THE ROLE OF THE EXTERNAL FACTORS ON ANTERIOR CRUCIATE LIGAMENT REHABILITATION

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ABSTRACT

Rehabilitation programme following anterior cruciate ligament (ACL) reconstruction is multifaceted and may be influenced by a variety of factors. The role of the environment for care and the levels of supervision from physiotherapists on the outcomes of ACL rehabilitation, have not received robust attention in the literature. In this thesis, two trials were carried out to investigate the role of these factors on the outcomes of ACL rehabilitation. In the first trial, a total of 76 patients [hospital-based rehabilitation group, n = 48 (age: mean ± sd: 31.5 ± 12.1 yr, height: 1.74 ± 0.06 m, body mass: 78.2 ± 10.8 kg, waiting time: 37.3 ± 33.7 months) and community-based rehabilitation group, n = 28 (age: mean ± sd: 34.5 ± 9.9 yr, height: 1.71 ± 0.07 m, body mass: 75.2 ± 12.4 kg, waiting time: 31.1 ± 26.7 months)] self-selected themselves into the hospital- and the community-based rehabilitation programmes. The patients in both the hospital- and the community-based rehabilitation programmes were assessed by selected patient-reported outcome measures (PROMs) included IKDC, KOOS, K-SES, VAS and Lysholm at four different occasions (pre-surgery and at the 6th, 12th and 24th weeks post-surgically). Significant differences at early phase of rehabilitation (up to 12th week post-surgery) on PROMs of function, favouring the outcomes of the hospital-based rehabilitation programme compared to the community-based rehabilitation programme, were observed. However, no differences between the outcomes of the latter two programmes were observed across 24 weeks rehabilitation programme following ACL reconstruction. This suggested that community-care had offered a similar environment to the hospital for achieving the outcomes of rehabilitation. In the second trial, the patients in the hospital-based rehabilitation programme (n=48) were
further randomly allocated to the fully-supervised and the minimally-supervised rehabilitation groups [ fully-supervised rehabilitation group, n=24 (age: mean ± sd: 32.2 ± 11.1 yr, height: 1.73 ± 0.07 m, body mass: 75.8 ± 10.7 kg, waiting time: 35.8 ± 29.4 months), minimally-supervised rehabilitation group, n=24 (age: mean ± sd: 31.0 ± 13.2 yr, height: 1.75 ± 0.06 m, body mass: 80.6 ± 10.7 kg, waiting time: 28.8 ± 25.1 months)]. The patients in both the fully-supervised and the minimally-supervised rehabilitation groups were assessed on four different occasions (pre-surgery and at the 6th, 12th and 24th week post-surgery) on estimates of function (single-leg hop), physical performance (peak force, rate of force development, sensorimotor performance and electromechanical delay) and musculoskeletal performance (anterior tibio-femoral displacement) alongside the selected PROMs. Significant differences during the early phase of rehabilitation (up to 12th week post-surgery), favouring outcomes of the fully-supervised rehabilitation programme on some aspects and the outcomes of the minimally-supervised rehabilitation programme on other aspects, were observed. However, similar knee function across 24 weeks rehabilitation was observed on the selected objective measures and PROMs amongst the outcomes of the latter two rehabilitation programmes. This indicated that the outcomes of ACL rehabilitation had not influenced by the levels of supervision from the physiotherapists. In short, the environment and the levels of supervision from rehabilitation team were less likely to influence the final outcomes of ACL rehabilitation.
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ABBREVIATIONS

ACC  Accident Compensatory Corporation
ACL  Anterior Cruciate Ligament
ACLQoL  Anterior Cruciate Ligament Quality Of Life
ADL  Activities of Daily Living
ANCOVA  Analysis of Covariance
ANOVA  Analysis of Variance
AOSSM  American Orthopaedic Society of Sport Medicines
ATFD  Anterior Tibio-Femoral Displacement
BMI  Body Mass Index
BPBT  Bone-Patella Bone-Tendon
CONSORT  Consolidated Standards of Reporting Trials
EMG  Electromyography
HSS  Hospital of Special Surgery
ICC  Intra-class Correlation Coefficient
IKDC  International Knee Documentation Committee
KG  Kilogram
KOOS  Knee injury and Osteoarthritis Outcome Score
K-SES  Knee Self-Efficacy Scale
MCID  Minimally Clinically Important Difference
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>MDC</td>
<td>Minimal Detectable Change</td>
</tr>
<tr>
<td>MHLC</td>
<td>Multidimensional Health Locus of Control</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NNKLR</td>
<td>Norwegian National Knee Ligament Registry</td>
</tr>
<tr>
<td>PCL</td>
<td>Posterior Cruciate Ligament</td>
</tr>
<tr>
<td>PEDro</td>
<td>Physiotherapy Evidence Database rating scale</td>
</tr>
<tr>
<td>PROMs</td>
<td>Patient-reported Outcome Measures</td>
</tr>
<tr>
<td>SEM</td>
<td>Standard Error of Measurement</td>
</tr>
<tr>
<td>SHA</td>
<td>Strategic Health Authorities</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
</tr>
<tr>
<td>WOMAC</td>
<td>Western Ontario and MacMaster Universities Osteoarthritis Index</td>
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<tr>
<td>yr</td>
<td>Years</td>
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</table>
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DEDICATION

