DEVELOPING A STANDARDISED PRE-OPERATIVE PHYSIOTHERAPY PROGRAMME TO IMPROVE THE OUTCOMES OF PATIENTS UNDERGOING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION IN RIYADH (KSA)

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Abstract

Background: Anterior cruciate ligament (ACL) injury is associated with pain, limited function and reduced quality of life (QoL), with prevalence associated with sports participation, which represents a clinical and financial burden to patients and healthcare systems. ACL reconstruction is the main treatment and pre-operative physiotherapy potentially plays a role in preparing patients for surgery and improves post-surgery health outcomes. Its effectiveness on patients' health outcomes pre- and post-surgery and awareness of patients and healthcare professionals have not been investigated in the Kingdom of Saudi Arabia (KSA). There is a lack of standardised protocols used in practice for pre-operative physiotherapy management of patients undergoing ACL reconstruction, and the clinical and financial effects have not been investigated.

Aims: This thesis aims to develop a standardised pre-operative physiotherapy programme for patients undergoing ACL reconstruction based on clinical and literature evidence, and to investigate the effectiveness of the developed protocol in KSA.

Methods: This study included three inter-related phases. **Phase 1** - a survey of the prevalence of ACL injury in Riyadh, KSA, and of pre-operative physiotherapy awareness of healthcare professionals and ACL-deficient patients. A sample of 200 patients and 200 practitioners was surveyed and the Ministry of Health and 3 hospitals were contacted about ACL injury cases. **Phase 2** - a systematic review of literature on pre-operative physiotherapy programmes and effectiveness in ACL injury management. **Phase 3** - a quasi-randomised clinical trial of a standardised pre-operative protocol, using Phase 1 and 2 findings. This protocol was administered to ACL-deficient patients undergoing reconstruction in KSA. Two patient groups were included: an intervention group (n = 39), who received the developed pre-operative programme; and a control group (n = 45), who did not receive pre-operative physiotherapy. The primary outcome measures were based on the Knee injury and Osteoarthritis Outcome Score (KOOS), and secondary outcomes included range of motion, quadriceps and hamstring muscle strength, health status (using the EQ-5D-5L tool), pain score, QoL and resource use.

Results: Phase 1 showed ACL injury is the most prevalent knee related injury (53%), with young, active participants being mostly affected (60%). The prevalence in Riyadh (31 per 100,000) was similar to international figures. 82% healthcare professionals were aware of pre-operative physiotherapy, whereas 55% of surveyed patients were aware. **Phase 2** suggested that pre-operative physiotherapy is beneficial to ACL injury patients. **Phase 3** demonstrated that primary and secondary outcomes were improved prior to surgery in the intervention group compared to baseline ($p < 0.01$). Post-surgery outcome measures were better in the intervention group than the control group ($p < 0.05$) except function in sports activity, which was similar. The incremental cost-effectiveness ratio (ICER) related to pre-operative physiotherapy intervention was estimated at 13449 SR (£2241) per QALY gained and the intervention was cost-effective.

Conclusions: The findings showed the clinical and cost-effectiveness of the developed, evidence-based pre-operative protocol in preparing patients for ACL reconstruction and improving health outcomes post-surgery. Therefore, pre-operative physiotherapy for ACL injury should be integrated routinely into the Saudi healthcare system.

Declaration

No portion of this work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institution of learning.

Dedication

This thesis is dedicated to my parents, family and my wife

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List of Abbreviations

ACL	Anterior cruciate ligament
ADL	Activities of daily living
ADLS	Activities of daily living scale
AKP	Anterior knee pain
ATT	Anterior tibial translation
BMI	Body mass index
BSc	Bachelor of science
CI	Confidence interval
CKC	Closed kinetic chain
CSA	Cross-sectional area
EQ-5D-5L	EuroQol 5-dimension 5-level survey tool
HHD	Hand-held dynamometer
ICER	Incremental cost-effectiveness ratio
IQR	Inter-quartile range
kg	Kilogramme
KOOS	Knee injury and Osteoarthritis Outcome Score
KSA	Kingdom of Saudi Arabia
K-SES	Knee self-efficacy scale
LCL	Lateral collateral ligament
m	Meter
MAFbx	Muscle atrophy f-box
MCL	Medial collateral ligament
MHLC	Multidimensional Health Locus Of Control
MIC	Minimum important change
MRI	Magnetic resonance imaging
n	Sample size
N	Newton
OKC	Open kinetic chain
p	Probability
PCL	Posterior cruciate ligament
PEDro	The Physiotherapy Evidence Database
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality-adjusted life year
QoL	Quality of life
QWB	Quality of Well-Being
RCT	Randomised controlled trial
RHCL	Reflex hamstring contraction latency

ROM	Range of motion
RTA	Road traffic accident
SD	Standard deviation
SLR	Straight leg raising
SPSS	Statistical Package for the Social Sciences
SR	Saudi Riyal
TAS	Tegner activity scale
VAS	Visual analogue scale
VIKDE	Vicon Interfaced Knee Displacement Equipment
χ^2	Chi-squared
%	Percentage

Chapter One: Introduction

1.1 Background to the Study

Anterior cruciate ligament (ACL) is one of the main static and functional stabilising structures of the knee (Margo et al., 2010). It creates the connection between the femur and the tibia, and serves to prevent anterior translation of the tibia relative to the femur (Rumian et al., 2007). As a consequence, ACL rupture can lead to a considerable loss of knee function and disability, and therefore, a reduction in a person's quality of life (QoL), and as such, has serious clinical and economic consequences (Keays et al., 2006; Mather et al., 2013). Furthermore, these detrimental issues have the tendency to persist for a patient in the absence of the application of appropriate treatment (Bach et al., 1998; McGinty et al., 2000). Therefore, it is imperative to understand that early diagnosis and effective management of an ACL injury are important, as the effects upon health are duly considered (Cimino et al., 2010; Mather et al., 2013).

In most studies that relate to ACL injuries, it has been shown that this form of injury is very common in individuals who have continued active participation in sports, which generally affect young and active individuals in the majority of cases (von Porat et al., 2004; Lyman et al., 2009). Accordingly, it has been highlighted that the action of playing football, in particular, on a regular basis is seen to be one of the main causes of

injury (Lohmander et al., 2007; Waldén et al., 2011). Nonetheless, other sports which have commonly been associated with a high ratio of incidence in regards to ACL injuries include American football, basketball and skiing (Orchard and Seward, 2001; Bradley et al., 2002).

As a particular case in point, the prevalence of ACL injury has been estimated to stand at approximately 30 cases per 100,000 of the American population as a whole (Csintalan et al., 2008), with an estimated 100,000-200,000 new cases each year (Huston et al., 2000; Griffin et al., 2000; Baachs and Bonoos, 2001; Evans et al., 2014). As a consequence, this high elevation in incidence leads to the necessity of approximately 100,000 reconstruction surgeries being undertaken annually in the USA alone (Griffin et al., 2000; Grindstaff et al., 2006). Yet, the prevalence of ACL injury in the Saudi Arabian population, which is the focus of the current study, is still unknown, as there has been a failure in adequate documentation and reports, although the total incidence of the injuries that are associated with football in general have been reported to be high in Saudi Arabian athletes (AlMutawa et al., 2013).

In particular, it is true that football is a very popular sport throughout the world (Waldén et al., 2011) and is particularly popular amongst young cohorts of the Saudi Arabian society as a whole, with approximately 33% of active youngsters within the country partaking in this sport in the Kingdom of Saudi Arabia (KSA) (Al-Refaee and Al-Hazaa, 2001). Nevertheless, for a more complete scope to the issue, it is imperative to provide a fully detailed report of all varieties of athletes in the country in relation to ACL injuries. As a result, additional research that is required in order to assess the prevalence and

epidemiology of ACL injuries, as well as to implement an investigation into its main causes in the context of Saudi Arabia.

In general, the main clinical features of ACL injury include: knee instability, a deficiency in balance, a reduction in muscle strength, impaired proprioception and a reduction in the range of motion (ROM) (Huston and Wojtys, 2000; Keays et al., 2003; Trees et al., 2011). Moreover, swelling, which has the tendency to occur in the early stages following a sustained injury, can subsequently lead to an increase in intra-articular pressure that is felt in the knee which then results in increased levels of pain and a reduction in ROM, together with impaired functional capacity for an individual (Cimino et al., 2010). As a result of pain and disability, patients are usually known to present with feelings of anxiety and reduced QoL (Lohmander et al., 2007). Hence, when the problems continue to persist, it is documented that knee-related symptoms can eventually lead to long-term impairments, such as muscle atrophy and sometimes osteoarthritis (Lohmander et al., 2007).

In addition, ACL injury can have serious detrimental economic consequences that affect both the patients and the healthcare system of that particular country (Mather et al., 2013). Meanwhile, it has been determined that overall, economic effects are commonly associated with the management of the injury, which are related to the direct costs; and there is also a distinct measure of productivity loss and claims as a result of temporary disability, which relate to indirect costs (Mather et al., 2014). Therefore, there have been useful protocols set in place in order to provide two management options for the occurrence of ACL injuries (Cimino et al., 2010). Firstly, it is possible for ACL reconstruction, which is mostly favoured by those who are young and active; and

secondly, patients have the opportunity for focused physiotherapy rehabilitation, which additionally comes with the option of delayed surgery. In accordance, it is known that non-operative physiotherapy can be used in the management process of ACL injury, although to provide a patient with the implementation of physiotherapy, ACL reconstruction is reported to be the most effective intervention formulation procedure in order for patients to return to their pre-injury levels of activity (van Grinsven et al., 2010).

The costs of managing ACL injuries were recently estimated in an American study on cost-effectiveness in the USA healthcare system and were reported to range from $38,000 to $88,500 per patient (Mather et al., 2014). Indeed, there have been conclusive reports that the higher end of the estimated cost ratio is generally associated with physiotherapy that results in delayed surgery (Mather et al., 2014). As a consequence, ACL reconstructions in their entirety across the country have been reported to cost the healthcare system in the USA over $7 billion per year, while the figure is distinctly elevated in relation to the focus on physiotherapy with optional surgical management which actually costs over $17 billion per year to the health service (Mather et al., 2013; Mather et al., 2014). Nonetheless, up to the present day, the economic burden of ACL injuries and its pre-operative management have not yet been investigated in the context of Saudi Arabia. It is imperative to provide an assessment of the cost-effectiveness of the treatment, as this can be of considerable importance in the evaluation of potential interventions and resource allocation that will result in the improvement of health outcomes for individual patients who are suffering from ACL injuries (Cohen et al., 2010).

Different research studies have defined pre-operative physiotherapy as a vital process that works by improving the functional ability of patients in order to enable them to cope with a physically stressful procedure, which could come in the form of surgery (Ditmyer et al., 2002; Shaarani et al., 2013). Interestingly, the role of physiotherapy through the process of preparing patients for ACL reconstructive surgery that creates an improvement in their knee function had been suggested originally in the early 1980s (Noyes et al., 1983). However, awareness about such an intervention amongst patients and healthcare professionals in Saudi Arabia is yet to be investigated. Awareness of health professionals in relation to pre-operative physiotherapy and its benefits are necessary for the progress of referrals to the physiotherapy department, which may increase the beneficial patient outcomes through this intervention (Acharya et al., 2011). Likewise, this also can lead to an increase in awareness from patients, who in turn, will provide a greater level of compliance with pre-operative physiotherapy once they have been referred to the service (Maruf et al., 2012). However, overall awareness in regards to such a form of intervention amongst patients and healthcare professionals in Saudi Arabia has yet to be investigated in any form of conclusive presentation.

As stated previously, the benefits of this pre-operative physiotherapy on the overall post-operative outcomes for patients were first proposed in the 1980s, and these originally included a reduction in the total amount of pivot shift episodes, alongside the enhancement of knee function recovery (Tegner et al., 1986). However, to date minimal research has been conducted to assess the effectiveness of pre-operative physiotherapy in restoring knee function and improving patient health outcomes following ACL reconstruction. Likewise, no studies have been undertaken that have examined pre-

operative physiotherapy treatment or its effectiveness in the context of Saudi Arabia. Furthermore, evidence within literature suggests that there is a lack of standardised protocols for pre-operative physiotherapy.

In general, the few studies that have examined the proposed benefits of pre-operative physiotherapy in patients undergoing ACL reconstruction unfortunately contain a minimal level of content. Yet, the studies that have presented explanations have shown conflicting findings and evidence that requires to be synthesised, and as such, it is difficult to establish the effectiveness of pre-operative physiotherapy as an intervention (Keays et al., 2006; Hartigan et al., 2009; Eitzen et al, 2010; Frobell et al., 2010; Shaarani et al., 2013). Therefore, an evidence-based pre-operative physiotherapy management protocol that can be adapted for the specific different needs of individual patients is required to formulate a process. This will be implemented in order to examine the proposed benefits of this specific intervention on the patients' health outcomes, which will be compared and contrasted both prior to and following ACL reconstruction in order to analyse the effectual changes.

The current study aims to utilise past studies from outside of Saudi Arabia in order to advance the understanding and formulate a beneficial protocol of effective pre-operative physiotherapy within the country. Indeed, the studies that previously investigated the effectiveness of pre-operative physiotherapy have been conducted in Western countries and due to a variety of cultural differences that can often be prevalent, the findings of these analysed studies may have restricted minimal relevance or impact upon a study that focuses on the benefits for Saudi Arabian patients. Therefore, the required protocol needs to be tailored around the needs of these patients, and hence, clinical data from

Saudi Arabian patients are required, in addition to literature evidence, which will be utilised in order to develop a protocol in the relevant context.

1.2 Aims and Objectives of the Study

1.2.1 Primary aim

The main aim in the current study is to develop a standardised, evidence-based pre-operative protocol and evaluate its effectiveness on a sample of patients with ACL injury in a clinical setting through the use of a range of outcome measures.

1.2.2 Secondary aims

1. To investigate the prevalence of ACL injury in the population of Riyadh, Saudi Arabia.
2. To investigate the awareness of healthcare practitioners in the KSA in relation to pre-operative physiotherapy treatment for ACL injury.
3. To investigate the awareness of patients with ACL injury in the KSA in relation to pre-operative physiotherapy treatment.
4. To conduct a systematic review in order to examine the current level of evidence in relation to the effectiveness of pre-operative exercise physiotherapy on the outcomes of treatment following ACL injury.

5. To assess the cost-effectiveness of pre-operative physiotherapy in a sample of patients with ACL injury in KSA.

1.3 Structure of the Study

The process described in the current study is conducted in three inter-connected phases:

Phase 1 is a survey conducted in a clinical setting in order to investigate the prevalence of ACL injury and the awareness of patients and healthcare professionals regarding pre-operative physiotherapy. The methodology used in the current study was through implementing a questionnaire survey method, and the study was conducted in Riyadh, which is the capital city of Saudi Arabia. The study investigated the prevalence of ACL injury in Riyadh, alongside the level of awareness of healthcare professionals (orthopaedic surgeons and physiotherapists) and patients in relation to pre-operative physiotherapy management of ACL injury. Overall, the details of the clinical survey are presented and discussed in Chapter Four.

Phase 2 is a systematic review undertaken in order to identify published evidence in relation to the effectiveness of different pre-operative physiotherapy programmes for patients who are undergoing ACL reconstruction. This was intended to be used, along with the clinical evidence collected in Phase 1, as a means to develop an appropriate standardised pre-operative physiotherapy programme for patients undergoing ACL reconstruction in KSA. As a consequence, based on the systematic review, the physical exercise content and the duration and frequency of the pre-operative physiotherapy

intervention were determined. The full details of this phase are evaluated in Chapter Five.

Phase 3 is a pragmatic controlled trial that is utilised in order to test the developed protocol based on Phases 1 and 2 in a clinical setting. Through this process, primary and secondary outcome measures were determined at baseline, pre-surgery and post-surgery. Additionally, through this phase, the economic burden of ACL injury in KSA, as well as the cost-effectiveness of pre-operative physiotherapy as an intervention, were also duly assessed. The overall details of the study conducted in this phase are presented and discussed in Chapter Six.

1.4 Outline of the Thesis

The work conducted in this thesis is presented in eight individual chapters.

Chapter 1 is an introductory chapter that includes a general background and outline to the study, as well as details of the aims and objectives of the investigation.

Chapter 2 presents the background to ACL injuries in general and describes the anatomy of the knee, including ACL structure and function, in addition to the mechanism, clinical features, prevalence and economic burden of ACL injury. Furthermore, the treatment options for potential ACL injuries are also briefly described.

Chapter 3 describes the management of ACL injuries and includes potential forms of diagnosis and treatment. Moreover, ACL reconstruction and physiotherapy are described

in the chapter and followed by an evaluation of their cost-effectiveness. Likewise, awareness in regards to physiotherapy treatment is also investigated in this chapter.

Chapter 4 details a clinical survey that investigates the prevalence of ACL injury in the city of Riyadh, KSA, and the awareness of patients who present with ACL injuries, as well as the awareness of their treating practitioners in regards to pre-operative physiotherapy management. The chapter also includes the recommendations of the surveyed healthcare professionals in relation to the pre-operative physiotherapy protocol.

Chapter 5 presents a systematic review of the literature, which examines the effectiveness of pre-operative exercise physiotherapy on patient health outcomes following an ACL injury.

Chapter 6 reports a pragmatic clinical trial to investigate the effectiveness of pre-operative physiotherapy in the treatment of ACL injuries. A pre-operative physiotherapy protocol was designed based on clinical and literature evidence and was tested in a clinical setting on patients who were to undergo ACL reconstruction in Riyadh, KSA. Moreover, the primary and secondary outcome measures were assessed and utilised in the investigation into the effectiveness of the programme and cost-effectiveness of pre-operative physiotherapy intervention.

Chapter 7 discusses the findings from all the three previous chapters and links them to the wider literature. In addition, the limitations of the study are also discussed in this chapter.

Chapter 8 summarises the findings of the current study and also evaluates the implications of the findings and recommendations for practice, policy and future research.

1.5 Summary

It is evident that ACL injuries are common in young, active individuals, as this trend is associated mainly with active participation in sports. Consequently, this form of injury presents major health and economic burdens to individual patients and the state. Accordingly, these issues have been evaluated previously in other countries, especially in Western culture, although they have yet to be investigated within the context of Saudi Arabia.

The main management options that are utilised to improve the problems associated with ACL injuries include ACL reconstructive surgery and physiotherapy rehabilitation with the option of delayed surgery. Although the role of pre-operative physiotherapy had been suggested previously, the effectiveness of such an intervention is yet to be assessed in relation to Saudi Arabian patients undergoing ACL reconstruction. This may be due to the fact that there is presently a distinct lack of standardised pre-operative protocols. Consequently, the evaluation of clinical data is required in the process in order to develop an evidence-based pre-operative protocol, which will then be used to evaluate the clinical and cost-effectiveness of such a form of intervention through the use of suitable outcome measures.

The following chapter provides an overview of the anatomy of the knee joint, the structure and function of the ACL, the clinical features ACL injury and its epidemiology, before concluding with a brief description of the main treatment options with the economic implications of the injury and its management.

Chapter Two: Anterior Cruciate Ligament Injury

2.1 Introduction

This chapter provides an overview of the structure and function of the anterior cruciate ligament (ACL) and associated structures and explores the main theories in relation to ACL injury. The chapter provides details of the anatomy of the knee, including ACL structure and function, in addition to the mechanisms, clinical features and prevalence of the injury. Subsequently, it concludes by providing a brief description of the available management options for ACL injury, including surgical ACL reconstruction and physiotherapy rehabilitation, as well as the economic burden associated with the injury.

2.2 Anatomy and Biomechanics of the Knee

The knee joint is the largest and most complex joint in the human body and bears the majority of a person's overall body weight (McGinty et al., 2000). Consequently, injuries that occur to the knee joint can cause considerable functional impairment and disability, and therefore, to understand its structure is an essential component of

studying knee injuries, including ACL rupture, and the necessary treatment that follows (McGinty et al., 2000; Solomon et al., 2001).

The osseous anatomy of the knee is described as an inclusion of four bones: femur, tibia, fibula and patella (Figure 2.1). Attached to these bones are four main ligaments: the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL), as well as the medial and lateral collateral ligaments.

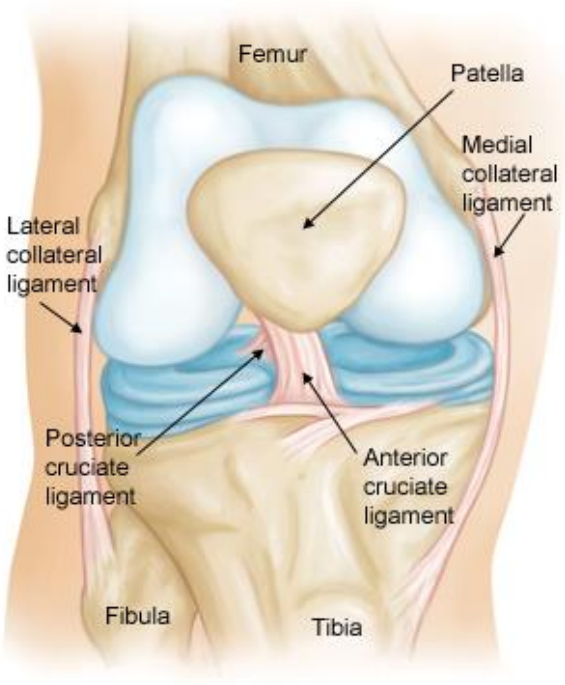


Figure 2.1. A schematic of a normal knee joint showing the intact anterior cruciate ligament (Reproduced with permission from AAOS, 2009)

The ACL connects the posterior part of the inner surface of the lateral femoral condyle, which runs anteromedially and distally to the tibial attachment. This structure runs diagonally, although this is in the opposite direction that is in front of the PCL, and is

known as a primary stabiliser to the knee joint in the sagittal plane (Duthon et al., 2006). In functional terms, the ACL is the main static and functional stabilising ligament in the knee joint against anterior translation of the tibia in relation to the femur (Matsumoto et al., 2001; Liu-Ambrose, 2003; Rumian et al., 2007; Margo et al., 2010). Furthermore, a secondary function of the ACL stems from its restriction of internal and valgus rotation of the tibia when the knee joint is at full extension (Masouros et al., 2010). It has been suggested through clinical observation that the activity level of the patient is directly affected by the partial or complete loss of function to the ACL (Imran et al., 1998). It is true that the ACL is known to be a vital stabiliser to the human knee joint and is actually the primary restraint to anterior tibial translation (ATT), while it is also the secondary restraint in relation to internal tibial rotation (Zantop et al., 2007).

There have been various studies that have detailed and investigated ACL anatomy, which have shown the ACL to be distinguished into 2 distinct functional bundles (Petersen et al., 2006). Firstly, there is the anteromedial (AM) bundle, which has fibres that stem from the most proximal section of the femoral origin and subsequently become inserted on the anteromedial part of the tibial insertion section; and secondly, the posterolateral (PL) bundle, which has fibres that stem from the most distal area of the femoral origin that subsequently become inserted into the posterolateral part of the tibial insertion site (Petersen et al., 2006). Through a combination of these bundles and in response to anterior tibial loads and combined rotatory loads, the AM and PL bundles create stabilisation of the knee joint in a synergistic manner (Zantop et al., 2007). Additionally, the ACL has a band-like structure composed of dense connective tissue

(Duthon et al., 2006; Rumian et al., 2007). Figure 2.1 above shows a schematic of a normal knee joint that highlights the position of the ACL.

The PCL is responsible for static stabilisation against posterior translation of the tibia on the femur (Margo et al., 2010). Moreover, the medial and lateral collateral ligaments play two roles; their primary role is static stabilisation against knee valgus stress and knee varus stress, respectively. Meanwhile, as a secondary role, the medial and lateral collateral ligaments assist the ACL and PCL, respectively, in their roles of restraining anterior and posterior translation of the tibia relative to the femur (Margo et al., 2010; Masouros et al., 2010).

In addition, there are two menisci in the knee joint: the medial meniscus, which is C-shaped, and the lateral meniscus, which is almost circular in shape. The peripheral surface of the menisci has a convex and thick structure and is attached to the peripheral border of the inner knee capsule, whereas the inner surface is thin and concave and has a free surface (Margo et al., 2010). The two menisci deepen the surface of the plateau of the tibia for articulation with the femoral condyles, and the meniscal structure is composed mainly of collagen (75% of solid structure) and non-collagenous material, mainly glycosaminoglycans (Margo et al., 2010; Makris et al., 2011). In accordance, the two menisci play an important role in static stabilisation of the knee joint through load bearing and transmission, shock absorption and lubrication. As a result, this support helps to protect the knee from different forms of forces, which include shear, compression and tension (Makris et al., 2011). The medial meniscus can also play a role in anteroposterior stabilisation of the knee in patients with ACL deficiency (Margo et al.,

2010). However, meniscal tearing frequently accompanies ACL injury, especially in regards to sports related cases (Kurosaka et al., 2002; Makris et al., 2011).

2.3 Muscles of the Knee

The muscles of the knee are commonly classified according to their anatomical position situated around the knee joint and placed into four distinct groups, even though the full function of the knee is defined through the overlapping motion combinations of these groups. Thus, the specific groups that are found around the knee joint cannot function autonomously. Yet, it must be noted that from an individual perspective, the quadriceps muscles (the rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius) are the main muscles of the anterior portion of the knee (Kary, 2010). Meanwhile, the pes anserinus (sartorius, gracilis, and semitendinosus) and the semimembranosus muscles constitute the medial portion and are the main dynamic medial stabilisers (Satterwhite, 1996). Additionally, the posterior part of the knee contains the medial and lateral parts of the gastrocnemius and the plantaris muscles, while the lateral musculature of the knee includes the biceps femoris, iliotibial band, and popliteus muscles (Thompson, 2010). Indeed, from the knee's lateral musculature, the iliotibial band functions as a lateral stabiliser of the knee joint (Dutton, 2012).

In addition, based on their function within the lower extremities, all the muscles that are associated with the knee joint can also be classified into knee extensors, knee flexors and knee rotators. The knee extensor muscles include: the rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius, which make up the quadriceps muscles (Kary,

2010). Indeed, these muscles act as dynamic stabilisers of the knee (Rudolph et al., 2001). They act on the tibia, which causes it to translate anteriorly during knee extension, while the knee extensors can generate a force of more than 2000 Newtons during maximal concentric contractions, which could consequently cause a rupture to the ACL (Woo et al., 1991). Moreover, in the absence of an ACL, a strong extensor force during knee extension could result in the tibia being shifted anteriorly, which could in turn destabilise the knee (Rudolph et al., 2004). In one specific investigation, it was shown that the weakness in a person's quadriceps was often profound in the population of ACL-deficient 'non-copers'; who are defined as individuals who do not compensate well for the injury (Williams et al., 2005). It was found that in the 3 month period following the injury and after undergoing rehabilitation, the average quadriceps strength of the affected leg was 75% compared to that of the unaffected leg (Williams et al., 2005). Even though the strength of the quadriceps femoris is directly related to the functional outcome of the knee, it is not possible to use merely the strength of the quadriceps alone to fully characterise the stability of the knee following an ACL rupture (Rudolph et al., 2001). Thus, it is important to consider the role of the knee flexors in counteracting these forces and their contribution to the dynamic stability of the knee.

The knee flexors include semitendinosus, semimembranosus and biceps femoris, which are known collectively as the hamstring muscles (De Smet and Best, 2000; Masouros et al., 2010). The hamstring muscles play a role in dynamic stabilisation of the knee, and assist the ACL in its role of actively preventing anterior translation of the tibia (Yanagawa et al., 2002). Accordingly, due to their ability to draw the tibia posterior in relation to the femur, the hamstring muscles become a potential knee stabiliser, as

contractions of the hamstring have been ascertained to create a reduction in the strain found upon the ACL, as well as decreasing anterior tibial translation simultaneously (Terese et al., 2002).

The hamstring muscles work to counterbalance the anterior force that is applied from the quadriceps on the tibia, which smooths the motion of the knee joint (Begalle et al., 2012). Thus, there are opposite applications to be found from the quadriceps and hamstring muscles, as they draw anterior and posterior forces upon the tibia, respectively (Bryant et al., 2008). Additionally, the sartorius and gracilis also assist with knee flexion, as the gastrocnemius muscle acts primarily as a plantar flexor of the foot, although it has an additional role as a weak flexor of the knee joint (Dutton, 2012).

The semitendinosus and the semimembranosus also act as medial rotators, while the biceps femoris functions as a lateral rotator of the knee (Terry and LaPrade, 1996). The popliteus muscle functions as a lateral or medial rotator of the knee depending on the position of the femur and tibia, as when the femur is free to move and tibia is fixed, this muscle acts as a lateral rotator. However, the popliteus muscle acts as a medial rotator when the femur is fixed and the tibia is free (Müller, 2012). This overall ability to create and implement a controlled degree of force through the function of precise and sensitive muscle activity is known as neuromuscular control (Williams et al., 2003).

The evaluation of the function of the knee in regards to neuromuscular control focuses on common tasks that are performed by the body. For instance, jumping, running and walking are potentially challenging activities, as they can be difficult to separate all the intricate biomechanical and neuromuscular reactions and systems that occur during the

process of these specific movements, which also relate to the functionality of the ACL and how it is affected. What is more, the voluntary neuromuscular control strategies that are utilised in the process of these activities create compensatory muscle actions in direct association with pathological knee motion, which comes from excessive anterior translation or rotation (Williams et al., 2003).

When neuromuscular function in the process of more general tasks is examined, for instance force production being controlled in isometric preparation, further insight into the strategies of voluntary muscle control may be enhanced in regards to post-ACL injury motion and movement. In one particular study, Buchanan and Lloyd (1997) provided an evaluation of the activity patterns for 10 different muscles that are fixed around the knee, which was undertaken by plotting electromyographic (EMG) data through opposite co-ordinates, while simultaneously describing the main load direction that occurred in each muscle, which Williams et al. (2003) stated to be necessary. Hence, this specific approach produced an established method in the study of strategies for neuromuscular control.

Therefore, structuring an examination similar to the one that was utilised by Buchanan and Lloyd (1997) helps to detail the muscle activation patterns of those people with ACL-deficient knees and may potentially provide beneficial insight into how an ACL injury has an effect upon the function of neuromuscular control. As a result, this acquired knowledge could provide valuable development in the process of treatment advancements for ACL injuries, as well as the development of programmes for rehabilitation, which specifically address neuromuscular function post-ACL injury (Williams et al., 2003). However, to fully understand the neuromuscular control function

in the knee joint, it is necessary to evaluate the entirety of the anatomy of the joint in relation to dynamic stabilisation, load bearing and shock absorption.

2.4 Causes and Mechanisms of ACL Injury

ACL injury is mainly associated with sports and leisure activities (Kobayashi et al., 2010). In athletes, for example, about 85% of all ACL injuries occur during training and competitions. Separately, road traffic accidents have also been reported to cause certain cases of ACL injury (Bispo et al., 2008). Kobayashi et al. (2010) classified the mechanism of ACL injury into contact and non-contact incidents (Table 2.1). In non-contact incidents, there is no contact with another person when the injury takes place. In contact incidents, there is contact with another person but on a body part, which is not a lower limb. In collision incidents, the load from physical contact is applied directly to the affected lower limb. Finally, accidents relate to particular situations that occur during sporting activities, such as falls during skiing, as well as motor accidents (Kobayashi et al., 2010). Table 2.1 provides details related to the most common causes and mechanisms of injury based on the type of contact with the body. Moreover, Figure 2.2 below shows a schematic of an ACL tear.

Overall, approximately 60% of ACL injuries are suggested to occur in non-contact incidents. Non-contact injuries include stopping after fast running; cutting to a different direction; and sudden deceleration prior to a change of direction or landing motion from a jump (Arendt and Dick, 1995; Boden et al., 2000; Agel et al., 2005). Sudden cutting to a different direction causes a significant strain on the ACL, which was not shown to be

reduced by the hamstring muscle, even at maximum contraction (Simonson et al., 2000; Colby et al., 2000). A proposed mechanism of non-contact ACL injury suggests that rotation of the tibia with forceful quadriceps muscle contraction in valgus position can cause the ACL to impinge on the femoral condyle leading to rupture of the ligament (Olsen et al., 2004).

Ireland (1999) identified a common mechanism of non-contact incidents, for which she used the term 'the position of no return'. This position is characterised by the loss of control at the level of the hip and pelvis, internal rotation of the femur, knee valgus, external rotation of the tibia, and external rotation of the foot in a pronated position. This position is especially pertinent in non-contact ACL injuries in female athletes who demonstrate increased external hip rotation in comparison to male athletes (Zeller et al., 2003).

Kobayashi et al. (2010) used video evidence to assess the dynamic alignment at the time of injury in over 1500 athletes and found out that the 'knee-in and toe-out' was the alignment most frequently associated with ACL injury in both male and female athletes (approximately 50% of all cases), regardless of the mechanism of injury. This suggests that conditions at the time of injury also need to be taken into consideration in order to further understand how ACL injury occurs. The authors go on to speculate that other factors, such as static knee alignment in relation to the rest of the body, knee range of motion (ROM) and lower limb muscle strength may have an effect on the dynamic knee alignment of the lower extremity of athletes at the time of injury.

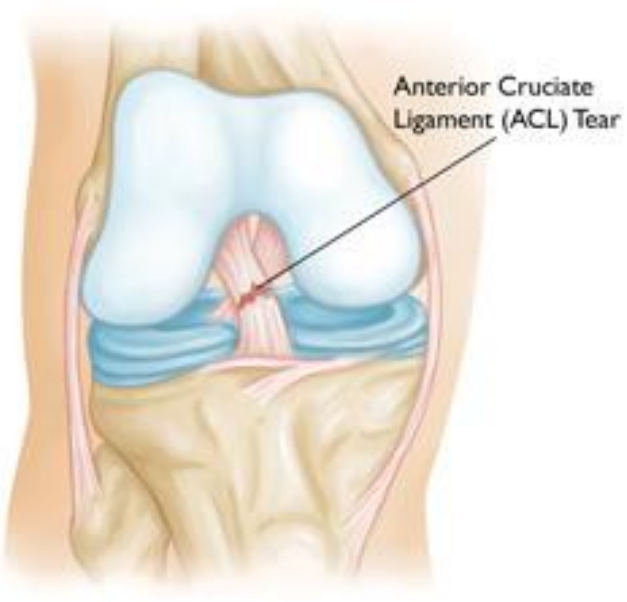


Figure 2.2. A schematic of an injured knee showing a torn anterior cruciate ligament (Reproduced with permission from AAOS, 2009)

By contrast, contact injuries account for approximately 40% of ACL injuries (see Table 2.1), and they generally occur when the knee joint is placed in valgus collapse following direct contact with another player. This is the most common contact ACL injury that can occur, as when the knee is placed in an external rotation with 10-30° knee flexion, the valgus knee position leads to a significant increase in the load that is applied to the ligament (Kobayashi, 1994; Teitz, 2001; Olsen et al., 2004; Kobayashi et al., 2010). Overall, the different forms of contact injury are divided into three distinct categories, which comprise contact in sports (13.7%), collisions (9.5%) and other accidents (16%) (see Table 2.1)

Table 2.1. The most common causes and mechanisms of ACL injury in athletes (adapted from Kobayashi et al., 2010)

Cause of injury (n = 1,718 athletes)		Mechanism of injury (n = 1,661 athletes)	
Competitions	49.20%	**Non-contact**	60.80%
		Contact	39.20%
Practice sessions	34.80%	**Contact categories**	
		Contact sports	13.70%
Leisure activities	8.50%	**Collisions**	9.50%
Other	7.50%	**Accidents**	16.00%

2.5 Prevalence of ACL Injury

In epidemiology, prevalence is a measure of how common a condition is in a certain population, whereas incidence signifies the rate at which new cases of a particular condition occur at a certain time (Shields and Twycross, 2003). In particular, ACL is the most affected ligament as a result of sports injuries, with young, active people being the most affected cohort (von Porat et al., 2004; Beynnon et al., 2005). Accordingly, several studies reported on the prevalence of ACL injury in different sports, including football (soccer), American football and other sports (Orchard and Seward, 2001; Bradley et al., 2002; Waldén et al., 2011). Football is considered the most popular sport globally with over 260 million active participants worldwide, 10% of whom are female (Waldén et al., 2011). It is therefore considered to be one of the main causes of sports related ACL injury, which explains the high prevalence of ACL injury in athletes, and specifically in footballers (Hawkins et al., 1999; Lohmander et al., 2007).

In a recent review that investigated the prevalence of ACL injury in professional football players in several European leagues, the prevalence of ACL injury ranged between 5 and 63 cases per 1000 players (Waldén et al., 2011). In particular, reports indicated that in professional football, the incidence of ACL injury in competitions is much higher than that in training, with an estimated rate of 2-70 new cases per 1000 hours of competitive play compared to less than 20 cases sustained in training through the same number of hours (Ekstrand et al., 1983; Arendt and Dick, 1995; Árnason et al., 1996; Waldén et al., 2011).

In a study carried out on 1012 patients in Sweden (Roos et al., 1995), ACL injuries accounted for 40% of all knee injuries sustained in football. This rate, however, was lower at approximately 19% in basketball (Arendt and Dick, 1995) and 22% of all reported knee injuries in skiing (Viola et al., 1999). These figures indicate that ACL injuries account for a significant proportion of knee injuries in sports. Other data report that approximately 70% of all ACL injuries are sports related (Griffin et al., 2000). Compared to literature on the prevalence of ACL injury in athletes, the population prevalence of this injury is less commonly reported due to the logistic difficulty of such studies that usually lead to underestimated population figures (Lohmander et al., 2007; Frobell et al., 2007). Accordingly, Table 2.2 below highlights example population prevalence figures of ACL injury per year in different countries. However, the population prevalence has yet to be investigated in the Kingdom of Saudi Arabia (KSA), and therefore, was identified as one of the gaps in current knowledge that relates to ACL injury in the Saudi Arabian society (see Chapter Four). The figures in Table 2.2 below

are based on in-hospital clinical or emergency unit diagnosis of ACL injury in those patients who sought healthcare (Lohmander et al., 2007).

Table 2.2. The annual population prevalence of ACL injury in different countries based on literature reports

Country	Annual population prevalence	Place of study	Period of study	References
USA	30 per 100,000 38 per 100,000[a]	Southern California area San Diego area	2001-2005 1985-1988	Csintalan et al., 2008 Miyasaka et al., 1991
Denmark	30 per 100,000 38 per 100,000[b]	City of Aarhus Nationwide study	1986 2005-2007	Nielsen and Yde, 1991 Lind et al., 2009
Sweden	81 per 100,000 78 per 100,000[c]	City of Helsingborg Nationwide study	2001-2002 2001-2009	Frobell et al., 2007 Nordenvall et al., 2012
New Zealand	37 per 100,000[b]	Nationwide study	2000-2005	Gianotti et al., 2009
Norway	34 per 100,000[b]	Nationwide study	2004-2006	Granan et al., 2008

[a] The prevalence of knee ligament injuries (including injuries to the ACL, PCL and collateral ligaments) during this period was 60 per 100,000 per year (Miyasaka et al., 1991) with ACL injuries accounting for 64% of these injuries

[b] Prevalence of ACL injuries that required ACL reconstruction surgery

[c] The injury was identified in the study (Nordenvall et al., 2012) as cruciate ligament injury and indicated by the authors as predominantly ACL injuries (> 97% of all cases)

In the USA, ACL injury is currently the most common injury in relation to the knee, which accounts for an estimated 30 cases per 100,000 of the population annually (Csintalan et al., 2008) leading to an incidence of approximately 100,000 new injuries every year (Griffin et al., 2000; Huston et al., 2000; Baachs and Bonoos, 2001). In fact,

Evans et al. (2014) estimated the incidence of this injury to be double the figure reported in the year 2000. Csintalan et al. (2008) reported that the USA population prevalence to have an ACL injury was based on patients aged between 12 and 85 years who sought healthcare and were diagnosed in hospitals. However, slightly higher annual population prevalence (38 per 100,000) was reported in the USA by Miyasaka et al. (1991). In that study, the majority of ACL injuries were caused by sporting activity (70%) and road traffic accidents accounted for only 6% of the cases.

Generally, the highest incidence of ACL injury was reported among younger active individuals (15-25 years of age) with high sporting participation (Griffin et al., 2000). Of the 100,000 new ACL injuries reported to occur in the USA annually, approximately 80,000 cases undergo reconstruction (Griffin et al., 2000), translating to 80% of all cases. Other countries, such as Denmark, New Zealand and Norway reported prevalence figures (30-38 cases per 100,000), which are similar to those found in the USA (Granan et al., 2008; Gianotti et al., 2009; Lind et al., 2009).

Higher prevalence was reported in Sweden at approximately 80 cases per 100,000 of the population, which was based on patients aged between 10 and 64 years (Frobell et al., 2007), and lead to approximately 5,000 new ACL injuries each year (Lohmander et al., 2007). A similar prevalence figure (78 per 100,000) was reported by a large nationwide study in Sweden that included nearly 57,000 patients (Nordenvall et al., 2012) in a period spanning nine years (2001-2009). The leading cause of these injuries was reported to be sports (75% of all cases), especially football (60% of sports related injuries) (Frobell et al., 2007). Additionally, national statistics in Sweden reported on

average 3,000 ACL reconstructions annually (Lohmander et al., 2007), which translates to 60% of ACL injury cases.

Separately, with the increasing participation of women in sports, reported figures indicate that the frequency of ACL injuries in female athletes is higher than that in males, with an incidence ratio of 2 to 9 (Nordenvall et al., 2014) that is mostly attributed to non-contact incidents (Kobayashi et al., 2010). Several studies suggest different reasons for this trend, which stem from anatomic, environmental, hormonal and biomechanical factors; however, the etiology of this injury trend is not well-understood (Griffin et al., 2000; Huston et al., 2000; Hewett et al., 2002). The higher risk in females is most likely multifactorial, with no one single factor being the predominant reason for the higher rates of ACL injury in females.

Amongst the most prevalent anatomic and physiological risk factors are related to an increased Q-angle, decreased femoral notch width, higher hypermobility and increased joint laxity (Griffin et al., 2000; Renstrom et al., 2008). Additionally, hormonal cycle changes were reported to alter ligament and muscle strength, and these have been suggested as possible contributing factors to the documented differences (Hewett, 2000; Renstrom et al., 2008). Nonetheless, data on the effects of hormonal changes on susceptibility to ACL injury are limited and controversial (Ford et al., 2003).

Neuromuscular imbalances associated with biomechanical factors include: ligament dominance, quadriceps dominance and lower limb dominance (Hewett et al., 2001). Ligament dominance occurs when the muscles in the lower limb do not sufficiently absorb forces during activity, which ultimately leads to excess load upon the knee

ligaments, especially the ACL; in this case, it plays a role in resisting anterior translation of the tibia and knee valgus motion (Ford et al., 2003). Moreover, quadriceps dominance is an imbalance in the recruitment of knee flexor and extensor muscles, with females normally relying on quadriceps muscles to maintain dynamic stability of the knee during sporting activity (Hewett et al., 1996; Huston and Wojtys, 1996). Leg dominance is an imbalance in muscle strength and patterns of recruitment between opposite lower extremities, with one limb constituting higher dynamic control (Knapik et al., 1991; Hewett et al., 1996). Accordingly, this reliance on one limb over the other tends to lead to more stress on the more capable knee, while the other may possess a lower ability to absorb forces associated with movements during sporting activity (Ford et al., 2003).

Evidence on the effects of biomechanical factors, however, remains to be a factor that is lacking due to the limited studies that support the significance of these differences (Kobayashi et al., 2010). Nevertheless, most studies emphasise that gender-associated differences in valgus knee motion during sports activities exist, especially during movements such as jumping and landing (Ford et al., 2003; Renstrom et al., 2008), and consequently, these differences may contribute to the higher incidence of non-contact ACL injury in females (Kobayashi et al., 2010). However, the current study focuses on ACL injury in males, which could subsequently be compared to other contrasting investigations relating to females.

2.6 Clinical Features of ACL Injury

The primary impairment following ACL injury is instability of the knee, or a 'giving-way' episode, which is demonstrated clinically by a pivot shift, and results in the patient experiencing difficulties in participating in sporting activities (Cimino et al., 2010). Secondary impairments include: a deficit in balance, reduced muscle strength, impaired proprioception and ROM of the knee joint as a result of limited knee function due to ACL injury (Corrigan et al., 1992; Wilk et al., 1994; Zätterström et al., 1994; Huston and Wojtys, 2000; Keays et al., 2003). As a result, a poorer degree of balance occurs as a direct result of the injured ACL mechanoreceptors, which consequently reflects upon an increase in sway, which has been shown through stabilometric studies to impact negatively on overall function (Terese et al., 2002).

In general, the disruption of the ACL can lead to functional impairment, meniscal damage and even gradual degeneration of the knee joint (Daniel et al., 1994). Moreover, it was stated by Jonsson et al. (2004) that the increased ATT and internal tibial rotation that occurs in a knee that is ACL-deficient can potentially be partially responsible for the consequential degenerative developments that occur in the knee joint. However, tears to the ACL do not often occur in an isolated manner, as more than 50% of these cases, which are defined as acute tend to occur in association with additional sprains to ligaments, as well as meniscal tears, articular cartilage injuries, bone bruises, and seldom intra-articular fractures (Beynnon et al., 2005). Approximately 60-70% of all ACL injuries are characterised with associated meniscal lesions and localised swelling almost immediately following the injury (Nagano et al., 2009).

