		6 Weeks – 12 Weeks Post-op	
	NPRS at Rest	NPRS during Exercise	NPRS at Rest	NPRS during Exercise	NPRS at Rest	NPRS during Exercise
Ortho-Glide Group	**2.05**	**1.88**	**2.72**	**2.87**	**0.67**	**0.99**
Significance of Difference	**MCID**	**N/A**	**MCID**		**N/A**	
Standard Physiotherapy Group	**2.86**	**2.58**	**3.86**	**4.28**	**1.0**	**1.7**
Significance of Difference	**MCID**		**MCID**		**N/A**	
Key:	Greater Difference		MCID = difference >2 (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011)			
	Lesser Difference					

Appendix 10.4 Summary of Differences, and Significance of Difference, between NPRS at Rest and NPRS during Exercise Scores at Each Data Collection Point

	Baseline			6 Weeks Post-op			12 Weeks Post-op		
	NPRS at Rest	**NPRS during Exercise**	**Difference**	**NPRS at Rest**	**NPRS during Exercise**	**Difference**	**NPRS at Rest**	**NPRS during Exercise**	**Difference**
Ortho-Glide Group	3.87	6.33	2.46	1.82	4.45	2.63	1.15	3.46	2.31
Significance of Difference	MCID			MCID			MCID		
Standard Physiotherapy Group	4.56	6.88	2.32	1.7	4.3	2.6	0.7	2.6	1.9
Significance of Difference	MCID			MCID			N/A		
Key:	Greater Difference			MCID = >2 (Farrar et al., 2001, Childs et al., 2005, Michener et al., 2011)					
	Lesser Difference								

Appendix 11

Estimated Marginal Means

	Estimated Marginal Means			
Outcome Measure	Ortho-Glide	Standard Physiotherapy	Difference	Significance of Difference
KOOS Aggregate	**59.89**	**55.79**	**4.1**	
KOOS Symptoms	**61.08**	**62.38**	**1.3**	
KOOS Pain	**64.10**	**63.64**	**0.46**	
KOOS ADL's	**70.01**	**62.89**	**7.12**	
KOOS Sport & Recreation	**25.83**	**21.82**	**4.01**	
KOOS QoL	**46.41**	**37.79**	**8.62**	MCID (Roos & Lohmander, 2003, Lyman et al., 2018)
EARS	**19.23**	**20.48**	**1.25**	
NPRS at Rest	**2.28**	**2.32**	**0.04**	
NPRS During Exercise	**4.75**	**4.59**	**0.16**	
Key:	Greatest Difference			
	Least Difference			