I dedicate this work to my beloved parents [Ammi (my mother) and Dagi (my father)]. Dagi had below knee amputation in March 2014, during the last year of my PhD. Dagi, I really do feel the pain of your amputated leg and while writing these sentences I cannot stop tears falling down from my eyes. I feel sorry for myself for not being with you on this occasion. However, I know you have been a self-reliant person throughout your life and my absence would have not affected your courage. Ammi, I know you desperately missed me during these four years. I am sure; you both would feel proud of your son, after completing this research programme.
SUMMARY OF THIS THESIS

Anterior cruciate ligament (ACL) rupture is one of the commonest musculoskeletal injuries affecting a large proportion of population every year. The prevalence of ACL injuries has been reported 35-37 per 100,000 inhabitants in large-scale epidemiological surveys of general population carried out in different countries. Despite the fact that young age, female gender and exposure to high demanding activities are some of the major contributing factors to the ACL injuries, nevertheless, a large number of adult males with non-athletic background have been reported to sustain ACL injuries. It is widely accepted that surgical reconstruction followed by an extensive rehabilitation is the only choice for the patients to achieve optimal levels of functional capabilities in the knee joint following rupture to ACL. Over the last two decades, rehabilitation programme following ACL reconstruction has seen drastic changes. However, the role of some the factors [i.e. environment (hospital and community), levels of supervision (full and minimal) from physiotherapists during rehabilitation sessions in the hospital] are still in infancy and warrant further research. Therefore, the aim of this thesis was to investigate the effects of the latter two factors on the final outcomes of rehabilitation following ACL reconstruction.

The first chapter of this thesis (Introduction and Literature Review), set out to highlight background of this research by introducing the ‘problem’ and providing information about its potential consequences on the individual’s life. A literature review containing information about the incidence, surgical management and consequences caused by the ACL injury has been discussed in the latter chapter. General aims and hypotheses of this thesis are given at the end of the first chapter.
The second chapter of this thesis (Systematic Review of the Community-based Rehabilitation Programmes), reported a systematic review of the literature on the effects of the community-based rehabilitation programmes following ACL reconstruction. The purpose of the latter was to identify gaps in the literature and design clinical trials for addressing the gaps identified (chapter 5, 6 and 7).

The third chapter of this thesis (Clinimetrics of the Selected Outcome Measures), reported a review of the literature on patient-reported outcome, functional, physical performance and musculoskeletal performance measures. In this chapter, clinimetric characteristics (minimal detectable change, minimally clinically important differences) associated with the latter measures have been summarised.

The fourth chapter of this thesis (Methods), reported the generic methodology adopted during this research. Ethical approvals, inclusion criteria, exclusion criteria, recruitment of the participants for this research, general overview about the number of the participants and information about the data protection have been discussed in the latter chapter.

The fifth chapter of this thesis (Trial I), examined the effects of the environment on patient-reported outcome measures (PROMs) across 24 weeks rehabilitation programme following ACL reconstruction. For the latter purpose, a total of 76 patients who were willing to participate in this research, self-allocated themselves to the hospital- and the community-based rehabilitation programmes (n= 48 and 28, respectively). The patients in the hospital-based rehabilitation programme followed contemporary rehabilitation in the hospital where they attended an average of 14 supervised physiotherapy sessions in the hospital. In contrast, the patients in the community-based rehabilitation programme attended an average of 4 supervised
physiotherapy sessions in the hospital and self-managed the rest of their rehabilitation programme in the community. The patients in both the hospital- and the community-based rehabilitation programmes were tested at four different occasions (pre-surgery and at the 6th, 12th and 24th weeks post-surgery) for knee function on PROMs [International Knee Documentation Committee (IKDC), Knee injury and Osteoarthritis Outcome Score (KOOS), Knee Self-efficacy Scale (K-SES), Visual Analogue Scale (VAS) and Lysholm]. The patients in the hospital-based rehabilitation programme showed statistically superior outcomes compared to the patients in the community-based rehabilitation programme on some aspects of PROMs (K-SES, KOOS), suggesting the significant role of the environment on the final outcomes of rehabilitation following ACL reconstruction. In contrast, the patients in the community-based rehabilitation achieved same levels of function on other aspects of PROMs (IKDC, VAS and Lysholm), suggesting that the patients with self-managing rehabilitation in the community can achieve similar outcomes of rehabilitation to the patients in the hospital-based rehabilitation programme. Despite some differences observed amongst the group mean responses for the patients in the latter two rehabilitation programmes on some aspects of rehabilitation, on balance, it can be concluded that similar outcomes of function and pain on PROMs can be achieved in both hospital- and community-based environments following ACL reconstruction.