The mechanism underlying meniscal tears typically involves cutting movements, hyperextension, twisting of the knee joint, or applying a heavy force on the knee (Greis et al., 2002). Haemarthrosis and swelling, which result in an increase in intra-articular volume, often present with ACL injury, resulting in pain and reduced ROM and functional mobility. As a consequence of pain, the patient commonly suffers from spasms of the hamstring muscles (Cimino et al., 2010). Meniscal tears may also cause a disruption in the arthrokinematics of the knee and can lead to difficulties in achieving full knee extension (Shelbourne and Rowdon, 1994). Subsequently, limited activity due to knee impairment and muscle disuse will commonly lead to muscle atrophy and joint instability in the affected lower limb (Trees et al., 2011).

Pain and loss of physical knee function are commonly associated with reduced quality of life (QoL) (Shapiro et al., 1996; McAllister, 2003) and psychological effects, such as fear of injury even post-recovery, which is most commonly reported in athletes (McAllister, 2003; Filbay et al., 2015). In a recent systematic review that investigated the effect of ACL injury and its management on the QoL in over 470 ACL-deficient patients (Filbay et al., 2015), eight out of 11 reviewed studies used the Knee injury and Osteoarthritis Outcome Score (KOOS) to measure QoL in patients. Hence, through the use of this outcome measure, the study reported a strong positive correlation between patients' QoL and pain (Spearman correlation test, $R = 0.86$, $p = 0.01$); symptoms including swelling ($R = 0.79$, $p = 0.02$); function in activities of daily living ($R = 0.79$, $p = 0.02$); and function in sports and recreation ($R = 0.74$, $p = 0.04$).

Therefore, it is suggested that there is a close associated between knee-related QoL and the clinical features of ACL injury, including pain, symptoms and knee function.

Additionally, the impairment of QoL may be long-term (5-25 years) following ACL injury, irrespective of operative or non-operative management (Filbay et al., 2015), which is generally due to joint degenerative complications, such as osteoarthritis.

It has, therefore, been suggested that a multidimensional patient outcome measure that includes QoL, in addition to knee-related function and overall patient activity, should be incorporated into the pre-operative patient evaluation leading to ACL injury management (Mohtadi, 1998; Calvisi et al., 2008). QoL is therefore an important patient outcome that can be used to measure the effectiveness of treatment interventions and provide information on the patients' perception of their own injury and treatment progress. Consequently, QoL was considered as an outcome measure in the current study (see Chapter Six).

In addition to its mechanical stabilising function, the ACL plays an important role in providing sensory information, mediating position perception and regulating threshold of motion detection in the knee joint (Johansson et al., 1991; Bonfim et al., 2003). Therefore, one of the underlying causes of the limited recovery of knee function following ACL injury has been suggested to be long-term motor and sensory deficits that can persist even post-treatment (Shiraishi et al., 1996; Jerosh and Prymka, 1996; Lephart et al., 1997).

Sensory deficits may persist due to the ligament being ruptured or replaced by a graft in the case of reconstructed knees, and thus, many of the original proprioceptors, mechanoreceptors and nerve connections are lost and unlikely to be restored to pre-injury levels (Bonfim et al., 2003). Hence, in the rehabilitation of patients who have

suffered from an ACL injury, there is growing emphasis that strength and motion impairments are not the only parts that need to be analysed, as proprioception or joint awareness is required to be evaluated and treated (Lephart et al., 1997). In fact, there is a decrease in proprioception following any ACL injury, and the anatomical structure may not fully recover following surgical reconstruction (Roberts et al., 1999).

In one particular study, Pap et al. (1999) measured proprioception in 20 ACL-deficient patients compared to an age-matched control group. Position sensing and movement detection was significantly impaired in ACL-deficient knees compared to the control group ($p < 0.01$). In addition, impairment of proprioception correlated strongly with diminished hamstring to quadriceps muscle strength ratios that were measured in the injured limbs ($p < 0.01$). Indeed, patients with lower strength in hamstring muscles compared to quadriceps muscles showed lower position sensing. Comparatively, this correlation was not observed in the control group or the intact knees in the test group (Pap et al., 1999).

Similarly, Zhou et al. (2008) also assessed the effect of ACL injury on proprioception in 36 ACL-deficient individuals in comparison to 13 adults who did not present with any specific knee injury, and the results showed that there was a significant difference ($p < 0.05$) between the reconstructed and control groups. The findings of these studies strongly suggest that hamstring/quadriceps muscle strength is related to proprioception. Furthermore, there was a direct linear correlation with proprioception 6 months following operation, which was measured and shown to be significant ($R = 0.71$, $p < 0.05$) (Zhou et al., 2008).

Beard et al. (1993) reported an increase in the latency in hamstring muscle reflex in 30 patients with ACL-deficient knees, as compared to their healthy limbs (99 milliseconds compared to 53 milliseconds, respectively). This differential increase in reflex contraction latency was used as a measure of proprioception and was shown to correlate with the frequency of 'giving-way' episodes ($p < 0.05$). The authors, therefore, recommended assessing proprioception in the process of measuring functional instability of the knee and to incorporate such information in the management ACL-deficient patients.

ACL injury does not only lead to mechanical instability of the knee joint due to damage to the ligament itself, but also causes neuromuscular disturbances, which are mainly due to the loss of sensory and mechanical receptors. Dhillon et al. (2012) argued that proprioception can be restored to some extent with ACL reconstruction; however, they warned that the results can vary from one patient to another. Using morphological and biochemical tests, remnants of the ACL were shown to contain functional proprioceptors and mechanoreceptors (Dhillon et al., 2010). These receptors may act as a source of innervation of the graft following reconstruction, although the number and the functional state of these receptors are dependent on the physical characteristics of the ligament at the time of ACL rupture and the duration of the injury (Dhillon et al., 2012).

Therefore, there is evidence to suggest that ACL injury is associated with knee-joint instability, known as 'giving-way' episodes, deficits in balance, proprioception, diminished muscle strength and knee ROM. Likewise, pain, haemarthrosis and swelling tend to happen immediately after the injury and lead to reduced mobility. Other clinical features that can occur with ACL injury include functional disability, meniscal tears and

degeneration of the knee joint, which usually lead to poor QoL. Consequently, treatment is required for ACL-deficient patients to alleviate the symptoms, regain knee function and stability, improve QoL and prevent long-term complications.

2.7 Physiotherapy and Reconstruction Theory for ACL Injury

The standard treatment following ACL injury that is recommended by surgeons is ACL reconstruction, as the ligament does not heal by itself in cases of complete rupture (Bach et al., 1998). Surgeons recommend reconstruction to restore stability and kinematics of the affected knee, as the injury might lead to degenerative changes, such as osteoarthritis, which could also affect the hip or ankle joint on the same side as a result of changes in the gait and weight bearing (Lohmander et al., 2007). Several factors can contribute to variable outcomes of the management of ACL injury. For example, obesity, smoking and concurrent joint conditions, such as chondrosis, were shown to be significantly associated with poorer patient outcomes, such as level of general activity and knee function, following ACL reconstruction (using mutivariate regression modelling for individual outcomes) (Kowalchuk et al., 2009).

Other treatment options include knee-related rehabilitation, which can be used as a non-operative option or in association with ACL reconstruction. In a randomised controlled trial that was conducted in Australia in order to assess the effectiveness of a specific pre-operative exercise programme on patients with ACL injury, orthopaedic surgeons were reported to recommend pre-operative physiotherapy treatment for patients with chronic ACL injury (Keays et al., 2006). In that particular study, it was found that

improvements occurred in relation to the strength of quadriceps for both speed and balance, while participants had their eyes closed. Similarly, the overall balance of these individuals improved significantly between the days of analysis for those with their eyes closed ($p < 0.001$), while a trend was also noted for the individuals who had their eyes open ($p = 0.036$). Moreover, a particular improvement in speed was highlighted for all tests ($p < 0.001$). Likewise, the ACL deficiency group who were treated demonstrated notable improvements in their strength of quadriceps, which measured at a mark of 60° and 120° per second ($p < 0.001$). Similarly, in another randomised controlled trial that was conducted in the USA that focused on investigating the efficacy of perturbation training in the treatment of ACL-deficient knees, physiotherapy management was shown to be effective in non-operative ACL injury treatment (Fitzgerald et al., 2000).

In 1983, pre-operative physiotherapy treatment was suggested to restore knee function prior to surgery (Noyes et al., 1983); however, a limited number of studies have attempted to investigate the effectiveness of pre-operative physiotherapy and its role in ACL injury management (Keays et al., 2006). Yet, it has been demonstrated that pre-operative physiotherapy treatment with intensive muscle strength exercises can reduce episodes of pivot shift ‘giving-way’, prevent further joint damage, improve post-operative outcomes, and in some cases, circumvent the need for surgery (Frobell et al., 2010). Hence, physiotherapy may serve to strengthen the muscles that support the stability of the ACL structure, although the process of strengthening muscles alone may not be adequate as proprioceptors and mechanoreceptors are also impaired by the ACL injury, while the effects of this impairment tend to be long-term (Dhillon et al., 2012). Therefore, it is suggested that strength training and proprioception training could be

beneficial on a mutual basis in the development of improvements to knee-related neuromuscular function through a positive correlation between proprioception and muscle strength (Zhou et al., 2008).

The effects of physiotherapy on non-operative ACL-injured knees were investigated by Chmielewski et al. (2005). That study found that following perturbation training, participants with ACL rupture had reduced co-contractions of quadriceps femoris-hamstring muscles and quadriceps femoris-gastrocnemius muscles and also normalised knee kinematics, thus more closely resembling non-injured participants. These findings seem to suggest that pre-operative physiotherapy with perturbation training may have an important role to play in improving muscle coordination. In line with these findings, a separate study by Zätterström et al. (1994), which investigated the effect of a 3-6 month physiotherapy programme on balance, showed that ACL-injured knees restored normal balance parameters 12 months post-physiotherapy treatment.

Two randomised controlled trials investigated the effectiveness of a specific pre-operative treatment versus standard treatment in the management of ACL injury. The initial study reported significant improvements in proprioception and knee function in a group of ACL-deficient patients who received proprioceptive enhancement treatment, when compared to those receiving muscle strengthening alone (Beard et al., 1994). Following this, the later study by Fitzgerald et al. (2000) showed that perturbation training combined with a standard physiotherapy programme has a significant role ($p < 0.05$) in decreasing the risk of ‘giving-way’ episodes and in maintaining knee function in athletes for an extended duration when compared to the use of only standard physiotherapy. However, another study suggested that there is a lack of evidence to

support one protocol of physiotherapy (non-operative, pre- or post-operative) over another, which raises concerns that exercise physiotherapy management is not always based on evidence (Trees et al., 2011). Hence, there is a requirement to synthesise the available evidence in order to examine the effectiveness of exercises that are focused on pre-operative physiotherapy rehabilitation in improving the outcomes of treatment following ACL injury. As a result, a systematic review was conducted as part of the current study (see Chapter Five).

2.8 Economic Burden of ACL Injury

ACL injury does not only have health-related effects on the patient (pain, disability, limited QoL, and psychological impact), it can also have separate economic and societal effects, some of which have long-term implications. Even though the direct economic burden of treatment (e.g. cost of medication, cost of surgery and rehabilitation sessions) in this population is fairly well-documented, the long-term, indirect effects on society (societal effects), such as loss of productivity and claims due to disability, have not been adequately reported (Mather et al., 2013).

Currently, the main two treatment options that exist in relation to ACL injury are surgical reconstruction and focused rehabilitation. Early reconstruction is widely used for young, active patients, whereas rehabilitation is typically preferred by older and lower-demand individuals (Mather et al., 2014). Additionally, two types of costs of ACL injury can be identified: direct costs (mainly costs of diagnosis and treatment) and indirect costs (lost wages, lost productivity, disability claims) (Mather et al., 2013). In

accordance, even though societal costs are related to both types, direct costs tend to be reported more often as they are easier to measure (Mather et al., 2013). Meanwhile, time taken off work due to ACL injury management, which translates to lost wages, is usually estimated to be on average 28 workdays that are missed due to ACL reconstruction and 40 workdays missed due to knee arthroplasty surgery. Furthermore, disability claims can be variable depending on the welfare system, the sex and age of patients. In total, the average annual disability payment ranged from $9,000 to $17,000 per claimant per year in the USA based on the 2011 Current Population Survey (Mather et al., 2013).

Considering these two different treatment options, short-term direct costs of early reconstruction are estimated to be $20,000 per patient compared to $21,500 associated with rehabilitation with the option of delayed reconstruction based on 2012 figures in the USA (Mather et al., 2014). However, when indirect long-term societal costs are considered, the average lifetime cost of the management of ACL injury becomes $38,000 per patient undergoing early reconstruction compared to $88,500 per patient for rehabilitation with delayed reconstruction. This translates to an economic burden of $7.6 billion each year for reconstruction and $17.7 billion for rehabilitation in the USA. Other long-term complications also represent a considerable concern, due to the added costs and health implications for the patients.

Table 2.3 shows estimations of the cost of management of complications associated with ACL injury. Based on 2012 statistics in the USA, nearly 16% of all patients who underwent early reconstruction tended to develop symptomatic osteoarthritis and most of these patients would eventually need complete knee arthroplasty. These figures tended to increase three-fold in the presence of meniscal tears (Øiestad et al., 2009).

With rehabilitation, nearly 20% of patients who received physiotherapy without reconstruction were expected to develop symptomatic osteoarthritis, and subsequently this resulted in the necessity of knee arthroplasty in most of these patients (Muraki et al., 2012; Mather et al., 2013). These figures emphasise the huge economic burden of this injury and its management, and thus, this highlights the importance of assessing the most clinical and cost-effective options in the treatment of ACL-deficient patients in KSA, as related to the aim of the current study (see Chapter Six).

Table 2.3. Estimated economic burden associated with complications following ACL injury based on 2012 USA based statistics (Mather et al., 2013). The estimations include direct and indirect costs

Cost of management option [a]	ACL injury with meniscal symptoms	ACL tear with radiographic osteoarthritis [b]	ACL tear with symptomatic osteoarthritis [c]	Total knee arthroplasty due to ACL injury [d]
ACL reconstruction	$44,000-$44,100	$38,500-$49,000	$40,000-$47,700	$42,800-$46,000
Rehabilitation	$83,500-$86,000	$85,000-$89,000	$81,800-$91,700	$84,700-$88,700

[a] Costs are estimated in US Dollars

[b] Rate of progression to radiographic osteoarthritis is estimated at 0-13% in the absence of meniscal tears and 21-48% with meniscal tears (Øiestad et al., 2009)

[c] The initial rate of progression to symptomatic osteoarthritis is 21% with a subsequent annual incidence rate of 1.3% (Muraki et al., 2012)

[d] Incidence rate of 2.3% (based on United Healthcare Database data for the year 2009)

2.9 Conclusion

This chapter reviewed the anatomy of the knee and the function of the anterior cruciate ligament. This was then followed by an overview of the epidemiology, mechanism and clinical features of ACL injury. Moreover, different management options and the economic burden of the injury and its management were also discussed.

Overall, ACL tears represent a highly prevalent form of injury in society, especially among young, athletic individuals, which poses both economic and health burdens upon individuals and governments. Rehabilitation combined with delayed reconstruction tends to be more costly than reconstruction alone; however, assessment of the comparative cost of rehabilitation in combination with early construction has yet to be conducted.

Furthermore, the management process following the diagnosis of ACL injury and the awareness in regards to pre-operative physiotherapy treatment need to be evaluated, and thus, they are detailed in the following chapter.

Chapter Three: Management of Anterior Cruciate Ligament Injury: Diagnosis and Treatment

3.1 Introduction

The anatomy of the knee joint, as outlined in Chapter Two, shows that this structure is stabilised by four ligaments: the ACL, posterior cruciate ligament, medial collateral ligament and lateral collateral ligament. ACL is considered one of the main stabilising structures of the knee joint (Margo et al., 2010). Moreover, ACL injury is associated with pain, swelling and limited physical function, which usually leads to lower QoL. As a result of the clinical features of the injury, an assessment is required prior to an appropriate management option is used. This chapter explores the management of ACL injury, which starts from the diagnosis to the treatment of the injury.

3.2 General Assessment of ACL Injury

In order to explore the surgical and physiotherapy management of ACL injury, and the effectiveness of clinical outcomes in relation to this, medical and physical assessments of the ACL need to be considered initially. When ACL injury occurs, evaluation of the

knee joint should be carried out as soon as possible in order to prevent complications and improve a patient's QoL. However, this assessment is usually affected by pain and swelling, which tend to occur and progress very quickly following the incidence of injury. Therefore, to achieve the best outcome of therapy, the assessment process of ACL injury should be complete and performed promptly and correctly (Cimino et al., 2010).

The assessment starts by a general observation of the patient, which includes an inspection of the gait and the position that the patient finds most comfortable (Solomon et al., 2001; Cimino et al., 2010). Through this process, attention should be paid to any asymmetry, effusion or haemarthrosis (indicated by loss of the peri-patellar groove). Haemarthrosis is experienced due to physical damage to the vasculature of the ACL anatomical structure, which is supplied by branches of the middle genicular artery and the lateral and medial inferior geniculate artery (Zantop et al., 2005).

Likewise, palpations are used to detect subtle symptoms and the first symptom to look for is the differences in temperature between the normal and affected knee, which can be indicative of inflammation (Solomon et al., 2001). In addition to redness, a common feature of haemarthrosis is pain, which is associated with impairment of the range of motion (ROM), due to the effect of increased intra-articular volume on the knee joint (Cimino et al., 2010).

Reduced ROM is usually characterised by difficulty in knee flexion, however, a lack of hyperextension is more characteristic of ACL injury, while limited ROM is also complicated by effusion of the knee joint and an increase in pain (Shelbourne and

Rowdon, 1994). As a consequence, it is imperative to measure these specific characteristics that relate to the knee joint prior to diagnosis using knee function tests.

3.3 Knee Function Tests

The three most commonly used clinical tests in the evaluation of the integrity of the ACL in routine diagnosis of knee injury are: the Lachman test, anterior drawer test, and pivot shift test (Benjaminse et al., 2006). However, the most analytically precise data are to be found in the Lachman test in acute cases, as well as the pivot shift test that is specific for conditions that are determined to be either acute or chronic (Benjaminse et al., 2006).

The Lachman test

The Lachman test is a simple test that is carried out while the patient lies in supine position with the knee joint flexed at an angle of 20-30º. The physician holds the femur in a fixed position and gives the tibia an abrupt forward pull. A positive result of the test can be seen when a discrete end point is not felt (Solomon et al., 2001). Several studies assessed the Lachman test and they have shown that it has very high sensitivity (in excess of 94%) and specificity (up to 100%), which makes it a very reliable test in diagnosing ACL ruptures, especially in acute cases (Solomon et al., 2001; Makhmalbaf et al., 2013).

In contrast to the other two tests, the Lachman test is largely unaffected by injuries to other ligaments and menisci, and thus, this reduces the frequency of false positives (Malanga et al., 2003). Limitations of the Lachman test include technical difficulties, such as the experience of assessors with small hands who struggle to correctly stabilise patients with large thighs. Another limitation is the requirement of anaesthesia with acute cases for a reliable test result (Malanga et al., 2003; Makhmalbaf et al., 2013).

The anterior drawer test

The anterior drawer test is conducted as the patient lies in the supine position while the knee is flexed at 90º. The physician pulls the upper part of the tibia in a forward motion while the hamstring muscles are relaxed and the tibia is not rotated. A positive test result can be seen when the anterior movement of the tibia does not reach an abrupt end point (Malanga et al., 2003). A different study assessed the validity of this test, which showed that it suffers from relatively low and very variable sensitivity (62% average, 10 fold variability) and specificity (67% average, 5 fold variability), especially when anaesthesia is not used (Solomon et al., 2001).

The variability in the anterior drawer test is observed particularly in relation to the differences between acute and chronic cases, with evidence of more accurate test results in chronic cases, where this test is most beneficial (Malanga et al., 2003). Indeed, for people with acute versus chronic injury, differences in the accuracy from the test are also noted. Specifically, for chronic injuries, a positive anterior drawer test is present in between 50% and 95% of cases (Konin, 1997). Validity of the anterior drawer test is

compromised when a concurrent injury is present leading to false positive cases, which are mainly related to when patients suffer from meniscal injuries, medial collateral ligament damage (Konin, 1997) or insufficiency of the posterior cruciate ligament (Malanga et al., 2003).

In addition, it was stated that the figures for those individuals who tested positive for ACL injury are: 54% presenting no other injuries; 67% who present with commonly connected medial meniscal injuries; 82% of people with correlated lateral meniscal injuries; as well as 89% of people who have medial collateral ligament (MCL) injuries (Konin, 1997). In general, this particular test is more valid under anaesthesia, which leads to results sometimes nearly as valid as the Lachman test, as shown by Makhmalbaf et al. (2013) who compared the validity of the two tests in a sample of 653 patients. The results demonstrated the sensitivity of the anterior drawer test with general anaesthesia to measure at 96.4%, while it came to 94.4% without anaesthesia. Similarly, the Lachman test with general anesthesia measured at 96.9% sensitivity, while without it, sensitivity was shown to be lower at 93.5%.

The lateral pivot shift test

The third test is the lateral pivot shift test, which is performed while the patient is in the supine position using a combination of valgus stress and internal twisting of the tibia while the knee is flexed at 45º. A positive test is indicated by a clear ‘jerk’ at 10-20º flexion, which means anterior subluxation (dislocation) of the tibia on the femur (Solomon et al., 2001). Overall, research results indicated that this test performed better

than the anterior drawer test with relatively high sensitivity (up to 98%) and specificity (98%) when carried out under anaesthesia; however, lower validity was reported in alert patients (Malanga et al., 2003). Validity of this test can be complicated by concomitant ligament or meniscal injuries and a positive test result in alert patients is usually indicative of cases that may not be responsive to non-operative management (Malanga et al., 2003).

3.4 Radiographic Assessment

Generally, the physical tests that are outlined above are combined with medical tests to reliably diagnose ACL injury and guide the decision of which management options would be more suitable. Surgeons routinely make a decision to perform arthroscopy based only on clinical assessment, with over 300,000 knee arthroscopies carried out in England within the NHS in the period 2005-2010, representing an annual incidence of approximately 10 per 10,000 of the population (Jameson et al., 2011). Nonetheless, this clinical assessment has a prediction accuracy of only 35-71% (Lawson and Nutton, 1995; Solomon et al., 2001).

Magnetic resonance imaging (MRI) represents a superior non-invasive tool in the clinical assessment for diagnosing knee abnormalities, while its performance level was also shown to be close to that of arthroscopy, with a diagnostic accuracy of over 85% in identifying ACL tears (Oei et al., 2003; Crawford et al., 2007). In addition, MRI is capable of diagnosing meniscal and other ligamentous tears with high accuracy, and thus, it represents a very useful screening tool prior to therapeutic arthroscopy with

advantages, such as speed and low risk levels (Crawford et al., 2007; Ng et al., 2011). Nevertheless, this diagnostic tool is expensive when compared to clinical examination, whilst it is also not routinely available for use (Kocabey et al., 2004). Indeed, it has been stated that an MRI can only be beneficial from a fiscal perspective, in comparison to clinical examination, when the cost is less than $250, which is uncommon (McKiernan et al., 1993). Furthermore, MRI radiographic test is the method of choice for general knee assessment with measurements of sensitivity and specificity at 86% and 95%, respectively, in the detection of ACL damage, which is confirmed through the use of arthroscopic surgery (Crawford et al., 2007).

Successful diagnosis of ACL injury is necessary for effective management. The medical and physical tests above are utilised by the treating healthcare professionals to ascertain the existence and extent of ACL injury (partial or complete rupture), the existence of concomitant damage (meniscal tears, ligament lesions or fractures), or associated complications (joint effusion and haemarthrosis). Accordingly, these factors are the main determinants of the most appropriate course of action in the treatment of ACL injury.

3.5 Management of ACL Injury

In this section, medical and physiotherapy management of ACL injury is considered. When the practitioner suspects ACL injury upon the initial assessment, it is appropriate to refer the patient to physiotherapy immediately in order to manage swelling and pain with modalities and to improve muscle strength and ROM (Shelbourne and Patel, 1995;

Cimino et al., 2010). Additionally, the use of crutches is only offered as an option for the patients when they suffer from discomfort upon movement, although this is only for a limited period of time, while knee immobilisers are usually considered unnecessary (Cimino et al., 2010).

It has been stated that non-surgical management has considerable benefits for a patient, such as improved QoL and symptoms (Fitzgerald et al., 2000; Keays et al., 2006). In a study that assessed the success of treatment of ACL injury, patients who received specific perturbation training with non-operative management were recorded as 4.88 times more likely to achieve successful recovery compared with those who received non-operative treatment only (Fitzgerald et al., 2000). Likewise, a study by Keays et al. (2006) demonstrated that pre-operative physiotherapy would have a positive effect on motor function in patients who were ACL- deficient, which means that this needs to be undertaken routinely in order to maximise the potential of muscle stabilisation prior to reconstruction, as passive muscle elasticity affects the passive joint restraint stiffness.

Nonetheless, evidence suggests that ACL remnants (the ligamentous tissue remaining after injury) have biomechanical properties that do not favour stability of the knee joint one year following injury (Nakamae et al., 2010). This is crucial in comprehensive understanding as it signifies that the potential of ACL reconstruction is an important decision for the treating surgeon within the first year following the injury (Kennedy et al., 2010). The management of ACL injury pre- and post- surgery, which includes physiotherapy rehabilitation, is different depending on the patient’s state of health and its general improvement (Shaarani et al., 2012).

3.5.1 ACL reconstruction surgery

ACL tears are very common with an incidence of approximately 100,000 new cases each year in the USA alone (Irrgang et al., 1996; Huston et al., 2000; Griffin et al., 2000; Baachs and Bonoos, 2001). Comparatively, a more recent study shows the incidence of this injury is higher at 200,000 new cases per year (Evans et al., 2014). Although both incidence levels related to the USA, the former incidence was reported based on 1985-1988 figures compared to the latter one which was related to 1996 statistics.

In addition, statistics have shown that due to the high incidence of this injury, it is estimated that over 100,000 ACL reconstruction interventions take place in the USA every year (Evans et al., 2014). Commonly, ACL tears are a sports-related injury, with football marked as one of the highest risk sports that predispose to this injury (Kobayashi et al., 2010).

In general, referrals to an orthopaedic surgeon for ACL reconstruction are made routinely based on the preferences of the patients and their activity levels. Meanwhile, young and athletic patients normally opt for surgical intervention in preference to conservative rehabilitation. Patients who intend to carry on with sporting activities that involve acceleration, deceleration, pivoting, cutting and rapid changes in direction should be assessed for reconstruction, as these specific actions increase the level of strain felt on the ACL (Cimino et al., 2010). Moreover, another factor that is also considered prior to a referral stems from the likelihood of the joint ‘giving-way’, which would result in accompanying damage that includes other ligament and/or meniscal damage (Shelbourne and Rowdon, 1994; Eastlack et al., 1999; Cimino et al., 2010).

Furthermore, two factors that affect the success of ACL reconstruction relate to the timing of the surgery and the type of graft that is utilised to maintain strength and biomechanical properties of the joint (Beynnon and Johnson, 1996).

3.5.1.1 Timing of ACL reconstruction

Even though the timing of the surgery in relation to the incidence of injury is crucial, there remains a lack of consensus on the optimal time for the best outcome (Evans et al., 2014). A recent systematic review indicated that there are no differences in the outcomes of surgery between early (within three weeks of injury) and delayed surgery (after six weeks) (Smith et al., 2010). However, that particular study identified substantial methodological limitations in the six reviewed studies, such as limited sample size, lack of blinding and poor randomisation, which suggests that the conclusions may require a well-designed randomised controlled trial to confirm their validity. Similarly, patient preferences is another factor that may play a significant role in the timing of surgery as athletes usually choose early surgery in order to return to physical activity as soon as possible, whereas people who do not require extensive physical ability normally delay the process of surgery due to professional or social factors. However, in both cases, complications of the injury, which are potentially increased through delays to reconstruction, may significantly affect the outcome of surgery (Evans et al., 2014).

Shelbourne et al. (1991) retrospectively reviewed the effect of surgery timing on reconstruction outcomes in 169 patients with ACL injuries and reported higher levels of arthrofibrosis in patients who had undergone surgery within the first week of injury

compared with those who had delayed the surgery for approximately three weeks ($p < 0.05$). Arthrofibrosis is defined as a severe complication that may follow acute ACL reconstruction and can cause scarring of tissue, which leads to limited range of motion of the affected knee compared to the contralateral joint (Shelbourne et al., 1991; Mayr et al., 2004).

Consequently, a delay of implementing reconstructive surgery by a minimum of 3 weeks following the acute ACL injury results in quicker strength development, and thus, a marked decreased in arthrofibrosis levels, which improves a patient's ROM by up to 5° in full extension. Another study that evaluated complications following ACL reconstruction in over 280 patients reported that 18% of participants who underwent surgery within one week of injury went on to develop arthrofibrosis, which was in comparison to only 6% of those who delayed the surgery for four weeks (Passler et al., 1995).

Mayr et al. (2004) investigated the causative factors of the complications that are associated with early reconstructive surgery, particularly arthrofibrosis. Their findings indicated a strong correlation between detrimental pre-operative knee symptoms (e.g. swelling, hyperthermia, pain, effusion) and the incidence of arthrofibrosis. Individuals with these symptoms who had undergone surgery after 4 weeks presented with approximately the same frequency of arthrofibrosis development as those individuals who had undergone earlier reconstruction (Mayr et al., 2004).

In addition, Shelbourne and Patel (1995) examined pre-surgery factors that are important in considering the timing of surgery and suggested that different factors, such as

psychological readiness, knee-related pathology, physiological knee condition (swelling, pain, muscle strength, ROM) should be evaluated to ascertain the most beneficial timing for ACL reconstruction surgery. However, it was found in the study by Shelbourne and Patel (1995) that surgery that has been delayed for a minimum of 3 weeks post-acute ACL injury actually reduces stiffness in the knee, as well as achieving a greater level of extension in comparison to acute surgery (< 3 weeks post-acute injury). As a result, it was determined that the knee's pre-operative condition presenting with lack of swelling, together with hyperextension and flexion, was not specific to the time lapse following the injury.

In summary, several factors can affect the timing of surgery, including the patient's physical and psychological health state, as well as personal preferences. However, evidence strongly suggests that surgery should not be performed immediately following the incidence of ACL injury (especially within the first week) in order to avoid arthrofibrosis. The time prior to surgery can therefore be used to manage symptoms and improve knee function in order to prepare patients for surgery, which highlights a potential role of physiotherapy prior to surgery.

3.5.1.2 Grafts used in ACL reconstruction

In ACL reconstruction surgery, a graft is required to replace the ruptured cruciate ligament (Herrington et al., 2005). In accordance, in order for the management of ACL injury to be successful, the type of graft has to be appropriate for the patient. The characteristics of grafts used for ACL reconstruction should include: similarity of the graft in structure and biomechanical properties to the native ACL ligament; fixation with

the graft should be secure; effective biological incorporation; and limited donor morbidity. Moreover, the graft should ideally be of similar or higher mechanical and physical strength than the undamaged original ACL structure (Miller and Gladstone, 2002; West and Harner, 2005); while the grafts can be either biological or non-biological tissue and biological grafts can be either autografts or allografts (Herrington et al., 2005).

The most commonly used graft types in clinical practice are the patellar tendon graft (bone-patellar-tendon-bone) (PT) and the 4-strand semitendinosus gracilis graft (quadrupled hamstring) (HT) (Feller et al., 2001). However, no differences were reported in the outcomes of ACL reconstruction through the use of either one of the two grafts following one year of surgery (Beard et al., 2001). In support of this view, a review of 13 studies on the use of different grafts, especially the two most commonly used grafts mentioned earlier, concluded that there is little evidence to suggest that one graft offers superior patient outcomes post-ACL reconstruction surgery (Herrington et al., 2005). Accordingly, the percentage of early tibiofemoral osteoarthritis was considerably higher in post-reconstruction with a patellar tendon at 62%, in comparison to post-grafting with a hamstring tendon, which measured at 33% ($p = 0.002$).

Shelbourne and Johnson (2004) investigated the effect of graft width on quadriceps muscle strength following surgical management of ACL injury in over 500 patients, where measurements of quadriceps muscle strength and the width of the patellar tendon graft were taken pre- and post-reconstruction. In that particular study, a reduction in the width of the graft correlated with reduced quadriceps muscle strength in patients up to 3 months post-ACL reconstruction surgery. As a result, this shows that the type and

characteristics of the graft should be considered as they may have a potential impact on ACL reconstruction outcomes.

Table 3.3 shows a range of clinically used grafts, together with their advantages and disadvantages. Along with the timing of surgery and the type of grafts, another factor that affects the recovery of patients following ACL injury relates to the type of rehabilitation that they receive post-surgery (Saka, 2014). Therefore, ACL reconstruction surgery is normally accompanied by physiotherapy in order to rehabilitate patients into the recovery of normal knee function and physical activity (Saka, 2014). Indeed, the levels of required post-operative physiotherapy as a patient outcome are linked directly to the implemented pre-operative intervention and its potential effects.

Table 3.1. Advantages and disadvantages of the different types of grafts used in ACL reconstruction

Graft	Advantages	Disadvantages	References
Bone-patellar-tendon-bone (BPTB)	Bone to bone biological healing	Anterior knee pain, large incision required	(Markolf et al., 1996)
Quadrupled hamstring	Small incision required, less pain in the anterior knee	Hamstring weakness, soft-tissue healing required, bone tunnel widening	(Hamner et al., 1999)
Quadriceps tendon	Bone to bone healing, thick, can be used as two bundles	Anterior knee pain, large incision, patella fracture bone plug is taken, soft-tissue healing required	(Harris et al., 1997; Staubli et al., 1999)
Patellar tendon allograft	Bone to bone healing	Incorporation takes a longer time	(Chan et al., 2010)
Achilles allograft	No particular advantage	Longer time for incorporation, soft-tissue healing required	(Lewis and Shaw, 1997; Louis-Ugbo et al., 2004)
Tibialis anterior allograft	No particular advantage	Longer time for incorporation, soft-tissue healing required	(Chan et al., 2010)

3.5.2 Physiotherapy rehabilitation for ACL injury

Even though surgery is the main intervention strategy, a set of patients may be able to recover and resume normal activity without reconstruction (Eastlack et al., 1999). Accordingly, the results from examinations that favour conservative management (i.e. physiotherapy rehabilitation) without reconstruction include: a lack of or a limited number of 'giving-way' episodes; close to normal extension ROM; absence of meniscal damage based on an MRI examination; strong quadriceps muscles; and the absence of difficulties in carrying out the crossover hop test (Shelbourne and Rowdon, 1994; Eastlack et al., 1999). However, the success rates of conservative management differ between relevant sources. For instance, Barrack et al. (1990) reported a standard protocol management of rehabilitation and bracing of the knee at an early stage on 72 patients with ACL injury who were monitored for 38 months. As a result, only 30% were shown to have positive outcomes on their knee function, muscle strength and activity levels, with approximately 6% returning to the same activity levels that were present prior to the injury following physiotherapy rehabilitation.

Meanwhile, another study reported that 86% of 40 evaluated patients suffered symptoms, such as 'giving-way' following physiotherapy rehabilitation management, and 30% required surgical intervention following conservative management. As a result, only approximately 14% returned to full athletic activity, while 87% had fair or poor results in relation to knee grading measurements (Hawkins et al., 1986). Therefore, both studies fail to prove conclusive benefits of conservative management without the requirement of ACL reconstruction (Hawkins et al., 1986; Barrack et al., 1990).

By contrast, a more recent radomised controlled trial (Frobell et al., 2010) examined the performance of conservative rehabilitation treatment with the option of delayed reconstruction in comparison to early surgical intervention and involved 121 patients with ACL injury. After 2 years of follow-up, the study did not report any differences between the two groups in relation to pain, as well as other symptoms, such as swelling, sports related functionality and QoL. Subsequently, after 5 years of follow-up, there were still no differences in patient related outcomes, including QoL. It was shown that for those assigned to rehabilitation plus early ACL reconstruction, the Knee injury and Osteoarthritis Outcome Score (KOOS) measurement recorded up to a two-year period came to 39.2, while it came to 39.4 for those individuals who received rehabilitation including optional delayed reconstruction (Frobell et al., 2010), which shows no differences between the two options. Moreover, approximately 50% of participants in the optional delayed surgery group did not require ACL reconstruction after undergoing the rehabilitation programme (Frobell et al., 2013). The KOOS tool is a test of knee-related outcome measures first introduced by Roos and colleagues in 1998 for the assessment of knee health and functionality. The test comprises five outcome measures: knee-related pain severity and frequency; symptoms, such as knee stiffness, swelling and grinding; difficulties during activities of daily living; difficulty during sports and recreational activities; and knee-related quality of life (QoL). These components are scored based on patients' perception about their health status (Collins et al., 2011), with higher KOOS scores indicating better outcomes.

Indeed, it was shown in that study that this may be due to the beneficial effect of rehabilitation, especially in ACL-deficient patients who are identified as 'copers'. It was

recorded that for those assigned to rehabilitation plus early ACL reconstruction following five years from the incident injury scored 42.9 points on the KOOS test, whilst the score measured at 44.9 for those individuals who were assigned to rehabilitation that included optional delayed reconstruction. As a result, this highlights the importance of physiotherapy as an alternative management option to surgery for certain patients.

3.5.2.1 Physiotherapy rehabilitation in combination with surgery

ACL reconstruction is usually combined with physiotherapy rehabilitation in the clinical setting in order for patients to return to their pre-injury levels of activity (van Grinsven et al., 2010). The reconstructive surgery serves to structurally repair the torn ligament, while the rehabilitation ensures maintenance of the repair process and protection of the ligament and the knee joint to restore normal physical activity (Saka, 2014).

Whilst post-operative physiotherapy is a well-established rehabilitation step, relatively few studies have investigated the effectiveness of pre-operative rehabilitation in the management of ACL injury and its outcomes following surgery (Shaarani et al., 2012). A contributing factor to this is the lack of a standardised pre-operative protocol, which is detailed fully in the results in Chapters Four and Five. Patients scheduled to undergo surgery should undertake intensive rehabilitation with programmes that usually have duration of 4 to 12 weeks, which include activities that are designed to improve muscle strength and ROM (Keays et al., 2000; Eitzen et al., 2010; Cimino et al., 2010).

Recent literature on ACL rehabilitation has mostly focused on issues such as: the mechanisms of patient coping in conservative management; the impact of balance exercises in pre-operative management; the effects of intensive post-operative rehabilitation; and the various physiotherapy protocols used mainly post-operatively (Shaarani et al., 2012). A more detailed critique of the effectiveness of physiotherapy in the management of ACL injury is provided as a systematic review, which is presented in Chapter Five.

3.5.2.1.1 Pre-operative physiotherapy rehabilitation

Pre-operative rehabilitation can be defined as physiotherapy and other training that is aimed at improving the physical performance capacity of patients who present with ACL injury, to alleviate the effect of inactivity (Ditmyer et al., 2002) and to prepare the knee joint for reconstructive surgery by increasing neuromuscular control (Tagesson et al., 2008). This is routinely performed by increasing quadriceps muscle strength and coordination, in addition to improving proprioception and knee-related ROM (Risberg et al., 2004).

Noyes et al. (1983) were the first to suggest the adoption of rehabilitation prior to ACL reconstruction in order to improve muscle strength and ROM with a view to increase recovery rates post-surgery. However, only a few studies have investigated the effectiveness of pre-operative physiotherapy on patient outcomes of this type of injury, and thus, there is a requirement to undertake a systematic review that would assess available evidence in relation to this specific area (see Chapter Five).

As a primary requirement, the management of ACL injury through reconstruction requires symmetry in the strength of quadriceps and hamstring muscles, as well as sufficient knee proprioception performance (Shaarani et al., 2012). Therefore, it is imperative that a patient undertakes muscle strength training, as well as proprioceptive and neuromuscular improvement.

A. Muscle strength training

Although quadriceps muscle strength is used as a marker for the progress of rehabilitation, there are no clearly defined guidelines for the progress of ACL injury management before and after reconstruction (Shaarani et al., 2012). A study that investigated the effect of quadriceps strength pre-operatively and post-operatively in patients undergoing reconstruction assessed muscle strength in 17 patients prior to surgery and on four different occasions after surgery (Elmqvist et al., 1989). A reduction of 50% in quadriceps strength was recorded in the affected leg three months after ACL injury, prior to reconstruction surgery. One year after reconstruction, physical muscle strength in the affected and unaffected legs was still different, although the performance level of the affected leg had almost returned to normal.

Notably, a recent study showed that a 5-week muscle strengthening physiotherapy programme prior to surgery with progressive muscle strength development is effective in improving knee joint function, quadriceps strength and activity in ACL-deficient patients (Eitzen et al., 2010). However, this strategy did not lead to significant changes in hamstring function, which may be due to the limited effect of ACL injury on these

muscles. Another study enrolled patients with ACL injury in a pre-operative rehabilitation programme of 4-6 weeks followed by a post-operative rehabilitation of at least 4 months (Keays et al., 2000). Six months following surgery, there was less than 30% deficiency in the quadriceps muscles post-surgery, while no deficiency recorded in hamstring muscles pre- and post-surgery. Consequently, this may suggest that the type of exercises used in the training programme may be important in achieving the required muscle strength for better physical activity and knee control.

Closed kinetic chain (CKC) and open kinetic chain (OKC) exercises can both be used in the process of strengthening the weak quadriceps muscles in the affected leg. CKC exercises rely on the closed relation between the movement of one joint and another in the affected leg, whereas OKC exercises are based on the movement of one link in the kinetic chain, which is independent of the distal segment whose movement is not restricted (Palmitier et al., 1991; Wilk et al., 1997). Nonetheless, the selection of particular exercises and the time of introducing them are still a subject of debate (Saka, 2014).

In a randomised controlled trial conducted by Bynum et al. (1995), it was shown that CKC training can be recommended to improve arthrokinematics, as compared to OKC exercises. CKC exercises are also considered to be safer than OKC exercises, and thus, the former are more commonly used and recommended on a more frequent basis for the management of muscle deficiency in ACL-damaged patients (Shelbourne and Nitz, 1990; Palmitier et al., 1991; Beynnon and Fleming, 1998; Henriksson et al., 2002). This is mainly due to the fact that OKC exercises tend to produce more extensive anterior shear forces than CKC exercises (Lutz et al., 1993; Yack et al., 1993), which is

especially true in the last 30º of extension of the knee joint (Wilk et al., 1996). However, OKC exercises seem to result in significantly greater quadriceps strength ($p < 0.01$) according to a randomised controlled trial performed on 42 patients with ACL injury (Tagesson et al., 2008). A combination of both types of muscle strengthening exercises was also recommended in order to better strengthen quadriceps and hamstring muscles (Hooper et al., 2001).

A systematic review on the effects of open and closed kinetic chain exercises on patients with ACL-injury concluded that these two forms of exercises have similar effects on knee joint laxity, pain and functionality and that these two types can be used together for rehabilitation post-surgery (Glass et al., 2010). The combined use of open and closed kinetic chain exercises was also advocated by Mikkelsen et al. (2000). As a conclusion, Glass et al. (2010) recommended that even though CKC exercises should be initiated early, OKC exercises should be recommended 6 weeks following ACL reconstructive surgery. This analysis can be understood to suggest that a careful balance between open and closed kinetic chain exercises can be used in the muscle strengthening programme, with the possibility of changing the content of the programme based on a patient's progress.

B. Proprioceptive and neuromuscular improvement

ACL injury causes the impairment of proprioception and latency in the reflex contraction of hamstring muscles (Barrack et al., 1989), which were previously discussed in relation to clinical features of ACL injury (see Chapter Two). It can be seen

that proprioception impairment is a risk factor that leads to degenerative joint disease and instability of the knee joint (Shaarani et al., 2012). Moreover, a prospective study on knee joint proprioceptive performance showed that normal proprioception was achieved within six months post-reconstruction surgery (Angoules et al., 2011). Meanwhile, a different study demonstrated the effectiveness of post-operative rehabilitation in restoring proprioception (van Grinsven et al., 2010), while a separate investigation examined the effectiveness of pre-operative rehabilitation in improving proprioception following ACL injury (Beard et al., 1994).

In the study by Beard et al. (1994), only patients with ACL injury who were confirmed with knee arthroscopy were enrolled, and these were subjected to a 12-week pre-operative proprioceptive exercise regime, while a control group received a traditional exercise programme. As a result, the findings indicated that patients who received the proprioceptive training had significantly better knee functionality ($p < 0.01$). However, there are other forms of injury which were excluded from the study and need to be considered in regards to a proprioceptive exercise regime to make the evidence conclusive, such as complex meniscal tears, grade III collateral ligament damage, and significant chondral damage. As a consequence, the results are inconclusive in relation to the overall improvement in knee functionality following different injuries.

The perturbation technique is a neuromuscular training exercise that uses a roller and tilt board for balance training, which was introduced in the year 2000 (Fitzgerald et al., 2000). The different techniques that were included comprised of side sliding, which is the lateral movement both left and right with a rapid directional change every 4.5 meters, together with crossovers of forward and backward motion with right/left lateral

movements with rapid directional change every 9 meters (Fitzgerald et al., 2000). This also included shuttle runs for start-and-stop movements that were both forward and backwards, which incorporated multidirectional shuttle running, a 45-degree cutting-and-spinning exercise, and figure-eight running (Fitzgerald et al., 2000). This training programme was used on patients who presented with ACL injury for a period of 5 weeks and resulted in better rates of successful pre-operative rehabilitation in the perturbation group (92%), as compared to the control group who received standard training (50% success rate, $p < 0.05$). Subsequently, the proposed guidelines suggested non-operative management of patients with a successful outcome of physiotherapy.