The sixth chapter of this thesis (Trial II, Part A), evaluated the effects of the levels of supervision on knee function and pain (PROMs) amongst the patients receiving rehabilitation programme in the same environment (hospital) but with different levels of supervision (fully-supervised and minimally-supervised) from rehabilitation team
following ACL reconstruction. For this purpose, the patients in the hospital based rehabilitation programme (n= 48), were randomly allocated to the fully-supervised and the minimally-supervised rehabilitation groups (24 patients in each group) [please see figure 1 for allocation of the patients]. The patients in the fully-supervised rehabilitation group received full supervision (associated with contemporary clinical practice in a ‘long-standing’ and regularly audited rehabilitation programme and pathway of care), while the patients in the minimally-supervised rehabilitation group were guided to the same exercises prescribed to the patients in the fully-supervised rehabilitation group in the beginning of each physiotherapy session and were advised to continue these exercises in the hospital gymnasium without further supervision (i.e. no feedback or alteration of exercise dosage) from the rehabilitation team. All the patients in both the fully-supervised and the minimally-supervised rehabilitation groups were assessed on knee function of PROMs (IKDC, KOOS, K-SES, VAS and Lysholm) at four different occasions (pre-surgery and at the 6th, 12th and 24th weeks post-surgery). A statistical significant group × time interaction for subsections ‘physical activities’ (F (3,0,114) =2.6, p=0.02) of the K-SES in the latter clinical trial suggested achievement of superior functional levels on PROMs by the patients in the fully-supervised rehabilitation group compared to the patients in the minimally-supervised rehabilitation group. Apart from this subsection of the K-SES, no differences were observed for the remaining subsections of the K-SES, all five subsections of the KOOS, IKDC, VAS and Lysholm. This suggested that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups had achieved similar levels of function on PROMs at the end of rehabilitation programme following ACL reconstruction.
Based on the findings of this clinical trial, it can be concluded that the patients receiving fully-supervised and minimally-supervised rehabilitation programmes in the hospital can achieve similar levels of function on PROMs.

The seventh chapter of this thesis (Trial II, Part B), evaluated the effects of the levels of supervision on knee function (single-leg hop), physical performances (peak force, rate of force development, sensorimotor performances, electromechanical delay) and musculoskeletal [anterior tibio-fibular displacement (ATFD)] performance estimates in the same group of the patients reported in chapter 6 of this thesis. Findings of this clinical trial suggested no differences amongst the group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups on single-leg hop ($F_{(2.0,76.0)} = 1.8, p=0.18$), all selected physical performances [knee flexors and extensors musculatures; peak force; ($F_{(2.0,76.0)} = 1.4, p=0.32$) and ($F_{(2.0,76.0)} = 2.1, p=0.34$), rate of force development; ($F_{(3.0,114.0)} = 1.1, p=0.41$) and ($F_{(3.0,114.0)} = 1.4, p=0.29$), sensorimotor performances; ($F_{(3.0,114.0)} = 0.5, p=0.41$) and ($F_{(3.0,111.0)} = 1.9, p=0.30$), respectively] and musculoskeletal performance [ATFD ($F_{(3.0,114.0)} = 0.5, p=0.32$)] estimates. Based on the findings of this chapter, it can be concluded that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups can achieve the same levels of functional capabilities and secondary physical performance estimates at the end of rehabilitation.

In summary, it can be concluded that the patients managing rehabilitation in the community can achieve similar levels of knee function on PROMs to the patients receiving rehabilitation in the hospital. Similarly, the patients with minimal-supervision from rehabilitation team in the hospital can achieve the same levels of
function on patient-reported and objectively measured outcomes compared to the patients who are fully-supervised during rehabilitation in the hospital.

Figure 1: Figure showing allocation of the patients into the two trials carried out during this PhD research programme.
1 CHAPTER: INTRODUCTION AND LITERATURE REVIEW
OUTLINES OF THIS CHAPTER

This chapter set out to highlight background of this research by introducing the ‘problem’ and providing information about its potential consequences on the individuals’ life. Literature review containing information about ACL and its injury were included in this chapter. Finally, general aims and hypotheses of this thesis were discussed.

Section 1.1 Introductions
Section 1.2 Anterior Cruciate Ligament
Section 1.3 Incidence of ACL injuries
Section 1.4 Gender and age-specific incidence of ACL injuries
Section 1.5 Mechanism of ACL injuries
Section 1.6 Classifications of ACL Injuries by Mechanism
Section 1.7 Role of the flexor and the extensor musculatures of knee joint
Section 1.8 Consequences of ACL injuries
Section 1.9 Management ACL injuries
Section 1.10 Rehabilitation following ACL reconstruction
Section 1.11 Factors influencing outcomes of ACL rehabilitation programme
Section 1.12 Aims of this thesis
Section 1.13 Research hypotheses
1.1 INTRODUCTION

The conceptual model of the human musculoskeletal system depicts an interactive action of the bones, muscles, ligaments, tendons and joints (Qin et al. 2005). The muscular part of this system is associated with producing purposeful movements following directives from the higher centres (the brain), while the osseous part is regarded to protect the internal structures of the human body alongside providing a stable framework for the movements (Farley et al. 2012). Due to the essential role of musculoskeletal system in the locomotion of an individual, it is more prone to injuries and a large proportion of population has been reported to suffer from these injuries every year (Segui-Gomez and MacKenzie 2003). The acute response of these injuries leaves an individual to experience a high-risk of loss of function in the areas affected (Stucki et al. 2005), while the long-term consequences of these injuries are apparently associated with impairments or even disabilities to the individuals (Mock and Cherian 2008). Rupture to anterior cruciate ligament (ACL) is one of the commonest musculoskeletal injuries that has been reported to affect a large number of athletic and non-athletic population every year (Granat et al. 2008, Gianotti et al. 2009). Despite some controversies related to the long-term adverse effects of reconstructive surgery following ACL rupture (Oiestad et al. 2010, Oiestad et al. 2013, Spindler et al. 2011), it is widely accepted that surgical reconstruction followed by an extensive rehabilitation is the only choice for the patients to achieve optimal levels of functional capabilities in knee joint following rupture to ACL (Wilk et al. 2012). Rehabilitation programme following ACL reconstruction has seen drastic changes over the last two decades (Biggs et al. 2009). However, the role of some the factors [i.e. environment (hospital and community), levels of supervision
from physiotherapists during rehabilitation sessions (full-supervision and minimal-supervision)] is still in infancy and warrants further research.

1.2 ANTERIOR CRUCIATE LIGAMENT

The ACL is an intra-articular ligament in knee joint that connects the femur to the tibia (Zantop et al. 2005). The generic function of the ACL along with its counterpart posterior cruciate ligament (PCL), with two collateral ligaments (the lateral and the medial collateral ligaments) allows knee joint to move and produce smooth movements through its normal range of motion when a tensile load is applied (Frank 2004). The specific function of the ACL is to resist the anterior tibial translation and the medial rotation of the tibia in relation to the femur during the movement of knee joint (Tashman and Araki 2013, Gleeson et al. 2003, Matsumoto et al. 2001). The presence of multiple microstructures in collagen bundles provides sufficient strength to ACL to effectively perform the latter function (Mall et al. 2013).

Anatomically, the ACL consists of dense connective tissues surrounded by the synovial membrane. Proximally it is attached to the lateral femoral condyle while distally it is attached between the medial and the lateral tibial spines (Shen et al. 2007). Morphologically, ACL can be differentiated into two distinct bundles; the posteriolateral and the anteriomedial bundles (Chabra et al. 2006). The posteriolateral bundle has been reported to be relatively smaller, having an average length of 22.50 mm in comparison to the length of the anteriomedial bundle [average length of 34.00 mm] (Harner et al. 2001). Both of these two distinct bundles of ACL work synergistically with each other to provide an enhanced restraining function
during the knee joint movements. These bundles experience different patterns of strain during the passive knee flexion; the anteriomedial bundle lengthens and tightens during flexion while the posteriolateral bundle responds in the opposite manner to the same movement by becoming shorter and relaxed (Hollis et al. 1991). The length and width of ACL have been reported between 22 to 41 mm (mean, 32 mm) and 7 to 12 mm (mean, 10 mm), respectively (Duthon et al. 2006). The anatomy of ACL, PCL and two collateral ligaments (medial and lateral) is shown in Figure 1.1.

![Figure 1.1: Figure showing anatomy of the two cruciate ligaments (ACL and PCL), two collateral ligaments (later and medial) and two menisci (lateral and medial). (adapted from Culmbach and Hutchens 2003)]
1.3 INCIDENCE OF ACL INJURIES

It has been reported that a large proportion of the population whether involved or not involved in sporting activities, sustain ACL injuries every year (Renstrom et al. 2008). However, the exact number of these injuries in the latter two populations had always remained a matter of debate (Ireland 1999) and different incidence rates of these injuries have been reported in the available literature (Gianotti et al. 2009, Granan et al. 2008, Clayton and Court-Brown 2008). The reason for the latter variation in the incidence of the ACL injuries might be explained by the fact that not in every country a comprehensive health system exits in which each individual injury is documented. The true incidence rate of this injury might only be obtained from such countries where a comprehensive mechanism for registering these injuries exists. For the latter purpose, data regarding the incidence of the ACL injuries have been relied on from two countries; New Zealand and Norway, where a comprehensive registry system for reporting these injuries exits. The New Zealand Accident Compensatory Corporation (ACC) provides a detailed national descriptive epidemiology and associated cost caused by musculoskeletal injuries in the country (Gianotti et al. 2009). A 5-year report between 2000 and 2005 has suggested an incidence rate of 37 persons per 100,000 per year of ACL injuries in the country. Similar results have been reported in the other country (Norway) from a data base on large scale of population in the country (Granan et al. 2008). According to the latter trial, the Norwegian National Knee Ligament Registry (NNKLR) was specifically established to collect information on ACL injuries prospectively in Norway. For the latter purpose, data from all over the country regarding ACL injuries was retrieved from 57 hospitals where a large number of ACL reconstructive surgeries had been
performed. A total of 2793 ACL ruptures were reported in the latter trial, which represents an annual population incidence of 34 persons per 100,000 of ACL rupture in the country. These figures (34 per 100,000 population) are quite similar to the figures reported by Gianotti et al. (2009) (37 per 100,000). Apart from the two countries mentioned above, in some countries a lower rate of the ACL injuries has been reported. The incidence of ACL injuries in Scottish population is an example of the trials where a low rate of ACL injuries (14.7 per 100,000) has been reported in the country (Clayton and Court-Brown 2008). In the latter trial, a range of musculoskeletal injuries was reported from a trauma centre with a well-defined catchment population of 535,000. According to this 5-year trial, the average number of ACL injuries remained at 14.7 per 100,000 population per year in Scotland. This Figure (14.7) is less than the half of that reported by Gianotti et al. (2009) [37 per 100,000] and Granan et al. (2008) [34 per 100,000]. In the clinical trial reported by Clayton and Court-Brown 2008, ACL injury with injury to other soft tissue had not been included. This might be one of the reasons for reporting lower incidence of ACL injuries in Scottish population. The number of ACL injuries reported in Scandinavian countries (Denmark, Norway and Sweden), ratio of male and female population sustaining these injuries and the graft-type used for ACL reconstruction are shown in Table 1.1.
Table 1.1: Table showing incidence of ACL injuries in Scandinavian countries