Nevertheless, the overall clinical results following ACL reconstruction are perceived to be good, although there has not been sufficient evidence in relation to the predictive factors for a good post-operative clinical outcome following ACL reconstruction. Moreover, the pre-operative factors, which stem from the pivot shift, knee function, and ROM, potentially provide a prediction of a good post-operative outcome and show an improvement level of approximately 25% in relation to health-related quality of life post-ACL reconstruction. However, the prediction of a higher level post-operative outcome has been measured through the use of the Short Form 36 (SF-36) and KOOS in the period of up to six years post-ACL reconstruction (Fitzgerald et al., 2000).

3.5.2.1.2 Post-operative physiotherapy rehabilitation

ACL reconstruction surgery is normally combined with physiotherapy that incorporates various post-operative rehabilitation programmes that are utilised by different healthcare

establishments in a variety of countries (Trees et al., 2011). The overall objectives of rehabilitation, prior to returning to daily or sporting activities stem mainly from: control of symptoms (such as pain and swelling); normal ROM; alleviating muscle atrophy; restoring normal gait; and achieving normal proprioception (Saka, 2014). Currently, the most commonly used approach by practitioners is through the process of deciding the type of programme based on their experiences and subjective interpretation of the patient's condition. However, there is lack of consensus in relation to the specific details, such as the optimal time for the start of rehabilitation, types of modalities, time of surgery, duration of rehabilitation and types of exercises to be used in the physiotherapy regimen.

3.5.3 Cost-effectiveness of management interventions of ACL injury

One of the main challenges that face the healthcare sector stems from the decision relating to the value of a new treatment intervention (Cohen et al., 2008). A specific tool that is used to objectively evaluate healthcare interventions is cost-effectiveness analysis by assessing incremental health benefits associated with a particular intervention in relation to incremental costs (Mark, 2002). In an effort to facilitate categorising healthcare interventions based on their benefits relative to their cost, the USA Panel on Cost-Effectiveness in Health and Medicine issued recommendations on methodological evaluation of the most preferred healthcare interventions (Gold et al., 1996; Weinstein et al., 1996).

Nevertheless, even though there is an abundance of literature in regards to ACL injury, there is no consensus on the overall management and optimal intervention to restore functional activity and improve QoL (Farshad et al., 2011). Currently, the most preferred intervention by orthopaedic surgeons is ACL reconstruction, which especially relates to young, active patients (Eastlack et al., 1999; Cimino et al., 2010); however, some surgeons may favour conservative treatment that consists of immobilisation and physiotherapy (Farshad et al., 2011). Specifically, certain studies that evaluated the cost-effectiveness of surgical intervention in relation to conservative treatment include Gottlob et al. (1999), Farshad et al. (2011) and Lubowitz et al. (2011).

Gottlob et al. (1999) evaluated the cost-effectiveness of surgical ACL reconstruction and conservative intervention in young adults in the USA over 7 years post-injury. Exercises were performed in order to regain the full level and range of motion in the knee, as well as to improve the strength in quadriceps muscles, while in the period following the initial stage of rehabilitation, patients who did not undergo surgery implemented modifications to their activities of sport and work (Mihelic et al., 2011). The authors reported that surgical intervention was more cost-effective compared to conservative management, as it came to $6,000 per quality-adjusted life year (QALY).

Similarly, Farshad et al. (2011) investigated the cost-effectiveness of ACL reconstruction compared to conservative treatment (physiotherapy) and arrived at the conclusion that surgical ACL management is cost-effective with an incremental cost of approximately $5,000 per additional QALY compared to conservative management. This figure is comparable to cost-effectiveness ratio reported by Gottlob et al. (1999) at $5857 per QALY for ACL reconstruction. However, the additional benefit in QoL was

lower in the study by Farshad et al. (2011) than that reported by Gottlob et al. (1999), with a measured 0.12 additional QALY in the first study as opposed to 1.61 QALY for the surgical intervention in the second study. These differences can be attributed to several factors including the country where the study is conducted, which highlights that the Saudi Arabian context has to be taken into account when investigating cost-effectiveness in the present study. However, very limited research has been conducted in the Saudi context to allow any comparisons. Likewise, other factors that can result in differences in the assessment of cost-effectiveness include the form of economic evaluation and the interventions that are compared, which may or may not include the cost of pre-operative physiotherapy. This is due to the different types of costs implicated in ACL injury and its treatment including short and long-term, direct and indirect costs.

Lubowitz et al. (2011) investigated the cost-effectiveness of ACL reconstruction and knee arthroscopy in 35 and 93 patients, respectively, with ages that ranged from 11 to 79 years. The outcome of this study demonstrated that both interventions were cost-effective with costs per QALY of approximately $10,000 and $6,000 for ACL reconstruction and knee arthroscopy, respectively. In this study, the effectiveness component of the analysis was measured using life expectancy and quality of life, which were assessed by using the Quality of Well-Being (QWB) scale. The two interventions scored equally on the QWB scale (measured improvement of 0.03); however, ACL reconstruction scored higher than knee arthroscopy on the life expectancy element with mean years of life remaining of 40 and 34 years, respectively (Lubowitz et al., 2011).

The additional value of the study by Lubowitz et al. (2011) comes from the fact that the authors did not limit their investigation of cost-effectiveness to young patients only,

unlike Gottlob et al. (1999). In this particular study, a questionnaire was administered to 285 university students, who were all young adults, which helped determine the utility values, and estimated operative strategies to cost $11,768 and conservative strategies to be at $2333 (Gottlob et al., 1999). Altogether, the consequential marginal cost-effectiveness ratio came to $5857 for every QALY, which means that ACL reconstruction is a cost-effective method of treatment for young adults suffering from acute ACL-injury. This was defined in the USA healthcare setting as a procedure with a cost per QALY of less than $29,300 (adjusted in relation to inflation) (Lavernia et al., 1997); this threshold value was more recently revised to $50,000 by Cohen et al. (2010). This is related to the cost-effectiveness plane, which provides different types of strategy based on effectiveness and cost, with more beneficial procedures at lower costs deemed favourable (Cohen et al., 2010).

It is worth noting that conservative treatment, which includes physiotherapy management, is only applicable when a patient is classified as a suitable recipient after screening for structural damage and clinical symptoms. Often, patients with extensive damage to the ACL structure require reconstruction regardless of suitability to receive conservative treatment (Strehl and Eggli, 2007).

Although the utility of physiotherapy rehabilitation prior to surgery to improve functional activity and patient recovery rates was proposed (Noyes et al., 1983), there is a lack of cost-effectiveness analysis studies on pre-operative physiotherapy management and the effects of including this type of intervention on patient health outcomes, including recovery of physical activity and quality of life. This was the motivation for conducting a cost-effectiveness assessment of pre-operative physiotherapy rehabilitation

as described in Chapter Six, which also provides the necessity to understand the relevance of pre-operative physiotherapy management awareness from both clinical professionals and patients.

3.5.4 Awareness about physiotherapy management

With the widespread influx of information due to globalisation and advances in technology, there has been an increase in medical awareness in relation to different health issues that affect functional activity and their management, which includes physiotherapy (Acharya et al., 2011). There has been a demand for the recognition of physiotherapy as provision of an essential intervention in a rapidly changing healthcare environment (CAIPE, 2001). As a result, physiotherapy is currently recognised as a primary healthcare service and equity of access necessitates that this service should be provided to anyone who needs physiotherapy and that efforts should be made to increase awareness of its benefits.

In 2011, the World Confederation for Physical Therapy (WCPT) adopted a description of physiotherapy, which was intended to inform patients, as well as healthcare practitioner (WCPT, 2011). The WCPT defined physiotherapy to be a process that is concerned with the identity and increase in the quality of life for patients, as well as in the potential of prevention, treatment/intervention, and rehabilitation, which includes all forms of well-being: physical, psychological, emotional, and social. It has been shown that physiotherapy includes physiotherapist and patients/clients interaction, together with different professionals in healthcare. Moreover, families, care givers and communities

are included within the prevention, treatment/intervention, and rehabilitation potential assessment, as the aims are agreed through the use of knowledge and skills. This description stated that physiotherapy offers services to different populations in order to restore, improve and maintain functional activity and mobility throughout life (Wallace, 2003; WCPT, 2011). As a result of the research-based advancement of its practice, physiotherapy is now used extensively in the healthcare setting, which leads to increased awareness of physiotherapy and confidence in its benefits (Acharya et al., 2011).

Even though physiotherapy has become routine practice in the restoration of functional activity following ACL injury, pre-operative physiotherapy is not commonly prescribed by orthopaedic surgeons for the management of this condition (Keays et al., 2006). This may partly be due to the lack of awareness of the benefits of this intervention in the management of ACL injury within healthcare systems and also among patients (Acharya et al., 2011). The situation of awareness in patients who come from developing countries in regards to physiotherapy management as an intervention is even more challenging due to other confounding factors, such as poverty, lower levels of education and contrasting cultures, compared to developed countries (Maruf et al., 2012).

Lack of awareness in these countries is not only observed in patient populations but also in a significant proportion of healthcare professionals (Acharya et al., 2011). Evidence suggests that healthcare professionals, such as medical doctors, may not have sufficient knowledge about all the available physiotherapy interventions and the way these services can help their patients (Harris, 1992; Summers, 1993). Therefore, the process of generating awareness among patients and healthcare professionals, particularly in

developing countries, remains one of the main challenges for physiotherapists (Jackson, 1987; Acharya et al., 2011; Maruf et al., 2012).

Studies that have investigated awareness of the benefits of physiotherapy among patients in Nigeria (Maruf et al., 2012) and among clinical practitioners in Nepal (Acharya et al., 2011) pointed out this lack of awareness in both providers and receivers of healthcare. Acharya et al., (2011) observed in Nepal that although 98% of the surveyed 115 physicians were generally aware of physiotherapy, only 63% had adequate knowledge in regards to the benefits of pre-operative physiotherapy management and agreed to refer their patients to these services. In Nigeria, although over 75% of the surveyed 885 individuals believed physiotherapy should be available in hospitals, only just over 50% of respondents believed their awareness of physiotherapy is sufficient to make a recommendation to use physiotherapy (Maruf et al., 2012). However, this study investigated awareness of patients related to physiotherapy in general and not in relation to ACL injury or to surgery, and thus, it is difficult to extrapolate the findings from these studies to ACL injury management, which is the area that the current thesis investigates.

Certainly, there is a need for more studies to investigate patients' and healthcare practitioners' awareness, expectations and attitudes towards pre-operative physiotherapy services (Grimmer et al., 1999) and ways to improve this awareness. Indeed, such studies are lacking in developing countries, which include Saudi Arabia, where the investigation of the current study takes place, which is why the study in Chapter Four is an attempt to address this gap in knowledge.

From the evidence presented above, it is clear that respondents within the evaluated studies in developing countries generally failed to have high levels of awareness, or hold positive attitudes and beliefs that relate to physiotherapy, and thus, physiotherapy service utilisation is not conclusively recommended in these countries. Therefore, these same factors need to be analysed sufficiently and in detail in relation to Saudi Arabian patients' and health practitioners' awareness, which is currently not available from prior investigations.

3.6 Conclusion

This chapter explored the options available for the management of ACL injury. Diagnosis is carried out using physical and medical assessment. Treatment of ACL injury includes ACL reconstruction surgery and physiotherapy rehabilitation. Post-operative rehabilitation is routinely used to maintain the ligament repair process and achieve normal knee functionality in patients after surgery. Pre-operative physiotherapy is not used routinely but can offer benefits such as preparing patients for surgery through increased muscle strength, improved ROM and enhanced proprioception.

Physiotherapy rehabilitation was also proposed as an alternative to reconstruction surgery in some ACL injury cases. Awareness of both patients and healthcare professionals about pre-operative physiotherapy intervention is still lacking especially in developing countries.

The next Chapter is an investigation into the prevalence of ACL injury in Saudi Arabia and the awareness amongst Saudi patients and healthcare practitioners about pre-operative physiotherapy management of ACL injury.

Chapter Four: Anterior Cruciate Ligament Injury in Riyadh, KSA: Prevalence of Injury, and Awareness of Pre-operative Physiotherapy

4.1 Introduction

Participation in sport in the Kingdom of Saudi Arabia (KSA) has been promoted on the basis of the health benefits associated with an active lifestyle, with football (European football) being recognised as the most popular sport in KSA and around the world (Junge et al., 2002). Anterior cruciate ligament (ACL) injury is the most common injury associated with sports participation and accounts for approximately 30 injuries per 100,000 individuals in the USA (Csintalan et al., 2008).

ACL injury is very common in football, as was mentioned previously in Chapter Two, and the statistics indicate that the chance of sustaining the injury in the Middle East is higher than North America (International Harvard Medical, 2007). This has been related both to the enormous popularity of the sport (Faunø and Wulff Jakobsen, 2006) and the resultant increased number of participants (Hutchinson and Ireland, 1995). Determining

the prevalence of ACL injury in Riyadh, the capital city of KSA (see Section 4.3.1 for reasons for choosing Riyadh in this study), can highlight the importance of such injury in KSA and assist in developing a view to set appropriate preventative measures to reduce the incidence of ACL injury. Evaluating the prevalence of this injury may also assist in providing a basis for raising awareness about it and introducing appropriate interventions for ACL-deficient patients. To date, the prevalence of ACL injury in KSA is still unknown.

There are a set of pre-operative protocols that rely primarily on physiotherapy being performed to aid the effectiveness of the outcome of reconstruction and to restore knee function prior to surgery (Noyes et al., 1983). It is also possible that pre-operative rehabilitation could limit episodes of pivot shift known to cause continuing knee joint damage, facilitate post-operative recovery and, in some patients, avoid the need for surgery altogether (Tegner et al., 1986; Frobell et al., 2013).

Compared to Europe (British Orthopaedic Association, 2001) and the USA, there is a lack of pre-operative physiotherapy programmes for patients undergoing ACL reconstruction surgery in Saudi Arabia (International Harvard Medical, 2007). This may be in part due to lack of awareness among healthcare professionals, such as orthopaedic surgeons and physiotherapists, as well as patients about the benefits of such intervention to ACL reconstruction surgery and injury recovery in general in KSA. Additionally, studies on the awareness among patients and practitioners about pre-operative physiotherapy management in relation to the outcomes of ACL reconstruction are still lacking (Grimmer et al., 1999).

Knowing the level of awareness of orthopaedic surgeons, physiotherapists and patients about pre-operative rehabilitation may help to improve the current physiotherapy practice in relation to the management of ACL injury cases in KSA. Therefore, the aims of this clinical survey were:

- To investigate the prevalence of ACL injury in the population of Riyadh, Saudi Arabia.
- To investigate the awareness of healthcare practitioners in KSA about pre-operative physiotherapy treatment for ACL injury.
- To assess the awareness of patients with ACL injury in KSA about pre-operative physiotherapy treatment.

This chapter will first introduce operational definitions for the concepts used in this study. This will be followed by examining the prevalence of ACL injury in the population of Riyadh, KSA, and the final section will investigate the awareness of patients with ACL injury and the healthcare professionals caring for them about the benefits of pre-operative physiotherapy.

4.2 Operational Definitions

Prevalence is a measure of how common a condition is in a certain population at a certain time (Shields and Twycross, 2003). **Incidence**, on the other hand, is a measure of the rate at which new cases of a particular condition occur (Shields and Twycross, 2003). It is pertinent to measure the prevalence of ACL injury in KSA, as this has yet to

be investigated. This in turn may further highlight the need to investigate effective preventive measures and appropriate management interventions for this condition, including pre-operative physiotherapy rehabilitation. The two terms, prevalence and incidence, tend to be used interchangeably; however, the extent of the spread of a particular injury in a population is usually reported using prevalence figures.

Questionnaire survey is a research tool designed and used to collect specific information from a particular population group using a set of questions (Denscombe, 2003).

A **healthcare practitioner** is a person trained to provide a specific health service to patients. In the case of this study, practitioners included physiotherapists and surgeons treating patients with ACL injury.

ACL injury is an injury that affects the anterior cruciate ligament (Keays et al., 2000). In this study, the definition of ACL injury required complete rupture of the ACL in only one knee (unilateral injury) without any other concomitant injury to the lower limbs, such as meniscal tears, other ligament rupture and bone fractures.

Pre-operative physiotherapy is defined as physical therapy administered to patients with ACL injury prior to surgery to prepare them for ACL reconstruction (Shelbourne and Klotz, 2006).

4.3 Materials and Methods

This section describes the research methodology used to investigate the prevalence of ACL injury and awareness of patients and practitioners in regards to pre-operative physiotherapy treatment for ACL injury. To implement this investigative process, a clinical survey was devised with a view to improve the quality of patient care through measuring potential deficiencies by analysing awareness in care (Hopkins, 1996). Indeed, this study intended to measure both the extent of prevalence of the injury and the awareness from patients and healthcare practitioners. The method used in this phase was a questionnaire survey method, which comprised of two questionnaires and a data extraction form that were designed to collect the required information from the surveyed patients and practitioners.

Questionnaires are tools designed and used to collect specific information from a particular population group (Denscombe, 2003). Accordingly, these tools were advantageous in addressing the objectives of the current study as they presented a more compact, more structured, less time-consuming and less costly method than other methods present, such as face-to-face interviews or observation and collection of data from patient files (Jones, 2008). Nonetheless, there is a wide debate relating to the advantages and drawbacks of these methods, which underpin the validity of their use (McKenna et al., 2006). The main advantage of using this method, along with the ones stated above, stems from the fact that it allows simple and effective collection of relatively focused information from a specific population, with the possibility of ascertaining qualitative and quantitative data analysis (Bowling, 2002).

On the other hand, survey methods have certain disadvantages, which include the possibility of low response rates (Jones, 2008); lack of control over the process after the distribution of the questionnaires (Oppenheim, 1992); and the possibility of inaccuracies in transcription and interpretation of responses (Jones, 2008). Yet, the control issue can be overcome by using structured and unambiguous questions, along with clear instructions on the questionnaires (Solomon, 2001). Additionally, more appropriate and relevant information can be obtained by focusing the questions through the use of pre-piloting and piloting approaches and also by using the participants' native language for ease of communication (Arabic in the present study). Hence, this strategy was adopted in the current research study, while clear instructions were included in the first page of the questionnaire document with a brief background to the study.

In addition, instructions were also explained to the treating practitioners face-to-face in order to clarify the requirements to them and in turn to their patients. Concerns over confidentiality were also raised as possible causes for lack of response (Dillman, 2000; Saewyc et al., 2004). In fact, this is a legitimate concern as patient confidentiality is legally protected under the Data Protection Act 1998 (Jones, 2008). Therefore, this concern was overcome by emphasising confidentiality and anonymity to the respondents both in a written form of the instructions and verbally to the practitioners. Overall, all these considerations were taken into account in relation to the use of the questionnaire methodology in the current study that helped address the aims of this phase with the specific sample size and setting.

4.3.1 Study setting

The city chosen to conduct the study of prevalence and awareness is Riyadh. This choice was informed by the following considerations:

- Riyadh is the capital city of Saudi Arabia and is home to a quarter (25%) of the population of the country; 7,516,959 out of Saudi population of 29,994,272 according to the 2013 census (KSA Ministry of Health, 2013).

- The highest number of hospitals are present in Riyadh (47 hospitals out of a total of 268 hospitals in KSA). These hospitals provide 7,737 public hospital beds and 4,369 private hospital beds, the highest bed capacity in the country in both the public and private sectors. Similarly, the highest number of primary health centres are also present in Riyadh (435 out of a total of 2,259 centres) (KSA Ministry of Health, 2013).

- Most of the main hospitals, both private and public, which treat ACL injury, are based in Riyadh (KSA Ministry of Health, 2013).

- Riyadh is the home of the major football clubs in Saudi Arabia, including Al-Hilal, Al-Nasr, Al-Shabab and Al-Riyadh clubs.

- Unlike other cities in KSA, sports facilities are widely available in Riyadh for people to practice sports, especially football.

4.3.2 Sample size estimation

Before a survey study can be undertaken, the minimal sample size for both patients and healthcare practitioners should be estimated to provide confidence in the information learned about the population. The sample size for surveys can be calculated using the equation below for categorical data (Bartlett et al., 2001). Using a confidence interval (CI) of 95% (Z-score of 1.96) with an error margin of 10% and standard deviation (SD) of 0.5 (default value for maximum possible sample size) (Bartlett et al., 2001; Charan and Biswas, 2013), the sample size (n) is estimated to be 96. A stricter CI (99%, Z-score of 2.58) and error margin (5%) led to a very large sample size (in excess of 660), which could not be surveyed within the timeframe of this study (Charan and Biswas, 2013).

By assuming a response rate of 50%, which is considered as a satisfactory response rate (Charan and Biswas, 2013), the minimum sample size was estimated at 192 surveyed participants (rounded up to 200 participants) (Bartlett et al., 2001). Therefore, a samples size of 200 for both patients and practitioners should be targeted to achieve the required sample of 96.

$$n = \frac{(Z_{score})^2 \times SD \times (1 - SD)}{(Error\ margin)^2}$$

4.3.3 Investigation of prevalence of ACL injury

Assessing the prevalence of ACL injury in the Saudi population was identified as a gap that needs to be addressed (see Chapter Two). This section describes the methods and

procedures used to investigate the prevalence of ACL injury in the Riyadh population, including the data extraction approach and direct contact with healthcare related establishments.

4.3.3.1 Data extraction form

A data extraction form was intended to investigate the prevalence of ACL injuries in the patient population in Riyadh and consisted of a section on personal and demographic details and a second section on the patients' medical history relevant to ACL injury occurrence and treatment. This section included history of the injury and whether the patient received pre-operative physiotherapy treatment or post-operative rehabilitation (Appendix 1 shows items of the data extraction form and their rationale). The supervisory team provided guidance for the design of the data extraction form and feedback about the completed form.

4.3.3.2 Data extraction procedure

For the data extraction form to investigate prevalence, the surveyed surgeons (3 surgeons agreed to participate, see Section 4.3.4.4) recommended a list of 200 patients under their care who were undergoing a surgery relevant to this study (see sample size estimation in Section 4.3.2 above). It is worth noting here that the 3 participating surgeons played the role of gatekeepers for other healthcare providers and patients in this phase.

It is normally desirable to include a sample that is as large and extensive as possible to better describe patterns in the general population (Nayak, 2010). However, this was not

feasible due to the limited timescale for this phase of the study in relation to the number of hospitals and patients with ACL injury that could potentially be included. Therefore, due to time constraints the number of practitioners and patients that were available to be contacted was 200 for each questionnaire.

Inclusion criteria for patients:

- Patients who had ACL injury and who were undergoing ACL reconstruction surgery
- Patients who were being treated in a clinic or a hospital in Riyadh, Saudi Arabia

The patients were identified by their treating surgeons and contacted by the researcher over the phone. All the data were collected anonymously (codes were used for patient and hospital information) and recorded on a written form (Section 4.3.3.1). The patients were informed by the researcher over the phone about the aims of the research and were assured that their confidentiality and anonymity will be maintained (see Section 4.3.5 for ethics). Patients who consented to participate in the research were then requested to answer the questions included in the data extraction form (see Appendix 2 for the form).

4.3.3.3 Direct contact with establishments for prevalence data collection

For further insight into the prevalence of ACL injury, another source of information was direct contact with health organisations and healthcare centres: the Saudi Ministry of Health, 1 military hospital and 2 private hospitals. The data were collected by the researcher in private meetings with the director of Physiotherapy Department and the Statistics Department in the Ministry of Health and the surgeons in the hospitals. The

information requested in this process consisted of the number of knee injuries in general and ACL injuries in particular, including those that required ACL reconstruction surgery according to the records of these healthcare establishments in the year from January 2012 to January 2013. Duplicate reports were removed.

4.3.4 Investigation of awareness of healthcare professionals and patients about ACL injury

Questionnaire survey method was used in this study as a tool to collect the required awareness data. The steps of the development of the questionnaires are described in Section 4.3.4.1. Awareness of pre-operative management of ACL injury by patients and healthcare practitioners in KSA was identified as one of the main gaps to be addressed in this study (Chapter Three). This section presents the questionnaire survey methodology used to investigate awareness of patients and practitioners about pre-operative physiotherapy treatment.

4.3.4.1 Questionnaire development

Two questionnaires intended to examine the awareness of both healthcare professionals and patients about available pre-operative physiotherapy treatment were designed and disseminated to practitioners and patients. The choice of the questions was guided mostly by the literature on ACL injury and physiotherapy (Dawson et al., 1996; Acharya et al., 2011; Maruf et al., 2012) and to address the questions highlighted by the aims

described above. Due to the limited literature on the subject, contributions made by the supervisory team were incorporated in the design process, which either extended the scope of the questionnaires or served to further improve their clarity by changing the wording. The pre-piloting and piloting processes also served to improve and introduce more confidence into the questionnaires by testing the validity of the items and incorporating feedback received from the pre-pilot and pilot step. After the questionnaires were pre-piloted and then piloted (see Sections 4.3.4.2 and 4.3.4.3, respectively), the study proceeded to using them for data collection. The different items in the practitioners' and patients' questionnaires were selected for specific purposes as shown in Appendices 3 and 4, respectively. Accordingly, literature on ACL physiotherapy management and critical discussions with the supervisory team informed the choice of items, while also maintaining focus on addressing the aims as a criterion for selection. Patients' views were, however, only sought at the piloting stage to ensure the clarity of the developed patient questionnaire (Elberse et al., 2010).

The questionnaire intended for healthcare professionals included two parts; the first part contained questions on personal and demographic details and professional credentials (7 items), and the second part investigated awareness of the healthcare professionals about pre-operative and post-operative physiotherapy treatment of ACL injury (16 items). This was conducted to allow comparison of awareness about pre-operative physiotherapy with the more established stage of physiotherapy treatment that happens post-operatively.

A similar format was followed in the questionnaire intended for the patients with the first part covering demographic information (7 items) and the second covering personal

awareness about pre-operative physiotherapy treatment following ACL injury (10 items). The questions were clear in addressing the purpose for which they were intended. For instance, awareness was assessed by a simple question of 'aware/not aware' and then further questions describing the procedure (duration of treatment, number and duration of sessions) re-enforced the awareness information.

The questionnaire items used a Likert scale for scoring (with 5 different options: from **strongly disagree**, which means the surveyed patient/practitioner is extremely against the statement, to **strongly agree**, which indicates extreme agreement with the statement). A Likert scale is usually used to measure views and attitudes with a range of responses for a specific statement or question. This scale was used because it is easy to construct and simple to read and complete by respondents (Cohen et al., 2000). It also allows the researcher to ask specific questions without causing the patients to diverge from the information being requested. Typically, a five point scale is used although there are some arguments that support the use of a seven point scale or a scale with an even number of options (Jamieson, 2004). Research suggests that 5-point and 7-point scales tend to produce comparable results, unlike scales with higher numbers of points, which were shown to be less favoured by survey participants (Dawes, 2008). Scales with a larger number of options tend to be confusing to patients and can sometimes lead to inaccurate information due to the inevitable overlap between the different options (Jamieson, 2004).

The use of a five-point scale in the present study was intended to provide sufficiently varied options while avoiding additional complexity in the responses and also to provide a scale that all patients in the study can use regardless of their educational level.

Although a Likert scale can provide useful information, which is simple to process and easy to analyse, the literature suggests that the information obtained using this type of scale can be biased and skewed towards more socially-accepted options (Jamieson, 2004). A study by Dawson et al. (1996) used a five-point Likert scale to assess the views and perceptions of patients after hip replacement. The information obtained using this method correlated with the outcomes of clinical tests, indicating the advantage of using such a scale.

4.3.4.2 Questionnaire pre-piloting

Following development of the questionnaires and critical review by the researcher's supervisory team, the first drafts of the patients' and practitioners' questionnaires were pre-piloted in the United Kingdom (UK) in order to assess the clarity and relevance of the questions and comprehensiveness of the questionnaire. This was done by distributing the English version of the questionnaires to a group of 12 Saudi physiotherapy students and one surgeon, practicing in KSA, as they had relevant knowledge in the field. The patients' questionnaire was given to 5 undergraduate physiotherapy students and the practitioners' questionnaire was distributed to 7 postgraduate physiotherapy students and one surgeon. Feedback included suggestions to change the wording of some of the items to improve clarity of the questions. An example of this type of feedback was related to Question 5 in Section 1 of the practitioners' questionnaire (Appendix 5), to which 'physiotherapist' was added in the rank options. This feedback assisted in making the questionnaires more understandable and hence removing any ambiguity that may occur when the patients and practitioners receive them. After this, the patients' questionnaire

was translated to Arabic by the researcher to ensure that the translation was done using accurate terminology that can be understood by patients.

4.3.4.3 Questionnaire piloting

The questionnaires were then piloted in Saudi Arabia by distributing them to 10 practitioners (all physiotherapists) and 10 patients in order to evaluate the questionnaires in a small sample before the study. A sample of convenience was used and the pilot was carried out in Riyadh, Saudi Arabia. The patients' questionnaire was piloted on a sample of patients with ACL injury while the practitioners' questionnaire was piloted on a sample of physiotherapists. At this stage, the patients' questionnaire was in Arabic, while the practitioners' questionnaire was not translated (still in English as the practitioners have been instructed and trained in English). Feedback from the piloting process resulted in changing the order of some of the questions. Both patients and practitioners were satisfied with the clarity of the questionnaires and thus no further changes were made. The final questionnaires for practitioners and patients are provided in Appendix 5 and 6, respectively.

4.3.4.4 Sampling of healthcare professionals and patients for the survey

For the questionnaires, a sample of 200 practitioners and 200 patients was selected due to time restrictions (see sample size estimation in Section 4.3.2 above). The inclusion criteria for patients in the awareness study were the same used for the prevalence

investigation (see Section 4.3.3.2). The inclusion criteria for healthcare professionals were as follows.

Inclusion criteria for practitioners:

- Physiotherapists and orthopaedic surgeons treating patients with ACL injury
- Practitioners (physiotherapists and surgeons) who work in a hospital or a clinic in Riyadh, Saudi Arabia

Surgeons and physiotherapists in public and private practice were contacted by the researcher in person and those who agreed to participate were included. Access to healthcare professionals was provided by the establishments in which they work. A total of 205 professionals (200 physiotherapists and 5 orthopaedic surgeons) participated in the study. The smaller number of surgeons was due to difficulty in contacting surgeons because of their busy schedules (multiple commitments with universities, surgeries, conferences and so forth). The researcher was unable to reach 2 out of the 5 surgeons (due to work commitments), and the ones who were available to meet consented to participate (3 surgeons). These 3 surgeons assisted in reaching patients for both prevalence and awareness investigations.

The professionals who participated in this study were practicing in 3 military hospitals, 4 Ministry of Health hospitals, 2 university hospitals, 2 private hospitals, 5 private clinics and 1 sports medicine hospital. These establishments constitute the main centres in Riyadh where ACL injury is treated and they reflect the distribution of hospital-based healthcare in Saudi Arabia.

Due to schedule restriction (patients have scheduled visits with the therapists), access to patients who participated had to be arranged through the healthcare professionals treating them to survey as large a patient group as possible. For this reason, the sample of 200 patients (undergoing both pre-operative and post-operative treatment) was selected by the healthcare professionals, based on the inclusion criteria.

4.3.4.5 Survey procedure

The final questionnaires were distributed to the sample of healthcare professionals (surgeons and physiotherapists) by the researcher. The practitioners' questionnaire was distributed in English whereas the one intended for patients was in Arabic. This is because practitioners in KSA receive their healthcare training in English and use the English language in hospitals, whereas the patients use Arabic as the language of communication. The practitioners were informed, by meeting with them in person, about the aims of the research and to provide instructions regarding how to complete the practitioners' survey questionnaires. The researcher also requested permission and the practitioners' assistance to distribute the patients' survey to the patients under their care (both pre-operative and post-operative patients). The questionnaire intended for the patients was then distributed to practitioners who agreed for their patients to participate. The researcher explained the instructions and the patients' questionnaire to the practitioner (item by item) and was contactable in case either the practitioners or their patients needed further assistance or had additional questions. The healthcare professionals informed their patients about the study. The patients were provided with a patient information sheet (in their native language, Arabic) and were offered a minimum

of 24 hours to consider if they wished to participate (see Appendix 7 for a translation of the information sheet provided to the participants). Consent forms (Appendix 8) were completed by the participating patients and returned to the practitioners. Both questionnaires were distributed face to face by the researcher to the practitioners and collected again in person from the practitioners.

4.3.5 Ethical considerations

This section discusses research ethical considerations followed in this study. Ethical practices were considered according to the guidelines of the Saudi Commission for Health Specialties (2014) on the code of ethics for healthcare practitioners, and in particular patient confidentiality was enabled by keeping the patients' information coded and anonymous. The information was kept confidential during and after the study and data were stored on a password-protected computer. Confidentiality measures were carried out in collaboration with their treating healthcare professionals. Participants were provided information about the research including: the nature and aims of the research, the setting of the study, any risks involved in participating, and any factors that may influence their convenience (Appendix 7). Consent was sought from patients and practitioners before starting the research process and participants were given sufficient time to consider prior to participation (Appendix 8). Patients and practitioners were informed that they had the right to withdraw themselves and their data from the study at any stage without needing to state the reasons for their decision.

4.3.5.1 Ethical approval for access to hospitals and health centres

Ethical approval was obtained from Manchester Metropolitan University, UK (Appendix 9) and the Saudi Cultural Bureau, UK (Appendix 10), which was used to obtain access to each hospital and health centre to survey healthcare professionals and patients under their care. Hospitals then issued internal ethical approval to allow contact with healthcare professionals and patients.

4.3.5.2 Ethical approval to conduct the research

Ethical approval of the study from the Saudi Cultural Bureau (Section 4.3.5.1) was also used at each step of the research process as surgeons requested to see the ethical approval to provide access to their patients for both the questionnaire survey and the data extraction form. Ethical approval was also used when the healthcare establishments were contacted directly by the researcher to request for prevalence data.

4.3.6 Data analysis

Analysis of data was conducted using the Statistical Package for the Social Sciences (SPSS) programme version 21 (IBM, USA). Descriptive statistics were used to give a general description of the sample including a measure of the awareness in regards to pre-operative physiotherapy treatment and prevalence of ACL injury in different patient groups. The choice of descriptive statistics was informed by the aims of the study as it was intended to estimate prevalence of the injury and awareness of pre-operative physiotherapy as a treatment option. The analysis was done by frequency distribution

(for example, different age groups, occupation, and causes of injury) with tables, pie charts and bar charts of the responses (Morgan et al., 2010). This allowed the researcher to uncover any trends and relationships between ACL injury and different characteristics of the populations including age and sports participation.

4.4 Results

The research presented in this study was undertaken to assess the prevalence of ACL injury in Saudi Arabian patients, and to investigate awareness of patients with ACL injury and healthcare professionals caring for them about the benefits of pre-operative physiotherapy.

For the patients' survey, 110 out of 200 patients agreed to participate in the data extraction process (prevalence study) and 103 out of the 200 surveyed patients agreed to answer the questionnaire (awareness study) (55% and 52%, respectively). For the practitioners' questionnaire, 107 out of the 200 physiotherapists and 3 out of the 5 surgeons agreed to participate in the questionnaire (awareness study) (54% and 60%, respectively).

The results of the prevalence of ACL injury in KSA will be presented first, followed by the results of the awareness of patients with ACL injury and healthcare professionals in relation to pre-operative physiotherapy.

4.4.1 Prevalence of ACL injury among patients in Riyadh, KSA

Prevalence data were collected directly from healthcare establishments. The ministry of health reported 1,800 ACL injuries, which reflected the number of injuries treated in public hospitals. A military hospital reported 109 injuries and two private hospitals reported 442 ACL injuries. Therefore, the total number of reported ACL injuries from January 2012 to January 2013 was 2,351 injuries out of 4,425 knee injuries as recorded

by the establishments contacted in this study. This suggests that ACL injury is the most prevalent knee-related injury in the population of the city of Riyadh, representing over 53% of all reported knee injuries.

The total population of the city of Riyadh reported in the 2013 census was 7,516,959 indicating a population prevalence of one ACL injury in every 3,200 individuals. This translates to 31 ACL injuries per 100,000 of the population of Riyadh, KSA. Table 4.1 below shows the prevalence of ACL injury in populations in different countries compared with the prevalence figure found in this study.

Figure 4.1 shows that out of the 110 patient participants, 99 reported a sports related accident resulting in their injury (90% of the sample), whereas road traffic accidents (RTA) and falls accounted for only 10% of all ACL injuries reported by the participants. In addition, most injuries (approximately 60%) were reported among younger patients aged 18-30 years (mean age of the sample 31 years) (Figure 4.2).

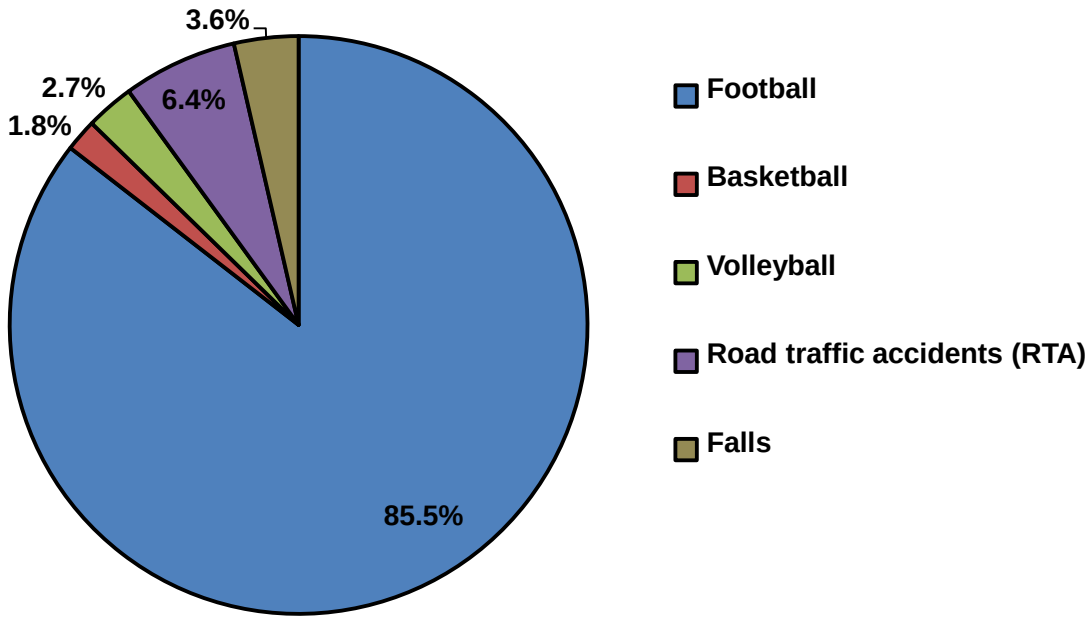


Figure 4.1. Prevalence of sports related ACL injuries in Riyadh, Saudi Arabia. Approximately 90% of all ACL injuries reported in the area of Riyadh are sports related (n = 110)

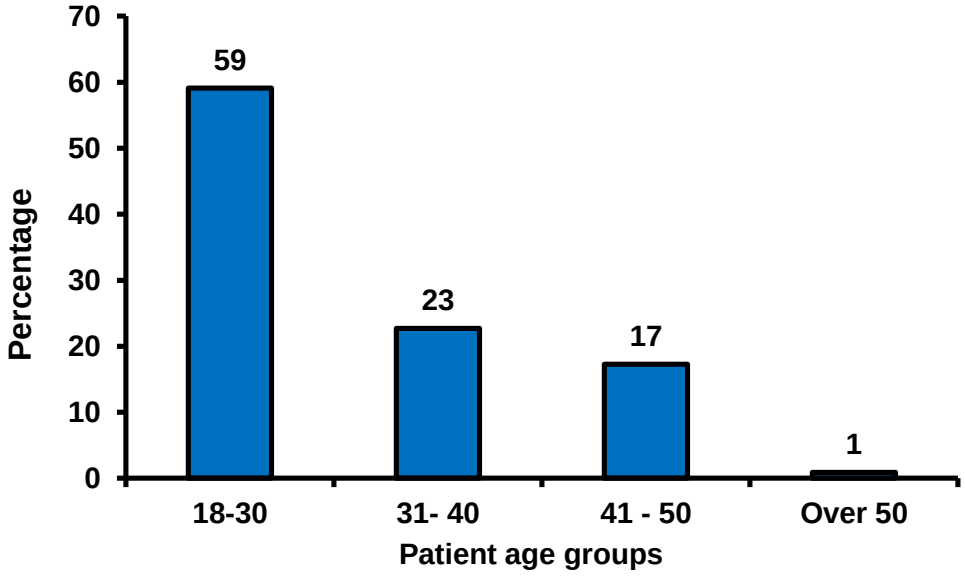


Figure 4.2. Distribution of ACL injuries in different age groups of the surveyed patient sample (n = 110). Approximately 60% of all ACL injuries are among younger patients aged up to 30 years

4.4.2 Awareness of patients with ACL injury and healthcare professionals about pre-operative physiotherapy management

A questionnaire survey was conducted to investigate the awareness of patients and healthcare professionals about the benefits of pre-operative physiotherapy rehabilitation in the management of ACL injury.

4.4.2.1 Characteristics of patient participants

Most of the patients were male (99%) in their twenties or thirties (97%). Their marital status was balanced with approximately half of them single. The occupational background of the patients was varied with nearly a third being students and approximately a half of civil employment background. Military employed patients constituted a minority (15%). Approximately three quarters of all patients used private healthcare for ACL injury treatment and the rest went to public hospitals (Figure 4.3).

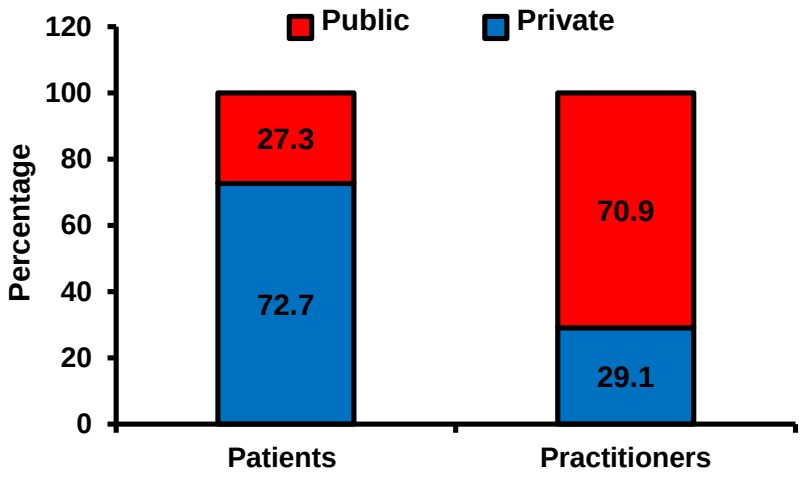


Figure 4.3. Distribution of surveyed patients with ACL injury (n = 103) and practitioners caring for them (n = 110) between private and government health facilities

The vast majority of all ACL injuries (over 90%) in the surveyed patients were caused by sports related activities, especially football (approximately 90% of all sports related ACL injuries). Almost all patients had not had a previous ACL injury and were having treatment for the first time. Just over half of the patients (51%) received pre-operative physiotherapy, whilst all surveyed patients (100%) received post-operative treatment (Figure 4.4).

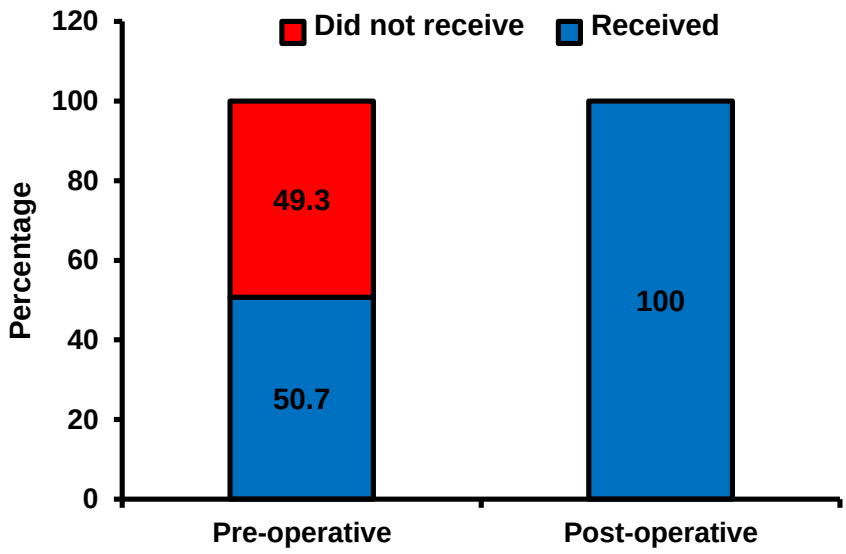


Figure 4.4. The percentage of surveyed patients who received pre-operative or post-operative physiotherapy rehabilitation (n = 103)

4.4.2.2 Characteristics of practitioner participants

Almost all of the surveyed practitioners (98%) had experience of caring for patients with ACL injury. Practitioners were mostly male (three quarters) of 40 years or younger age group (nearly 90%) (mean age 32 years). Around 3% were surgeons and 75% physiotherapists; the surgeons were of an older age group. Educationally, all practitioners had a relevant BSc degree (required for practice), with 30% having

additional higher qualifications including Master's and PhD degrees. Figure 4.3 shows that approximately 70% of the practitioners worked in the public sector and nearly 30% worked in private health centres.

4.4.2.3 Awareness of patients about pre-operative physiotherapy

Just over half of all patient participants (55%) were aware of the importance of pre-operative physiotherapy as part of ACL injury treatment (Figure 4.5). Most of the patients who were aware of the benefits of pre-operative rehabilitation had received this type of management and those patients who received the treatment believed they benefited from the rehabilitation. The majority of patient participants who received pre-operative physiotherapy (95%) believed that the sessions should be longer than 30 minutes, which is the average duration of the sessions in practice in KSA. All the surveyed patients were aware of post-operative physiotherapy and had received it (100% of the sample).