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Denmark</th>
<th>Norway</th>
<th>Sweden</th>
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<tr>
<td>total number</td>
<td>4972</td>
<td>5329</td>
<td>7331</td>
</tr>
<tr>
<td>annual average</td>
<td>1886</td>
<td>1520</td>
<td>2444</td>
</tr>
<tr>
<td>hospital</td>
<td>37</td>
<td>60</td>
<td>52</td>
</tr>
<tr>
<td>age at surgery</td>
<td>30(10-71)</td>
<td>27(12-67)</td>
<td>25(8-67)</td>
</tr>
<tr>
<td>age at injury</td>
<td>27(7-70)</td>
<td>25(6-65)</td>
<td>23(5-66)</td>
</tr>
<tr>
<td>males</td>
<td>60%</td>
<td>57%</td>
<td>58%</td>
</tr>
<tr>
<td>hamstrings graft</td>
<td>71%</td>
<td>61%</td>
<td>86%</td>
</tr>
<tr>
<td>BPTB graft</td>
<td>22%</td>
<td>38%</td>
<td>14%</td>
</tr>
<tr>
<td>other graft</td>
<td>7%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

(adapted from Granan et al. 2008)

1.4 GENDER AND AGE-SPECIFIC INCIDENCE OF ACL INJURIES

Despite the recent extensive research on ACL injuries, the relative proportion of injuries affecting males and females is still not clear. In addition, specific age associated with increased risk of injury could not be identified from the available literature. In this part of the thesis, consideration has been given to those information where a huge number of these injuries has been reported. For this reason, findings of a 2-year survey (2004-2006) based on the NNKLR has been discussed in this part of the thesis involving a total of 2793 ACL injuries (Granan et al. 2008). This research had documented ACL injuries in the general population including both genders and individuals of all ages. The annual incidence of ACL injuries in the latter population (Norway) was reported 1396. A high incidence of these injuries, 79%, was reported for individuals aged between 16-39 years. This indicated that 85 persons per 100,000 of the population in this age group had sustained ACL injuries, while the
overall incidence of this injury in the population mentioned was reported as 34 persons per 100,000. Similar findings of increased risk of ACL-injury in 20-39 year-olds has been reported in Sweden in a large-scale epidemiological survey (Gianotti et al. 2009). It has been speculated that greater levels of active involvement in athletic pursuits for this age-group might contribute to an increased risk of injury (Brooks et al. 2005). Moreover, a high number of males (57%) compared to females counterparts has been reported in the latter trial. Similar findings of high proportions of males sustaining ACL injuries 57% (Spindler et al. 2011) and 52% (Gianotti et al. 2009) have been reported. Despite the general consensus that females are at a higher-risk of ACL injury compared to their counterpart males, the reported number of the males in the above mentioned trials having ACL injuries was higher than females. The reason for the latter might be higher frequency and greater exposure of males to the high-risk activities compared to their counterpart females. If the same number of males and females is exposed to the same high-risk athletic activities, then the number of females affected by ACL injuries might be higher than their counterpart males. This assumption could be justified from the literature where equal number of both the males and the females was exposed to the same athletic activities (De Loes et al. 2000). The latter assumption of females being vulnerable to the ACL injuries, has been endorsed in a systematic review carried out on RCTs with a total sample size 46472 athletes (Parkkari et al. 2001). It was reported in the latter trial, that females were at a 4-7 folds at a higher-risk of sustaining ACL injury compared to their counterpart males. Evidence from other studies that females are at a higher-risk to ACL injuries compared to their counterpart males is shown in Figure 1.2.
Chapter 1

Figure 1.2: Figure showing incidence of ACL injuries in males and females in different sporting activities. The percentage of females who sustained ACL injuries in different athletic events is higher than their counterpart males. (adapted from Renstrom et al. 2008)