4.4.2.4 Awareness of practitioners about pre-operative physiotherapy

The majority of healthcare professionals (82%) were aware of pre-operative physiotherapy treatment as an option for the management of patients undergoing ACL reconstruction and knew about its benefits (Figure 4.5). These professionals recommended pre-operative physiotherapy for patients who were scheduled to undergo ACL surgery. All the surveyed healthcare practitioners were aware of post-operative physiotherapy and all of them recommended it (100% of the sample).

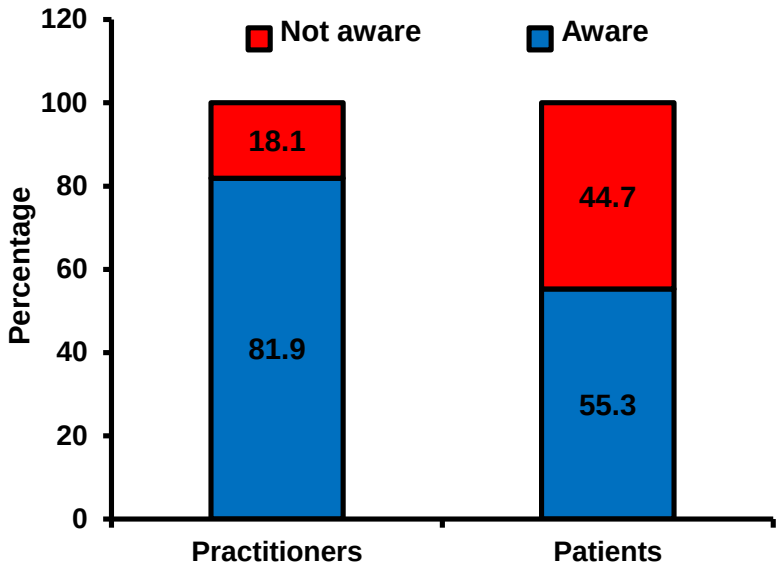


Figure 4.5. Awareness about pre-operative physiotherapy in ACL injury treatment amongst surveyed patients (n = 103) and practitioners (n = 110)

4.4.2.5 The pre-operative physiotherapy programme

The patient and practitioner questionnaires included items about specific details of the pre-operative programme and the recommended modifications to improve it; these details included the duration of treatment (in weeks), the number of sessions and the duration of each session (in minutes). The recommendations to improve the pre-operative programme were provided by the healthcare practitioners and were compared to the actual treatment received by the patients (Figures 4.6 to 4.8).

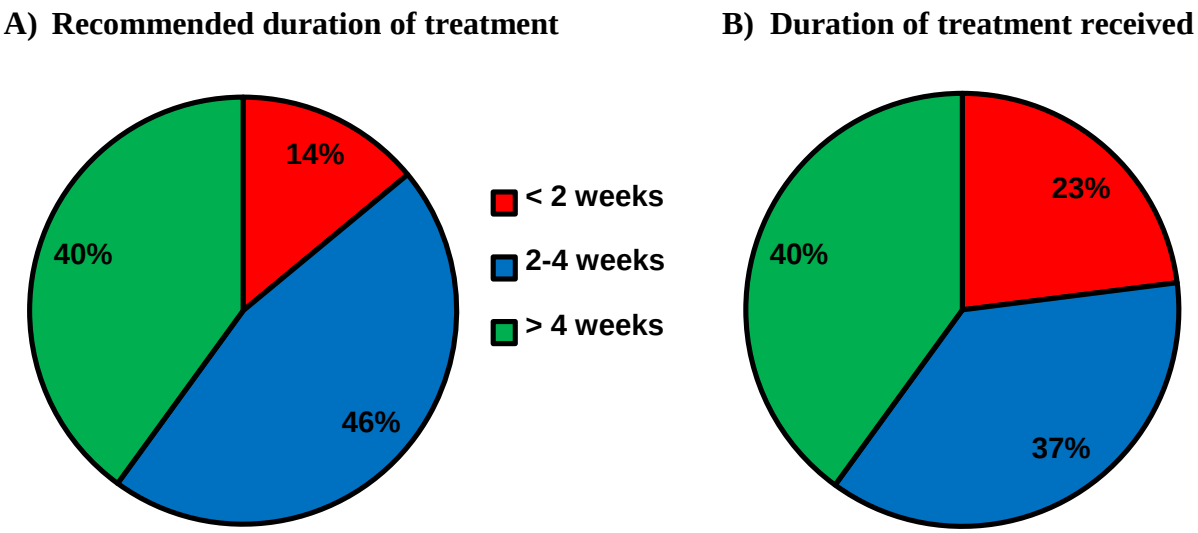


Figure 4.6. The pre-operative physiotherapy programme: the duration of treatment recommended by surveyed practitioners (A) and the duration of treatment received by surveyed patients (B)

Approximately 80% of practitioners recommended that patients who require ACL reconstruction should receive more than 2 weeks of physiotherapy and about a third indicated patients should be treated for more than 4 weeks (Figure 4.6 A). Most health professionals (82%) recommended that patients needed more than 6 sessions of pre-operative therapy and a third stated that patients required at least 13 sessions (Figure 4.7 A). Just over two thirds of the practitioners stated the sessions of pre-operative physiotherapy should be over 30 minutes each (Figure 4.8 A).

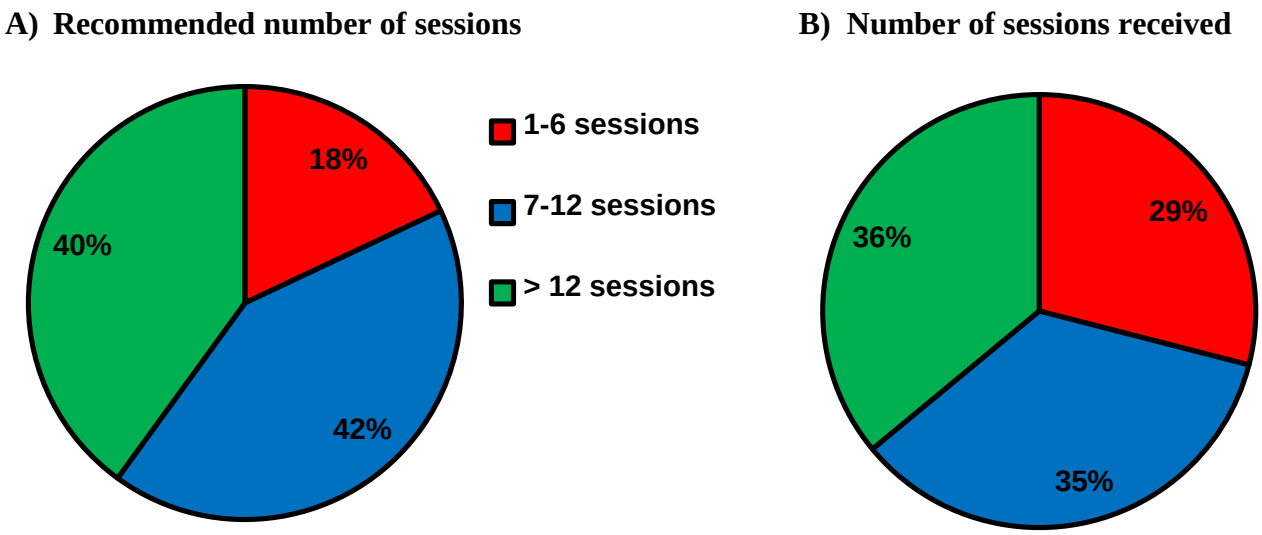


Figure 4.7. The pre-operative physiotherapy programme: the number of treatment sessions recommended by surveyed practitioners (A) and the number of sessions received by surveyed patients (B)

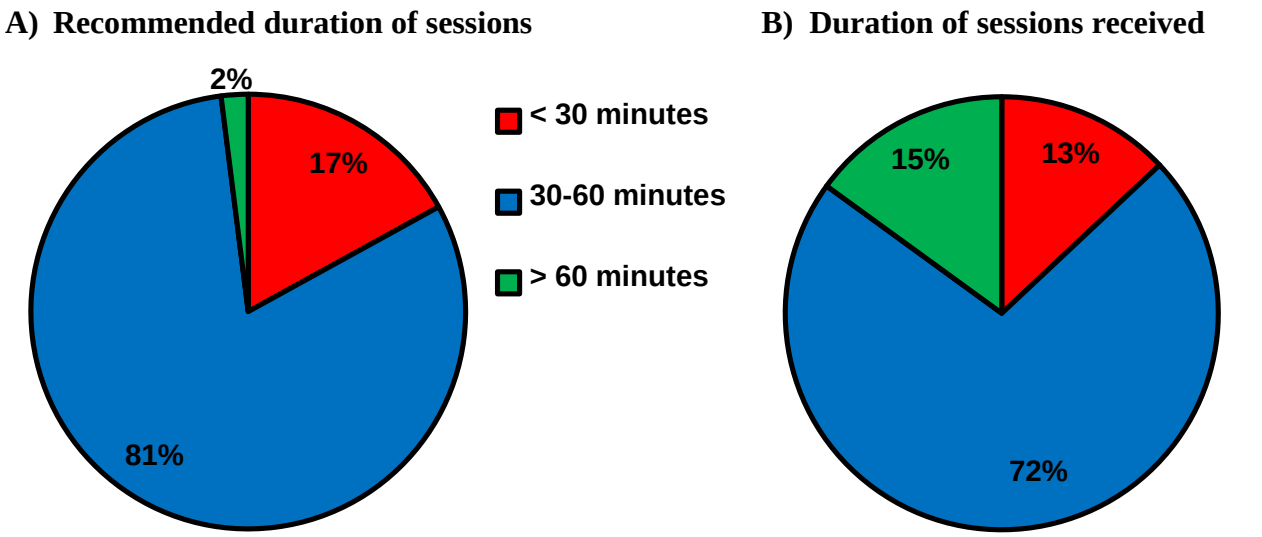


Figure 4.8. The pre-operative physiotherapy programme: the duration of treatment sessions recommended by surveyed practitioners (A) and the duration of sessions received by surveyed patients (B)

The duration of treatment for patients who received pre-operative physiotherapy was more than 2 weeks for over three quarters of the patients and 4 or more weeks for 40% of the patients (Figure 4.6 B). Out of all patients who received pre-operative physiotherapy, just over 70% received more than 6 sessions and approximately 35% received at least 13 sessions (Figure 4.7 B). The duration of each session was more than 30 minutes for nearly 90% of patients who received pre-operative treatment (Figure 4.8 B).

4.5 Discussion

The aim of this clinical survey was to investigate the prevalence of ACL injury among the Saudi Arabian population and assess the awareness of patients with ACL injury and healthcare professionals caring for them about the benefits of pre-operative physiotherapy. This study used a survey methodology on a sample of Saudi patients and healthcare professionals. The findings provided insights into the prevalence of ACL injury, its main causes and awareness about pre-operative physiotherapy management by both healthcare professionals and ACL-deficient patients.

While anterior cruciate ligament (ACL) injury is a common knee injury worldwide (Beynnon et al., 2005), the prevalence of this injury in the Saudi Society has not been investigated prior to the present study. Knowing the prevalence of such an injury may assist in developing appropriate preventive measures aimed at reducing the incidence of the injury, especially in sports. Football is reported to be the main sport where most injuries occur due to its popularity around the world and in particular among the Saudi

population (Hutchinson and Ireland, 1995), with approximately 1 in 3 active Saudi adults participating in this sport, as discussed in detail below (Al-Refaee and Al-Hazzaa, 2001).

In general, one of the most important aspects of ACL injury is the reduced quality of life (QoL) and pain associated with the injury often causing patients to become functionally impaired for long periods of time, which has negative effects on the affected individuals and the system as a whole (Schmidt, 2004). Generally, the usual course of treatment is surgical ACL reconstruction, which is normally required to restore knee function (Kowalchuk et al., 2009). However, before a patient is considered for surgical intervention, a normal range of motion (ROM), normal gait and adequate knee control are required (Shelbourne and Klotz, 2006), and these can be achieved with pre-operative physiotherapy rehabilitation (Beard et al., 1994; Fitzgerald et al., 2000).

The role of pre-operative rehabilitation was suggested in the 1980s (Noyes et al., 1983); however, more than three decades on, this intervention has not been established as mainstream therapy in clinics and hospitals in most countries around the world, including KSA. Indeed, there is a lack of pre-operative physiotherapy programmes designed for patients with ACL injury prior to reconstruction surgery in Saudi Arabian health institutions and this may be due to many factors including lack of awareness among orthopaedic surgeons, physiotherapists and patients about the benefits of this intervention.

Creating awareness among patients and healthcare organisations about the importance of physiotherapy is a challenge facing healthcare practitioners (Jackson, 1987; Grimmer et

al., 1999). Raising the level of awareness about the role of physiotherapy within healthcare organisations may in turn have a positive influence on introducing, utilising and integrating this type of rehabilitation into standard treatment of ACL injury (Achterbergh and Vriens, 2002).

4.5.1 Prevalence of ACL injury among the Riyadh population

The findings from the current study indicated that ACL injury is the most prevalent knee-related injury (approximately 53% of all reported knee injuries), which is consistent with previous studies that indicate that ACL tears are the most common knee ligament injuries (Beynnon et al., 2005; Lohmander et al., 2007; Gianotti et al., 2009; Nordenvall et al., 2012). However, collateral ligament injuries are sometimes reported to be as common as ACL tears (Nielsen and Yde, 1991).

The data also indicated that the population prevalence of ACL injury is approximately 31 in 100,000 of the Riyadh population, which is comparable to the prevalence reported in the USA, New Zealand, Norway and Denmark populations (30-38 per 100,000) and lower than that reported in Sweden (78-81 per 100,000). Table 4.1 shows the prevalence of ACL injury in the KSA in comparison to international figures. Some of the population figures reported in the literature are based on limited areas and not on nationwide studies due to the logistic difficulties inherent to conducting such large scale investigations.

Table 4.1. The prevalence of ACL injury in Riyadh, KSA, compared with other countries based on literature

Country	Annual population prevalence	Place of study	Period of study	References
USA	30 per 100,000 38 per 100,000[a]	Southern California area San Diego area	2001-2005 1985-1988	Csintalan et al., 2008 Miyasaka et al., 1991
Denmark	30 per 100,000 38 per 100,000[b]	City of Aarhus Nationwide study	1986 2005-2007	Nielsen and Yde, 1991 Lind et al., 2009
Sweden	81 per 100,000 78 per 100,000[c]	City of Helsingborg Nationwide study	2001-2002 2001-2009	Frobell et al., 2007 Nordenvall et al., 2012
New Zealand	37 per 100,000[b]	Nationwide study	2000-2005	Gianotti et al., 2009
Norway	34 per 100,000[b]	Nationwide study	2004-2006	Granan et al., 2008
KSA	31 per 100,000[d]	Riyadh region	2012-2013	The present study

[a] The prevalence of knee ligament injuries (including injuries to the ACL, PCL and collateral ligaments) during this period was 60 per 100,000 per year (Miyasaka et al., 1991) with ACL injuries accounting for 64% of these injuries

[b] Prevalence of ACL injuries that required ACL reconstruction surgery

[c] The injury was identified in the study (Nordenvall et al., 2012) as cruciate ligament injury and indicated by the authors as predominantly ACL injuries (> 97% of all cases)

[d] This study was based on figures reported by the Ministry of Health and hospitals in the Riyadh region, KSA. The population figures were also provided by the Ministry of Health for the year 2013

The studies conducted in Sweden and Denmark represent an interesting example. Figures reported based on the city of Helsingborg (Frobell et al., 2007) were very similar to those reported based on nationwide figures in Sweden (Nordenvall et al., 2012). A similar trend is seen for the figures reported in Denmark, with similar prevalence in the city of Aarhus (Nielsen and Yde, 1991) to that in the general Danish population (Lind et al., 2009). The nationwide figures for Denmark (Lind et al., 2009), Sweden (Granan et al., 2009; Nordenvall et al., 2012) and Norway (Granan et al., 2008) were reported by Scandinavian national ACL registries responsible for collecting such data, which facilitated conducting these large scale studies. However, the reporting of ACL injuries by hospitals to these national registries is a voluntary exercise in Sweden and Norway, whereas it is a legal requirement in Denmark, which may lead to underestimation of the prevalence figures. The higher prevalence figures in Sweden may be due to the quality of injury records in the Swedish health system and the importance of research on ACL injury reflected by the number of research studies on ACL injury conducted in Sweden (as an example, four out of eight studies in the systematic review in Chapter Five were from Sweden).

Another factor that may lead to underestimation in these nationwide reports is that only patients that undergo reconstruction surgery are reported to the national registries (Granan et al., 2009). The present study represents an investigation similar to some of the reports in Table 4.1 and provides information on the prevalence of ACL injury in the Riyadh region; however, any conclusions about the prevalence of this injury in the general Saudi population based on these figures should be drawn carefully.

ACL injury was more prevalent among younger patients, who are more active (nearly 60% of all ACL deficient patients were 30 years of age or younger) (Figure 4.2). A similar observation was reported in studies that examined the prevalence of ACL injury in different age groups in the USA (Miyasaka et al., 1991; Csintalan et al., 2008), which indicated that over half the patients with ACL injury were 30 years old or younger. This trend may relate to the main cause of the injury being active participation in sports.

One has to note though that population figures reported in the literature are quoted in healthcare systems where records are closely kept including the history of the injury, which is most frequently sports related (Miyasaka et al., 1991; Nielsen and Yde, 1991; Frobell et al., 2007). However, concerns were raised recently that there is no systematic collection of injury information in Saudi Arabia, even in professional sports (Almutawa et al., 2014). This trend may lead to underestimation of prevalence figures in the general population and also amongst athletes. The data collected in this study indicated that most cases of ACL injury were related to sports participation, similar to wider literature, although the patient participants were not professional athletes and exhibited moderate sports participation with an active lifestyle.

Out of all the patient participants, approximately 90% of the cases reported a sports related incident resulting in their injury, which reflects the most common cause of ACL injury worldwide. This explains the higher prevalence of ACL injury among people who practice sports, especially football, in Saudi Arabia.

In professional football competitions, 12 cases of ACL injury were reported in Saudi Arabia in the season 2014-2015, which is a relatively higher number compared to the

English premier league (7 cases), the Italian league (4 cases) and the Spanish league (2 cases) (Al-Gannas, 2015). This has been attributed to many reasons, including limited healthcare provision to players and the lower quality of training equipment and football pitches in KSA (Almutawa et al., 2014); however, the full reasons are still unknown (Al-Gannas, 2015). Other factors may include the increased incidence of ACL injury in hot weather conditions due to high levels of fatigue (Silvers and Mandelbaum, 2011), which can be relevant to patients practicing sports in the Saudi Arabian weather. In physical activity lasting longer than 30 minutes within extremely hot conditions, impairment of performance is inevitable, which is different to that caused in cool weather (Maughan et al., 2007). Indeed, hot weather conditions create a higher blood lactate concentration, as well as a faster rate of muscle glycogen depletion (Jentjens et al., 2002).

It is worth noting that although sports are a leading cause of ACL injury, 53% of the Riyadh population were reported to be physically inactive and approximately 30% engaged in physical activity irregularly (Al-Refaee and Al-Hazzaa, 2001). The data in this study also indicated that the injury is more prevalent in males than females most likely due to Saudi culture, which encourages females to have a more sedentary lifestyle. In terms of age, the injury seemed to be more prevalent in males in their twenties and thirties as they represent the most active, sports-participating cohort in the Saudi society.

4.5.2 Awareness of pre-operative physiotherapy among patients and practitioners

The majority of participating healthcare professionals (82%) and just over a half of the surveyed patients (55%) were aware of pre-operative physiotherapy and all of the patients who were aware of the treatment had already received it (Figure 4.5). When awareness figures are compared to post-operative physiotherapy (100% of all practitioners), there seems to be a lack of awareness among practitioners about this intervention prior to surgery. This can be reflected in the observation that all patients with ACL injury (100%) received post-operative and only half (51%) received pre-operative physiotherapy (Figure 4.4).

Interestingly, all health professionals who were aware of pre-operative rehabilitation recommended its use to their patients. It seems that reasons underlying this lack of awareness include lack of recommendation by the management to administer such intervention compared to post-operative rehabilitation which is part of routine ACL treatment, as indicated by the surveyed physiotherapists. Another reason may be the lack of studies on the effectiveness of pre-operative rehabilitation, which hinders its integration into clinical practice on a regular basis (Keays et al., 2006). Recommendation by healthcare professionals, as seen in this study, seemed to be based on their own judgment and patients had a choice of receiving the rehabilitation once the recommendation has been made. Comments from patients re-enforced education about pre-operative physiotherapy and psychological preparation before surgery as areas that require more attention for patients undergoing reconstruction of the ACL.

The situation of awareness in developing countries, such as Saudi Arabia, about physiotherapy as a treatment option may be similar to other developing countries, where education and healthcare are challenging areas. Lack of awareness about physiotherapy, as seen in this study, is not only observed in patient populations but also in healthcare professionals. The literature indicates that healthcare professionals, such as clinical practitioners, may not have adequate awareness about the physiotherapy management available to their patients and the benefits of such intervention (Harris, 1992; Summers, 1993). Therefore, generating awareness among patients and healthcare professionals remains a major challenge for physiotherapy practitioners, especially in developing countries (Acharya et al., 2011; Maruf et al., 2012). It is worth noting, however, that the present study looked into the awareness of physiotherapists and did not include other healthcare professionals.

Recent studies that investigated awareness about the benefits of physiotherapy among patients in Nigeria (Maruf et al., 2012) and among clinical professionals in Nepal (Acharya et al., 2011) indicated this lack of awareness in both receivers and providers of healthcare. The study conducted in Nepal surveyed 115 physicians and indicated that the majority (98%) of respondents were aware of physiotherapy treatment. Although nearly all practitioners (93%) participating in this study reported referral of their patients for post-operative physiotherapy, only 63% were sufficiently aware of the benefits of pre-operative physiotherapy management to refer their patients to these services (Acharya et al., 2011).

In the Nigerian context, although 66% of the surveyed 885 individuals were aware of the benefits of physiotherapy and 75% supported the view that physiotherapy should be

available in hospitals, approximately 56% believed their awareness is adequate to recommend these services to other patients (Maruf et al., 2012), which was highlighted previously in relation to physiotherapy management awareness in Chapter Three. Nevertheless, the findings of this study reflect a similar level of awareness amongst patients to that indicated by the present study.

The trends reported in these two studies are very similar to the awareness situation in Saudi Arabia, with the majority of the practitioners and just over half the patients showing adequate awareness about pre-operative physiotherapy. One can speculate that the reasons may relate to the level of education and the healthcare systems in these countries; however, investigating the reasons for this lack of awareness was beyond the scope of this thesis. Raising awareness about the benefits of pre-operative physiotherapy may lead to increased use of this intervention for patients with ACL injury prior to reconstruction surgery, which may lead to improved patient outcomes.

4.5.3 Pre-operative rehabilitation programmes

The questionnaires included items intended to investigate the specific details of the pre-operative programme and the recommended modifications by practitioners to improve it. The recommendations included the duration of treatment (in weeks), the number of sessions and the duration of each session (in minutes). These were compared to the actual treatment received by the patients (Figures 4.6 to 4.8). It seems that the consensus of most surveyed healthcare professionals about the recommended pre-operative

physiotherapy protocol is a 4-week long programme with a frequency of 3 sessions per week, with each session lasting 30-60 minutes on average.

Unlike post-operative rehabilitation, pre-operative physiotherapy did not seem to follow a particular programme indicating a lack of a standardised pre-operative physiotherapy programme. In addition, the recommendations of healthcare professionals were closer to the actual received treatment in post-operative than pre-operative rehabilitation. This shows that there is a gap between recommendations by practitioners and real practice in conducting pre-operative physiotherapy treatment. In this setting, healthcare professionals recommended physiotherapy regimes to their patients, which were based on their clinical experience and the patients' conditions. This is indicative of a lack of standardised protocols for pre-operative rehabilitation and a need for an evidence-based programme (see Chapter Six).

This study presented novel findings in the Saudi context in relation to the prevalence of ACL injury and awareness of patients and healthcare professionals about pre-operative physiotherapy, adding to the international literature on the subject. The questionnaires served their purpose because they were designed with clear aims and developed further in pre-pilot and pilot steps. Appraisal of methodology shows its suitability for this type of exploratory study, where a trend or a phenomenon is being qualified in a sample. However, one of the limitations of the questionnaire methodology is that interpretation of the data is not always accurate and using a Likert scale may lead to missing important findings because of restricting the respondents to limited options. Limitations of this survey study also include the limited quality of records in Saudi hospitals, which can affect the collected information related to the history of ACL injury. As an example

from this study, information related to the injury was sometimes not specified in the correct category of knee injury in the patient's record, which necessitated reviewing the whole file to find the relevant information. Another limitation was the restriction of the study to the Riyadh region, which does not allow accounting for variability between regions in KSA. This was mainly due to time and access constraints. Furthermore, this study could also be complicated by the possibility that patients from outside of the Riyadh region may be treated in these hospitals, which are considered centres of excellence, leading to the possibility of overestimated prevalence figures.

4.6 Conclusion

This study aimed to investigate the prevalence of anterior cruciate ligament (ACL) injury in the population of the region of Riyadh, KSA, and to assess awareness of healthcare practitioners and patients about pre-operative physiotherapy for this injury.

The findings showed that ACL injury in KSA is most prevalent in younger, active males and that the most prevalent ACL injuries are sports related. In Riyadh city population, the prevalence of ACL injuries was shown to be approximately 31 per 100,000, similar to prevalence figures in several countries; however, this figure may well be an underestimation. However, patients from other regions who were treated in the participating hospitals were not identified. Their numbers can also play a role in increasing the prevalence figures.

Most healthcare professionals were aware of pre-operative physiotherapy whereas just over half of the surveyed patients demonstrated sufficient awareness about such treatment. This shows a clear contrast to awareness about post-operative physiotherapy. Most importantly, this study showed that there is a lack of standardised, pre-operative physiotherapy programme in practice in KSA. This indicates that there is a need to raise awareness about the role of pre-operative physiotherapy to prepare patients for ACL reconstruction surgery. In practice, incorporation of pre-operative physiotherapy into routine clinical management will require standardised and cost-effectiveness protocols.

The next chapter is a systematic review of the literature to investigate the effectiveness of pre-operative physiotherapy for the treatment of ACL injury.

Chapter Five: The Effectiveness of Pre-operative Exercise Physiotherapy Rehabilitation on the Outcomes of Treatment Following Anterior Cruciate ligament Injury: A Systematic Review

5.1 Introduction

After assessing the awareness of patients and healthcare practitioners about pre-operative physiotherapy management of anterior cruciate ligament (ACL) injury, the effectiveness of this type of rehabilitation is assessed in this chapter. Critical analysis of the effectiveness of pre-operative physiotherapy can support the adoption of this type of management into routine clinical practice. This in turn can impact on the awareness about its use and benefits. In addition, synthesising the current level of evidence can help in identifying the best practice, together with detailing the development of different exercises and their effects on patient outcomes that can assist in developing a standardised, evidence-based pre-operative protocol, which is one of the main aims of this thesis.

Internal knee injuries account for nearly 45% of sports related injuries, with ACL injury being the most prevalent structure damaged (Hartigan et al., 2009). The prevalence of ACL injuries was assessed in the Saudi society in the previous chapter and was shown to be similar to international figures (Chapter Four). ACL injury is associated with pain, instability of the joint, muscle weakness, functional limitation, poor quality of life (QoL), and an increased risk of knee-related osteoarthritis (Arangio et al., 1997; Shaarani et al., 2012). ACL reconstruction surgery is the main treatment for ACL injuries (Kowalchuk et al., 2009). Over 200,000 ACL reconstruction surgeries take place each year in the USA, which costs the more than $3 billion annually (Hartigan et al., 2009; Frobell et al., 2010).

Arguably, pre-operative physiotherapy, such as an exercise rehabilitation programme, is often performed to prepare the knee for reconstruction surgery and to maximise the outcomes of rehabilitation (Mikkelsen et al., 2000; Kvist and Gillquist, 2001; Keays et al., 2006). Physiotherapy rehabilitation prior to ACL surgery is used to increase muscle strength and functional ability (Noyes et al., 1983; Beynnon et al., 2005). In addition, pre-operative physiotherapy can reduce the risk of pivot shift episodes, which can often cause progressive joint damage, as well as facilitate recovery after reconstruction (Tegner et al., 1986).

Although the potential of pre-operative physiotherapy to restore knee function was suggested previously (Noyes et al., 1983), there is no standardised, evidence-based rehabilitation approach for patients with this injury. Development of such protocol and assessing its clinical and cost effectiveness can assist in the wide adoption of pre-operative physiotherapy management in clinical practice. Whilst there are a number of

clinical trials that have investigated the effectiveness of pre-operative rehabilitation on the outcomes (pain, quality of life, range of motion, muscle strength and function) of treatment following ACL injury, there is a lack of consensus in these findings. Therefore, the aim of this systematic review was to examine the current level of evidence in relation to the effectiveness of pre-operative exercise physiotherapy rehabilitation on the outcomes of treatment following ACL injury.

5.2 Materials and Methods

5.2.1 The search strategy

A systematic review was undertaken based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). The following electronic databases were searched: PubMed, Ovid (AMED, MEDLINE) The Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register), and Web of Science (science and social science citation index). Studies published between the inception of the databases and December 2015 (completion date of the search) were sought. The keywords used for the search were: ‘anterior cruciate ligament injury’, ‘pre-operative rehabilitation’, ‘pre-operative exercise’, ‘pre-operative protocol’, ‘pre-operative physiotherapy’ and ‘quality of life’. These keywords were selected guided by the literature with relevance to ACL injury and its pre-operative physiotherapy management. These keywords were then combined to refine the literature search and focus the review to the aim of the study (Appendix 11).

Articles searched were those conducted on human patients and published in English, and 'randomised controlled trial' was used as a filter for the search. The reference lists of the selected articles were also checked manually for any relevant studies that may not have been available electronically. The search strategy was complemented by a manual search of selected journals: Archives of Physical Medicine and Rehabilitation, British Medical Journal, Clinical Rehabilitation, Journal of Sport Rehabilitation, Physical Therapy, the New England Journal of Medicine, the American Journal of Sports Medicine, the Journal of Bone and Joint Surgery, International Scholarly Research Network Rehabilitation, Orthopaedic Journal of Sports Medicine and Physiotherapy Research International, to identify any missing relevant literature.

Studies were included if:

- They were randomised controlled trials.
- They included human participants with unilateral ACL injury.
- Pre-operative exercise physiotherapy rehabilitation was used to treat the patients.

Studies were excluded if they were:

- On bilateral ACL injuries.
- They were not in the English language.

5.2.2 Assessment of quality of the studies

The Physiotherapy Evidence Database (PEDro) scale was used to assess the quality of methodology applied in the selected studies (Beard et al., 1994; Fitzgerald et al., 2000;

Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013). Two reviewers (SA and GY) applied the scale to the studies and a high level of agreement was achieved (89%). A consensus method was used where there was disagreement, and an independent reviewer (FF) was consulted to make a decision regarding the final score and the inclusion of the article in the review.

The PEDro scale (Table 5.1) is an 11-item scale with the first item assessing the external validity of the trial. Usually, this item is not included in the assessment of the study; hence, the assessment was based on items 2 to 11 in the present study as recommended by Maher et al. (2003) and has been previously used elsewhere (Behm et al., 2015). These items were scored equally as 1 for yes and 0 for no. Studies with a PEDro score of 0 to 4 were considered to be of poor methodological quality. Scores of 5 or 6 were considered to be of moderate quality, and those with scores of 7 and above were considered to have high methodological quality (Maher et al., 2003). Three items on the PEDro scale refer to blinding procedures. However, it is acknowledged that it is difficult to blind patients and therapists delivering physiotherapy interventions (Hicks, 2009), and therefore, the maximum score that can be achieved by the studies included in this review was 8 out of 10.

Table 5.1. Criteria for the methodological quality assessment (PEDro Scale) adapted from Maher et al. (2003)

	PEDro items	Answer
1.	Eligibility criteria were specified	Y/N
2.	Participants were randomly allocated to groups (in a crossover study, participants were randomly allocated an order in which treatments were received)	Y/N
3.	Allocation was concealed	Y/N
4.	The groups were similar at baseline regarding the most important prognostic indicators	Y/N
5.	There was blinding of all participants	Y/N
6.	There was blinding of all therapists who administered the therapy	Y/N
7.	There was blinding of all assessors who measured at least one key outcome	Y/N
8.	Measures of at least one key outcome were obtained from more than 85% of the participants initially allocated to groups	Y/N
9.	All participants for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	Y/N
10.	The results of between-group statistical comparisons are reported for at least one key outcome	Y/N
11.	The study provides both point measures and measures of variability for at least one key outcome	Y/N

Y = Yes, scores 1; N = No, scores 0; Item 1 is not scored

5.2.3 Data collection and extraction

The two reviewers (SA and GY) extracted data from the studies that fulfilled the inclusion criteria (Table 5.2) by independently using a data extraction form. To ensure that no significant information was omitted from the studies, the following were recorded during data extraction: author information, date and place of publication, sample information, drop-outs, types and duration of intervention, outcome measures used, patient assessment and follow-up period, results and any other comments specific to each study (Table 5.3). Due to the small sample sizes and the heterogeneity in the

outcomes assessed in the studies, a meta-analysis or statistical assessment of the outcomes was not performed (O'Rourke and Detsky, 1989; Palmer et al., 2014). The applicability, reliability and validity of the studies were assessed using the randomised controlled trials checklist provided by the Critical Appraisal Skills Programme (CASP, 2013). The outcomes that were assessed included: pain, quality of life, physical knee function, swelling, range of motion, muscle strength and functional activity.

Table 5.2. Summary of methodological quality assessment using the Physiotherapy Evidence Database (PEDro) scale. Scores are out of 10

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Total score (/10)
Beard et al., 1994; UK	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	7/10 High quality
Fitzgerald et al., 2000; USA	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5/10 Moderate quality
Frobell et al., 2010; Sweden	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7/10 High quality
Frobell et al., 2013; Sweden	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	6/10 Moderate quality
Hartigan et al., 2009; USA	Y	Y	N	N	N	N	N	N	N	Y	Y	3/10 Low quality
Shaarani et al., 2013; Ireland	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	7/10 High quality
Tagesson et al., 2008; Sweden	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	6/10 Moderate quality
Thomeé et al., 2010; Sweden	Y	Y	Y	Y	N	N	N	N	N	Y	Y	5/10 Moderate quality

N, no (Score = 0); Y, yes (Score = 1)

5.3 Results

The results are reported based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines with descriptive and narrative findings (Moher et al., 2009). Based on electronic and manual searches using the keyword search strategy, a total of 500 studies were identified (PubMed, 156; Ovid, 118; Web of Science, 220; Cochrane Library, 4; manual search, 2). After removing duplicates, applying the inclusion criteria and abstract screening, eight studies were found to satisfy these criteria (Figure 5.1). These eight studies were included in the review (Table 5.3).

5.3.1 Methodological quality of the selected studies

The eight studies (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013) accepted for inclusion in the systematic review were then assessed for quality. The methodological quality of the studies included ranged from 3 to 7 out of 10 (Table 5.2). The mean score of the studies was 5.8, which reflects an overall moderate methodological quality. One study was of a low methodological quality (Hartigan et al., 2009), four studies were of a moderate methodological quality (Fitzgerald et al., 2000; Frobell et al., 2013; Tagesson et al., 2008; Thomeé et al., 2010) and three were of a high quality (Beard et al., 1994; Frobell et al., 2010; Shaarani et al., 2013**)**. Intention-to-treat analysis was used in two studies (Beard et al., 1994; Frobell et al., 2010). Three studies (Beard et al., 1994; Fitzgerald et al., 2000; Hartigan et al., 2009) failed to report a concealment of treatment employed. The outcome assessor was blinded

to the intervention in two studies (Beard et al., 1994; Shaarani et al., 2013). All the studies included reported that participants were randomised and described the methods used for randomisation.

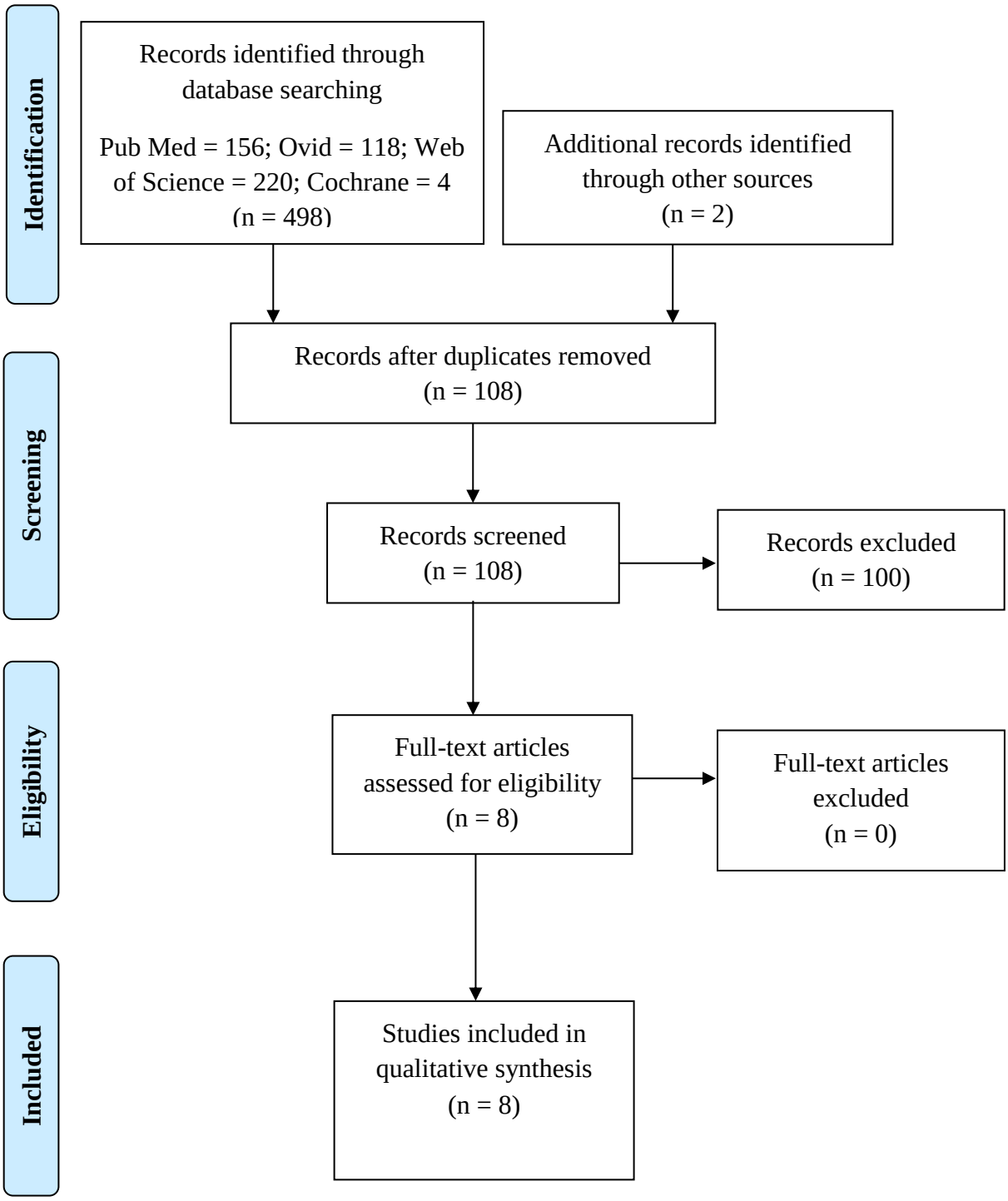


Figure 5.1. PRISMA flow diagram (Moher et al., 2009) through the different phases of the systematic literature search

5.3.2 Participant characteristics

The eight studies investigated a total of 451 participants, of which 71% (n = 319) were male participants. One study (Shaarani et al., 2013) included only male participants (n = 23). The age of the participants in the eight studies ranged from 15 to 57 years. There were 36 drop-outs in the trials. The reasons for dropping out included: fractures and other injuries that could interfere with the rehabilitation, the ACL was not completely torn or the treatment schedule was not maintained. The average number of participants in the treatment group after randomisation was 28 (range 9-59), with two studies having intervention groups containing more than 30 participants (Frobell et al., 2010; Frobell et al., 2013).

Table 5.3. Summary of data from studies that satisfied the criteria for inclusion

No.	Authors, year, origin of study	Sample Size (drop-outs)	Patient characteristics	Intervention/control	Outcome measures	Patient assessment / follow-up	Results/comments
1	Beard et al. 1994; UK	50 (7)	- 18-35 years old; mean 25 - Active - Recreational sports person	**Control group:** - Quadriceps and hamstring muscles strengthening exercises (Open kinetic chain); group T **Intervention group:** - Quadriceps and hamstring muscles strengthening exercises (Closed kinetic chain); group P -Proprioception enhancement/training ***-12 weeks (twice weekly) for one hour.***	-*Knee function*; **using** The validated functional scoring scale of Lysholm and Gillquist**.** -*Proprioception***; using** The Vicon Interfaced Knee Displacement Equipment (VIKDE)	-Baseline -12-weeks after physiotherapy course.	After treatment, both groups had a reduction in reflex hamstring contraction latency (RHCL) and an increase in functional score. The RHCL score in group P was higher than in group T (40ms, SD 30; 14ms, SD 35 respectively, $p < 0.05$) and the functional score in group P was greater than in group T (29.4, SD 15; 11.2, SD 15 respectively, $p < 0.005$).
2	Fitzgerald et al. 2000; USA	28 (2)	- 15-57 years old, mean 28 - Active - Recreational sports person	**Control group:** - Strengthening exercises - Functional rehabilitation - Open and closed kinetic chain exercises **Intervention group:** - Strengthening exercises - Functional rehabilitation	-Knee Outcome Survey's Activities of Daily Living Scale (ADLS) and Sports Activity Scale -A global rating of knee function, scores on a series of single-limb hop tests. -Measurements of maximum isometric quadriceps femoris muscle force output; **using** a Kin-Com II	-Baseline -Post treatment -6 months post treatment.	More participants had unsuccessful rehabilitation in the control group (7 out of 14) compared with the perturbation group (1 out of 12) (Chi-square analysis: $\chi^2 = 5.27$, critical value = 3.84, $p < 0.05$). - There was a within-group 3 time interaction for the ADLS, global rating of knee function, and crossover hop test scores. These scores decreased from post-training to the 6-month follow-up for the standard group. - There were no differences between the

				- Open and closed kinetic chain exercises - Balance training **-5 weeks, *2-3 sessions per week (10 sessions)*** ***Duration of sessions not reported.***	dynamometer. -Passive anterior knee laxity measurement; **Using** KT-2000		mean hop scores (crossover and timed hop tests) for the control and intervention groups pre- and post-intervention ($p > 0.05$).
3	Frobell et al. 2010; Sweden	121 (0)	- 18-35 years old; mean 26 - Active - Recreational sports person	- Gait rehabilitation - Quadriceps and hamstring muscles strengthening exercises - Balance and coordination training Both control and intervention groups received the same exercises with early reconstruction for the control group and the option of delayed surgery for intervention group. ***- 24 weeks*** ***Frequency and duration of sessions not reported***	-*Pain, symptoms, difficulty in sports and recreational activities and quality of life*; **using** (KOOS) score - *Physical component and mental component;* **using** *(SF-36) survey* -*ACL insufficiency*; **using** Tegner activity scale (TAS) questionnaires	-Baseline -3 months -6 months -12 months -24 months	The absolute change in mean KOOS score from baseline to 2 years was not significant (mean scores, 39.2 (control) and 39.4 (intervention); absolute difference, 0.18; 95% confidence interval, − 6.5 to 6.8; $p = 0.96$, adjusted for baseline KOOS score). There were no significant differences between the two treatment groups with respect to outcomes. -More patients avoided the need for surgery with no implications on clinical outcomes in the intervention group. -No significant difference between mean scores for secondary outcomes for the first two years due to the intervention including pain ($p = 0.87$), function in daily living ($p = 0.68$) and sport ($p = 0.95$) and quality of life ($p = 0.28$).
4	Frobell et al. 2013; Sweden	121 (1)	- 18-35 years old; mean 26 - Active - Recreational sports person	- Gait rehabilitation - Quadriceps and hamstring muscles strengthening exercises	-*Pain, symptoms, difficulty in sports and recreational activities and quality of life*; **using** (KOOS) score	-Baseline -5 years follow-	No significant differences between groups were seen in KOOS, mean difference (95% CI) 1.5 ($p = 0.45$), any of the KOOS subscales ($p \geq 0.12$), SF-36 ($p \geq 0.34$), Tegner activity scale

				- Balance and coordination training Both control and intervention groups received the same exercises with early reconstruction for the control group and the option of delayed surgery for intervention group. ***- 24 weeks*** ***Frequency and duration of sessions not reported***	*- Physical component and mental component; using (SF-36) survey* *-ACL insufficiency*; **using** Tegner activity scale (TAS questionnaires -Meniscal surgery -Radiographic osteoarthritis.	up	(p = 0.74), or incidence of radiographic osteoarthritis of the index knee (p = 0.17). -No differences between groups were seen in the number of knees having meniscus surgery (p = 0.48) or in a time to event analysis of the proportion of menisci operated on (p = 0.77). -No significant difference between mean scores for secondary outcomes for the first five years due to the intervention including pain (p = 0.73), function in daily living (p = 0.38) and sport (p = 0.23) and quality of life (p = 0.89).
5	Hartigan et al. 2009; USA	19 (0)	- 17-50 years old, mean 29 - Active - Recreational sports person	**Control group: (Strengthening group = Str)** -Quadriceps strengthening exercises **Intervention group: (Perturbation group = Pert)** - Specialised neuromuscular training - Quadriceps strengthening exercises **Control group** – 10 sessions over an average 3.1 weeks **Intervention group** - 10 sessions over an average 3.7 weeks	- Quadriceps strength indexes **using** a Kin-Com dynamometer. - knee excursions during the mid-stance phase of gait **using** a passive, eight camera 3-D motion analysis system (VICON)	-Pre-intervention -6 months post-ACL reconstruction	- Quadriceps strength indexes before intervention (Pert: 87.2%; Str: 75.8%) improved 6 months after ACL reconstruction in both groups (Pert: 97.1%; Str: 94.4%). - The intervention group had no differences in knee excursions between their limbs 6 months after ACL reconstruction (mean: 3.5 degrees; 95% CI: 8.3 to -1.4; p = 0.14), whereas the control group continued to have smaller knee excursions during the mid-stance phase of gait (mean: 7 degrees; 95% CI: 11.6 to 2.5; p = 0.007). Strength and knee excursions were more symmetrical 6 months post-operatively in the group that received perturbation training and progressive quadriceps strength training than the group who received strength training alone.

6	Shaarani et al. 2013; Ireland	23 (3)	- 18-45 years old, mean 29 - Active - Recreational sports person	**Control group:** No intervention **Intervention group:** - Quadriceps muscle strengthening exercises - Balance training - Proprioception training ***-A 6-week exercise programme consisting of 4 exercise periods per week: 2 supervised gym sessions interspersed with 2 supervised home sessions.***	-*Strength assessment*; **using** isokinetic dynamometry. - *Function;* **using** the single-legged hop test and Cincinnati Knee Rating System -*Changes in quadriceps CSA*; **using** magnetic resonance imaging (MRI) - *Detect myosin heavy chain (MHC) fiber types***; using** a BioRad DC (detergent compatible) protein assay. -*RNA isolation*; **using** TRI reagent (Sigma-Aldrich)	-Baseline -6 weeks pre-operative -Before ACL reconstruction -12 weeks post-operatively	Quadriceps peak torque in the injured limb improved with similar gains in CSA compared with baseline (p = 0.001). However, this was not significantly increased compared with the control group. Quadriceps and vastus medialis CSA were also larger in the exercise group than in controls (p = 0.0024 and p = 0.015, respectively). The mean modified Cincinnati score was better in the exercise-injured limb compared with baseline (85 vs 78, p = 0.004). Mean single legged-hop test scores were higher pre-operatively in the exercise group than the control group (183 vs 156, p = 0.001). At 12 weeks post-operatively, the rate of decline in the single-legged hop test was reduced in the exercise group compared with control (p = 0.001).
7	Tagesson et al. 2008; Sweden	49 (7)	- 15-45 years old, mean 26 - Active - Recreational sports person	- Muscle strengthening - Coordination and Neuromuscular control - Closed kinetic chain exercises (Control group) - Open kinetic chain exercises (Intervention group) - Range of motion (ROM) - Balance and proprioception - Functional specific rehabilitation exercises - Plyometrics	-*Swelling*; **using** a tape measure. -*Passive ROM for knee extension and flexion*; **using** standard plastic goniometer. -*Knee Function and activity level*; **using** Lysholm score and the Knee Injury and Osteoarthritis Outcome Score and Tegner score. -*Sagittal static translation and dynamic tibial translation;* **using** CA-4000 electrogoniometer. -*Muscle torque for quadriceps and*	-Baseline -4 Months after rehabilitation	There were no group differences in static or dynamic translation after rehabilitation. The OKC group had significantly higher isokinetic quadriceps strength after rehabilitation (CKC mean = 84, SD = 15; OKC mean = 96, SD=14; p = 0.009). -No differences between the two groups in swelling and passive range of motion before and after the intervention (p > 0.05). -The hamstring strength, performance on the 1 repetition maximum squat test, muscle activation, jump performance, and functional outcome were not significantly different between groups (p > 0.05).

				The control group received closed kinetic chain exercises and the intervention group received open kinetic chain exercises. **-16 weeks, 3 times per week** ***Duration of sessions not reported.***	*hamstring muscles*; **using** a Biodex machine.		
8	Thomeé et al. 2010; Sweden	40 (16; 4 dropouts and 12 excluded)	- 16-55 years old; mean 30 - Active - Recreational sports person	- Gait re-education - Quadriceps and hamstring muscles strengthening exercises - Range of motion (ROM) -Coordination and balance training - Open and closed kinetic chain exercises - Functional specific rehabilitation exercises Both groups received the same exercises with the intervention group receiving exercises administered by self-efficacy trained physiotherapists. ***-24 weeks, one hour exercise twice a week***	-*Perceived knee function self-efficacy*; **using** The knee self-efficacy scale (K-SES) -*Physical Activity*; **using** Tegner Activity Scale -*Knee function, knee-related symptoms and QoL*; **using** the Knee injury and Osteoarthritis Outcome Score (KOOS) -*Locus of control*; **using** the Multidimensional Health Locus of Control (MHLC).	-Baseline -4 months -6 months -12 months	Current knee-function self-efficacy improved significantly (p = 0.05) in both groups during rehabilitation (Exp Group: mean = 2.9, SD:2.7, range: 0.3 – 9.3; Control Group: mean = 3.0, SD:2.6, range: 0.2 – 8.4) -A significant increase (p = 0.05) was detected for both groups on KOOS Sport (Exp Group: mean = 50.4, SD:19.8, range: 5 – 85; Control Group: mean = 59.6, SD: 25.5, range: 20 – 95) and KOOS QoL (Exp Group: mean = 50.5, SD:12.6, Range: 25–69; Control Group: mean = 53.7, SD:13.7, range: 31 – 81) between the 4- and 12-month follow-ups -Both groups had a significantly (p = 0.05) lower physical activity level at 12 months than pre-injury. No significant differences were found between groups.

ACL, anterior cruciate ligament; ADLS, Activities of Daily Living Scale; CSA, cross-sectional area; IGF-1, insulin-like growth factor 1; KOOS, Knee injury and Osteoarthritis Outcome Score; K-SES, knee self-efficacy scale; MAFbx, muscle atrophy f-box; MHC, myosin heavy chain; MHLC, Multidimensional Health Locus of Control; MRI, magnetic resonance imaging; QoL, Quality of life; RCT, randomised controlled trial; RHCL, reflex hamstring contraction latency; ROM, range of motion; TAS, Tegner activity scale; VIKDE, Vicon Interfaced Knee Displacement Equipment.

5.3.3 Types and duration of interventions

Pre-operative rehabilitation protocols were different in their content, duration and frequency of intervention. The average duration of the pre-operative intervention was 14 weeks (range 3-24 weeks) (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013). Two studies did not report the frequency of treatment (Frobell et al., 2010; Frobell et al., 2013); however, for the remaining six studies, the average frequency of treatment was three times per week (range 2-4 times per week).

The content of the pre-operative intervention consisted of: quadriceps and/or hamstring strengthening exercises (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013); proprioception and/or balance training (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013); gait re-education (Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013); treatment to increase range of motion (Tagesson et al., 2008; Thomeé et al., 2010); functional specific rehabilitation (Tagesson et al., 2008; Thomeé et al., 2010) and plyometrics (Tagesson et al., 2008).

Beard et al. (1994) administered mostly open kinetic chain (OKC) exercises to increase lower limb muscle strength in the control group, whereas the intervention group received mainly closed kinetic chain (CKC) exercises to improve dynamic stability through proprioceptive enhancement techniques. Shaarani et al. (2013) used OKC and CKC

exercises focusing mainly on strengthening the quadriceps muscles, and proprioception training by using a wobble cushion. Tagesson et al. (2008) compared OKC and CKC programmes. The two rehabilitation programmes consisted of muscle strengthening, coordination and neuromuscular exercises. The intervention group received open chain exercises whereas the control group received closed chain exercises. The rehabilitation programmes aimed to increase muscle strength, neuromuscular control, muscle coordination and functional stability. Thomeé et al. (2010) focused on improving the symptoms of the knee joint, such as reducing pain and swelling, restoring full knee extension and flexion range of motion, hamstring and quadriceps control, gradually increasing the strength of quadriceps and hamstring muscles. Exercises included balance and coordination exercises and pool exercises.

Hartigan et al. (2009) focused on quadriceps strengthening and neuromuscular training. In the study by Fitzgerald et al. (2000), both groups received strengthening exercises for quadriceps and hamstring muscles, cardiovascular endurance exercise, agility exercise and sport specific skills exercise. In addition, the intervention group received (a) anteroposterior and mediolateral perturbation using a Balanced Master motorised force platform, (b) anteroposterior and mediolateral rotatory perturbations with tilt board, (c) multidirectional perturbations while the patients were standing with one leg on a roller board and the opposite leg on a stationary platform and (d) multidirectional perturbations while the patients were standing on one leg support on a roller board. All patients received two to three sessions per week for five weeks.

5.3.4 Outcome measures

Several outcome measures were used to assess the effectiveness of pre-operative exercise physiotherapy rehabilitation. **Pain** was used as an outcome in three studies (Tagesson et al., 2008; Frobell et al., 2010; Frobell et al., 2013). Pain was measured as one of four sub-scales of a Knee injury and Osteoarthritis Outcome Score (KOOS), which also included symptoms, function, and QoL related to the injury. No significant difference was found in patient reported pain between the intervention and control groups in any of the studies.

Physical function (in recreational or sports activities) was used as an outcome in seven of the eight studies (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013). Two studies found a significant improvement in physical function in the intervention group compared to the control (Beard et al., 1994; Shaarani et al., 2013). Beard et al. (1994) reported greater physical function in the intervention group following a rehabilitation programme designed to enhance proprioception and hamstring reflexes compared to the group that received a programme designed to improve muscle strength. Shaarani and colleagues (2013) found a significant increase in function from baseline to pre-operatively and at 12 weeks post-operatively in the intervention group who received pre-operative physiotherapy rehabilitation compared to the control group who received no pre-operative physiotherapy intervention. Five studies found no significant difference in physical function between the groups (Fitzgerald et al., 2000; Tagesson et al., 2008; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013).

Quality of life (QoL) was examined in three studies (Frobell et al., 2010; Frobell et al., 2013; Thomeé et al., 2010) using a subscale of the Knee injury and Osteoarthritis Outcome Score (KOOS). Whilst there was a significant improvement in QoL from baseline following intervention in both groups, none of the studies reported any significant difference in quality of life between the control and intervention groups.

Range of motion (ROM) was used as an outcome in only one study (Tagesson et al., 2008). There was no significant difference in ROM between the two rehabilitation programmes using open and closed kinetic chain exercises.

Muscle strength and function (quadriceps and/or hamstring) were measured in four studies using a Biodex isokinetic dynamometer (Tagesson et al., 2008), a Cybex isokinetic dynamometer (Shaarani et al., 2013), or a Kin-Com isokinetic dynamometer (Fitzgerald et al., 2000; Hartigan et al., 2009). Tagesson et al. (2008) reported that the intervention group had greater quadriceps muscle strength; however, no other significant differences in strength were found. Hartigan et al. (2009) found that quadriceps strength increased in both groups, although there was no significant difference between the groups. However, they did find that quadriceps strength and knee excursions were more symmetrical 6 months post-operatively in the intervention group that received perturbation training and progressive quadriceps strength training than the control group who received strength training alone. The remaining two studies (Fitzgerald et al., 2000; Shaarani et al., 2013) found no significant difference in muscle strength between the intervention and control groups.

The outcomes of **knee-related symptoms**, including swelling, were measured in four studies (Tagesson et al., 2008; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013). No significant differences in symptoms between the control and intervention groups were found. Fitzgerald et al. (2000) examined the effect of perturbation training on episodes of 'giving-way' of the knee. They found that a greater number of participants in the control group had increased episodes of 'giving-way' ($p < 0.05$).

5.4 Discussion

Despite the range of pre-operative approaches used in the studies examined in this review, this study found that pre-operative physiotherapy rehabilitation is effective for improving the outcomes of treatment following ACL injury. Furthermore, the diversity of approaches used in this review reflects the nature of pre-operative physiotherapy in clinical practice in relation to this patient population and as such, enhances the clinical validity of the findings.

Of the eight studies included in this review, only Shaarani et al. (2013) did not include pre-operative physiotherapy intervention for both groups, with the control group receiving no intervention. They found significant improvements in function and physical performance in the intervention group following pre-operative physiotherapy compared to the control group.

All of the seven remaining studies included pre-operative physiotherapy exercise rehabilitation programmes for both the intervention and control groups (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al.,

2010; Frobell et al., 2010; Frobell et al., 2013). All seven studies showed improvements in function in both groups following pre-operative rehabilitation programmes. Of these studies, five found significant improvements in the intervention group compared to the control group in a range of outcomes, including: function, strength, and reflex hamstring contraction latency (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010). In the studies by Frobell et al. (2010; 2013), a strategy of rehabilitation plus early anterior cruciate ligament reconstruction was not more effective at five years than a strategy of initial rehabilitation with the option of having a later anterior cruciate ligament reconstruction. Furthermore, in using the second approach, 50% of patients avoided the need for surgery with no implications on clinical outcomes in the intervention group (Frobell et al., 2013).

The average duration of the pre-operative intervention was 14 weeks (range 3-24 weeks) (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013; Shaarani et al., 2013) with the frequency of sessions ranging between 2–4 sessions per week (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Shaarani et al., 2013). Thus, on average, patients received a total of 27 pre-operative treatment sessions (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Hartigan et al., 2009; Thomeé et al., 2010; Shaarani et al., 2013). However, this number of treatment sessions is resource intensive and in the current economic climate, with healthcare budgets under increasing financial pressure, the clinical applicability of this may be questioned.

The Physiotherapy Evidence Database (PEDro) scores for seven of the eight papers included in the review ranged from 5-7, which indicated that they were of moderate to high methodological quality (Maher et al., 2003); however, one study was of low methodological quality (Hartigan et al., 2009). There were a number of methodological flaws in the eight selected studies. The sample sizes for the studies included in the review were small, ranging from 23 to 121, with some of the studies not reporting how sample size was determined, hence limiting the external validity of their findings.

In addition, whilst all the studies reported their randomisation procedures, there was no blinding of therapists who administered the therapy in any study, and only two studies reported blinding of all assessors who measured at least one key outcome (Beard et al., 1994; Shaarani et al., 2013), with only one study reporting blinding of the participants (Beard et al., 1994). This may have increased the risk of bias in these studies. However, it is acknowledged it may not be possible to blind some of the individuals, such as the therapist or patients, in a clinical trial. Furthermore, some important outcomes such as quality of life were not assessed in the majority of the studies, except those by Frobell et al. (2010; 2013) and Thomeé et al. (2010). In addition, the range of motion was examined in only one study (Tagesson et al., 2008). Thus, further research is needed to assess the effectiveness of pre-operative physiotherapy rehabilitation on these outcomes of treatment following ACL injury.

This is the first systematic review that has been undertaken to investigate the effectiveness of pre-operative rehabilitation for improving the outcomes of patients with ACL injury undergoing reconstruction. The review used a clear and effective search strategy and employed specific outcome measures to assess the effectiveness of pre-

operative physiotherapy. Limitations of this review included restriction to randomised controlled trials, which reduced the scope of reviewed evidence, as well as including only studies published in the English language.

5.5 Conclusion

In summary, pre-operative rehabilitation is effective in the improvement of health outcomes for these patients. Therefore, clinicians are required to be aware of these findings, as pre-operative rehabilitation may be of value to patients with this condition. The continued use of pre-operative rehabilitation programmes for patients who undergo ACL reconstruction is justified by the findings of the current study. However, the lack of standardised pre-operative physiotherapy programmes precludes the routine use of this intervention in clinical settings. Therefore, this leads to the following chapter, which develops a standardised pre-operative protocol and presents an evaluation of its effectiveness in a sample of Saudi patients with ACL injury, which was devised from the data questionnaire survey in Chapter Four and the systematic review of literature in the current chapter.

Chapter Six: Development of a Standardised Pre-Operative Physiotherapy Programme for Patients Undergoing Anterior Cruciate Ligament Reconstruction

6.1 Introduction

Anterior cruciate ligament (ACL) injury is associated with pain, functional limitation, muscle weakness, impaired joint proprioception as well as a financial burden to the individuals and the healthcare system (Schmidt, 2004). ACL reconstruction is commonly used to treat ACL injuries (Kowalchuk et al., 2009). Surgical reconstruction of the ACL is performed to re-establish the ligamentous stability of the knee joint (Risberg et al., 2004). However, even if the static stability of the joint is recuperated, reconstruction does not itself restore knee function (Cimino et al., 2010). Before surgery is considered, patients are expected to meet a series of conditions, including a normal range of motion (ROM) equal to that of the opposite knee, reduced knee effusion, normal gait, and good knee control (Shelbourne and Klotz, 2006).

Since there is no standard evidence-based pre-operative physiotherapy protocol after ACL injury reported in the literature (Chapter Five) or in clinical practice in Saudi Arabia (Chapter Four), the study described in this chapter involved the development of a protocol for pre-operative physiotherapy based on published evidence and testing the proposed protocol in a clinical setting on patients with ACL injury in Saudi Arabia. This was done to investigate whether reduced muscle strength, range of motion and joint instability encountered by ACL-deficient patients due to the injury can be improved based on an appropriate pre-operative rehabilitation plan involving the use of physiotherapy. This physiotherapy intervention is proposed to achieve the following outcomes: (1) restoring full range of motion in the injured knee, including full extension, (2) improving muscle strength, (3) reducing pain, swelling and other symptoms, and (4) restoring normal gait and knee control, and (5) improving quality of life (Shelbourne and Gray, 1997).

These outcomes were assessed post-surgically in two patient groups: Control group and Intervention group, enrolled from three different hospitals. ACL reconstruction surgery was performed on both groups and a range of health outcome measures were used to explore the effectiveness of the proposed protocol. The Control group did not receive any pre-operative physiotherapy. However, they received standard management in hospital, which consisted of modalities to reduce swelling and pain management, in order to prepare them for surgery (Micheo et al., 2010). The aims of this study were:

- To develop a standardised protocol for the pre-operative physiotherapy rehabilitation of patients with ACL injury undergoing reconstruction; and

- To examine the clinical and cost-effectiveness of the developed pre-operative protocol in patients with ACL injury who undergo reconstruction.

6.2 Materials and Methods

6.2.1 Developing a pre-operative exercise programme

There is a lack of evidence-based exercise regimens in use by hospitals and healthcare establishments in Riyadh, KSA (see Chapter Four). This led to exploring the international literature on treatment of ACL injury for indications of guidelines to be followed in a clinical setting for the pre-operative rehabilitation of patients with this injury. To achieve this, a systematic review was conducted as presented in Chapter Five. The main finding of the review showed that a standardised and tested protocol of pre-operative physiotherapy is still lacking; however, there are international guidelines on pre-operative physiotherapy management of ACL injury (Kraemer et al., 2002; Adams et al., 2012) and numerous empirical protocols used in different health establishments, including in KSA.

The main focus of the proposed protocol was knee function improvement, which was assessed using the Knee injury and Osteoarthritis Outcome Score (KOOS) as a primary outcome measure. The part of this protocol that focused on muscle training was based on guidelines of the American College of Sports Medicine for resistance training (Kraemer et al., 2002) and included both open and closed kinetic chain exercises; these exercises serve to strengthen quadriceps and hamstring muscles (Eitzen et al., 2010).

Based on the findings of the questionnaires carried out in the study discussed in Chapter Four and the systematic literature review outlined in Chapter Five in addition to the practitioners' recommendations, a physiotherapy programme was designed. Moreover, the duration of treatment and frequency and duration of sessions were informed by clinical guidelines (Kraemer et al., 2002) and guided by recommendations of physiotherapists and orthopaedic surgeons practicing in KSA hospitals who were surveyed in the study reported in Chapter Four. As a result, the programme was intended to last for 4 weeks and to include 3 exercise sessions weekly (one session per day) with each session lasting for 45 minutes (Chapter Four), which were intended to reach maximum effort through 3 to 4 sets of exercises comprising of 6 to 8 repeated movements. Likewise, the exercise sets needed to be interspersed by standardised periods of rest of approximately 10 seconds, the length of which was based on a pre-pilot of the protocol through the use of a set of healthy volunteers (see Section 6.2.3).

Other important considerations specified in this protocol are cautions and contra-indications. The protocol is contra-indicated for patients with swelling, pain and ROM deficiency. These patients cannot usually tolerate exercise physiotherapy because of these symptoms, and therefore, they normally undergo preparation using modalities and pain management until they are able to undergo training exercise (Micheo et al., 2010). Patients having those symptoms should wait until these issues are resolved based on recommendation by the treating healthcare professional (Eitzen et al., 2010). The involvement of orthopaedic consultants is recommended at the main stages of this rehabilitation programme. Thus, patients in this study, whose participation was contra-indicated due to these symptoms, were re-assessed by the treating physiotherapists two

weeks later to determine if they met the inclusion criteria. Those who met the inclusion criteria on re-assessment were invited to participate in the programme subject to their consent (see Appendix 13 for Patient Consent Form).

6.2.2 Details of the developed protocol

The pre-operative physiotherapy protocol was designed to include physical exercise with progression dependent on the patient's performance, age and health status. This allowed the programme to be made specific by the physiotherapists for individual patients. The included exercises are in line with guidelines for the frequency of training, recovery, and the volume of exercise as recommended for recreational, intermediate level (Kraemer et al., 2002; Rhea et al., 2003; Wolfe et al., 2004; Peterson et al., 2005). The progression through the exercises was carried out in the present study according to a dose-response framework, in which the load was raised from a target repetition number in each exercise set with an increment of 2 repetitions in each progression stage, the '+2 principle' (Kraemer et al., 2002; Eitzen et al., 2010). This is done in order to gradually increase the exercise load and individualise the protocol according to the physical capacity of the patients. In the +2 principle, the patient was initially requested to carry out as many repetitions and he/she was able to do in the final set of the third or fourth sets of exercises. If the patient had been able to perform 2 more repetitions, the load was raised in the next session of physiotherapy treatment. With this principle, the protocol would become more and more individualised with the progress of the treatment and on the basis of the patient's health status.

The treatment programme started with a warming up stage, which lasted for 10 minutes on a stationary cycle and 10 minutes on a treadmill; this was guided by literature on warming up before physiotherapy (Eitzen et al., 2010; Sozen, 2010). Warming up usually consists of mild to moderate exercise carried out to prevent potential injuries during physical activities (Young and Behm, 2003). Subasi et al. (2008) recommended at least 10 minute warming up sessions and reported improved balance and proprioception compared to warming up for less than 10 minutes.

Warming up was followed by physical exercises chosen to address the deficits exhibited by ACL deficient patients, including muscle weakness and impaired proprioception (Keays et al., 2003). The exercises were focused on unilateral strengthening, balance and muscle control with the aim of improving muscle contribution to knee function and reducing further damage to the knee joint (Keays et al., 2006).

Muscle training was based on guidelines of the American College of Sports Medicine (Kraemer et al., 2002) and included a combination of open kinetic chain (OKC) and closed kinetic chain (CKC) muscle strengthening exercises (Mikkelsen et al., 2000; Micheo et al., 2010; Glass et al., 2010). These exercises were recommended together in order to strengthen quadriceps and hamstring muscles (Hooper et al., 2001). Mikkelson et al. (2000) showed that a combination of OKC and CKC can lead to improved muscle strength and more rapid recovery of the knee joint compared to using CKC exercises alone.

The first part of the programme was a single limb squat exercise, repeated 6 times initially in 3 sets. This CKC exercise was designed to maintain knee stability and

increase both balance and muscle strength especially that of the quadriceps. This exercise could be aided by a parallel bar to ensure the balance of patients who cannot maintain their standing position because of the injury (Beard et al., 1994; Keays et al., 2006; Eitzen et al., 2010).

The next stage of the programme consisted of straight leg raising (SLR) exercises to maintain and increase weight resistance. This stage contained 4 different types of OKC exercises: supine lying weight resisted SLR exercises to strengthen quadriceps muscles, prone lying weight-resisted SLR exercises to strengthen hamstring muscles, side lying adduction exercises to strengthen adductor muscles, and side lying abduction exercises to strengthen abductor muscles (Beard et al., 1994; Keays et al., 2006; Frobell et al., 2010).

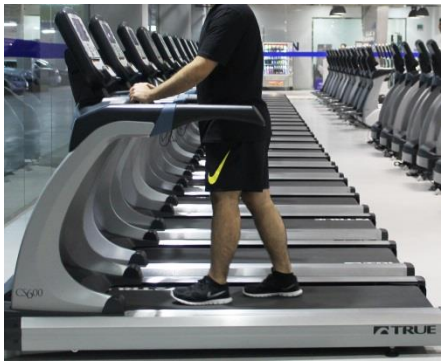
Again, these exercises were performed as 6 repetitions in 3 sets initially and subsequent progression was based on the '+2 principle' outlined above. This was followed by balance board exercises which were designed to maintain knee alignment and core stability, and progression was based on squat and bounce up and down cycles (Fitzgerald et al, 2000; Frobell et al., 2010). Further progression was based on a ball catching exercise on a balance board (Eitzen et al., 2010). This was initially repeated 20 times in 2 sets then progression of the absolute load was based on the '+2 principle'.

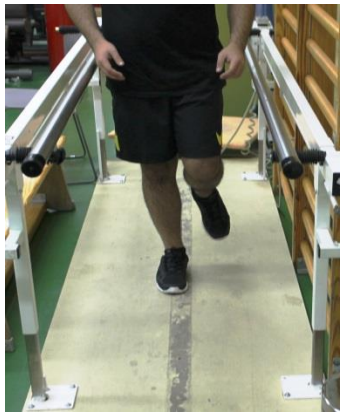
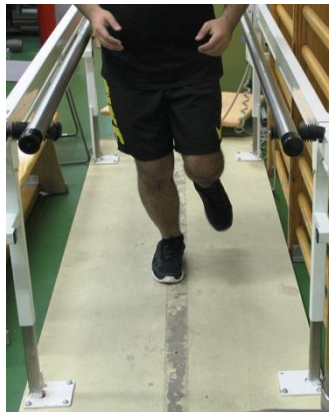
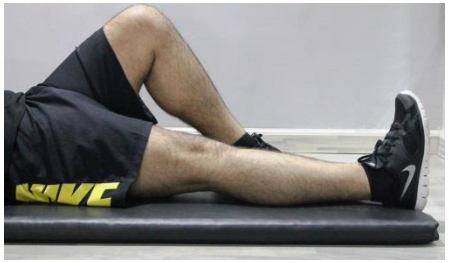
These exercises were followed by single-limb leg press and extension exercises, which started as a 90º knee flexion (Frobell et al., 2010; Eitzen et al., 2010). This was initially repeated 6 times in 3 or 4 sets depending on the patient's state and then progress was based on increases of two repetitions per set. Finally, a leg curl exercise was performed,

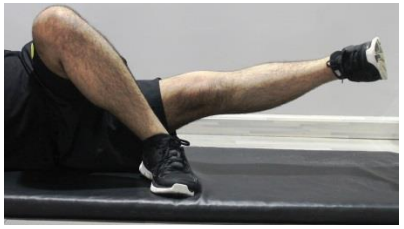
in which the patient started in full extension, lifted a pad as far as possible towards the buttocks then returned back to full extension (Beard et al., 1994; Eitzen et al., 2010). This exercise was repeated 6 times initially in 3 sets and then the repetitions were increased based on the '+2 principle' as the programme progressed. For the different stages of the programme, the number of sets could also be increased to 4 sets as and when required by the patients based on their health status and progression in the programme. Table 6.1 shows the details of the programme with illustrations.

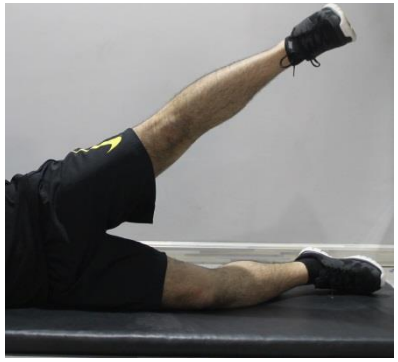
Cautions and contra-indications were also highlighted in the programme to avoid complications in the ACL injury, such as: swelling, severe pain and deficiency in ROM, which were the main contra-indications. In addition, orthopaedic consultation was recommended at each stage of the pre-operative physiotherapy programme.

Table 6.1. Details and illustrations of the proposed pre-operative physiotherapy programme

Exercise [a]	Description	Sets by number of repetitions (Duration) [b, c]	Figures
Stationary cycle	Warming-up	10 min	
Treadmill	Warming-up	10 min	

Single-limb squat	Parallel bar	6 (+2) repetitions 3 sets	 
Supine lying weight-resisted "Straight leg raising (SLR)" (Quadriceps)	↑Weight resistance	6 (+2) repetitions 3 sets	 

Prone lying weight-resisted "Straight leg raising (SLR)" (Hamstring)	↑Weight resistance	6 (+2) repetitions 3 sets	 
Side lying adduction	weight-resisted "straight leg raising" SLR	6 (+2) repetitions 3 sets	 

Side lying abduction	Weight-resisted “straight leg raising” SLR	6 (+2) repetitions 3 sets	 
Balance board	Progression: squat/ bounce or catch a ball	20 repetitions 2 sets	

Single-limb leg press	Start in 90 degree knee flexion	6 (+2) repetitions 3 sets	 
Single-limb knee extension	Start in 90 degree knee flexion	6 (+2) repetitions 3 sets	 

Leg curl	Start in full extension, lift the pad as far as it will go toward the buttocks	6 (+2) repetitions 3 Sets	 

[a] The duration of the programme is 4 weeks and it contains 3 sessions per week with each session lasting 45 minutes. Because specific evidence-based guidelines for strength training in the early stage after ACL injury do not exist, the strength training is developed based on the principles outlined in the progression models for resistance training for healthy adults developed by the American College of Sports Medicine. The strength training was standardised and performed as multiple sets of exercises for a minimum of 2 and a maximum of 4 sessions per week, with maximal effort in 3 or 4 sets of 6 to 8 repetitions per set. These guidelines are consistent with recent recommendations for training frequency, recovery, and exercise volume for recreational athletes at an intermediate level.

[b] Progression is guided by a dose-response theoretical framework, where the absolute load is increased from a target repetition number in each set. To assure progressive load, the "+2 principle" was used. This principle implies that the patients are instructed to perform as many repetitions as they can manage in the last of the third or fourth set. If they are able to add 2 extra repetitions, load will be increased in the next treatment session. 10 seconds between each exercise and the next.

[c] The protocol aims to become more and more individualised as treatment progresses based on the patient's health status.

6.2.3 Pre-piloting and piloting the developed protocol

After designing the pre-operative protocol, pre-piloting and piloting were conducted on a set of volunteers (male, aged 18-50). Pre-piloting was carried out on 10 healthy volunteers in the UK in order to determine the most appropriate order of the exercise sets and the duration of rest between the different exercises (estimated at 10 seconds). Piloting was then carried out on 5 Saudi ACL-deficient patients in KSA in order to decide if the protocol was appropriate for patients with ACL injury. Patients were asked if the protocol was suitable for their level of physical function and health status, and whether it put an excessive strain on their knees. Similarly to patients recruited for the clinical trial, patients in the pilot process were provided with a patient information leaflet (Appendix 12) and signed a consent form (Appendix 13). The same inclusion/exclusion criteria which were applied in the clinical trial were also applied in the piloting (Section 6.2.4).

6.2.4 Inclusion and exclusion criteria

Patient participants were selected based on recommendations by their treating consultant surgeons. The inclusion criteria were: male patients; aged 18-50 years; with isolated ACL injury; and those who had not undergone reconstruction surgery. Indeed, the recruitment of female participants was not possible due to the gender segregated nature of the Saudi society, which is also common in the provision of healthcare due to social restrictions. Patients in the acute phase of injury, which is within two weeks of ACL injury (Anderson et al., 2001) and is characterised by pain and swelling, were not

included in the study. These patients are normally prepared using modalities and pain management until they can tolerate physiotherapy exercises (Micheo et al., 2010). The inclusion criteria were informed by the demographics of the patients most affected by ACL injury in KSA as indicated in the study reported in Chapter Four, who were mostly young, male individuals. The researcher was responsible for instruction of patients with the physiotherapy protocol in liaison with the treating surgeons. Exclusion criteria included: if the patients had associated fractures, meniscal tears, collateral ligament injury, concomitant morbidity contra-indicating physical exercise and any symptoms of damage to the other knee, the ankles, hips or feet. This was guided by previous studies (Eitzen et al., 2010; Frobell et al., 2010; Frobell et al., 2013). Another exclusion criterion was inability to travel to the hospitals where the study took place (Eitzen et al., 2010).

6.2.5 Research design

The current study was designed as a pragmatic randomised controlled trial (RCT), as the sampling process was pragmatic and the research question evaluated the benefits of therapy (a treatment protocol) in an appropriate and relevant setting (the clinic). A pragmatic RCT tests the effectiveness of an intervention in routine clinical practice, with the view to generalise the findings to the wider patient population (MacPherson, 2004). Comparatively, a traditional RCT explores the efficacy of an intervention using a design that maximises the effects of the intervention, i.e. under optimal conditions, which are measured in comparison to a different treatment or placebo. Therefore, the advantage of using a pragmatic trial is represented by its ability to assess the effectiveness of an

intervention in a real life clinical situation and to achieve high external validity, which allows generalisation of the findings to various other settings (Patsopoulos, 2011).

The present pragmatic study was carried out with the assistance of the treating surgeons with two of them agreeing for their patients to undergo pre-operative physiotherapy using the developed protocol. Two groups were included in the study: a Control group and an Intervention group (pre-operative physiotherapy).

6.2.5.1 Patient recruitment

The developed protocol was tested in a clinical study conducted in three different hospitals in Riyadh, Saudi Arabia. These hospitals included two major private hospitals and one security forces hospital. Access to these hospitals was facilitated by contact with surgeons who agreed to participate in this study (the same surgeons who participated in the study reported in Chapter Four). Other hospitals were contacted; however, no further recruitment was agreed. Due to time constraints, further efforts were not made to involve more hospitals.

Participants were recruited from the three hospitals that agreed to participate in the study. Participants in the Control group were recruited from all three hospital sites. However, participants for the Intervention group could only be recruited from one hospital site (due to consent restrictions from the surgeons); thus randomisation took place in only one hospital (the security forces hospital).

6.2.5.2 Sample size determination

A power calculation based on the primary outcomes (KOOS) was carried out which indicated that the required number of participants was 36 (35.1 rounded up) per group (two groups: Control and Intervention). By assuming 20% drop-out rate, the total number becomes 88 participants in total for the two groups. The drop-out rate was guided by the systematic review of randomised controlled trials done in Chapter Five, which showed true drop-out rates of less than 20%.

The sample size was calculated using the equation below (Rigby and Vail, 1998) based on the following parameters: standard deviation (SD) of 15, minimum important change (MIC) of 10 (MIC of 8-10 is considered appropriate for the KOOS tool (Roos and Lohmander, 2003)), power of 80% (magic number of 7.8) representing a significance level of 0.05. Although minimal important change of 8 gave a higher number of required participants (132), the lower number (88) was used because of time constraints.

$$n = \frac{2 \times SD^2}{MIC^2} \times (Magic\ number)$$

6.2.5.3 Procedure of the study

The allocation of patients into two separate groups was conducted through a randomisation process: the Control group (46 patients from 3 different hospitals) and the Intervention group (42 patients from one hospital site). Out of the participating patients, one patient dropped out of the Control group (leaving 45 participating patients) and 3 dropped out of the Intervention group (leaving 39 participating patients). Reasons for dropping out were: discontinuation of treatment due to work or family reasons (1 drop-

out from each group) or lack of response to communications by the investigator (2 drop-outs from the Intervention group).

The remaining set of patients fulfilled the required number of 36 participants in each group indicated by the power calculation above. For randomisation in the security forces hospital site, concealed allocation was carried out using a conventional envelope draw (colour-coded as red for Intervention and yellow for Control). See Figure 6.1 for a flow chart of the sampling process.

Blinding of the investigator (the researcher) was not feasible, while blinding the patients was also stated to be unfeasible and unethical. The Intervention group received the developed standardised rehabilitation programme, which was individualised depending on the injury condition and patient feedback. Similarly, the exercise load was increased gradually as the patients' endurance improved in order to make the protocol indivisualised according to the physical ability of the patients. Patients were provided with water and towels during the exercise sessions to ensure they were kept hydrated and comfortable throughout the duration of physiotherapy treatment.

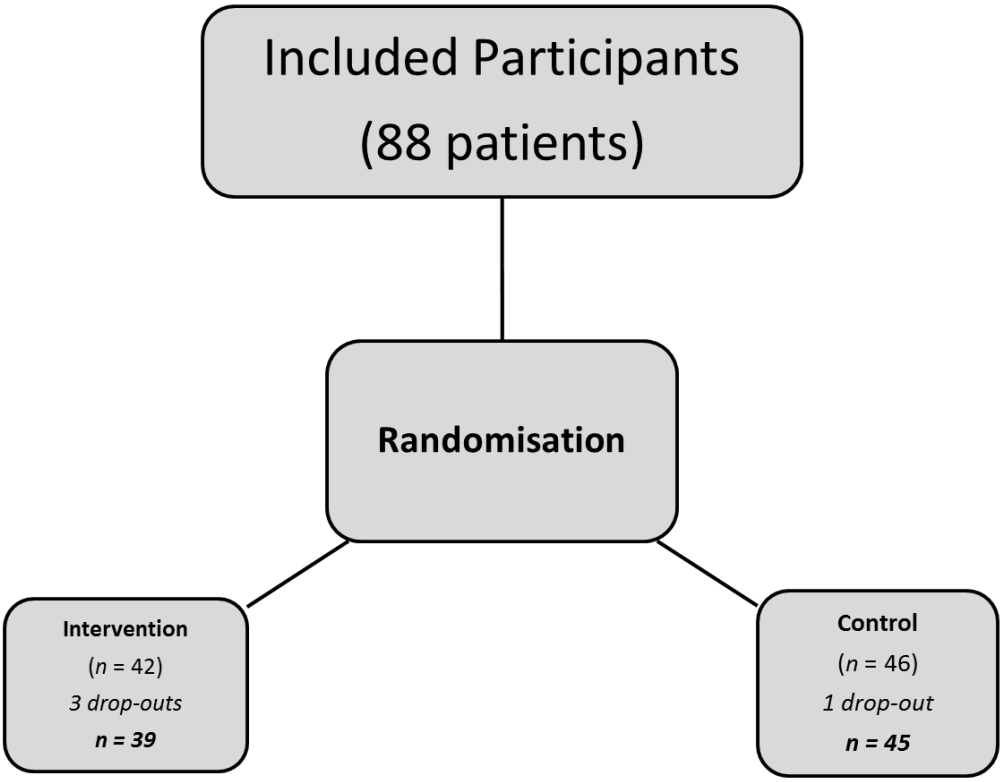


Figure 6.1. The Control and Intervention groups of patients participating in this study. Patients in one hospital were recruited and randomised into the two different groups and patients from two other hospitals were enrolled into the Control group. Excluding the drop-out cases, the Control group contained 45 patients whereas the Intervention group included 39 patients

6.2.5.4 Ethical consideration

Ethical considerations were followed in accordance with the guidelines of the Saudi Commission for Health Specialties (2014) on the code of ethics for healthcare practitioners. Confidentiality of patients was assured by maintaining patients' details coded and anonymous. These details were password-protected during and after the study. Measures to maintain confidentiality of patients were performed in association

with the treating surgeons. Participants were informed about the aims, the setting and procedure of the study, including the risks involved in participation (Appendix 12). Informed consent was acquired from patients who agreed to participate prior to conducting the clinical trial (Appendix 13). Participants were allowed sufficient time to consider participation. Patients were always reassured that they were able to withdraw themselves and their data from the study at any stage without needing to state a reason for withdrawing.

Ethical approval for conducting the study was granted by Manchester Metropolitan University, UK, and the Saudi Cultural Bureau, UK (Appendices 9 and 10 show copies of approval letters). Specific approval was then provided by the participating hospitals (Appendix 14 shows written approval from security forces hospital; the two other hospitals agreed access based on approvals shown in Appendices 9 and 10).

6.2.6 Assessment of rehabilitation outcomes

Several assessment tools were used to assess the patient outcomes in the Control and Intervention groups. These tests were undertaken at baseline (upon enrollment), after pre-operative physiotherapy (for the Intervention group only) and post-surgery (14 days post-reconstruction) during their routine follow-up appointment intended for graft checking. At this stage, patients should be able to undergo the tests required for this study because inflammation and swelling should be under control (van Grinsven et al., 2010). All assessment tools and questionnaires are included in the appendices

(Appendix 15 to 20). Assessed outcomes were classified into primary outcomes and secondary outcomes.

6.2.6.1 Primary outcomes

The KOOS tool was developed by Roos et el. (1998) for the assessment of knee-related problems and functionality and includes five outcome measures: (1) pain severity and frequency, especially during functional activities; (2) other symptoms, including knee joint stiffness, swelling, grinding, clicking, and restriction to knee joint ROM; (3) difficulties during activities of daily living (ADL); (4) difficulty during sports and recreational activities; and (5) knee-related quality of life (QoL). These are scored out of 100 according to patients' opinions about their knee-related health status (Roos and Toksvig-Larsen, 2003; Collins et al., 2011). The higher the KOOS score for each subset, up to 100, the better the outcome (Appendix 15). The choice of this test was based on the systematic review presented in Chapter Five.

An Arabic version of this tool was used for this clinical trial. Considerable levels of validity and reliability of the KOOS tool for testing physical knee function have been demonstrated (Roos and Toksvig-Larsen, 2003; Torad et al., 2015). Test-retest reliability was demonstrated by high intra-class correlation coefficients (ICCs) ranging from 0.78 to 0.97 for all subscales of the KOOS tool, with 95% of all readings within two standard deviation values. Validity was tested using two scales, Short Form 36 (SF-36) and WOMAC tools based on Spearman correlation, and showed considerable correlation between various subscales, including KOOS pain versus SF-36 bodily pain (R_s = 0.62),

KOOS ADL vs SF-36 vitality and bodily pain (R_s = 0.50 and 0.68, respectively), and KOOS QoL vs SF-36 social functioning and bodily pain (R_s = 0.40 and 0.60, respectively) (Roos and Toksvig-Larsen, 2003). An Arabic version the KOOS test was previously evaluated for cross-cultural adaptation and reliability (Almangoush et al., 2013) and was shown to be highly reliable and valid for adaptation. The same version developed by the Almangoush et al. (2013) was used in this study.

6.2.6.2 Secondary outcomes

Secondary outcomes were measured using simple questionnaires that include assessment of range of motion (ROM), muscle strength, pain assessment, health status, and resource use.

Range of motion (ROM) is widely used as an outcome measure either independently or as a subscale of an outcome test. ROM is an important predictor of the patient's ability to safely perform activities of daily living (Lavernia et al., 2008). Information on ROM requires clinical examination as ROM data reported by patients tend to be less accurate than those reported by an examiner (Miner et al., 2003).

ROM assessment of the knee joint included both passive and active range of knee flexion and extension, using a standard plastic goniometer, with the patient in the supine position on an examination table. Passive range of motion was measured as the researcher assisted the patient in extending or flexing and it is usually higher than active range of motion where the patient is not assisted. Measuring knee extension was assisted by positioning a folded towel underneath the patient's heel to achieve hyperextension.

Passive range of motion was used to limit the inference of restricted ROM related to pain and muscle weakness associated with ACL injury (Everman and Robin, 1998). The axis of the goniometer was aligned with the knee joint and its arms were aligned with the lateral malleolus and the greater trochanter. High reliability and validity of using a plastic universal goniometer to measure knee ROM has previously been demonstrated by Brosseau et al. (2001) using intra-class correlation coefficients, with inter-tester reliability correlation coefficients ranging from 0.97 to 0.99 and validity ranging from 0.98 to 0.99 compared to radiographic measurements.

ROM of the knee joint was measured as the maximum angle, in degrees, of flexion or extension. This is normally close to 135º for flexion and close to 0º for extension; therefore, the higher the flexion ROM (up to 135º) and the lower the extension ROM (closer to 0º), the better the outcome (Appendix 16).

Muscles strength outcome measure included quadriceps and hamstring muscle strength measured using a hand-held dynamometer (HHD) and expressed as the force of the muscle in Newton units (Kelln et al., 2008); the higher the muscle strength, the better the outcome (Appendix 17). High reliability and considerable validity of muscle strength measurement in the lower extremities using a HHD has previously been demonstrated (Kelln et al., 2008; Arnold et al., 2010). Intra-tester and inter-tester ICC correlation coefficients ranged from 0.90 to 0.98 and 0.77 to 0.85, respectively (Kelln et al., 2008; Arnold et al., 2010). Validity was demonstrated using ICC coefficients of 0.44 to 0.52 when compared to measurements using Biodex 3 (Arnold et al., 2010). Other advantages of strength measurement using a HHD device include ease of use, portability and low cost (Kelln et al., 2008).

The measurement was carried out using the ‘make’ test approach under static conditions (Arnold et al., 2010) with the patient in the prone position on an examination table and the knee joint flexed at 90º. During measurement, the HHD device was positioned 5 cm above the lateral malleolus and the researcher applied resistance to the force of the patient to sustain isometric muscle contraction. The device was calibrated once every three weeks using calibration weights of 10 lbs.

Pain assessment was carried out as one of the main therapy outcomes in the rehabilitation of patients with ACL injury. Chronic and acute pain can have a major effect on both quality of life and physical functionality. A visual analogue scale (VAS) was chosen as a tool for the assessment of pain in the proposed study (Appendix 18).