1.5 MECHANISM OF ACL INJURIES

The ACL is regarded as being vulnerable if knee joint is in a slightly flexed position (knee joint flexion <30°), valgus strain is applied to knee joint (knee joint is pivoted), direction is changed during the lower limb movements (cutting manoeuvres are combined with deceleration), landing is done after jumping (foot plantation), or simply when valgus and axial rotational movements are performed near knee joint extension (Feagin and Lambert 1985, Fauno and Jakobsen 2006, Minshull et al. 2012). To explain the exact mechanism of ACL injuries, findings of the systematic review by Ireland (1999) has been discussed in the next section. The latter review has been carried out on epidemiological studies that had been reported to have a vast scope in findings ‘causes and effects’ of specific problem in a large scale population (De Haven and Lintner 1986, Gwinn et al. 2000). In the review carried out by Ireland (1999), a position termed as ‘position of no return’ had been reported as the
most challenging position of vulnerability to the ACL. In this specific position, hip abductors and extensors lose counterbalancing the latter joint in response to the movements preformed in the knee joint. The ultimate result of this phenomenon results in adduction and internal rotation in the hip joint, which would otherwise be maintained in an upright neutral position by the combined action of these muscles groups. The ACL is regarded vulnerable in the latter position. Apart from this mechanism, ACL-injury mechanism may vary according to the demand of athletic events. i.e. axial compression might cause the ACL injury in wakeboard athletes (Starr and Sanders 2012).
1.6 CLASSIFICATION OF ACL INJURIES BY MECHANISM

A variety of factors associated with ACL injuries have been reported in the literature. A generic classification of these factors has focused on intrinsic and extrinsic categories (Hewett et al. 2006, Smith et al. 2012b). Intrinsic factors are factors that are within the body of an individual while extrinsic factors are related to the external environment influencing an individual (Smith et al. 2012a). Due to the specific characteristics of these factors, some authors have classified them into controllable and non-controllable factors (Ireland 1999). The role of the intrinsic factors in the ACL injuries is to predispose an individual to a high-risk anatomical position that make ACL vulnerable to the external forces. Once the individual is predisposed, the
external factors overcome ‘the individual’s capacity to resist the threat of ACL-injury, which in turn makes him/her vulnerable to the injury. Then a stimulus in the form of knee joint movement is required to cause the ACL injuries. A generic model explaining how the intrinsic and the extrinsic factors predispose ACL to injuries is shown in Figure 1.4. The obvious reasons for sustaining ACL injury seems extrinsic shearing forces (Kramer 2010). However, intrinsic forces play a critical role in the causation of injuries to the latter ligament (Fauno and Jakobsen 2006, Griffin et al. 2000). The latter occurs as a result of the one’s own movement rather than caused by an external contact to the environment (Yu and Garrett 2007). A large proportion of the ACL injury has been reported in non-contact sports (Renstrom et al. 2008), suggesting that the intrinsic factors may have a greater contributing role in causing the injury to the ACL.

The classification of the ACL injury by external forces had remained a matter of debate amongst the researchers. In this part of the thesis, outcomes of the American Orthopaedic Society of Sports Medicines (AOSSM) conference has been relied on for differentiating types of the ACL injury caused by extrinsic factors (reported by Kramer 2010). The external forces that causes injury to the ACL, have been classified into direct and indirect types in the latter trial. A direct type of ACL injury has been defined as injury to the ACL caused by the shearing force applied to knee joint directly. By contrast, in the indirect type of ACL injury the shearing force is applied to other parts of the body that are then transferred to knee joint. Apart from the non-contact mechanism which makes the ACL more vulnerable to injuries, a variety of other factors, which may or may not be controlled by the individual, have
been reported in the literature (Smith et al. 2012a) [please see Table 1.2 for the details of the latter factors].

Figure 1.4: Figure showing factors that make ACL prone to injuries. In this model, both the intrinsic and extrinsic factors predispose an individual to a high-risk for ACL injuries. (adapted from Bahr and Krosshaug 2005)
Table 1.2: Table showing factors for ACL injuries

<table>
<thead>
<tr>
<th>Factors</th>
<th>uncontrollable</th>
<th>controllable</th>
<th>partially controllable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of Q Angle</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACL size</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint Laxity</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle Flexibility</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATFD</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot Pronation</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navicular Drop</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puberty</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormonal</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weather</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Playing surface</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of footwear</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protective bracing</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuromuscular</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Proprioception</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Biomechanical</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

1.7 THE ROLE OF THE FLEXOR AND THE EXTENSOR MUSCULATURES OF KNEE JOINT IN ACL INJURY

It is evident from the literature that both the flexor and extensor musculatures around knee joint have a direct impact on the structures inside the joint (Fleming et al. 2001). The ACL is one of the structures that has been reported to be significantly influenced by the contraction of both these musculatures (Markolf et al. 1990). The contraction of the extensor musculature of knee joint produces anterior shear forces on the tibia at small knee flexion angles (Durselen et al. 1995, Beynnon et al. 1995, Fleming et al. 2001). In response, the ACL works as an antagonist to counter the
shearing forces produced by the extensor musculature of the knee joint. This role of 
ACL is supported by the flexor musculature of the knee joint in the form of 
producing posterior shear forces on the tibia (Yasuda and Sasaki 1987, Beynnon et 
al. 1995, Fleming et al. 2001). Co-contraction of both the flexor and the extensor 
musculatures of knee joint have been reported to facilitate a reduction on the strained 
ACL that is believed to be caused by the extensor musculature of knee joint alone 
(Beynnon et al. 1995, Renstrom et al. 1986). In addition, the flexor and extensor 
musculatures of knee joint work together to provide a constant smooth environment 
for the movements produced in the joint in frontal plane (Lloyd and Buchanan 1996, 
Lloyd and Buchanan 2001). Based on the function of the flexor and extensor 
musculatures of knee joint, it seems plausible that the extensor musculature of knee 
has a preferential role over the flexor musculature of the joint by putting an 
individual to a high-risk of ACL injury. However, both of these muscle groups need 
to be strong enough to oppose the external stimuli in order to protect the structures 
inside the joint. Moreover, a balance between the two muscles groups is needed for 
providing stability in knee joint that would ultimately decrease the occurrence of 
ACL injuries. To justify these two assumptions, a critical review associated with the 
strength and balance of strength between the flexor and the extensor musculatures of 
knee joint is given in the coming paragraphs.

A consensus that female gender is one the factors that make an individual prone to 
ACL injury, may be found in the literature. Apart from several others factors that 
make female gender prone to ACL injuries, limited capability of female to produce 
high intensity forces in in the flexor and the extensor musculatures of knee joint have 
been associated with ACL injury (Huston and Wojtys 1996, Barber-Westin et al.
2006, Hewett et al. 1996, Uhorchak et al. 2003, Lephart et al. 2002). In a cross sectional trial carried out on 1140 athletes, comparing strength of the flexor and the extensor musculatures between males and females population, females were found to have significantly weaker flexor and extensor musculatures of knee compared to age-matched males. These results are similar to the findings reported by Uhorchak et al. (2003), where a comparison of 859 (males and females) athletes showed that females were having significant lower strength in the flexor and the extensor musculatures of knee joint when compared to their counterpart males. Both the latter mentioned studies have suggested that in comparison to males, females are at a high-risk of ACL injury due to the fact that the flexor and the extensor musculatures of females were found weaker compared to their counterpart males.

Another important factor that makes ACL prone to injuries has been reported is an imbalance between the hamstrings strength and the quadriceps strength. Previous studies have shown that a smaller H/Q strength ratio, which represent quadriceps-dominant pattern, was significantly associated with injuries to ACL (Hewett 2000). Athletes with smaller H/Q strength ratios were thought to preferentially use their quadriceps muscles to stabilize the knee during dynamic activities that are believed to expose ACL to injuries. Females athlete have been reported to have decreased H/Q ratio, which make their ACL vulnerable to injuries compared to their counterpart males (Hewett et al. 1996). However, contradicting data regarding the H/Q ratio may be find in the literature which suggest further investigation in this area.

The role of strength of extensor musculature of knee joint has been associated with functional activities including single-leg hop (Reid et al. 2007). Single-leg hop is
one of the commonest objectively test used in clinical setups to judge readiness of an athlete to sporting activities. When compared to males, female athletes who demonstrated decreased quadriceps strength performed single-leg landing and forward hop tasks with less knee flexion and greater hip internal rotation. The combination of these factors suggested that the females had compensated for decreased quadriceps strength by stiffening the knee and using hip internal rotation range of motion to lower the center of mass (Lephart et al. 2002). Additionally, Claiborne and colleagues (2006) found a correlation between isokinetic knee flexor and extensor strength and knee valgus motion during a single-leg squat. Individuals with less strength demonstrated greater knee valgus at the initiation of the task. This may be justified by that both the quadriceps and the hamstrings are regarded main contributors to movements in frontal-plane control of the knee joint (Lloyd and Buchanan 1996, Lloyd and Buchanan 2001). Together, these studies suggested that inadequate quadriceps or hamstring strength might result in compensatory mechanisms, placing an individual at a high-risk for ACL injury.

1.8 CONSEQUENCES OF ACL INJURIES

As mentioned in the introduction of this chapter, ACL injuries affects a large proportion of population every year, especially those, who are exposed to high demanding physical activities (Gianotti et al. 2009, Granan et al. 2008, Clayton and Court-Brown 2008, Brooks et al. 2005). The immediate responses of the ACL injury are associated with severe pain and limited function in knee joint of the individuals who have sustained this injury while the long-term consequences of this injury may be seen in the form of an increased risk of early onset of post-traumatic osteoarthritis.
in the knee joint (Lohmander et al. 2007, Smith et al. 2012a). Apart from the degenerative changes in knee joint, patients who have sustained ACL injuries, are considered more vulnerable to another ACL injury. In a fifteen years follow-up clinical trial, it has been reported that 30% of the population who sustained ACL injuries had another onset of the same injury (Hui et al. 2011). It is well established fact that the expected outcomes following the second reconstructive surgery, are less favourable for the person to return to his previous status of knee condition (Hewett et al. 2013). In order to highlight the extent of short-term consequences caused by the ACL injuries in athletic population, a research trial carried out by Dallalana et al. (2007) has been appraised in this section. In the latter trial, short-term impact of musculoskeletal injuries has been reported in 546 rugby players who sustained a total of 211 injuries (178 during competition and 33 during training) in knee joint. The impact of these injuries was reported in the form of absence of athletes from training and competition. An absence of 7776 days (6214 days during competition and 1562 days during training) of rugby players from their sporting activities was reported in the latter trial. On average, athletes who sustained ACL injuries were reported worse than the other athletes who sustained injuries to other parts in the knee joint. The average number of 255 days taken off by the athletes from the competition or from the training sessions was reported by the athletes who had sustained injury to ACL. Apart from the days taken off from the athletic events or from the training programmes, changing of sporting activities by the athletes following the ACL injuries have been reported in the literature. One of such trials, which was carried out in a cohort of 30 patients, has reported that alongside the early degenerative changes in half of the population, 40% (12) of the patients had changed their first
choice sports following the ACL reconstruction (Ruiz et al. 2002). However, the study was limited in following-up the recruited patients in as only 20 patients were assessed at mean follow up time of 7 years and most likely making it underpowered.