There were multiple reasons for selecting the VAS. Firstly, it is a simple scale that is scored by patients very quickly in order to provide immediate feedback to the clinicians. Secondly, this tool is sensitive to treatment effects and can provide information on the change in pain and on the importance of this change (Watson and Parker, 2000). In addition, considerable reliability and validity of using the VAS have been demonstrated in the assessment of both chronic pain (Scott et al., 1979; McCormack et al., 1988; Gaston-Johansson et al., 1996; Boonstra et al., 2008) and acute pain (Bijur et al., 2001). Test-retest reliability was shown with ICC correlation coefficients of 0.87-0.97 for acute pain, within 95% of paired measurements within 1 cm of each other (Bijur et al., 2001). These correlations were also demonstrated for chronic pain, with Spearman correlation coefficients ranging from 0.86-0.88 (Boonstra et al., 2008). Validity was tested against the bodily pain component of the SF-36 tool, showing average spearman correlation coefficient of 0.54 for experienced pain with the VAS tool.

Furthermore, the VAS is compatible with the common culture where the study takes place, while a numerical scale is often viewed as more confusing (Watson and Parker, 2000). Additionally, by comparison to the numerical rating scale, the VAS tool has been more extensively studied and validated (Watson and Parker, 2000). The VAS was used to evaluate pain based on scores ranging from 0 cm, which indicates an absence of pain, to 10 cm, which corresponds to severe pain (Boonstra et al., 2008). The readings were rounded to the nearest cm unit.

Health status was assessed using the EQ-5D-5L scale developed by the EuroQol group (EuroQol, 1990), which takes into account the main aspects of patients' health including physical health (mobility, self-care, usual activities, pain/discomfort) and mental/psychological health (anxiety/depression). This tool was recently shown to be highly valid and reliable in assessing the health status of patients with musculoskeletal problems based on their overall quality of life (Conner-Spady et al., 2015). Test-retest reliability was demonstrated with ICC values ranging from 0.61 to 0.77. For validity assessments, SF-12, pain VAS tools and Oxford knee scores were used, with Spearman correlation coefficients ranging from 0.51 to 0.75 for all tools (Conner-Spady et al., 2015). The outcomes in the EQ-5D-5L tool are all scored from 1, which the best health outcome for each category, to 5, which indicates the worst health status (Appendix 19). Overall, this scale is simple and quick to use, which is also easily understood by patients as it does not over complicate health-state descriptors (Hawthorne, et al., 2000; Rabin et al., 2011).

Quality of life as a secondary outcome was measured based on the EQ-5D-5L health status tool. Two different scores were used based on different calculations of the

patients' quality of life: the quality of life (QoL) score and the quality-adjusted life year (QALY) score (Rabin et al., 2011). The QoL score was calculated as the direct sum of the scores of the five outcomes in the EQ-5D-5L (mobility, self-care, usual activities, pain/discomfort and anxiety/depression); this score ranges from 5 to 25, with lower scores indicating better QoL. The QALY utility score generated from the EQ-5D-5L test ranges from 0 (or sometimes negative values), indicating death, to 1, indicating the best health outcome. In particular, this tool was recently shown to be highly valid and reliable in assessing the health status of patients with musculoskeletal problems based on their overall QoL (Conner-Spady et al., 2015), as shown above.

A resource use questionnaire was used to assess healthcare resources that were associated with the intervention. This form of questionnaire was taken from the base structure devised by Cooke et al. (2009) and adapted to incorporate categories that related directly to ACL injuries and the KSA healthcare system as the original was formulated around ankle injuries in the NHS, UK. For instance, questions that had initially been formatted to detail NHS physiotherapy were changed to physiotherapy as experienced in the healthcare system in KSA. The categories of expenses included in the questionnaire were costs of physiotherapy sessions, imaging and medications in addition to inpatient and out of pocket expenses. The questionnaire also included an indirect expense in the form of loss of productivity measured by assessing the cost of inactive days. The number of items in the questionnaire was seven items covering the costs related to ACL injury and its management. The design of the questionnaire was carried out by the researcher and guided by the supervisory team, while the questionnaire procedure was conducted directly as an interview with patients after ACL reconstruction

surgery. Data were then transferred onto a spreadsheet for analysis and care was taken to accurately transcribe the data. Subsequently, currency exchange based on London Stock Exchange rates (August 2015) were used to convert the values into British Pound Sterling (see Appendix 20).

6.2.7 Data analysis

Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) programme version 22 (IBM, USA).

6.2.7.1 Descriptive statistical analysis

To achieve the research objectives, appropriate statistical analyses were applied. In statistics, there are two analysis approaches: parametric and non-parametric analysis. To use parametric methods, the data should follow normal distribution, particularly for small sample size (tested using the Shapiro-Wilk test) and should be of interval or ratio level; otherwise, non-parametric tests are used (Jamieson, 2004). For this research study, the data of interest were found not to be normally distributed, and hence non-parametric tests were used. The descriptive statistical analysis included medians and inter-quartile ranges (IQR) of the reported sets of data (Morgan et al., 2010).

6.2.7.2 Inferential statistical analysis

Between-group statistical comparison was carried out using the Mann-Whitney *U*-test applied to compare the medians of independent groups, Intervention vs Control (Leech et al., 2005; Munro, 2005). Within-group differences were assessed using the Wilcoxon matched signed-rank test (Leech et al., 2005; Munro, 2005). The alpha value for statistical significance in differences was set at 0.05.

6.2.7.3 Cost-effectiveness evaluation

The incremental cost-effectiveness ratio was calculated based on the difference between the two groups in the costs of treatment and in the quality of life (expressed as quality-adjusted life year, QALY) experienced due to the treatment using the following equation (Fenwick et al., 2006). No sensitivity analysis was included in this assessment.

$$ICER = \frac{Cost_{Intervention} - Cost_{Control}}{QALY_{Intervention} - QALY_{Control}}$$

Different models of sensitivity analysis are useful tools in presenting detailed and complex data in a simpler, more understandable structure. This can be useful in demonstrating relationships and interactions between various different factors; however, these models do not always create a close representation of a real situation (Taylor, 2009). One form of this type of assessment is one-way sensitivity analysis, in which only one parameter is altered at a specific time; for example, by changing the effectiveness of an intervention by 10%, the cost-effectiveness ratio may decrease by

20%. However, although one-way sensitivity analysis is beneficial in demonstrating the impact of varying one parameter on the final outcome (cost-effectiveness), it can often be necessity to analyse the correlation between two or more variables that change simultaneously; in this case, effectiveness and cost of the intervention. Unfortunately, such analysis can be complicated and is not necessary to address the question of whether the intervention is cost-effective or not. In addition, sensitivity analysis requires large amounts of data and extensive data analysis, which was not possible in the current study due to time and cost constraints.

6.3 Results

In this investigation, the patients were enrolled and the study was conducted in three hospitals in Riyadh, KSA, between July 2014 and January 2015. In total, 84 participants who met the inclusion criteria were recruited into the study, 45 in the Control group and 39 in the Intervention group. Participants for the Control group were recruited from all three hospital sites; however, participants for the Intervention group could only be recruited from one hospital site (due to consent restrictions); and therefore, randomisation took place in only one hospital. The Intervention group followed the proposed pre-operative rehabilitation programme (Table 6.1), whereas the Control group did not receive any pre-operative physiotherapy. The observed outcome measures were recorded at baseline level (on enrolment) and post-treatment (14 days post-reconstruction) for both groups.

The collected scores for the different outcome measures were tested for normality using the Shapiro-Wilk normality test. Normality testing indicated that most of the datasets

were not normally distributed ($p < 0.05$) (Appendix 21). The overall non-normal distribution of data led to using non-parametric statistics, including the Mann-Whitney *U*-test for inter-group comparison and the Wilcoxon matched signed-rank test for intra-group comparison.

6.3.1 General characteristics of the participants

Table 6.2 shows the characteristics of the two groups (Control *vs.* Intervention). There were no statistically significant differences between the two groups. All participants were male. The age distribution of participants between different age groups (18-30, 31-40, 41 and over) showed limited inter-group differences (Figure 6.2). Although no statistical differences were recorded in the body mass index (BMI) values between the two groups ($p = 0.08$) as can be seen in Table 6.2, the distribution of the patients within the clinical classification categories based on BMI (underweight, healthy weight, overweight and obese (Stommel and Schoenborn, 2009)), as can be seen in Figure 6.3, showed that more patients in the Control group were overweight and less were of normal weight than the Intervention group.

Table 6.2. General characteristics of the Control and Intervention groups

Characteristics	**Control Group (n = 45)**		**Intervention Group (n = 39)**		***p* value**
	Median	**IQR** [b]	**Median**	**IQR** [b]	
Age (years)	27.5	8	27	8.5	0.37
Body Mass Index (BMI) [a]	26.8	4.5	25.8	3.9	0.08
Injury to right knee_ number (%)	27 (60%)	-	23 (59%)	-	0.94
Dominant right leg _ number (%)	29 (64%)	-	29 (74%)	-	0.44

[a] BMI, calculated as the patient's weight (in kg) divided by height (in m) squared
[b] IQR, inter-quartile range

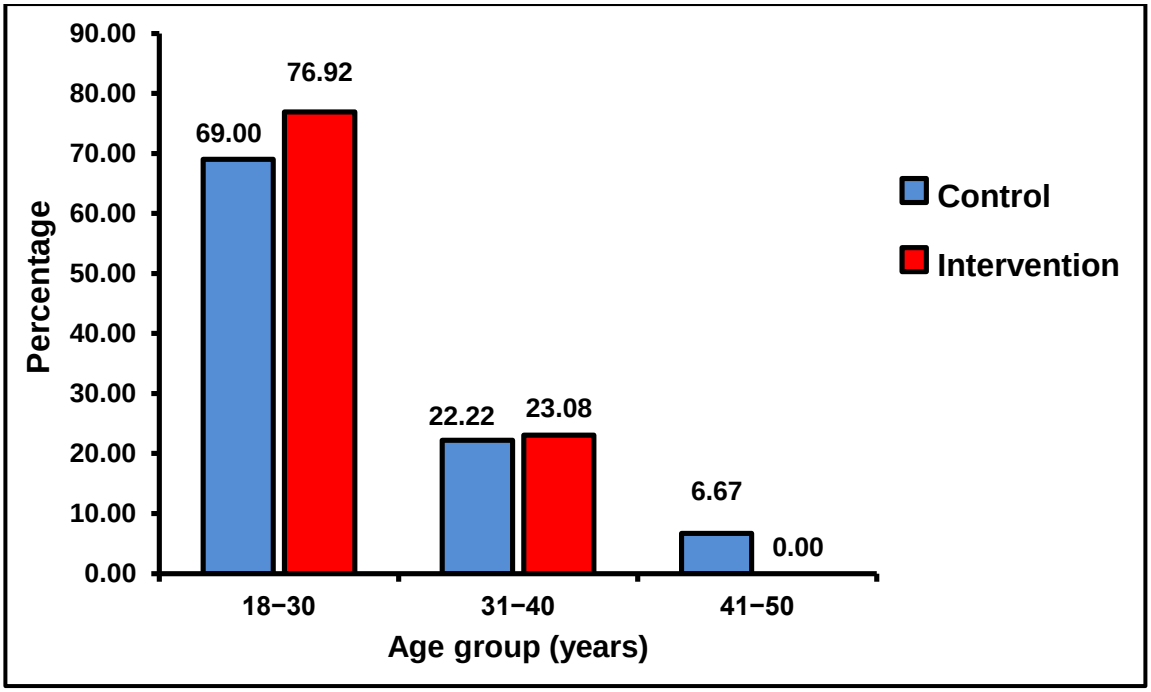


Figure 6.2. The age distribution of patient participants in the Control and Intervention groups

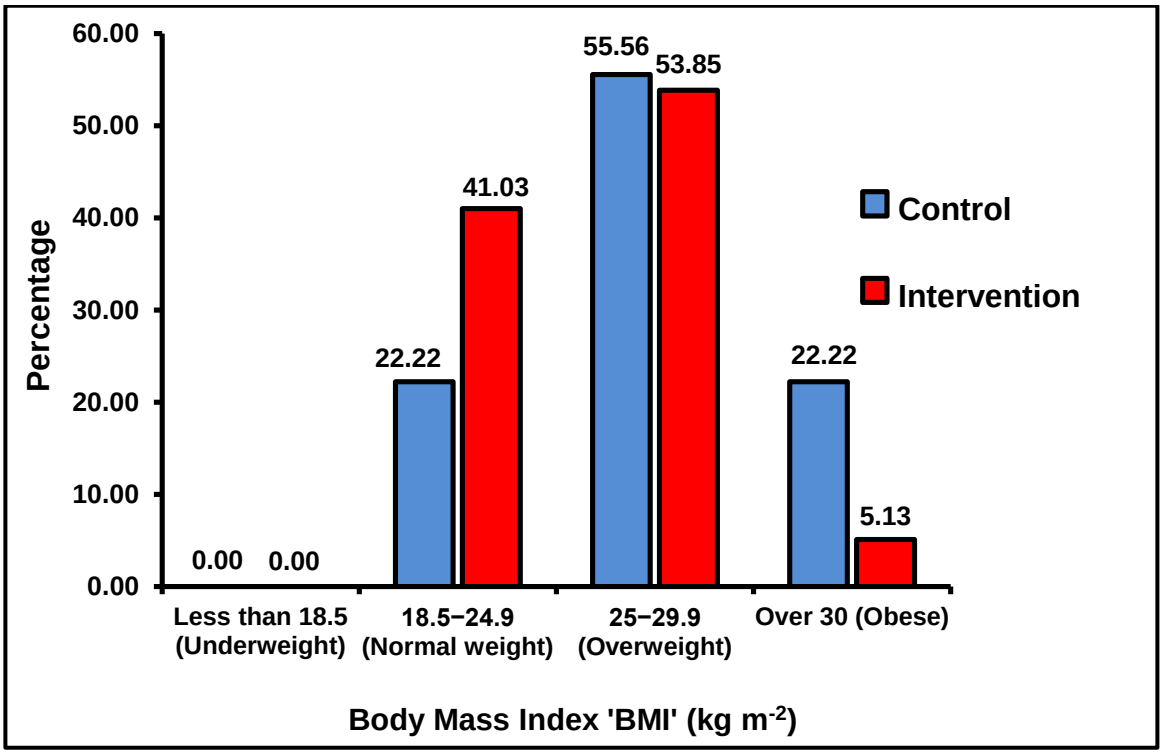


Figure 6.3. The distribution of patient participants based on BMI values into the clinical classes: underweight, healthy weight, overweight and obese

The occupational backgrounds of the participants varied and included military personnel, government employees and students. These three categories constituted approximately 90% of the participants in both groups indicating that they reflect an active part of society (Table 6.3). No statistically significant differences were seen in the distribution of patients within these occupational groups.

Table 6.3. Occupational background of the patients in the Control and Intervention groups

Occupation	**Control**		**Intervention**	
	Number	Percentage (%)	Number	Percentage (%)
Government employees	14	31.1	13	33.3
Military personnel	15	33.3	12	30.8
Students	11	24.4	11	28.2
Other	5	11.1	3	7.70
Total	**45**	**100**	**39**	**100**

Three main causes of anterior cruciate ligament injury were highlighted by the results: sports, falls and traffic accidents (Figure 6.4). The cause of most injuries documented by this study was sports with 93.3% and 94.9% of all injuries being sport-related in the Control and Intervention groups, respectively. The main sports played by the participants were football and volleyball; however, football was the cause of sport-related injuries in most cases, causing 95% and 100% of all sport-related ACL injuries in the Control and Intervention groups, respectively. The most affected knee was the right knee (60% in the Control group and 59% in the Intervention group). The right leg was also the dominant leg in most of the participants (64% in the Control group and 74% in the Intervention group).

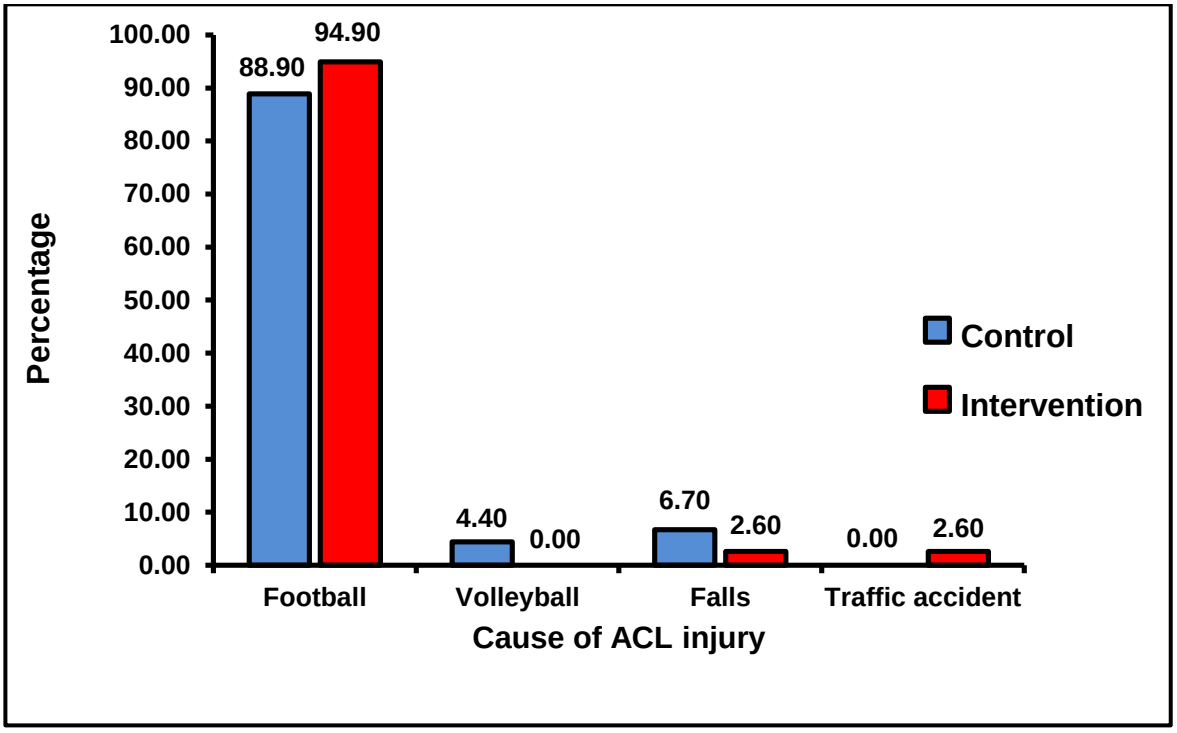


Figure 6.4. The distribution of patient participants based on the cause of ACL injury in the Control and Intervention groups

6.3.2 Comparisons of outcomes between Control and Intervention groups post-surgery

In order to assess the effect of pre-operative physiotherapy treatment on health outcomes after ACL reconstruction, primary and secondary outcome measures were compared between the Control group and the Intervention group.

6.3.2.1 Primary outcomes

Post-treatment KOOS measurements were taken 14 days post-reconstruction for both the Control and Intervention groups. Table 6.4 and Figure 6.5 show a summary of the results. The overall post-treatment KOOS score was higher in the Intervention group than in the Control group (median 55.2 and IQR 4.5 in the Intervention group compared to median 49.4 and IQR 8.6 in the Control group, $p < 0.001$) indicating a significantly better overall clinical outcome in the Intervention group.

Table 6.4. Primary outcome scores for patients in the Control and Intervention groups post-surgery

Primary outcome measures (KOOS) [a]	**Control (n = 45)**		**Intervention (n = 39)**		**Difference**
	Median	IQR [b]	Median	IQR [b]	*p* value
Pain	64	7	**71**	3	< 0.001***
Symptoms	64	8	**69**	4	< 0.001***
Function in activities of daily living (ADL)	85	13	**93**	8	0.001***
Function in sports and recreation	15	5	15	0	0.117
Knee-related quality of life (QoL)	19	12	**25**	6	0.002**
Global KOOS score	49.4	8.6	**55.2**	4.5	< 0.001***

[a] KOOS score is reported from 0 to 100, with higher scores indicating better outcomes
[b] IRQ, inter-quartile range
** indicates *p* values lower than 0.01, *** indicates *p* values lower than 0.001; **Bold font** indicates the better scores for each primary outcome measure

The sub-scale scores of primary outcomes based on the KOOS tool were significantly higher in the Intervention group than in the Control group indicating better patient outcomes, except the score for function in sports and recreation, which was similar between Control and Intervention groups. However, these differences were not clinically significant (based on the MIC of KOOS) (Roos and Lohmander, 2003).

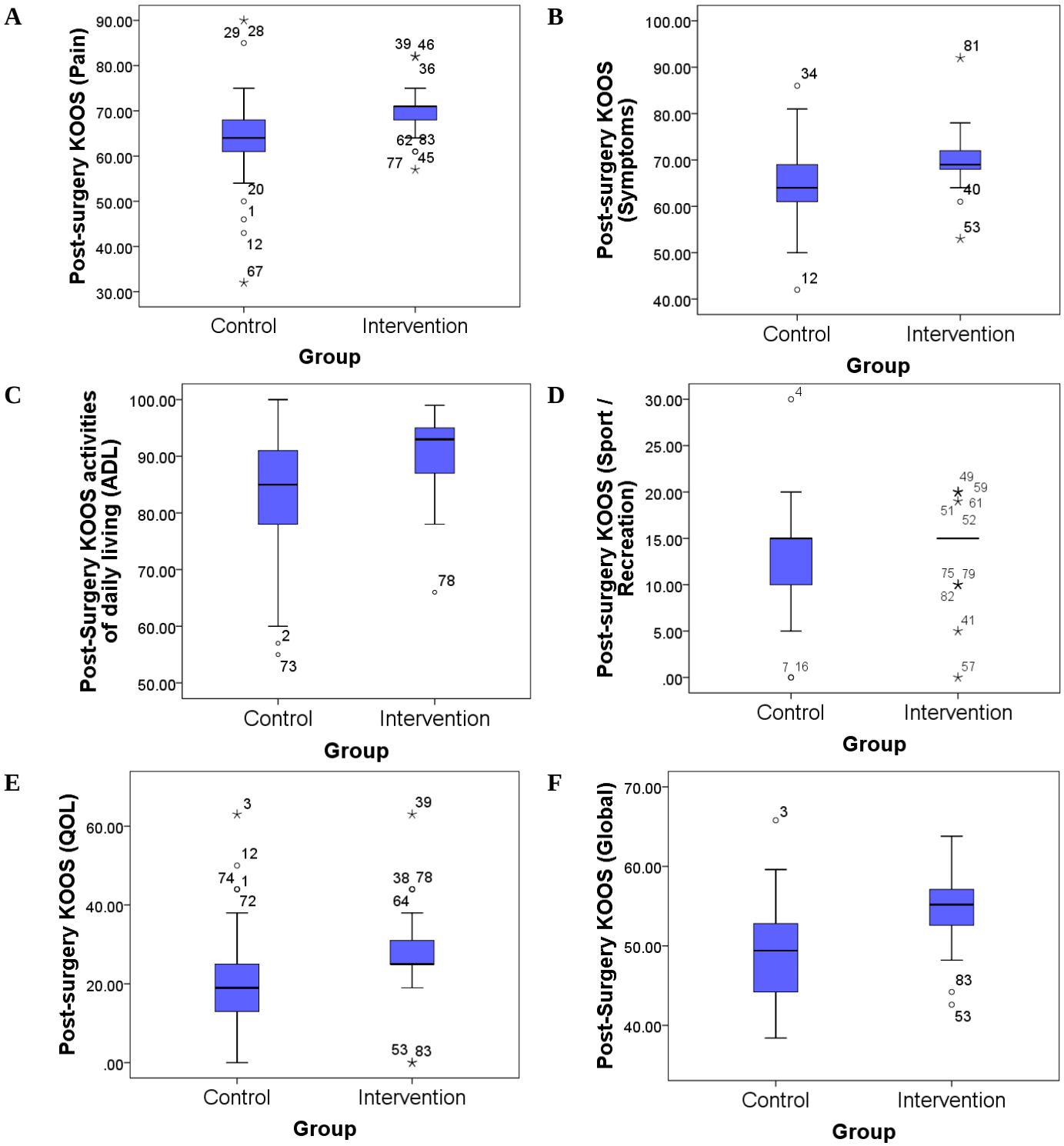


Figure 6.5. Box and whiskers graph representing median KOOS scores of Control and Intervention groups post-surgery. A: Pain, B: Symptoms, C: Function in activities of daily living (ADL), D: Function in sports and recreation, E: knee-related quality of life (QoL) and F: global KOOS score

6.3.2.2 Secondary outcomes

The secondary outcome measures used in this part of the study included assessment of knee range of motion (passive and active/flexion and extension), quadriceps/hamstring muscle strength, pain assessment using a VAS scale, health state assessment using EQ-5D-5L tool, and resource use in both the Control group and Intervention group. Table 6.5 and 6.6 and Figures 6.6, 6.7, 6.8 and 6.9 show a summary of the results. The post-treatment scores were overall contrasting for patients in the Intervention group compared to the Control group (measurements taken 14 days after reconstruction) with statistically significant differences.

As with the primary KOOS pain outcome, the score for pain as a secondary outcome measured using a VAS tool was lower in the Intervention group (median 0.7/10 in the Intervention group *vs* 1.9/10 in the Control group, $p < 0.001$) indicating lower pain experienced by the Intervention group (Table 6.5, Figure 6.8). However, this level of pain is considered mild in both patient groups, possibly because of the post-surgery pain management through the use of analgesics. Quality of life (QoL) was also assessed as a primary outcome within the KOOS tool and as a secondary outcome using the QoL and QALY tests based on the EQ-5D-5L survey (Table 6.5 and Figure 6.9); generally, lower QoL and higher QALY scores indicate better quality of life. All three measures reported statistically significantly better quality of life two weeks post-treatment in the Intervention group compared to the Control group of patients.

Range of motion is measured as the angle of maximum flexion or extension the patient can manage. The aim is to achieve flexion range of motion close to 135º and extension range of motion close to 0º. Scores for passive and active knee flexion and extension

range of motion (Figure 6.6) reported a higher range of motion in the Intervention group, which was reflected mainly by the increased active and passive flexion range of motion in the Intervention group than the Control group (median 110º *vs* 95º for active flexion ROM and 115º *vs* 110º for passive ROM in the Intervention *vs* Control patient groups, respectively, $p < 0.001$).

As shown in Figure 6.7, the mean quadriceps and hamstring muscle strength, measured as the force of the muscle in Newton units, was higher in the Intervention group than in the Control group (median 80.2 *vs* 62.3 for quadriceps and 31.1 *vs* 22.7 for hamstring in the Intervention *vs* Control patient groups, respectively, $p = 0.004$) (Figure 6.7).

EQ-5D-5L contains five different domains: mobility, self-care, usual activity, anxiety/depression and pain/discomfort, each is scored out of 5 with lower scores indicating better outcome (Table 6.5). Quality of life (QoL) measure using the EQ-5D-5L is the total score presented as the sum of the scores of those five measures. All these measures reported lower scores for the Intervention group patients compared to the Control group ($p < 0.05$), indicating better outcomes with pre-operative physiotherapy.

Table 6.5. Secondary outcome scores for patients in the Control and Intervention groups post-surgery

Secondary outcome measures	Control (n = 45)		Intervention (n = 39)		Difference
	Median	IQR [a]	Median	IQR [a]	*p* value
Flexion range of motion					
Active (degrees)	95º	10º	**110º**	15º	< 0.001***
Passive (degrees)	100º	10º	**115º**	7.5º	< 0.001***
Extension range of motion					
Active (degrees)	0º	5º	**0º**	0º	0.024*
Passive (degrees)	0º	0º	**0º**	0º	0.022*
Muscle strength					
Quadriceps (Newton)	62.3	30.8	**80.2**	57.4	0.004**
Hamstring (Newton)	22.7	12.9	**31.1**	12.6	0.004**
Pain [b]					
Pain VAS score	1.9	2.2	**0.7**	1.4	< 0.001***
EQ-5D-5L [c]					
Mobility	2	1	**2**	0	< 0.001***
Self-care	2	0	**1**	0	< 0.001***
Usual activity	3	1	**2**	1	0.004**
Anxiety and Depression	2	1	**2**	0	0.001***
Pain/Discomfort	2	1	**2**	0	< 0.001***
Quality of life					
QoL score [d]	12	3	**9**	2	< 0.001***
QALY score [e]	0.573	0.05	**0.679**	0.10	< 0.001***

[a] IRQ, inter-quartile range
[b] Pain was scored using a visual analogue scale (VAS), the higher the score the worse the pain
[c] EQ-5D-5L is a standardised health status survey developed by EuroQol Group; the higher the score (out of 5), the worse the outcome
[d] The total of EQ-5D-5L scores indicating the overall quality of life, the lower the better
[e] Quality of life and survival score (out of 1), the higher the better
* indicates *p* values lower than 0.05, ** indicates *p* values lower than 0.01 and *** indicates *p* values lower than 0.001; **Bold font** indicates the better scores for each outcome; statistical differences were based on all the individual results and comparisons were made based on all the results and not just the median

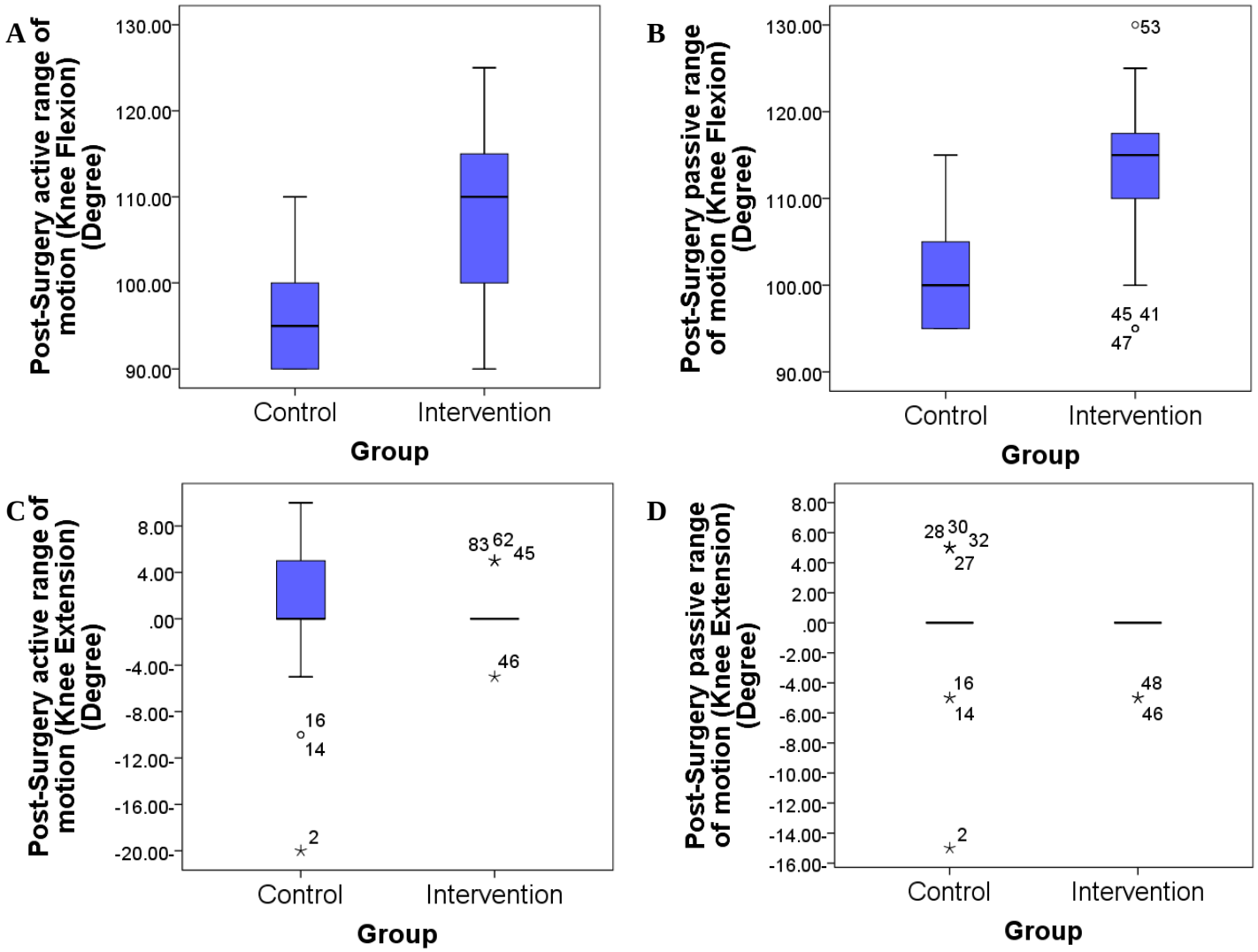


Figure 6.6. Comparison of post-surgery range of motion scores between Control and Intervention groups. Range of motion outcome post-surgery measure includes active flexion (A), passive flexion (B), active extension (C), and passive extension (D)

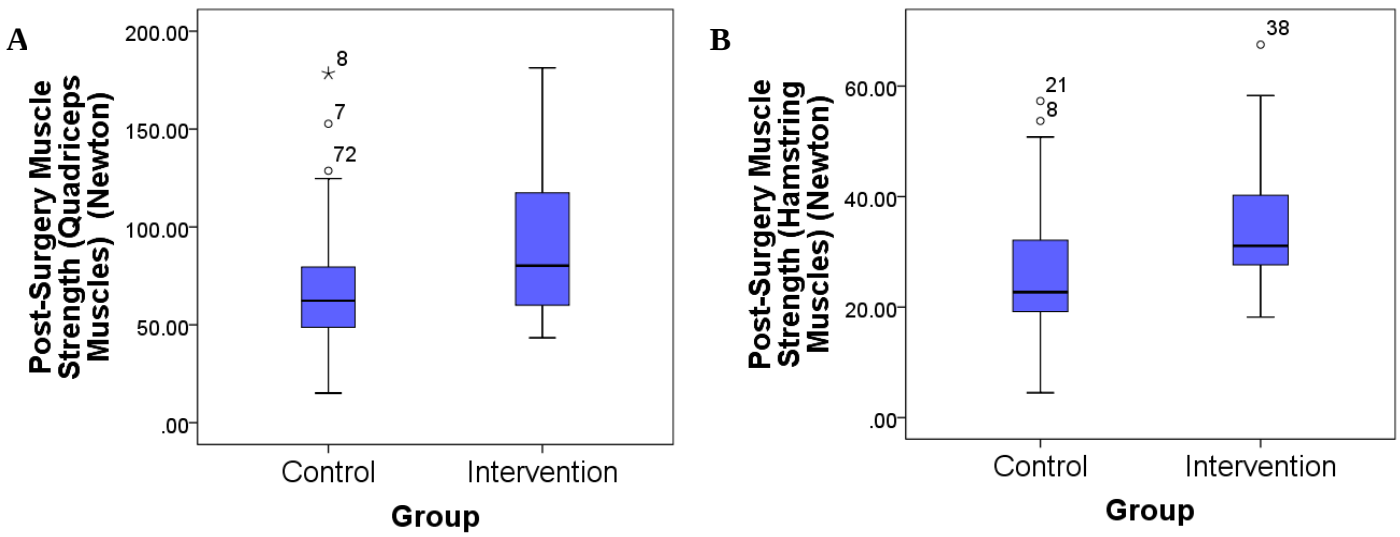


Figure 6.7. Comparison of muscle strength scores between Control and Intervention. Strength values of quadriceps (A) and hamstring (B) muscles were included in the outcome

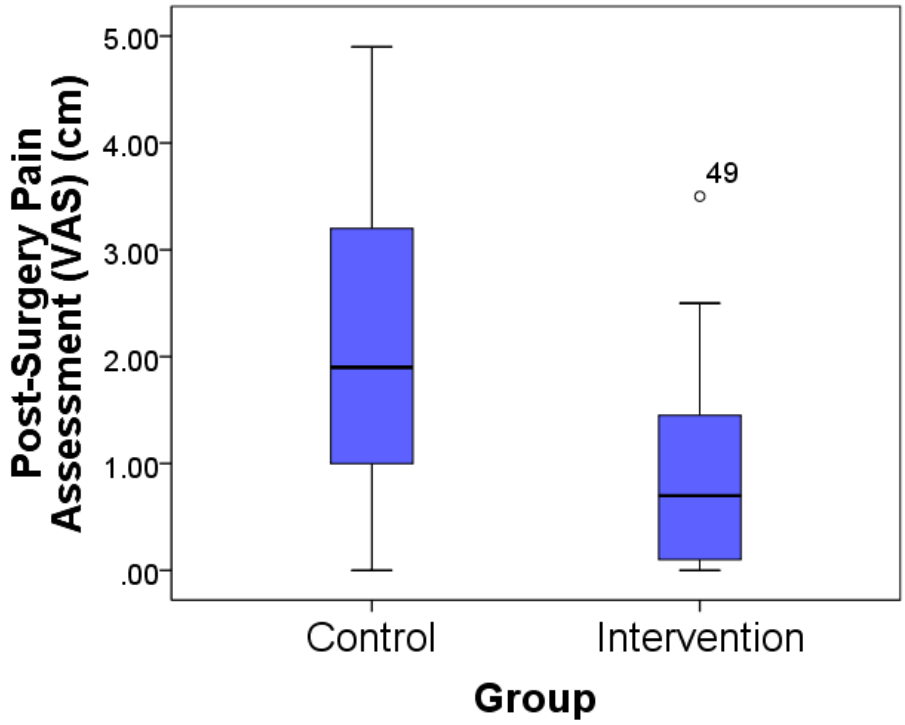


Figure 6.8. Pain assessments in the Control and Intervention groups using the visual analogue scale (VAS)

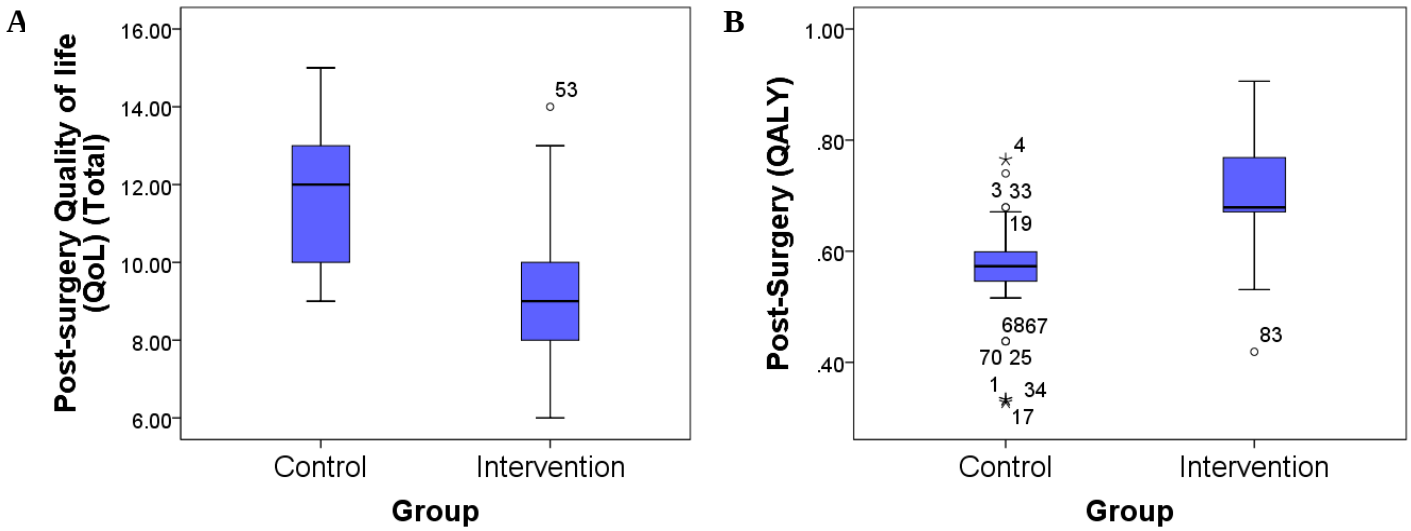


Figure 6.9. Comparison of quality of life scores between Control and Intervention groups. Two methods for scoring were used: the total score of EQ-5D-5L tool, QoL total, (A) and QALY score (B)

6.3.2.3 Economic evaluation

Resource use for the Intervention and Control groups was also compared. This included: imaging, medication, inpatient and out of pocket expenses for both groups and the costs of pre-operative physiotherapy for the Intervention group (pre-operative physiotherapy was only received by the Intervention group). This was carried out to explore the resource use by the two groups (Table 6.6). The costs are shown in Table 6.6 in Saudi Riyals (SR) and British Pound Sterling (£). It is worth noting that the cost of ACL reconstruction and physiotherapy after surgery was the same for both groups (36,000 SR i.e. £6,000), and therefore this was not included in the comparison. Table 6.6 below shows that the overall costs were higher in the Intervention group due to the costs involved in pre-operative physiotherapy. Indeed, the total calculated cost difference in relation to all the utilised resources between the two groups came to between 700 and 800 SR, which is the equivalent of approximately £130.

Table 6.6. Resource use by patients in the Control and Intervention groups (the costs are estimated in Saudi Riyals and converted to British Pound Sterling)

Resource use	**Median**		**Difference**
	Control (n = 45)	**Intervention (n = 39)**	*p* value
Physiotherapy	-	1512 SR (£252)	-
Medical consultation	225 SR (£37.50) [a]	225 SR (£37.50) [a]	-
Imaging	1800 SR (£300)	1800 SR (£300)	0.756
Medications	358.90 SR (£59.82)	339.35 SR (£56.56)	<0.001***
Inpatient	1800 SR (£300) [a]	1800 SR (£300) [a]	-
Inactive days (loss of productivity)	391.29 SR (£65.22)	324.43 SR (£54.07)	0.447
Total costs	4575.19 SR (£762.54)	6000.78 SR (£1000.13)	< 0.001***

[a] Average cost used

Cost-effectiveness analysis was performed using the incremental cost-effectiveness ratio (ICER), and the QALY score was used for this calculation. Table 6.7 shows the results of the calculation that indicate the average cost increment to be approximately £2241 per QALY gain.

Table 6.7. Incremental cost-effectiveness ratio (ICER) between the intervention and control treatments

	Control (n = 45)	**Intervention (n = 39)**
Total costs	4575.19 SR (£762.54)	6000.78 SR (£1000.13)
QALY score	0.573	0.679
ICER [a]	13448.96 SR (£2241.42) / QALY	

[a] Incremental cost-effectiveness ratio (ICER) is calculated by dividing the difference in cost by the difference in quality of life between the Intervention and Control

6.3.3 Comparison between baseline and pre-surgery outcome measures in the Intervention group

Health outcome measures were assessed in the Intervention group upon enrolment (at baseline) and after physiotherapy (following the 4-week programme, prior to surgery) in order to assess the effectiveness of pre-operative physiotherapy in preparing patients for surgery (n = 39). The role of physiotherapy management before surgery in ACL-deficient patients was first suggested by Noyes et al. (1983). Prior to surgery, patients are expected to reach acceptable levels of knee control and overall knee-related health, including an improved ROM, increased knee stability, improved symptoms and reduced pain (Noyes et al., 1983; Keays et al., 2006; Shelbourne and Klotz, 2006). Quadriceps and hamstring muscle strength are important indicators of knee stability and patients should not undergo ACL reconstruction before muscle strength is close to normal (no less than 20% of the unaffected leg) (Keays et al., 2006; Eitzen et al., 2009). Similarly to between-group assessment, the same outcome measures were evaluated for within-group assessment with the exception of estimation of resource use.

The primary and secondary outcome scores were significantly higher in patients after the physiotherapy programme (Tables 6.8 and 6.9). The overall pre-surgery KOOS score was higher than the baseline score in the Intervention group (median 79.6 and IQR 6.0 pre-surgery compared to median 69.2 and IQR 13.4 at baseline, $p < 0.001$) indicating better overall clinical outcomes and knee-function after physiotherapy (Table 6.8). The scores of primary outcomes in the KOOS test in all its five categories were significantly higher after the physiotherapy programme than at baseline ($p < 0.001$), indicating an increase in knee-related health and quality of life.

Particularly, two important indicators were measured using the primary and secondary tests, knee-related pain and QoL. Pain scores using the KOOS test and the VAS scale were both better after pre-operative physiotherapy, indicating that the pain significantly subsided after physiotherapy, without the use of analgesic medication (higher KOOS score of 93 post-physiotherapy *vs* 79 at baseline, Wilcoxon test $p < 0.001$; lower VAS score of 0.0 post-physiotherapy *vs* 1.4 at baseline, $p < 0.001$).

Table 6.8. Primary outcome scores for patients in the Intervention group at baseline and prior to surgery

Primary outcome measures (KOOS) [a]	**Baseline (n = 39)**		**Pre-surgery (n = 39)**		**Difference**
	Median	IQR [b]	Median	IQR [b]	*p* value
Pain	79	15	**93**	7	< 0.001***
Symptoms	81	17	**92**	8	< 0.001***
Function in activities of daily living (ADL)	94	9	**99**	2	< 0.001***
Function in sports and recreation	70	35	**85**	10	< 0.001***
Knee-related quality of life (QoL)	25	25	**31**	13	< 0.001***
Global KOOS score	69.2	13.4	**79.6**	6.0	< 0.001***

[a] KOOS score is reported from 0 to 100, with higher scores indicating better outcomes
[b] IRQ, inter-quartile range
*** indicates *p* values lower than 0.001; **Bold font** indicates the better scores for each primary outcome measure

Quality of life is also a general indicator of knee-related health and this measure was improved after the physiotherapy programme as indicated by the primary and secondary health outcome measures (higher KOOS score of 31 post-physiotherapy *vs* 25 at baseline, Wilcoxon test $p < 0.001$; lower QoL score of 8 post-physiotherapy *vs* 11 at baseline, $p < 0.001$; and higher QALY score of 0.736 post-physiotherapy *vs* 0.645 at

baseline, $p < 0.001$). All of these three tests indicated that the quality of life was improved prior to surgery most likely due to the physiotherapy programme. Here, significant improvements in other measures, such as reduced pain, better mobility and increased ability in activities of daily living as indicated by the tests, may explain the improved QoL.

Both muscle strength (quadriceps and hamstring) and ROM (both passive and active), upon flexion and extension, improved due to the physiotherapy programme (Wilcoxon test $p < 0.01$). Symptoms assessed in the KOOS primary outcome test also improved after physiotherapy (Wilcoxon test $p < 0.001$). The assessed symptoms in this test were indicative of a reduced likelihood of giving-way after physiotherapy (Keays et al., 2006).

Improvement in the assessed knee-related health outcomes (ROM, muscle strength, symptoms, pain, QoL, knee function) are in support of the suggestion that pre-operative physiotherapy can play a significant role in the rehabilitation of patients before undergoing ACL reconstruction (Noyes et al., 1983; Keays et al., 2006). These significant improvements in knee control and health suggest that physiotherapy management may also be effective in the non-operative management of ACL-deficient patients as previously suggested in Chapter Five (Fitzgerald et al., 2000; Frobell et al., 2010; Frobell et al., 2013).

Table 6.9. Secondary outcome scores for patients in the Intervention group at baseline and prior to surgery

Secondary outcome measures	Baseline (n = 39)		Pre-surgery (n = 39)		Difference
	Median	IQR [a]	Median	IQR [a]	*p* value
Flexion range of motion					
Active (degrees)	130º	5º	**135º**	5º	< 0.001***
Passive (degrees)	135º	5º	**135º**	5º	< 0.001***
Extension range of motion					
Active (degrees)	0º	0º	**0º**	5º [b]	0.002**
Passive (degrees)	0º	0º	**0º**	5º [b]	0.007**
Muscle strength					
Quadriceps (Newton)	198.7	31.2	**231.5**	35.5	< 0.001***
Hamstring (Newton)	177.5	57.0	**197.8**	26.7	< 0.001***
Pain [c]					
Pain VAS score	1.4	3.0	**0.0**	0.4	< 0.001***
EQ-5D-5L [d]					
Mobility	2	1	**1**	1	< 0.001***
Self-care	1	1	**1**	0	0.003**
Usual activity	3	1	**2**	0	< 0.001***
Anxiety and Depression	3	1	**2**	0	< 0.001***
Pain/Discomfort	2	1	**2**	1	< 0.001***
Quality of life					
QoL score [e]	11	4	**8**	2	< 0.001***
QALY score [f]	0.645	0.19	**0.736**	0.16	< 0.001***

[a] IRQ, inter-quartile range
[b] Some values were negative indicating ROM hyper-extension
[c] Pain was scored using a visual analogue scale (VAS), the higher the score the worse the pain
[d] EQ-5D-5L is a standardised health status survey developed by EuroQol Group; the higher the score (out of 5), the worse the outcome
[e] The total of EQ-5D-5L scores indicating the overall quality of life, the lower the better
[f] Quality of life and survival score (out of 1), the higher the better
* indicates *p* values lower than 0.05, ** indicates *p* values lower than 0.01 and *** indicates *p* values lower than 0.001; **Bold font** indicates the better scores for each outcome; statistical differences were based on all the individual results and comparisons were made based on all the results and not just the median

6.4 Discussion

To examine health outcomes of the developed protocol, a clinical study was designed and carried out using a pragmatic randomised controlled trial. All participants were male, aged 18−45 years (Table 6.2), coming from different occupational backgrounds (students, government employees and military personnel) (Table 6.3). Table 6.2 shows that there are limited differences between the Control group and Intervention group in terms of age and body mass index (BMI). When stratifying patients based on age groups (Figure 6.2) and BMI (Figure 6.3), more patients from the Control group appeared to be over 40 years of age and in the obese category compared to the Intervention group (22.2% of the Control group compared to 5.1% of the Intervention group with BMI over 30). This can have an effect on the incidence of injury as fitness tends to decrease with older age and increased body weight (Blair and Church, 2004).

Cause of injury in both groups was mainly sports, especially football, with about 90% in the Control group and 95% in the Intervention group sustaining ACL injury due to this sport (Figure 6.4). Interestingly, as can be seen in Table 6.2, the most affected knee was the right knee (60% in the Control group and 59% in the Intervention group), which was also the dominant leg in most patients in these two groups (64% in the Control group and 74% in the Intervention group), indicating a possible relationship between the amount of strain on the dominant leg, especially in sports activities, and the possibility of injury.

6.4.1 Differences in post-surgery outcome measures between Control and Intervention groups

In order to assess if the improvements due to pre-operative physiotherapy play a role in the recovery of ACL-deficient patients after surgery, outcome measures were assessed post-surgery (14 days after ACL reconstruction) and compared for patients in the Control and Intervention groups. The assessed outcome measures were classified into primary and secondary health outcome measures. The primary outcome measures were assessed based on the Knee injury and Osteoarthritis Outcome Score (KOOS) test (Table 6.4). Secondary outcome measures assessed in this study were: the range of motion (ROM) including both active and passive ROM upon flexion and extension, quadriceps and hamstring muscle strength, pain assessment using a visual analogue scale (VAS) tool, and health status using the EQ-5D-5L tool (Table 6.5) in addition to resource use by the patients in both groups (Table 6.6).

KOOS

The scores of primary outcomes measured post-treatment using the KOOS tool were statistically higher in the Intervention group than in the Control group except the score for function in sports and recreation, which was similar between Control and Intervention groups (Table 6.4, Figure 6.5). The overall KOOS score was also statistically higher in the Intervention group (median 71/100) compared to the Control group (median 65/100, Mann-Whitney U-test $p < 0.001$). The differences were statistically significant indicating a better outcome of treatment in the Intervention group

for pain, symptoms, activities of daily living and quality of life. The similar outcome of the sports and recreational function between the Control and Intervention groups may be due to the limited physical functionality in the early stages after reconstruction surgery (after 2 weeks) for both groups.

ROM

Range of motion (ROM) assessment showed better passive and active range of motion for both flexion and extension of the knee joint in the Intervention group compared to the Control group (Figure 6.6). The differences between the two groups were more observed in the flexion range of motion. Extension range of motion showed better results (closer to 0º) than flexion (lower than 135º) in both patient groups and this is quite expected as patients are not able to perform full flexion this early after surgery (contra-indicated in most cases) unlike full extension which is possible (Table 6.5).

Muscle strength

Quadriceps and hamstring muscle strength was higher in the Intervention group than in the Control group (Mann Whitney U-test $p < 0.01$) (Figure 6.7). One of the main objectives of physiotherapy is improving muscle strength in addition to range of motion, as reflected in the rehabilitation programme described in this study, with muscle training exercises being one of the main parts of the developed protocol. It can be argued that the

higher muscle strength in the Intervention group may be due to pre-operative physiotherapy.

Pain

Pain was assessed as a primary outcome as indicated in the first domain of the KOOS tool and as a secondary outcome using the visual analogue scale (VAS) tool (Figure 6.8). The score for pain as a secondary outcome was lower in the Intervention group (median 0.7/10 in the Intervention group compared to 1.9/10 in the Control group, Mann-Whitney *U*-test $p < 0.001$) indicating less pain experienced by patients from the Intervention group (Table 6.5), which is in agreement with the pain KOOS score (median 71/100 in the Intervention group compared to 64/100 in the Control group, Mann and Whitney *U*-test $p < 0.001$).

Quality of life

EQ-5D-5L is a tool for the assessment of overall health status developed by the EuroQol group and it contains five different domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The scores of the five different outcomes in the EQ-5D-5L tool were lower in the Intervention group compared to the Control group and these differences were statistically significant (Mann Whitney *U*-test $p < 0.01$). Quality of life is assessed based on the outcomes of the EQ-5D-5L using the Quality of Life (QoL) score and the Quality-Adjusted Life Year (QALY) score. The QoL score was

lower and the QALY score was higher in the Intervention group compared to the Control group ($p < 0.001$), indicating better quality of life experienced by the Intervention group patients 14 days post-reconstruction (Figure 6.9).

The EQ-5D-5L outcome measures, quality of life (QoL and QALY) and usual activity (Table 6.5), are similar to two items in the KOOS primary outcome measure tool: knee-related QoL and activity of daily living (ADL), respectively (Table 6.4). The scores of these two outcomes indicated that the Intervention group experienced better quality of life and daily living activity than the Control group based on the two different scoring tools.

Quality of life is an important factor that determines the outcome of reconstruction surgery for patients. Various pre-operative indicators were identified as predictors for better outcome of surgery and hence better patient QoL post-surgery; these indicators include: pain, physical function, knee stability and general health (Heijne et al., 2009; Månsson et al., 2013). In particular, knee-related pain, symptoms, activity and quality of life before surgery were found to be closely related to the outcome of ACL-reconstruction, explaining approximately 60% of variance in post-operative QoL (Månsson et al., 2013). In addition, no adverse effects to pre-operative physiotherapy which required medical attention were experienced by the patients during this study.

Resource use and cost-effectiveness

Resource use assessed in this study included costs of imaging and medication in addition to inpatient and out of pocket expenses for both groups and the cost of physiotherapy in the intervention group. Overall, patients in the Intervention group incurred on average 700 to 800 SR (£130) more than patients in the Control group (Table 6.6). This was mainly due to the cost of pre-operative physiotherapy rehabilitation (the cost of each session: 158-263 SR, equivalent to £26-44).

In health economic assessment, a clinical intervention is assessed based on health benefits and cost; this can be visualised using a cost-effectiveness plane (CE plane), as shown in Figure 6.10, where the x-axis represents effectiveness or clinical benefit and the y-axis represents cost. When an intervention adds clinical benefits and reduces cost, it is called an economically *dominant* strategy; the opposite case is called an economically *dominated* strategy, where cost is increased without additional clinical benefit. The usual case with new interventions is when a clinical benefit is seen at an increased cost (as is the case of this intervention). In this case, cost-effectiveness should be assessed using the incremental cost-effectiveness ratio (ICER), which is used by clinicians to make decisions in healthcare regarding resource allocation in relation to new and existing interventions (Cohen et al., 2008).

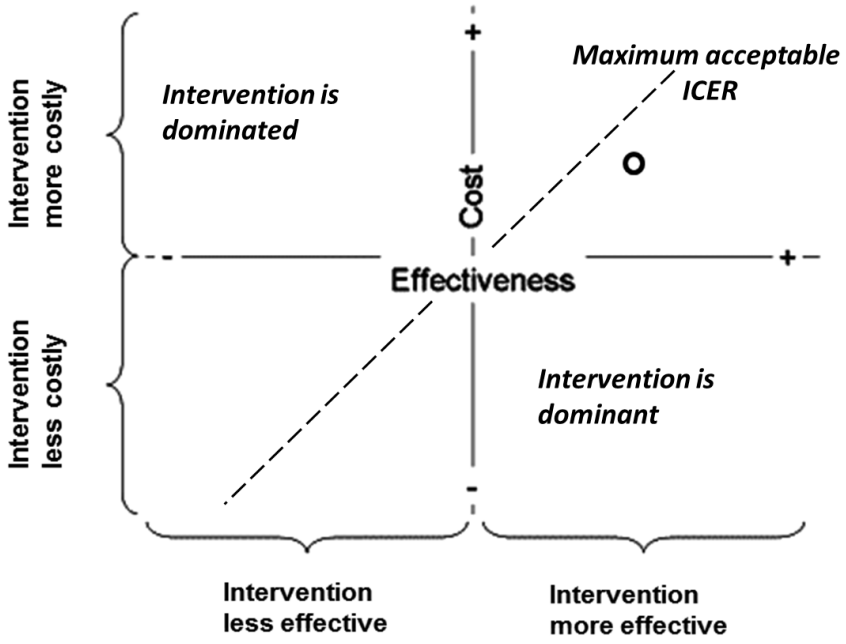


Figure 6.10. Cost-effectiveness plane: the x-axis represents effectiveness of the intervention and the y-axis represents its cost. Where there is increased cost and added clinical benefit, e.g. quality of life, assessment of cost-effectiveness is required. The circle indicates the intervention assessed in this study, which is more effective but also more costly. The maximum acceptable ICER is dependent on the type of study and the healthcare system (adapted with modifications from Cohen et al., 2008)

To assess cost-effectiveness of the intervention in this study, ICER was used based on the difference in cost and QALY between the Intervention group and the Control group (Table 6.7); the calculated ICER ratio was 13,448.96 SR (£2241.42) per QALY gained. The threshold for an acceptable cost-effectiveness ratio varies in the literature based on the country where the intervention is intended to be introduced. Unfortunately, such data is not available for KSA; however, a general guide used by the National Institute for Clinical and Care Excellence (NICE) in the UK indicates that ICER ratios of less than £20,000 per QALY gained due to the intervention are considered favourable and ratios

of above £30,000 per QALY are deemed to be unattractive (McCabe et al., 2008). In the USA, decision-makers use a cost-effectiveness threshold previously estimated in the range of $50,000 to $100,000 per QALY (Cohen et al., 2008). However, there are other factors specific to the country and healthcare system where the intervention is intended to be adopted that need to be considered (Cohen et al., 2008). Overall, based on the generic guidelines used in both the UK and USA, it can be argued that the developed pre-operative physiotherapy programme is a cost-effective intervention.

6.5 Conclusion

A pre-operative physiotherapy rehabilitation programme was developed based on literature and clinical guidelines for the management of ACL injury in Saudi Arabia. A clinical study was designed and carried out to test the developed protocol. Primary and secondary health outcome measures were used to compare the health state of patients 14 days post-reconstruction surgery. The primary health outcomes were based on the KOOS tool and the secondary outcome measures included assessment of muscle strength, ROM, pain, health state and quality of life in addition to resource use.

Overall, patients from the Intervention group showed better primary and secondary health outcomes than the Control group and the ICER indicated that the intervention cost about £2241 per QALY gained due to the intervention. The clinical and cost-effectiveness of the intervention indicated by the present clinical trial suggest that pre-operative physiotherapy is beneficial for the management of ACL-deficient patients and should be introduced to healthcare management of ACL injury in KSA.

The next chapter will present a summary discussion of the research undertaken in this thesis.

Chapter Seven: Overall Discussion

7.1 Introduction

The clinical effectiveness of pre-operative physiotherapy before anterior cruciate ligament (ACL) reconstruction has not been established before the current study (Månsson et al., 2013). This thesis aimed to develop a standardised pre-operative physiotherapy programme for patients undergoing ACL reconstruction based on clinical and literature evidence, and subsequently investigate the effectiveness of the developed protocol. The objectives of the thesis were addressed in the three phases that were conducted, which are inter-related and investigated specific aspects of ACL injury and its treatment.

The three phases were:

Phase 1 - clinical survey of the prevalence of ACL injury in Saudi Arabia and the awareness of patients with ACL injury and healthcare professionals about pre-operative physiotherapy;

Phase 2 - systematic review of pre-operative physiotherapy programmes and their effectiveness in managing ACL injury; and

Phase 3 - clinical trial of a developed standardised pre-operative protocol administered to patients with ACL injury undergoing reconstruction in KSA.

This chapter outlines the aims of this research in relation to each phase, the key findings from each phase and concludes with an overall discussion of all the findings in relation to the aims of each phase.

7.2 Findings and Discussion

Phase 1

Although ACL injury is a common knee injury worldwide (Beynnon et al., 2005), the prevalence of this injury in KSA has not been investigated prior to this study. The importance of such data is to identify how common this injury is in the Saudi society and which patient groups are most affected. This can provide important information to healthcare decision makers regarding the importance of assessing the different interventions and introducing the most appropriate ones to routine clinical practice. Therefore, the aims of **Phase 1** (see Chapter Four) were to:

1) Investigate the prevalence of ACL injury in the population of Riyadh, Saudi Arabia;

2) Investigate the awareness of healthcare practitioners in KSA about pre-operative physiotherapy treatment for ACL injury; and

3) Investigate the awareness of patients with ACL injury in KSA about pre-operative physiotherapy treatment.

This study also attempted to survey the recommendations of healthcare professionals in relation to physiotherapy protocols that are more suited to the needs of Saudi patients.

Overall, the findings of Phase 1 of the thesis are discussed below in relation to each of the three aims of the study.

Aim 1: The first aim of Phase 1 was to investigate the prevalence of ACL injury in the population of Riyadh, Saudi Arabia. To achieve this aim, a clinical survey was carried out.

The findings from the clinical survey indicated that ACL injury in KSA is most common in younger, active males and that the most prevalent ACL injuries are sports-related. The findings also showed that ACL injury is a common knee-related injury, representing over 50% of all knee-related injuries reported in KSA. This is in agreement with findings in other countries including Sweden (Lohmander et al., 2007; Nordenvall et al., 2012), the USA (Beynnon et al., 2005) and New Zealand (Gianotti et al., 2009).

In Riyadh city population, the prevalence of ACL injury was estimated to be 31 per 100,000. This is in line with prevalence figures reported in several other countries including the USA, New Zealand, Norway and Denmark (30-38 per 100,000) (Miyasaka et al., 1991; Nielsen and Yde, 1991; Csintalan et al., 2008; Granan et al., 2008; Lind et al., 2009; Gianotti et al., 2009). However, in Sweden, higher prevalence (78-81 per 100,000) was reported (Frobell et al., 2007; Nordenvall et al., 2012).

The reason for this could be that the population prevalence in KSA may be underestimated because only the main, and not all, hospitals in the Riyadh region were included in this study and concerns were recently raised that there is a lack of systematic collection of injury information in Saudi Arabia (Almutawa et al., 2014). These factors

together call for caution when drawing conclusions about the prevalence of ACL injury in the general Saudi population based on this estimation.

The use of retrospective data, collected in hospitals as part of routine practice, provides an opportunity to uncover valuable information about injury incidence; however, missing data and compromised recording systems can lead to lower quality information. The use of a national registry for reporting and recording prospective data about this type of injury, as practiced in Scandinavian countries (Granan et al., 2008; Lind et al., 2009; Nordenvall et al., 2012), may present a suitable alternative that can improve the quality of such data.

A common trend between the present study and reported literature figures is that the cohort mostly affected by ACL injury was young, active patients (Miyasaka et al., 1991; Csintalan et al., 2008). This may be related to the most common cause of injury, which is participation in sports, estimated in this study to be the cause of over 90% of all injuries reported in KSA. This is of importance due to the high economic and clinical burden of this injury in this cohort, which represents an economically very active section of society (Finkelstein et al., 2006; Leigh, 2011). Consequently, this observation may potentially require focused efforts that are dedicated to the process of raising awareness in regards to the most affected cohorts, as well as implementing preventative measures in a targeted manner to achieve effective prevention and management of the injury (Christoffel and Gallagher, 2006; Norheim, 2008).

Prevalence data also indicated that in the Saudi society, ACL injury is more prevalent in males younger than 30 years of age who are active participants in sports, with about

60% of all participants being among this social cohort. Reviewed studies reported a similar trend with young, active people being mostly affected (Miyasaka et al., 1991; Csintalan et al., 2008); however, previous research reported that females were more implicated in this injury compared to males (see Chapter Two) (Kobayashi et al., 2010). This may be attributed to the culture of the Saudi society in which females do not participate significantly in sports.

Investigation into the prevalence of sports related injuries indicated that sports are the main cause of ACL injuries (over 90% of cases), of which the majority (more than 90% of sports related injuries) were due to participating in football, which is the most popular sport in Saudi society (Al-Refaee and Al-Hazzaa, 2001). This is a similar trend to the majority of countries around the world, where participation in football is very popular (Faunø and Wulff Jakobsen, 2006), with implications on the risk of sustaining ACL injuries (Hutchinson and Ireland, 1995).

Other factors that may affect the prevalence of such an injury include lack of quality equipment, the weather, the quality of the grounds used for sports, the level of conditioning prior to sporting participation, and the availability of prevention awareness programmes (Silvers and Mandelbaume, 2011). Specifically, a high risk of sporting accidents and injuries have been reported to occur when poor quality footwear is used; when sports are played in humid and rainy weather; and when played on low quality grounds (Orchard et al., 1999; Hawkins and Fuller, 1999; Orchard et al., 2003; Orchard et al., 2005).

In addition, environments with hot climates were also associated with higher incidence of injury in comparison to cooler weather as fatigue would occur at a quicker rate due to factors such as higher blood lactate concentration (see Chapter Four) (Orchard et al., 2003). In particular, these factors are relevant to sports in KSA as outdoor weather conditions are extremely hot and ultimately increase the possibility of ACL injury (Almutawa et al., 2014; Al-Gannas, 2015). Utilising prevention programmes was shown to play a role in the reduction of sporting incidents related ACL injuries and awareness regarding conditioning, while warming up exercises prior to training are suggested to help prevent the majority of injuries and reduce the severity of those that occur (Hutchinson and Ireland, 1995; Mandelbaum et al., 2005; Olsen et al., 2005). However, evidence that defines awareness of potential prevention of ACL injury in KSA is still lacking, and thus, the prevalence of the injury is not adequately addressed or understood in the country due to this lack of documentation.

Aim 2 and 3: The second and third aims of Phase 1 were to investigate the awareness of healthcare practitioners and patients, respectively, in KSA in relation to ACL injury pre-operative physiotherapy treatment.

Phase 1 also investigated the awareness about the health benefits of pre-operative physiotherapy amongst both practitioners and patients in the Saudi context. Evidence from clinical practice reported in this research showed a lack of standardised pre-operative physiotherapy programme in all the establishments that participated in this study as indicated by discrepancies in the protocols administered to the surveyed patients. It also found that there was a lack of awareness about the potential benefits of

pre-operative physiotherapy management for patients undergoing ACL reconstruction among healthcare professionals (orthopaedic surgeons and physiotherapists) and patients.

A relatively high level of awareness about pre-operative physiotherapy was documented among healthcare professionals (82%); however, this level of awareness is still considered lower than that about post-operative physiotherapy, which is routinely received by all patients after undergoing reconstruction surgery. In addition, limited awareness about pre-operative management was demonstrated by Saudi patients (55%) with ACL injury. All patients who were aware of the benefits of pre-operative physiotherapy had already received this management option. Similar trends were observed in other studies investigating awareness about physiotherapy among patients in Nigeria (Maruf et al., 2012) and healthcare professionals in Nepal (Acharya et al., 2011).

In the present study, recommendation of pre-operative physiotherapy by practitioners was mostly based on their own judgment indicating that there was no referral system in place for pre-operative physiotherapy management. Although there was some level of awareness regarding the effectiveness of pre-operative physiotherapy in KSA, raising awareness about this intervention within healthcare organisations and among patients may lead to further integrating it into routine clinical practice (Achterbergh and Vriens, 2002). This is supported by the observation in the clinical survey that all healthcare professionals in KSA, who were aware of pre-operative rehabilitation, went on to recommend its utilisation for patients under their care. Nonetheless, raising awareness in patients may rely mainly on the information that is passed on from knowledgeable healthcare professionals, as higher levels of awareness were shown to exist among

healthcare professionals in comparison to patients. Indeed, the healthcare practitioners represent the first point of direct contact with patients, which makes them a valuable source of guidance and information for patients.

As indicated in previous studies (Acharya et al., 2011; Maruf et al., 2012), creating a satisfactory level of awareness among patients and healthcare professionals about the importance of physiotherapy is among the challenges facing physiotherapists (Grimmer et al., 1999), especially in developing countries, such as KSA. These countries tend to rely more on conventional medicine, such as surgical management, with lower levels of awareness about physiotherapy and less advanced healthcare systems (Acharya et al., 2011; Maruf et al., 2012). There are general uncertainties regarding the role of a physiotherapist in developing countries, including KSA, which are mainly due to the patients' level of education under the Saudi education system and the general lack of public health awareness.

Another factor that seems to preclude the introduction of such intervention in the Saudi context comes from the lack of recommendation by the management of healthcare establishments, which may be related to the lack of standard national healthcare policies regarding the use of pre-operative rehabilitation. This may be related to the lack of studies that provide evidence of the clinical and cost-effectiveness of pre-operative rehabilitation in the treatment of ACL injury in relation to patient health and return to normal activity (Keays et al., 2006; Månsson et al., 2013). Therefore, recommendations by individual healthcare professionals in KSA, as seen in the current study, appear to be based on autonomous clinical judgment as they prepare patients who are not fit to undergo ACL reconstruction. Consequently, this would result in the form of pre-

operative rehabilitation changing between practitioners' definitions and not being unified in the health service. This may lead to differences in the effectiveness of pre-operative rehabilitation or lack of standardisation.

The general trend observed in this investigation was that awareness about pre-operative physiotherapy is still lacking and therefore raising awareness about its benefits, using robust evidence, along with increased communication between surgeons and physiotherapists, can possibly increase the use of this intervention in physiotherapy units in Saudi hospitals and clinics.

In addition to the lack of investigations into the clinical effectiveness of this intervention, there is also a lack of clinical guidelines for pre-operative rehabilitation of patients with ACL injury in KSA. The development of pre-operative physiotherapy protocols and assessing the benefits of this intervention can lead to adopting the evidence on such benefits into standardised guidelines in pre-operative management of ACL-deficient patients in Saudi Arabia. In addition, there is limited referral of patients to the physiotherapy units and lack of defined referral processes to physiotherapy units prior to surgery. This may change if pre-operative physiotherapy becomes a routine practice in hospitals in KSA.

Phase 2

The aim of this phase was to conduct a systematic review to examine the current level of evidence in relation to the effectiveness of pre-operative exercise physiotherapy on the outcomes of treatment following ACL injury.

The findings of this systematic review are discussed in Chapter Five. The number of studies included in the systematic review was 8 randomised controlled trials, with methodological quality that ranged from 3 to 7 on the PEDro scale (average quality score 5.8). The overall finding of this review indicated that pre-operative physiotherapy can be effective in providing improved treatment outcomes following ACL injury; however, only certain exercise types were of significant benefit. This reflects the differences in evidence that support different types of exercise used in pre-operative and non-operative physiotherapy management of ACL-injury as indicated by the Cochrane Database of Systematic Reviews (Trees et al., 2011).

The second highlight of this systematic review was that the published pre-operative rehabilitation protocols are heterogeneous in relation to their content, duration and frequency, which reflects lack of standard protocols and can lead to different levels of effectiveness of this type of management. This lack of standardised, evidence-based pre-operative physiotherapy programmes is one of the reasons preventing routine use of such intervention in the clinic. More in-depth discussion of the findings of this phase has already been presented in Chapter Five.

Using the assessment carried out in this phase, only exercise types that showed significant evidence of benefit in ACL-deficient patients were included in the pre-operative protocol developed in Phase 3.

Phase 3

Studies conducted in Phase 1 (clinical survey - Chapter Four) and Phase 2 (systematic review - Chapter Five) indicated that, to date, there is no standard pre-operative protocol for patients undergoing ACL reconstruction in KSA.

Although pre-operative physiotherapy was suggested to be beneficial in preparing patients for ACL reconstruction, this intervention has not yet been established as mainstream treatment in hospitals around the world, including the healthcare system in KSA. The characteristics of patients with ACL injury are variable and they tend to represent a heterogeneous population (Keays et al., 2000; Keays et al., 2003), and therefore, there is a need for pre-operative physiotherapy programmes that are designed specifically for ACL-deficient patients in Saudi Arabia to ensure effectiveness of rehabilitation. These programmes should have the capacity to be personalised according to the health state and progressive requirements of the patients (Eitzen et al., 2010). Therefore, Phase 3 developed a standardised pre-operative protocol, and subsequently evaluated the clinical and cost-effectiveness of the protocol on a sample of patients with ACL injury in a clinical setting in KSA using a range of outcome measures.

Previous studies recommended the use of a well-established and evidence-based physiotherapy protocol (Mikkelsen et al., 2000; Beynnon et al., 2005), assessment of the effectiveness of this intervention and the different protocols used in pre-operative physiotherapy was carried out for the first time in Phase 2 of this study. Based on this assessment, the developed protocol was intended to improve muscle strength, balance and knee joint control. Literature evidence regarding the duration and frequency of the

intervention suggested protocols of 4 to 24 weeks with 2-4 sessions per week (Beard et al., 1994; Fitzgerald et al., 2000; Tagesson et al., 2008; Thomeé et al., 2010; Shaarani et al., 2013), each pre-operative session being up to 60 minutes long (Beard et al., 1994; Thomeé et al., 2010). This was corroborated by the recommendations of surgeons and physiotherapists who participated in Phase 1 of this research (Chapter Four). The protocol was individualised according to a dose-response framework (Kraemer et al., 2002) with progression being dependent on age, performance and health state (Eitzen et al., 2010).

To achieve the aim of the Phase 3 programme of work in this thesis, a pragmatic randomised controlled trial was conducted in Riyadh, KSA. The methodological quality of the clinical trial conducted in this study was assessed based on the Physiotherapy Evidence Database (PEDro) scale (Moseley et al., 2002; Maher et al., 2003; Kollen et al., 2009), which indicated that the study was of moderate methodological quality (5/10) (Appendix 22). This score was achieved because randomisation took place in one of the three participating hospitals and concealed allocation was used. Blinding the therapist and patients was not possible due to the nature of the study, and this may have led to bias in the results of the study as having knowledge of the treatment received can lead to biased responses by the participants (Kendall, 2003). Different levels of expectation, anxiety and other psychological factors can also affect patient reporting in both the intervention and control groups, especially in outcome measures that require their subjective response, for example reporting pain severity (Ferrucci et al., 2004). The retention of participants in the study can also be affected by lack of blinding (Kendall,

2003), which was also observed in the present study as more participants dropped out from the intervention group than the control group.

A range of outcome measures were used to evaluate the clinical effectiveness of the pre-operative physiotherapy intervention. Assessed outcomes were classified into primary outcomes (Knee injury and Osteoarthritis Outcome Score, KOOS) and secondary outcomes (muscle strength, range of motion, pain, health status, quality of life and cost-effectiveness).

The KOOS score measures five different categories related to knee function and health: knee-related pain, symptoms, activities of daily living, sports activity and quality of life (Roos and Toksvig-Larsen, 2003). The intervention group presented higher KOOS scores than the control group, reflecting better overall health outcomes post-surgery associated with pre-operative physiotherapy, except in participation in sports activities, which was the same in the two groups. This was expected because patients from both groups were in the early stages of recovery from surgery and sports activity was still contra-indicated at the time of assessment (14 days post-reconstruction). It would be of value to compare health outcomes between control and intervention groups at a later stage to monitor progress and to assess the effects of the intervention on recovery from injury and return to normal daily and sports activity.

The main objectives of pre-operative physiotherapy include improving proprioception, muscle strength and ROM (Cimino et al., 2010), which lead to improved knee function and control. Quadriceps and hamstring muscle strength scores were higher in the intervention group compared to the control group. In addition, better passive and active

ROM scores were also recorded for the intervention group. Therefore, improvement in these outcome measures seemed to be fulfilled by the developed exercise regime. Improvement in extension ROM due to the intervention was more significant than flexion ROM, and this is expected because full extension is easier to perform by both groups this early after surgery than knee flexion, which tends to return to normal levels at a later stage post-surgery (Shelbourne et al., 2011). Having a restricted knee flexion often leads to difficulties in movement in daily activities, such as kneeling or squatting, which usually contributes to lower QoL (Millett et al., 2001). The range of motion, related to both flexion and extension, is expected to improve gradually after surgery until it is comparable to ROM levels in the contralateral knee (Månsson et al., 2013); however, complete symmetry in both extension and flexion is not always achievable in the long term (Shelbourne and Gray, 2009).

Quadriceps and hamstring muscle strength was measured in patients post-surgery and was higher in the intervention group than the control group. In line with this finding, Tagesson et al. (2008) included a varied protocol for improving neuromuscular control and muscle strength and the study showed significant quadriceps muscle strength improvement following pre-operative physiotherapy. These findings are also in agreement with Eitzen et al. (2009) who suggested that the pre-operative quadriceps strength is a significant positive predictor for long-term knee function after ACL reconstruction. The authors recommended that pre-operative physiotherapy protocols should focus on quadriceps training to improve side-to-side symmetry in order to improve the outcome of surgery and avoid long-term post-surgery deficits in the affected knee (Eitzen et al., 2009).

Prior to surgery, deficits in quadriceps muscle strength are usually more common and larger than those in hamstring muscles, which are sometimes not affected by the injury (Keays et al., 2001; Keays et al., 2003). Patients with deficits of more than 20% in quadriceps muscle strength compared to the contralateral limb should be referred to the physiotherapy unit and surgery should be delayed (de Jong et al., 2007; Shelbourne et al., 2007). Pre-operative deficit in quadriceps muscle strength was shown to negatively affect gait patterns in ACL-deficient patients post-surgery and restrict their ability to walk and jog, and therefore, strong quadriceps muscles are a necessary pre-surgery requirement to ensure return to normal knee joint kinematics after ACL reconstruction (Lewek et al., 2002). The findings of this study showed that improvement in quadriceps muscle strength due to the exercise regime was more significant than improvement in hamstring muscles in the intervention group. In addition, strength of both quadriceps and hamstring muscles were significantly higher in the intervention group compared to patients who did not receive the exercise regime.

Keays et al. (2006) indicated that quadriceps strengthening has a more significant effect on knee function recovery than hamstring strengthening after a home-based pre-operative rehabilitation programme. Correlation analysis showed that quadriceps muscle strength correlated more closely with knee function tests than hamstring muscle strength (Keays et al., 2003), which further supports recommendations by Eitzen et al. (2009) for pre-operative protocols to focus on quadriceps training to achieve better post-surgery knee function outcomes, regardless of the type of graft. Indeed, graft types used in these two studies were either bone-patellar-tendon-bone graft or hamstring graft, which was also the case in the clinical study conducted in this phase. These findings emphasise the

inter-relation between muscle strength and knee-joint stability and functionality (Keays et al., 2003). Therefore, muscle strength training was shown in the analysis of this clinical study to be very effective and may have contributed to the improvement in knee function and stability prior to surgery. However, in common with the two highlighted studies, no assessment of differences in health outcomes in relation to using the two different grafts in this study.

In addition, Beard et al. (1994) included proprioception enhancement exercises for the intervention group and reported an improvement in functional scores and reflex hamstring contraction latency scores in the intervention group as compared to the control group. In addition, balance training, such as using a balance board, significantly improved proprioception (Beard et al., 1994; Fitzgerald et al., 2000; Shaarani et al., 2013). Balance board exercises were also used to improve balance, muscle control (Fitzgerald et al., 2000) and position sense (Keays et al., 2006). Additionally, there is evidence to suggest that balance training can improve range of motion and overall knee kinematics (Shelbourne et al., 2012). Accordingly, a lower level of balance results from the injured ACL mechanoreceptors that, as a consequence, increase the measurement of sway, which stabilometric studies have demonstrated as impacting negatively on the complete function (Terese et al., 2002). As a result, strength and proprioception training are both suggested to prove beneficial on a mutual basis upon the improvement of the neuromuscular function as a positive correlation is created between the proprioception and muscle strength (Zhou et al., 2008). In terms of long-term effects of balance-based perturbation, Zätterström et al. (1994) showed evidence of improvement in balance one

year after knee-specific exercise physiotherapy. However, assessment of these long-term benefits of pre-operative physiotherapy was beyond the scope of the present study.

Pain was assessed as a primary outcome by using the KOOS scale and also as a secondary outcome through the use of a visual analogue scale (VAS). Both the intervention and control groups of patients seemed to experience mild to moderate pain, which was higher in the control group compared to the intervention group. Lower pre-operative pain levels were observed in patients who received pre-operative physiotherapy in the absence of analgesic medication. However, the low pain level observed post-operatively may be due to the assessment being conducted early following surgery where patients are still taking analgesics. Heijne et al. (2009) observed that a lower level of pre-operative patellofemoral pain is an important predictor of better clinical outcomes in knee-related quality of life and function one year after ACL reconstruction. It was shown through a multiple regression model that anterior knee pain (AKP) as well as function were important predictors in the period before surgery. As a result, the findings have shown a lower level of AKP is the most beneficial predictor for QoL-KOOS, which was measured at 14%, as a good clinical outcome for the year following ACL reconstruction. Moreover, tendon grafts were both highlighted as beneficial to better clinical outcomes, although the patellar-tendon was defined through a measurement of 8% improvement in the Tegner Activity Scale to be preferred to the hamstring tendon graft.

According to findings by Arendt and Grossman (2003), lower pre-operative pain usually leads to lower post-operative pain, a trend which was also observed in the current study in patients who received pre-operative physiotherapy. This correlation can present

important information in patient prognosis related to the clinical outcome of surgery in patients with ACL deficiency (Heijne et al., 2008). As indicated by the findings of the present study, one of the benefits of pre-operative physiotherapy is significantly reduced pain in the absence of analgesic medication. Since reduced pre-operative pain is closely associated with reduced post-operative pain and improved knee-related quality of life, these findings may lend further support to using pre-operative physiotherapy for the management of ACL injury.

As indicated by the systematic review (Phase 2), QoL was not assessed independently in the literature studies included in the review; rather, this outcome measure was assessed as a sub-category of the KOOS test. Therefore, considering the importance of this outcome measure, QoL was evaluated in the clinical trial as both a primary outcome (in the KOOS scale) and a secondary outcome using the EQ-5D-5L scale. This scale also included a psychological category that allowed patients to score their level of anxiety and depression due to the injury and subsequent treatment. These two tools reported similar results with the intervention group experiencing better QoL than the control group. As for pain, QoL tends to be a subjective clinical outcome measure that relates to the overall health state of the patient (Kocher et al., 2002).

The findings of the present study are in agreement with a previous investigation that used pre-operative physiotherapy for the intervention group alone (Shaarani et al., 2013) and reported improvement in QoL (function and physical performance) in this group. Other studies that assessed the effect of pre-operative rehabilitation on QoL using the KOOS scale (Thomeé et al., 2010; Frobell et al., 2010; Frobell et al., 2013) reported no evidence of improvement in QoL due to pre-operative physiotherapy intervention. Post-

operative QoL seems to be closely related to various pre-operative indicators including pain, pre-surgery QoL, physical stability and function (Heijne et al., 2009; Månsson et al., 2013). Therefore, quality of life can be considered as an overall measure of patient health status and is used in considering cost-effectiveness of the intervention.

Aim 3: To assess the cost-effectiveness of pre-operative physiotherapy in a sample of patients with ACL injury.

In addition to the clinical effectiveness of pre-operative physiotherapy, cost-effectiveness of treatment was also assessed. The use of cost-effectiveness as an outcome of healthcare interventions is becoming increasingly important and should be considered when evaluating such interventions (Luce et al., 2009). Assessment of cost-effectiveness can assist policy-makers in making important decisions in relation to adopting new interventions or comparing between existing treatment options (Cohen et al., 2008).

The intervention group recorded higher costs mostly attributed to physiotherapy, and therefore, cost-effectiveness was assessed using the incremental cost-effectiveness ratio (ICER) based on incremental cost relative to incremental quality-adjusted life years (QALY) related to the intervention. The QALY score was significantly higher in the intervention group than the control group, indicating that whilst the intervention (pre-operative physiotherapy) was more costly, it was also more beneficial.

In Saudi Arabia, short-term management costs were estimated in this study at approximately 41,000 SR ($11,000) per patient for early reconstruction with an additional 1,500 SR ($400) for pre-operative physiotherapy option with delayed surgery

based on 2013 figures. These figures show the size of the cost of this injury for the Saudi healthcare system, in line with findings about costs related to ACL injury in the USA (Mather et al., 2013). These costs include costs of diagnostic tests, physiotherapy and reconstruction surgery as well as productivity loss associated with ACL injury in a very active society cohort (Finkelstein et al., 2006; Leigh, 2011). Compared to KSA figures, short-term management costs of ACL injury in the USA were recently estimated at $20,000 per patient for early reconstruction and $22,000 for pre-operative physiotherapy with delayed surgery based on 2012 figures, with up to four-fold increase in cost in long-term management including complications (Mather et al., 2014). However, the estimation of long-term costs was beyond the scope of this study as discussed in the section on limitations below.

The ICER for the intervention assessed in the present study was approximately 6,900 SR (£1,150) per QALY gained due to pre-operative physiotherapy. Based on NICE guidelines (McCabe et al., 2008), interventions which record ICER values of less than £20,000 per QALY are usually deemed cost-effective and attractive for implementation. Because this intervention is shown to be cost-effective, policy makers may be advised to invest in introducing this intervention into clinical practice in KSA to improve the health outcomes of patients with ACL injury.

Although clinical and cost-effectiveness of this intervention possibly justify the resources required for its use in the short-term, other factors, usually related to the country and healthcare system in which the evaluation is carried out, should be considered before introducing a certain treatment into routine practice even if evidence

suggests its cost-effectiveness. In addition, investigation of long-term clinical and cost-effectiveness should be considered to further reinforce these findings.

The main implication of this study is that patients with ACL deficiency should be provided with the option to be referred to pre-operative physiotherapy prior to surgical reconstruction. Outcome measures such as muscle strength, range of motion, symptoms and pain before surgery have previously been shown to be significant predictors of the outcome of surgery, and therefore, these should be improved in order to increase the success rates of reconstruction (Keays et al., 2006; Månsson et al., 2013). Physiotherapists are therefore advised to be vigilant when assessing ACL-deficient patients in order to identify cases that present surgery contra-indications and those that can benefit more from pre-operative physiotherapy. Even chronic deficiencies were shown to be reversible if the appropriate training is administered (Keays et al., 2006). Other long-term benefits of pre-operative physiotherapy in improving joint function and preventing complications have been suggested (Tegner et al., 1986; Keays et al., 2006; Frobell et al., 2010; Shelbourne et al., 2012).

7.3 Limitations of the Study

This study consisted of three inter-related phases and limitations were identified in each of these phases. Phase 1 was a clinical survey intended to investigate the prevalence of ACL in KSA and awareness of patients with ACL injury and their treating healthcare professionals about pre-operative physiotherapy. Due to access and time constraints, this study was limited to the Riyadh region, and therefore, any conclusions relating to

prevalence of ACL injury and awareness of healthcare professionals and patients cannot be generalised to the general Saudi population.

As indicated by Almutawa et al. (2014), the quality of recording injury information in the Saudi health system is sub-standard, which leads to incomplete records and missing information, which usually leads to compromising the quality of the collected information. In particular, clinical history details of ACL injury were sometimes lacking and in some cases the knee injury was not adequately specified in the patient notes.

Other limitations are related to the inherent disadvantages of survey questionnaires including low response rates, difficulty of interpreting the findings in some cases, the restrictiveness of the selected options, which leads to missing certain crucial information and the requirement for faithful transcription and unbiased analysis.

Phase 2 was a systematic review of the literature on the effectiveness of pre-operative physiotherapy in treating ACL injury. This systematic review has certain limitations. First, the review included only studies published in English, and therefore, there is a possibility that relevant literature published in other languages may have been excluded. A further limitation was that the present review included only published articles. Furthermore, the variations in the durations and types of intervention in the selected studies makes proposing clear, evidence-based guidance in pre-operative physiotherapeutic management of ACL injury a challenging task.

Additional limitations associated with systematic reviews include availability of only limited resources, which lead to partial conclusions. Misinterpretation and misrepresentation of the original findings can also occur when synthesising evidence in

reviews. Another limitation encountered in this study was the incompleteness and inconsistency of numerical data in the reviewed studies, which precluded the use of a reliable meta-analysis.

Phase 3 was a pragmatic quasi-randomised controlled trial to investigate the effectiveness of a designed pre-operative protocol in the management of ACL injury in KSA. Although this study was of moderate methodological quality, certain items of the PEDro scale were not fulfilled. First, randomisation took place only in one out of the three hospitals that participated in this study and blinding of the patients and the investigator were not possible as stated above. This may have introduced bias related to the investigator or to the hospitals where the study was conducted. Further limitations of RCT studies also affected this study, including the requirement for a reliable study design. This often requires information, which is not always available, including the level of improvement deemed clinically meaningful and the expected variation in improvement, which assist in estimating a sufficient sample size. Expense can also be an issue, and ethical consideration (e.g. blinding) can sometimes restrict the quality of the design of randomised controlled trials.

In addition to these limitations, this study was conducted in only three hospitals in the city of Riyadh, which was mainly due to access restrictions and lack of time to arrange wider participation. This may affect the possibility of generalising the findings of this study. One of the main limitations of this clinical study was the short time between the surgery and post-surgery assessment (2 weeks) and the lack of follow-up until recovery of patients. Timing of measurements for the control and intervention groups was different and this may have affected the results of the study. The timing of the post-

surgery measurement was mainly based on the recommendations of the treating surgeons and follow-up measurements were beyond the scope of this study. Therefore, only short-term assessment was possible and long-term effects of pre-operative physiotherapy were not investigated. These factors taken together can therefore affect the generalisability of the findings related to the clinical effectiveness of pre-operative physiotherapy. Due to these considerations, the findings of this study, although important, should be viewed with caution.

In addition, only short-term clinical and cost-effectiveness was evaluated in this study, which was due to time and access constraints; however, investigation of long-term clinical and cost-effectiveness should be considered due to the fact that ACL injury has long-term impact on patients and healthcare systems (Mather et al., 2014). In addition, no sensitivity analysis was conducted on the economic evaluation of the intervention due to the requirement for more data, the complexity of data analysis involved, and the need for more time and expense related to data collection and subsequent analysis. Furthermore, when considering the sample of patients who participated in the clinical trial, it is clear that female patients were not represented in this study, which may be considered as a drawback in the sampling process for two reasons. Firstly, a sample has to be as representative of the population as possible (Petersen et al., 2005); and secondly, active females tend to be more susceptible to ACL injury compared to their male counterparts due to anatomical and physiological differences as discussed in Chapter Two (Nordenvall et al., 2014).

The limitations of the present study should be considered when planning future studies to collect more generalisable evidence. Firstly, a sample more representative of the

general population has to be selected. This should include both male and female patients from different age groups. Secondly, the study should be planned to span a sufficient period of time for the assessment of both short and long-term health outcomes. An example of such a study with frequent follow-ups was conducted by Frobell et al. (2010; 2013), which extended for up to 5 years post-ACL reconstruction. This should also include the assessment of long-term cost-effectiveness, management of long-term complications and return to normal daily and sports activity. Thirdly, standard procedure of randomised controlled trials should be followed closely to ensure high methodological quality, based on such scales as the PEDro scale used in this study. Finally, recording and transcription of data should be done with care to ensure faithful transcription and sufficient quality of data recording.

7.4 Summary

This study assessed the effectiveness of a standardised preoperative physiotherapy protocol developed for patients with ACL reconstruction in improving patient health outcomes after surgery. The findings of this study showed that the designed protocol was beneficial clinically and cost-effective for the treatment of this type of injury. These findings support introducing pre-operative physiotherapy into routine clinical practice for the treatment of ACL injury in Saudi hospitals and clinics. As a result, clinicians and policy makers should be aware of these findings as such intervention may help to improve the health outcomes of patients undergoing ACL reconstruction.

The next chapter summarises the findings of this thesis and provides the implications and recommendations of the study.

Chapter Eight: Summary, Conclusions and Recommendations

8.1 Introduction

There are very few studies that have investigated the effectiveness of pre-operative physiotherapy for patients with ACL injury. A systematic review was conducted in order to evaluate previous studies relating to the subject, which revealed a variety of set protocols that included contrasting durations and contents, and subsequently, led to more than one specific conclusion (see Chapter Five). This was particularly seen in regards to the effects of physiotherapy on the quality of life and the knee function of patients. Therefore, these variations in conclusions may be due to heterogeneity in the contents of operative protocols, which were previously reviewed in the Cochrane Database of Systematic Reviews (Trees et al., 2011). As a result, the diversity of findings within the conducted systematic review helped develop a base to present a standardised protocol in the Kingdom of Saudi Arabia (KSA), which is the main aim of the present study.

The present investigation has helped in the design of a standardised, evidence-based pre-operative protocol for ACL injury management that can be used in the context of Saudi Arabian healthcare, as well as assessing its clinical and cost-effectiveness in a set

clinical trial. Subsequently, all this information has been evaluated and analysed. This chapter offers an overall summary of these findings and provides details of the implications and recommendations from these conclusions.

8.2 Summary and Key Findings

Although the present research was structured into a set of chapters, the overall process of reporting the findings in the current study was conducted in three inter-related phases, which were designed to address the aims of the study.

Phase 1 evaluated the prevalence of ACL injury in KSA and investigated the awareness of ACL-deficient Saudi patients and their treating healthcare professionals about pre-operative physiotherapy management. As a result, the findings from this phase indicated that the prevalence of ACL injury in KSA is estimated at 31 per 100,000 in the Riyadh region. In accordance, these findings were shown to be comparable to the prevalence of this injury around the world. Likewise, ACL injury was found to be the most prevalent knee-related injury and the most affected cohort in the Saudi society was found to be young, active males. Awareness about pre-operative physiotherapy seemed to be low among patients and limited among healthcare professionals.

Phase 2 of the current study systematically reviewed and assessed different published studies that detailed pre-operative physiotherapy in order to evaluate the effectiveness of this type of physiotherapy on patient health outcomes. It also assessed the evidence for the effectiveness of different exercise types that were used in various published pre-

operative protocols. The systematic review indicated that the use of pre-operative physiotherapy can potentially lead to an improvement in the patient's knee-related physical function and can sometimes help in reduction of the requirement for reconstruction surgery. However, it was noted that there were differences in published protocols that showed only certain types of exercise can be effective (i.e. muscle strengthening and balance perturbation exercises), suggesting evidence for lack of a standardised protocol.

Phase 3 implemented the purpose of designing an evidence-based pre-operative protocol for the treatment of ACL-deficient patients in KSA, which followed the combined process of reviewing the literature evidence that was ascertained in Phase 2 and the clinical recommendations from Phase 1. This pre-operative protocol developed included three stages: a warm-up stage, a physical training stage and a balance training stage. Additionally, both open and closed kinetic chain exercises were used in the second stage and balance board-based exercises were included in the third stage. Through the process of pragmatic randomised controlled trial, the clinical and cost-effectiveness of the protocol was evaluated in three hospitals in Riyadh, KSA.

The findings of the current study indicated that pre-operative physiotherapy improved health outcomes of patients who presented with an ACL injury and were to undergo reconstruction, which was demonstrated by a variety of sources: higher KOOS scores; improved quality of life; improved muscle strength and range of motion; as well as better health state scores. Separately, the assessment of the cost-effectiveness of pre-operative physiotherapy as a form of intervention also indicated that the incremental cost-effectiveness ratio (ICER) came to approximately 13449 SR (£2241) per quality

adjusted life year (QALY), which is considered to be cost-effective. However, understanding the relevance of these figures and potential resultant effects requires further consideration in relation to the case of the Saudi healthcare system.

8.3 Summary of Clinical Implications

- The present study has developed a pre-operative protocol and assessed the effectiveness of physiotherapy in preparing patients with ACL injury for reconstruction surgery in KSA. However, the overall awareness in regards to this type of intervention has been shown to be distinctly lacking, and therefore, the process of raising awareness relating to its benefits and increased communication between healthcare professionals may potentially contribute to the increased clinical use of such intervention.

- Raising awareness about ACL injury and its prevention and treatment may reduce the prevalence of such injury and its complications. Accordingly, prevalence was shown in the study to be particularly high in younger, active individuals, which may call for focused efforts to target the most affected cohorts of society.

- The development of clinical guidelines and standardised protocols for pre-operative physiotherapy management of ACL-deficient patients in Saudi Arabia can be adopted from the evidence that has been presented in the current study in relation to the benefits of pre-operative physiotherapy.

- Based on the findings of the present study, pre-operative physiotherapy should be integrated into the Saudi healthcare system as a routine practice in hospitals and rehabilitation clinics. Indeed, pre-operative physiotherapy can be administered in physiotherapy units already available in hospitals that treat ACL injury in KSA, and therefore, no additional infrastructure is required to introduce this intervention into routine practice.

- Based on the findings in relation to cost-effectiveness of the intervention in the present research, effectiveness of pre-operative physiotherapy in regards to the short term may potentially justify the resources that are required to implement it for use. Likewise, evidence of the benefits and costs-effectiveness of pre-operative physiotherapy can assist decision-makers in relation to routine use of pre-operative physiotherapy. Furthermore, additional evidence, which may include available infrastructure and budget funds, may be required to assess the feasibility of introducing this type of treatment.

8.4 Conclusions

Overall, the aims of the current study were successfully addressed. The estimation of the prevalence of ACL injuries in the Saudi population and the assessment of the awareness of patients who presented with ACL injury and their treating healthcare professionals in relation to pre-operative physiotherapy are the distinct innovative findings of the current research. In fact, ACL injury prevalence figures for KSA that were estimated in this study seem to be similar to international prevalence levels. Nonetheless, the general

level of awareness amongst healthcare professionals and ACL-deficient patients in regards to the benefits of pre-operative physiotherapy on clinical outcomes following reconstruction is still limited, which may require further efforts to raise awareness using an evidence-based approach. However, it must be noted that this research is the first study that has developed an evidence-based pre-operative physiotherapy protocol for patients who are undergoing ACL reconstruction. Moreover, it is also the first study to examine the clinical and cost-effectiveness of such protocol in the context of Saudi Arabia. Therefore, the current study presents a case for adopting such an effective protocol in Saudi hospitals and clinics for the treatment of ACL injuries.

In addition, analysed evidence from this study showed that this form of intervention can be of benefit in the overall preparation of patients for surgery by increasing muscle strength and improving knee function. As a consequence of this evidence, it can be used to confirm the suggestion of the role of physiotherapy in the management of ACL-deficient patients prior to reconstruction surgery. Furthermore, the findings of the current research also suggest an improvement in patient health outcomes post-surgery. The developed protocol was administered three times a week for four weeks, translating to 12 sessions in total, which seems to be manageable. The cost-effectiveness and clinical implications warrant considering pre-operative physiotherapy as a management option in the Saudi context.

8.5 Recommendations from the Study

8.5.1 Recommendations for clinical practice

The current research reported through the use of accumulated evaluated evidence that ACL injuries are prevalent in the Saudi Arabian society, which consequently results in considerable health and economic burdens upon both the patients and the overall provision of healthcare. Therefore, the effectiveness of pre-operative physiotherapy in improving health outcomes was demonstrated, and hence, a recommendation of integrating this type of treatment should be made. Moreover, orthopaedic surgeons should have the option to prescribe pre-operative physiotherapy for their ACL-deficient patients, and this highlights the need to be able to identify target patients for whom this intervention is required.

It has been determined through the current study that the design of a pre-operative protocol needs, as indicated, to be evidence-based and rigorously assessed before it can be introduced to clinical practice. The protocol should also have the capacity to become individualised once it is adopted and applied. Furthermore, based on their accumulation of experience, physiotherapists should play a key role in raising awareness amongst patients under their care, and offer greater insight into the benefits that are offered by pre-operative physiotherapy through direct counselling and/or information leaflets. Accordingly, patients in turn must be provided with the option to receive pre-operative physiotherapy wherever there is a perceived benefit.

8.5.2 Recommendations for policy

It can be concluded that policy makers need to be encouraged by healthcare professionals to play a positive role in the process of considering various forms of evidence that support the adoption of pre-operative physiotherapy into general routine practice within hospitals or as a home-based intervention. Clinical policy in the Saudi healthcare context, in relation to the administration of pre-operative physiotherapy, is distinctly lacking and thus, the development of such policy should be encouraged by healthcare professionals in order to improve the benefits experienced by patients. Moreover, policy makers should also be active participants in organising and funding programmes that raise awareness amongst patients in relation to pre-operative physiotherapy regimes that are available in healthcare institutions, whilst also informing how they can be of benefit to those patients who suffer from ACL injury.

8.5.3 Recommendations for future research

It can be seen from policy and practice implications that the clinical and cost-effectiveness of pre-operative physiotherapy intervention needs to be assessed in the long term in relation to patient health outcomes, as well as the economic burden to both patients and the healthcare system alike. Further studies are therefore recommended in order to investigate the effects of pre-operative physiotherapy on long-term knee function and QoL in patients, as well as the time that it takes to return to pre-injury levels of activity. These include sports participation; long-term complications including osteoarthritis and recurrence of ACL injury; together with long-term costs to patients and the healthcare system. Indeed, the implementation of this additional research should

be conducted in hospitals that treat ACL injuries in collaboration with the Ministry of Health, the welfare system and health insurance companies.

The research that has been presented in the current study has only focused on the region of Riyadh, Saudi Arabia, and thus, comprehensive studies on additional national regions may be required in order to investigate whether the findings of the current study can be generalised to the entirety of the country. Similarly, the consideration of females who are active in sports participation needs to be analysed as they have been shown to be more prone to sports related ACL injuries due to anatomical and hormonal factors (Kobayashi et al., 2010). As a consequence, the studies presented in the current research need to be extended in the future in order to provide a thorough investigation of the effects of pre-operative physiotherapy on a more comprehensive patient sample that includes female patients, which is more representative of society.

In addition, a recommended future study will investigate whether the benefits of the developed pre-operative physiotherapy programme can be gained when patients choose home-based treatment. Indeed, a home-based conservative physiotherapy programme was previously investigated by Keays et al. (2006) and it was found that the implementation of this specific structure was actually effective in the management of such a particular injury. Similarly, a home-based physiotherapy programme also presents the added advantage of offering more convenience to ACL-deficient patients who can often struggle with mobility due to their injury (Keays et al., 2006).

Publications and Conference Contributions Originating from this Study

Publication (attached to the end of this thesis)

Alshewaier, S., Yeowell, G., Fatoye, F. (2016) 'The Effectiveness of Pre-operative Exercise Physiotherapy Rehabilitation on the Outcomes of Treatment Following Anterior Cruciate Ligament Injury: A Systematic Review.' *Clinical Rehabilitation*. DOI: 10.1177/0269215516628617.

Conferences Contributions

- Attendance at the 9th Annual Research Institute for Health and Social Change Conference, July 2013
- Poster presentation on Phase 1 of the current study at the 8th Saudi Students Conference in London, UK, 31st Jan – 1st Feb 2015
- Poster presentation on Phase 1 of the current study at the 5th International Conference on Health, Wellness and Society, Universidad de Alcalá, Madrid, Spain, 3rd – 4th Sept 2015
- Attendance at the 8th Manchester Metropolitan University Postgraduate Research Conference, 5th Nov 2015
- Poster presentation on Phase 3 of the current study at the 9th Saudi Students Conference in Birmingham, UK, 13th – 14th Feb 2016

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Appendices

Appendix 1. The data extraction form items and the information they are intended to extract

Data extraction item	Rationale/purpose
Q1: Code of hospital	Personal and identifying details, also which patient groups have more prevalence of ACL injury (age groups, different genders, married and non-married, employed or unemployed). Are younger people who practise sports and are more susceptible to be involved in accident more prone to having an ACL injury? Are males, who are more active in sports and other activity in the Saudi society more prone to injury? Are married people less susceptible to injury to due to being more cautious and also due to lack of time?
Q2: Type of hospital: Private/Public	
Q3: Participant number	
Q4: Age	
Q5: DOB	
Q6: Gender: M/F	
Q7: Marital status: Married / Single / Divorced	
Q8: Occupation	
Q9: Weight	Clinical details, including the effect of weight on the prevalence of injury
Q10: Dominant limb: L / R	
Q11: Injured limb: L / R	
Q12: Date of the ACL injury	
Q13: Type of sport	Investigating relation of ACL injury with sports
Q14: How many times have they had ACL injury:	Experience of ACL injury/recurrence/ prevalence of injury
Q15: How the injury occurred	The cause of the injury/prevalence of sports related injury and injury related to other causes
Q16: Have they received any pre-operative physiotherapy treatment?	Experience of pre-operative physiotherapy
Q17: How many pre-operative physiotherapy sessions have they received?	Details of pre-operative therapy

Q18: What was the duration of pre-operative physiotherapy treatment they received?	
Q19: Have they received any post-operative physiotherapy rehabilitation?	Experience of post-operative physiotherapy
Q20: How many post-operative physiotherapy sessions have they received?	Details of post-operative therapy
Q21: What was the duration of post-operative physiotherapy treatment they received?	

Appendix 2. Data extraction form

Data extraction form

Code:

1) **Code of hospital**
2) **Type of hospital: Private/Public**
3) **Participant number:**
4) **Age:**
5) **DOB:**
6) **Gender:**
7) **Marital status:**
8) **Occupation:**
9) **Weight:**
10) **Dominant limb:**
11) **Injured limb:**
12) **Date of the ACL injury:**
13) **Type of sport:**
14) **How many times have they had ACL injury:**
15) **How the injury occurred:**
16) **Any treatment they have received:**
17) **Any type of investigations:**
18) **What type of reconstruction have they had?**
19) **Have they received any pre-operative physiotherapy treatment?**
20) **How many pre-operative physiotherapy sessions have they received?**
21) **What was the duration of pre-operative physiotherapy treatment they received?**
22) **Have they received any post-operative physiotherapy rehabilitation?**
23) **How many post-operative physiotherapy sessions have they received?**
24) **What was the duration of post-operative physiotherapy treatment they received?**

Appendix 3. The practitioners' questionnaire items and the information they are intended to extract

Questionnaire item	**Rationale/purpose**
Consent form	Ethical and legal requirement
Aim of study/instructions/contact details	Information about the study
Section 1	
Q1: Gender	Demographic details
Q2: Age	
Q3: Profession	
Q4: Number of years working as a practitioner	Experience of the practitioner
Q5: Rank of the practitioner	To distinguish between physiotherapists and surgeons and indicate experience
Q6: Level of education	Qualification of the practitioners
Q7: Description of professional practice	To distinguish between public and private health practice
Section 2	
Q1: Have you treated patients with ACL injury in your practice?	To establish relevance of clinical experience
Q2: I am aware of pre-operative physiotherapy treatment for patients undergoing ACL reconstruction	To establish awareness of pre-operative physiotherapy
Q3: Patients with ACL injuries undergoing ACL reconstruction should be referred for pre-operative physiotherapy	Awareness of referral for physiotherapy (filter question)
Q4: In your opinion why should patients undergoing ACL reconstruction be referred for pre-	Reasons for referral for physiotherapy

operative physiotherapy?	
Q5: What treatment should be included in pre-operative physiotherapy treatment for patients with ACL injury?	Awareness of procedure and specifics of the treatments
Q6: How many pre-operative physiotherapy treatment sessions do you believe patients undergoing ACL reconstruction require?	
Q7: Over how many weeks should these pre-operative physiotherapy treatment sessions take place?	
Q8: Over what period of time should a pre-operative treatment session be given?	
Q9: Patients who have undergone ACL reconstruction should be referred for post-operative physiotherapy	Awareness of post-operative physiotherapy (comparison with awareness of pre-operative therapy, filter question)
Q10: In your opinion, why should patients undergoing ACL reconstruction be referred for post-operative physiotherapy?	Awareness of importance and benefits of post-operative physiotherapy
Q11: What treatment should be included in a post-operative physiotherapy treatment for patients with ACL reconstruction?	Awareness of the specifics of post-operative physiotherapy treatment
Q12: How many post-operative physiotherapy treatment sessions do you believe patients with ACL reconstruction require?	
Q13: Over how many weeks should these post-operative physiotherapy treatment sessions take place?	

Q14: Over what period of time should a post-operative physiotherapy treatment sessions be given?	
Q15: I am aware that patients with ACL injury have benefited from pre-operative physiotherapy treatment	Awareness of the benefit of pre-operative physiotherapy
Q16: I am aware that patients with ACL injury have benefited from post-operative physiotherapy treatment	Awareness of the benefit of post-operative physiotherapy

Appendix 4. The patients' questionnaire items and the information they are intended to extract

Questionnaire item	**Rationale/purpose**
Consent form	Ethical and legal requirement
Aim of study/instructions/contact details	Information about the study
Section 1: Demographic details	
Q1: Age	Demographic details (incidence of injury in different age groups and different genders, and also whether marital status has an effect on the incidence of injury)
Q2: Occupation	
Q3: Marital status	
Q4: Gender	
Q5: Do you do any sporting activity? And what sport?	To investigate sports related injury
Q6: Is it the first time you having ACL injury?	To investigate recurrence of injury and awareness about it
Q7: How did the ACL injury occur?	The reason of ACL injury
Section 2	
Q1: Have you had ACL reconstruction surgery?	Is the patient pre- or post-operative? Experience of pre-operative and/or post-operative physiotherapy treatment
Q2: Have you had ACL pre-operative physiotherapy treatment before?	Related to awareness of the treatment. Are patients informed about pre-operative treatment before they receive it?
Q3: I am aware of importance of pre-operative physiotherapy treatment for patients undergoing anterior cruciate ligament (ACL)?	Awareness of importance of pre-operative physiotherapy (filter question)
Q4: How many pre-operative physiotherapy	Details and specifics of the received treatment,

treatment sessions did you receive before the ACL reconstruction?	relevant to awareness
Q5: Over how many weeks did you receive these pre-operative physiotherapy treatment sessions?	
Q6: Over what period of time did you receive these treatment sessions?	
Q7: In your opinion over what period of time should these treatment sessions be given?	Awareness of the benefits of pre-operative physiotherapy
Q8: I believe that patients who are undergoing ACL reconstruction should be referred for pre-operative physiotherapy treatment?	Awareness of the usefulness of pre-operative physiotherapy
Q9: I believe that I benefitted from the pre-operative treatment session that I received?	Actual benefits of preoperative physiotherapy
Q10: I am aware that pre-operative physiotherapy treatment is beneficial to patients undergoing ACL reconstruction:	Awareness of the benefits of pre-operative physiotherapy

Appendix 5. Awareness of pre-operative physiotherapy questionnaire: practitioners' version

Awareness of Pre-operative Physiotherapy Questionnaire

Surgeons and physiotherapists' version

The aim of this questionnaire is to collect data on your awareness of Pre-operative Physiotherapy for Patients undergoing ACL reconstruction

Questionnaire instructions:

I will appreciate it if you could please take some time to complete this survey.
It will take approximately *10* minutes to complete.You are eligible to participate if you have experience of managing patients with anterior cruciate ligament (ACL) injury.
Please circle or tick one number in each line or answer as requested according to your own current experience in Saudi Arabia with ACL patients.
Comment on your responses as appropriate in the areas provided.

- ***This questionnaire is anonymous, you don't need to write your name or contact details on the questionnaire.***

Thank you for your time in completing this questionnaire.

Email:

Mobile:

Kind Regards

Shady Alshewaier

PhD student

Section 1: Demographic information:

1. Gender:
   ☐Male
   ☐Female

2. Age: …….

3. Profession: ……

4. Number of years working as a Surgeon/Physiotherapist: …….

5. Please indicate your rank according to Saudi Health Commission
   ☐ Surgeon
   ☐Specialist
   ☐Senior Specialist
   ☐Consultant
   ☐Physiotherapist
   ☐Technician
   ☐Physiotherapy Student
   ☐Intern student
   ☐Other: …….

6. Education: please tick from the following your **HIGHEST** qualification and write the name of the country where the qualification was awarded.
   ☐BSc, Country: ……
   ☐DPT, Country: ……..
   ☐MSc, Country:……
   ☐MPhil, Country:…….
   ☐PhD, Country:…….
   ☐Undergraduate diploma for Technicians. Country:…….
   ☐Other ……

7. Which of the following describes your current professional practice?
   ☐Ministry of Health Hospital
   ☐Military Hospital
   ☐University Hospital
   ☐Private Hospital
   ☐Private Medical Centre
   ☐Private Clinic
   ☐Other, please specify …….

Section 2: Please answer the following questions according to your own experience and beliefs by choosing one answer.

1- Have you treated patients with ACL injury in your practice?

☐ **Yes**

☐ **No**

2- I am aware of pre-operative physiotherapy treatment for patients undergoing ACL reconstruction:

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

3- Patients with ACL injuries undergoing ACL reconstruction should be referred for pre-operative physiotherapy:

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

➢ ***If you disagree/strongly disagree with the above statement, please go to question 9***

4- In your opinion why should patients undergoing ACL reconstruction be referred for pre-operative physiotherapy?

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……
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……

……
……

5- What treatment should be included in pre-operative physiotherapy treatment for patients with ACL injury?

……
……
……
……
……
……
……

6- How many pre-operative physiotherapy treatment sessions do you believe patients undergoing ACL reconstruction require?

a) **1-6 sessions**
b) **7-12 sessions**
c) **13-24 sessions**
d) **Other: …….**

7- Over how many weeks should these pre-operative physiotherapy treatment sessions take place?

a) **Within 2 weeks**
b) **between 2-4 weeks**
c) **between 4-8 weeks**
d) **Other: …….**

8- Over what period of time should a pre-operative treatment session be given?

a) **Up to 30 minutes per session**
b) **30-45 minutes per session**
c) **45-60 minutes per session**

d) **Other …….**

9- Patients who have undergone ACL reconstruction should be referred for post-operative physiotherapy:

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

- ***If you disagree/strongly disagree to the above statement, please go to question 15***

10- In your opinion why should patients undergoing ACL reconstruction be referred for post-operative physiotherapy?

……
……
……
……
……

11- What treatment should be included in a post-operative physiotherapy treatment for patients with ACL reconstruction?

……
……
……
……
……
……
……
……

12- How many post-operative physiotherapy treatment sessions do you believe patients with ACL reconstruction require?

a) Up to 36 sessions
b) 37-48sessions
c) 49-60 sessions
d) 61-72 sessions
e) Other: …….

13- Over how many weeks should these post-operative physiotherapy treatment sessions take place?

a) Within 12 weeks
b) Between 12-16 weeks
c) Between 16-20 weeks
d) Between 20-24 weeks
e) Other: …….

14- Over what period of time should a post-operative physiotherapy treatment sessions be given?

a) Up to 30 minutes per session
b) 30-45 minutes per session
c) 45-60 minutes per session
d) Other …….

15- I am aware that patients with ACL injury have benefited from pre-operative physiotherapy treatment:

a) Strongly disagree
b) Disagree
c) Neither agree nor disagree
d) Agree
e) Strongly agree

16- I am aware that patients with ACL injury have benefited from post-operative physiotherapy treatment:

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

Thank you for your participation and taking time to complete this questionnaire.

Appendix 6. Awareness of pre-operative physiotherapy questionnaire: patient version [translated]

Awareness of Pre-operative Physiotherapy Questionnaire

Patient version

The aim of this questionnaire is to collect data on your awareness of Pre-operative Physiotherapy for Patients undergoing anterior cruciate ligament (ACL) reconstruction

Questionnaire instructions:

I would appreciate it if you could please take some time to complete this survey.
It will take approximately *10* minutes to complete. You are eligible to participate if you have experience with anterior cruciate ligament (ACL) injury.
Please circle or tick one number in each line or answer as requested.
Comment on your responses as appropriate in the areas provided.

- ***This questionnaire is anonymous, you do not need to write your name or contact details on the questionnaire.***

Thank you for your time in completing this questionnaire.

Email:

Mobile:

Kind Regards

Shady Alshewaier

PhD student

Section 1: Demographic information:

1) **Age:**

   ☐ **18-21**
   ☐ **22-30**
   ☐ **31-40**
   ☐ **41-50**
   ☐ **50 or above**

2) **Occupation:…….**

3) **Marital Status:**

   ☐**Single**
   ☐**Married**
   ☐**Divorced**

4) **Gender:**
   ☐**Male**
   ☐**Female**

5) **Do you do any sporting activity:**
   ☐**Yes**
   ☐**No**

   If YES, what type of sport do you play……

6) **Is it the first time you having ACL injury?**
   ☐**Yes**
   ☐**No**

   If the answer is No, please state how many times ……..

7) **How did the ACL injury occur?**

   a) **During sporting activity.**
   b) **Car accident.**
   c) **Other:……**

Section 2: Please answer the following questions.

1- Have you had ACL reconstruction surgery?

☐**Yes**
☐**No**

If the answer is YES, to which knee was the ACL reconstruction…….

2- Have you had ACL pre-operative physiotherapy treatment before?

☐ **Yes**
☐ **No**

3- I am aware of pre-operative physiotherapy treatment for patients undergoing anterior cruciate ligament (ACL)?

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

➢ ***If you strongly disagree or disagree please go to question 8***

4- How many pre-operative physiotherapy treatment sessions did you receive before the ACL reconstruction?

a) **1-6 sessions**
b) **7-12 sessions**
c) **13-24 sessions**
d) **Other:…….**

5- Over how many weeks did you receive these pre-operative physiotherapy treatment sessions?

a) **Within 2 weeks**
b) **between 2-4 weeks**
c) **between 4-8 weeks**
d) **Other:…….**

6- Over what period of time did you receive these treatment sessions?

a) Up to 30 minutes per session
b) 30-45 minutes per session
c) 45-60 minutes per session
d) Other …….

7- In your opinion over what period of time should these treatment sessions be given?

a) Up to 30 minutes per session
b) 30-45 minutes per session
c) 45-60 minutes per session
d) Other …….

8- I believe that patients who are undergoing ACL reconstruction should be referred for pre-operative physiotherapy treatment?

a) Strongly disagree
b) Disagree
c) Neither agree nor disagree
d) Agree
e) Strongly agree

9- I believe that I benefitted from the pre-operative treatment session that I received?

a) Strongly disagree
b) Disagree
c) Neither agree nor disagree
d) Agree
e) Strongly agree

10- I am aware that pre-operative physiotherapy treatment is beneficial to patients undergoing ACL reconstruction:

a) **Strongly disagree**
b) **Disagree**
c) **Neither agree nor disagree**
d) **Agree**
e) **Strongly agree**

Additional Comments (if you have any additional comments please write them here)

……
……
……
……
……
……
……

Thank you for your participation and taking time to complete this questionnaire.

Appendix 7. Information leaflet for participants: clinical survey

Information Leaflet for Participants [Translated]

Title of the research project: ***Developing a standardised pre-operative physiotherapy programme for patients undergoing Anterior Cruciate Ligament (ACL) reconstruction in Riyadh, Kingdom of Saudi Arabia (KSA)***

Contact the researcher:
Address: Riyadh - Saudi Arabia
Mobile:
E-mail:

You are being invited to participate in this research (questionnaire survey). Please kindly take some time to read the information presented here, which explains the details of this research project. Please feel free to ask the researcher any questions about any part of this questionnaire that you do not fully understand. It is very important that you are fully satisfied and that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate in this questionnaire survey. If you say no, this will not affect you negatively in any way whatsoever, it would not affect your rights and the treatment that you currently receive.

This study has been approved by the **Faculty Research Degrees Committee (FRDC) in Manchester Metropolitan University, UK.**

The aim of this questionnaire is to determine the level of awareness of orthopaedic surgeons, physiotherapists and patients of pre-operative physiotherapy programme for patients undergoing ACL reconstruction in Riyadh.

Will you benefit from taking part in this research?

- There are no personal benefits in participating in this study. The findings of this study will be used to determine the level of awareness of orthopedic surgeons, physiotherapist and patients of pre-operative physiotherapy programme for patients undergoing ACL reconstruction in Riyadh.

Who will have access to your personal records?

- No personal data will be recorded for this study.

Will you be paid to take part in this study and are there any costs involved?

- No, you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

Appendix 8. Participant consent form: clinical survey

Participant Consent Form [Translated]

By signing below, I agree to take part in a research study entitled. ***Developing a standardised pre-operative physiotherapy programme for patients undergoing Anterior Cruciate Ligament (ACL) reconstruction in Riyadh, Kingdom of Saudi Arabia (KSA)***

I declare that:

- I have read and understand the information for the above study☐
- I have had a chance to ask questions and all my questions have been adequately answered ☐
- I understand that taking part in this study is **voluntary** and that I free to withdraw at any time without giving any reason, without my legal rights being affected☐
- I agree to participate in the above study ☐

Signature of participant …… Date ……...……...

Declaration by researcher:

I am Shady Alshewaier I declare that:

- I explained the information in this document to the participant.
- I encouraged him /her to ask questions and took time to answer them.
- I am satisfied that he / she adequately understands all aspects of this questionnaire as discussed above.
- I did / I did not use a translator. (If a translator is used then the translator must sign the declaration below).

Translator's signature: ..... Date: .....

Signature of researcher: ..... Date: ……..

Appendix 9. Ethical approval: Manchester Metropolitan University

Manchester Metropolitan University

FACULTY OF HEALTH, PSYCHOLOGY AND SOCIAL CARE

Manchester Metropolitan University

Elizabeth Gaskell Building
Hathersage Road
Manchester
M13 0JA United Kingdom

Telephone
+44(0)161-247 2569

E-mail
Dan.oconnor@mmu.ac.uk

07/06/2013

Department of Health Professions
Programme of study: PhD full time

RE: Ethical approval for research*: Developing a standardised pre-operative physiotherapy programme for patients undergoing ACL reconstruction in Riyadh.*

To whom it may concern

This is to confirm that according to MMU ethical guidelines Mr Shady Alshewaier does not have to seek further ethical approval for his PhD research as it currently stands. The approval covers his data collection in Kingdom of Saudi Arabia. Mr Alshewaier's research proposal was reviewed and approved on 19th March 2013.

If you have any further questions then please contact me.

Yours sincerely,

Dan OConnor
Research Degrees Administrator

Appendix 10. Ethical approval: Saudi Cultural Bureau

ROYAL EMBASSY OF SAUDI ARABIA
CULTURAL BUREAU
LONDON

سفارة المملكة العربية السعودية
الملحقية الثقافية
لندن

To whom it may concern

Date: Friday, May 10, 2013
Ref: MJU25

Student: SHADY ABDULLAH HAMAD ALSHEWAIER

This is to confirm that the above named is a scholarship holder sponsored by the Government of Saudi Arabia to study Doctorate - PHD / Athletic Injuries - Bones in the UK.

The Scholarship includes payment of tuition fees and a monthly allowance to cover the student's living expenses. This sponsorship extends from 09/04/2012 to 08/04/2015

Shady is planning to conduct a data collection from hospitals which are based in Riyadh

Any assistance given to the aforementioned will be highly appreciated.

Yours sincerely,

Faisal M. Almohanna Abaalkhail
Cultural Attaché

الرقم : ..... التاريخ : ..... الموافق : ..... المرفقات : .....

630 Chiswick High Road, London W4 5RY Tel: +44 (0) 20 3249 7000 Fax: +44 (0) 20 3249 7001 E-mail: sacbuk@uksacb.org

Appendix 11. Exemplar of electronic search strategy for Ovid database

Number	Searches	Results
1	Anterior cruciate ligament injury.mp. [mp=ab, hw, ti, ot, nm, kf, px, rx, an, ui, tc, id, tm, tx, sh, ct]	**2224**
2	Preoperative rehabilitation.mp. [mp=ab, hw, ti, ot, nm, kf, px, rx, an, ui, tc, id, tm, tx, sh, ct]	**225**
3	Preoperative exercise.mp. [mp=ab, hw, ti, ot, nm, kf, px, rx, an, ui, tc, id, tm, tx, sh, ct]	**472**
4	Preoperative protocol.mp. [mp=ab, hw, ti, ot, nm, kf, px, rx, an, ui, tc, id, tm, tx, sh, ct]	**308**
5	Quality of life.mp. [mp=ab, hw, ti, ot, nm, kf, px, rx, an, ui, tc, id, tm, tx, sh, ct]	**630524**
6	1 and 2	**5**
7	1 and 3	**3**
8	1 and 4	**0**
9	1 and 5	**137**
10	6 or 7 or 8 or 9	**143**
11	Remove duplicates from 10	**129**
12	Limit 11 to english language [Limit not valid in Journals@Ovid,Your Journals@Ovid; records were retained]	**129**
13	Limit 12 to human [Limit not valid in AMED,Journals@Ovid,Your Journals@Ovid; records were retained]	**128**
14	Limit 13 to randomized controlled trial [Limit not valid in AMED, psycinfo, Journals@Ovid,Your Journals@Ovid; records were retained]	**118**

Appendix 12. Patient information leaflet: clinical trial

Patient consent form and information leaflet for participants in research

Title of the research project: Developing a standardised pre-operative physiotherapy programme for patients undergoing Anterior Cruciate Ligament (ACL) reconstruction in Riyadh, Kingdom of Saudi Arabia (KSA)

You are being invited to participate in this research project as you have had anterior cruciate ligament injury which requires surgery. Please, kindly take some time to read the information presented here, which explains the details of this research project and discuss it with others if you wish. For more information or if you have any queries please use the contact information given at the end of this leaflet. It is very important that you are fully satisfied and that you clearly understand what this research entails and how you could be involved. In addition, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever, it would not affect your rights and the treatment that you currently receive. You are also free to withdraw from the study at any point, even if you did agree to take part.

This study has been approved by **the Saudi Cultural Bureau and Faculty of Health, Psychology and Social Care Academic Ethics Committee, Manchester Metropolitan University, United Kingdom.**

What is this research study all about?

- The aims of the proposed project are to:
    1- Develop a standardised pre-operative physiotherapy rehabilitation programme for patients with ACL injury undergoing reconstruction.
    2- Investigate the clinical effectiveness of the developed standardised protocol.
    3- Investigate the cost effectiveness of the developed standardised protocol.

Why have you been invited to participate?

- You have been invited to take part in this research as your Consultant has identified you as a potential candidate based on your diagnosis of anterior cruciate ligament injury and your ability to complete exercise safely.

What will your responsibilities be?

- By agreeing to participate in this study, you will take part in either a pre-operative physiotherapy rehabilitation programme or receive standard pre-operative management.

Will you benefit from taking part in this research?

- There may be no personal benefits from participating in this study. The findings of this study will be used to develop intervention for people undergoing ACL reconstruction.

What are the risks involved in taking part in this study?

- There is little risk involved in taking part in this study other than the risk inherent in performing any physical activity. These risks will be minimised by screening for conditions that could make taking part in exercise a risk to health.

Who will have access to your personal records?

- Only the researcher will have access to your personal data. All of your personal data and information from the study will be stored in locked filing cabinets and not shared with any other parties. If you decide to take part you will be assigned a number to protect your anonymity and prevent the data taken during the study from being associated with yourself. The anonymised data will be shared with the research team after the study and may be published in the future but your identity will never be revealed.

Will you be paid to take part in this study?

- No, you will not be paid to take part in the study.

What if there is a problem?

If you have any complaints or concerns about the research study you may get in touch with the researcher, please see contact details below:

Contact Details

Shady Alshewaier

Mobile number:

Email address:

Postal address:

- ❖ You will receive a copy of this information and the consent form for your own records.

Appendix 13. Participant consent form: clinical trial

Declaration by participant [Translated]

By signing below, I ……..……. agree to take part in a research study entitled "Developing a standardised pre-operative physiotherapy programme for patients undergoing Anterior Cruciate Ligament (ACL) reconstruction in Riyadh, Kingdom of Saudi Arabia (KSA)".

I declare that:

· I have read, or had read to me, this information and consent form and it is written in a language which I am fluent in and comfortable with.

· I have had a chance to ask questions and all my questions have been adequately answered.

· I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

· I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

· I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interest, or if I do not follow the study plan as agreed.

Signature of participant: .....….....……..Date:……...……...

Declaration by researcher

I, Shady Alshewaier, declare that:

• I explained the information in this document to the participant.

• I encouraged him/her to ask questions and took time to answer the questions.

• I am satisfied that he/she adequately understands all aspects of this research as discussed above.

• I did / I did not use a translator (if a translator is used then the translator must sign the declaration below).

Signature of researcher: ..... Date: .....

Appendix 14. Specific approval from Security Forces Hospital

بسم الله الرحمن الرحيم

KINGDOM OF SAUDI ARABIA
MINISTRY OF INTERIOR
General Administration For Medical Services
SECURITY FORCES HOSPITAL PROGRAM

المملكة العربية السعودية
وزارة الداخلية
الإدارة العامة للخدمات الطبية
برنامج مستشفى قوى الأمن

إدارة الشئون الأكاديمية والتوعية الصحية

١/٨/٢٠١٣م

إلى من يهمه الأمر

السلام عليكم ورحمة الله وبركاته ،،،

نفيدكم بأنه تم قبول الطالب (**شادي بن عبد الله الشويعر**) لعمل بحث عن تطوير برنامج تأهيلي موحد قبل العملية للمرضى الخاضعين لعملية الرباط الصليبي بقسم العلاج الطبيعي ببرنامج مستشفى قوى الأمن بالرياض وذلك لمدة أربعة أشهر اعتبارا من تاريخ ١/٦/٢٠١٤م ، بأمل الأطلاع والإحاطة .

وتقبلوا وافر التحية ،،،

مساعد مدير إدارة الشئون الأكاديمية
والتوعية الصحية

د. مساعد بن محمد اليحيي

التعليم / محمد

منسق برامج التدريب ٠١١٨٠٢٤٤٢٤

تلفون ٨٠٢٤٤٢٤ فاكس: ٨٠٢٤٤١٥ ص ب ٣٦٤٣ الرياض ١١٤٨١ تلكس: ٤٠٤٠٤٠ الرياض المملكة العربية السعودية
Tel. : ٨٠٢٤٤٢٤ Fax: ٨٠٢٤٤١٥ P.O. Box ٣٦٤٣ Riyadh ١١٤٨١ Telex ٤٠٤٠٤٠ MSHOSP SJ Riyadh – Saudi Arabia

Appendix 15. KOOS survey questionnaire

KOOS KNEE SURVEY

Today's date: _____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms
These questions should be answered thinking of your knee symptoms during the **last week**.

S1. Do you have swelling in your knee?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your knee catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

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

S6. How severe is your knee joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your knee stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P4. Bending knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P5. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P6. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P7. At night while in bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P8. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P9. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining knee position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

Q1. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your knee?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

Appendix 16. Range of motion score sheet

Range of Motion (ROM)

- **Knee Flexion:**

- **Knee extension:**

Comments:

Appendix 17. Muscle strength score sheet

Muscle Strength

- **Quadriceps Muscles:**

- **Hamstring Muscles:**

Comments:

Appendix 18. Pain assessment score sheet using VAS scale

Pain assessment (VAS)

Visual Analogue Scale

No pain **Pain as bad as could possibly be**

Comments:

Appendix 19. EQ-5D-5L health status questionnaire

EQ-5D-5L

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

Appendix 20. Resource use questionnaire

Resource use questionnaire

1) **Since your ACL injury, have you consulted a doctor or therapist or received any treatment for your knee (*apart from the treatment you received as part of the trial*)?**

   Yes / No

   If 'yes', please specify which treatment by choosing the appropriate answer:

   Ministry of health consultant How many times?
   Private consultant How many times?
   Ministry of health physiotherapy How many times?
   Private physiotherapy How many times?
   Other (please specify) _____

   Did you pay for that? Yes/No
   If 'yes', was payment made by yourself or a private insurance company?

   Self / Insurance company / Government

   How much did it cost?_____

2) **Since your ACL injury, have you had any scans or radiographs because of your knee?**

   Yes / No

   If 'yes', what type of radiograph or scan? (choose more than one answer if needed)
   a) **Normal radiograph**
   b) **MRI scan**
   c) **Ultrasound scan**

   Did you pay for this/these scan(s)?

Yes / No

If 'yes', was payment made by yourself or a private insurance company?

Self / Insurance company / Government

How much did it cost?_____

3) **Since your ACL injury, have you been admitted to hospital because of your knee?**

   Yes / No

   If 'Yes', how many days did you spend in hospital? _____

4) **Has your doctor prescribed any medicines, creams or other treatments (e.g. brace/strapping) for your knee since your ACL injury?**

   Prescribed medicines/creams:

Item description	Name of item (e.g. ibuprofen)	Cost to you (e.g. prescription charge or other cost)
Painkillers		SR
Anti-inflammatories		SR
Creams/gels		SR
Aids/braces/strapping		SR
Injection		SR
Other		SR

5) **Since your ACL injury, have you bought any medicines, creams or other treatment (e.g. brace) for your knee?**

   Medicine/creams bought without prescription:

Item description	Name of item	Cost to you
Painkillers		SR
Anti-inflammatories		SR
Creams/gels		SR
Aids/braces/strapping		SR
Injections		SR
Other		SR

6) **Since your ACL injury, have you had to take any sick leave from work because of your knee?**

   Yes / No / Not applicable

   If 'Yes', how many sick days did you take?_____

7) **Have you been involved in any exercise/sport since your ACL injury?**

   Yes / No

   If 'Yes', which ones? (please choose all appropriate answers)

   a) **Swimming**
   b) **Weight training for the lower limb**
   c) **Aerobics/keep-fit**
   d) **Cycling**
   e) **Jogging/running**
   f) **Team sport (Please specify) :_____**
   g) **Yoga**
   h) **Athletics**
   i) **Walk of 3 km or more**
   j) **Heavy housework**
   k) **Other sports or exercise (please specify):_____**

   Approximately, how many times since your ACL injury have you done any of these activities?

   a) **Less than once a month**
   b) **Once a month**
   c) **Once a fortnight**
   d) **Once a week**
   e) **Twice a week**
   f) **More than twice a week**

Appendix 21. Testing the normality of distribution for the post-operative data using the Shapiro-Wilk test; *p* values lower than 0.05 indicate non-normal distribution

Variable	Group	Shapiro-Wilk test		
		Statistic	*n*	Significance
KOOS Pain	Control	0.911	45	0.002
	Intervention	0.868	39	0
KOOS Symptoms	**Control**	**0.975**	**45**	**0.419**
	Intervention	0.823	39	0
KOOS ADL	Control	0.923	45	0.005
	Intervention	0.891	39	0.001
KOOS Sport and Recreation	Control	0.857	45	0
	Intervention	0.803	39	0
KOOS QoL	Control	0.939	45	0.019
	Intervention	0.856	39	0
Active ROM (Knee flexion)	Control	0.816	45	0
	Intervention	0.935	39	0.027
Passive ROM (Knee flexion)	Control	0.804	45	0
	Intervention	0.93	39	0.018
Active ROM (Knee extension)	Control	0.752	45	0
	Intervention	0.426	39	0
Passive ROM (Knee extension)	Control	0.634	45	0
	Intervention	0.233	39	0
Muscle strength (Quadriceps)	Control	0.9	45	0.001
	Intervention	0.926	39	0.013
Muscle strength (Hamstring)	Control	0.93	45	0.009
	Intervention	0.93	39	0.018
EQ-5D-5L Mobility	Control	0.569	45	0
	Intervention	0.635	39	0
EQ-5D-5L Self-care	Control	0.747	45	0
	Intervention	0.553	39	0
EQ-5D-5L Usual activity	Control	0.75	45	0
	Intervention	0.706	39	0
EQ-5D-5L Pain/Discomfort	Control	0.731	45	0
	Intervention	0.712	39	0
EQ-5D-5L Anxiety/Depression	Control	0.853	45	0
	Intervention	0.665	39	0
EQ-5D-5L QoL	Control	0.941	45	0.023
	Intervention	0.929	39	0.017
EQ-5D-5L QALY	Control	0.926	45	0.007
	Intervention	**0.962**	**39**	**0.202**

Normally distributed data are shown in **bold** font

Appendix 22. Summary of methodological quality assessment of the conducted clinical trial using the Physiotherapy Evidence Database (PEDro) scale

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Total score (/10)
The present study, 2015; KSA	Y	Y	Y	N	N	N	N	Y	N	Y	Y	5/10 Moderate quality

N, no (Score = 0); Y, yes (Score = 1)