1.9 MANAGEMENT OF ACL INJURIES

Unlike other soft tissues of the human body, the ACL does not heal and the need for surgical management due to its rupture is described in the literature, especially for the individuals who want to pursue their sporting career (Duthon et al. 2006). The history of the surgical management of the ruptured ACL is more than hundred years old when in 1903, F. Lange suggested a complete replacement of the injured ACL. Later on in 1914, Grekow recommended autogenous transplant by using the fascia lata strip. However, it was in 1917 where for the first time, Hey-Groves presented his surgical techniques for the reconstruction of the ACL (cited in Eberhardt et al. 2002). The recent advancement in managing ACL rupture with less-invasive procedures and advances in the fixation techniques of the graft has enabled the young professional athletes to return to their previous competitive levels safely.

1.9.1 SURGICAL MANAGEMENT (SURGEONS’ CHOICE OF THE GRAFT)

Despite the fact that bone-patellar-tendon-bone (BPTB) has been considered as gold standard for the ACL reconstruction (Baer and Harner 2007, Reinhardt et al. 2010, Romanini et al. 2010), conflicting data have been reported in the literature on the effectiveness of the latter technique for surgical reconstruction of ACL. Recent development had indicated a change in the trend of the ACL graft choice. To report
the latter change in the trend, a clinical trial by Chechik et al. 2013 on the choices of 261 surgeons including senior surgeons (64 %), resident (22 %) and fellows (14 %) audited at two major international conferences of American Academy of Orthopaedic Surgeons at USA (February 2011) and Europe (June 2011), is appraised in this section of the thesis. A questionnaire addressing preferred choice of surgeons on the grafts (whether to use BPTB or hamstrings or allograft), surgical approaches for drilling the femoral tunnel (whether to approach anteromedial arthroscopic portal, arthroscopic trans-tibial or open), techniques (whether to use single- or double-bundle) and instruments to use for the fixation of the graft (metallic interference screw, bio-absorbable interference screw, Endo-button, rigid-fix) was distributed among all the participants. More than half (53 %) of the surgeons were from Europe, 23 % surgeons were from the North America, 7% were from Asia, 7% were from South America, 7% were from Middle East and 2 % were from Africa. The latter suggested that the survey was representative as it included opinions of surgeons from geographically disparate parts of the world. The majority (63 %) of the surgeons had favoured the hamstrings graft over the BPTB graft for the reconstruction. However, the reason for their preference of the hamstrings over the BPTB graft was not reported. In response to the remaining questions of the survey, anteriomedial arthroscopic portal (68 %) for choice for the drilling site, single-bundle graft (67%) for the choice of techniques and the endo-button fixation (40%) for the method of fixation had been reported in the trial. Despite the above information provided about the choice for surgeons for ACL reconstruction, the results of the use of BPTB graft are still priorities in some conditions (Biau et al. 2009). i.e. BPTB graft has been reported stronger compared to the hamstrings graft and the predictable success rate
of the latter technique had been favoured over the hamstrings graft (Aune et al. 2001). In contrast, the hamstrings graft is favoured by many surgeons due to its less iatrogenic characteristic in injuring the extensor mechanism and causing less complication to the donor sites (Corry et al. 1999).

1.9.2 NON-SURGICAL MANAGEMENT OF ACL INJURIES

The surgical reconstruction of the ACL is widely advocated for the athletic population. However, an agreement in the literature might be seen on the conservative management of ACL ruptures for the patients who are low-demand recreational athletes and had sustained either partial or isolated ACL rupture (Williams and Bach 1996). Traditionally, the non-surgical management of the ACL rupture is managed by suggesting patients, to carry out rehabilitation programmes that focus on the strength and endurance alongside the early joint mobility and agility training (Zatterstrom et al. 1992, Friden et al. 1991). However, the cost of the non-surgically managed ACL rupture had been reported in the form of compromising movement in knee joint that would ultimately modify the life style of an individual (Irrgang 1993). In this section of thesis, findings of the trial carried out by Casteleyn and Handelberg (1996) will be critically appraised in order to report the outcomes of non-surgical management of ACL in low-demanding athletes. One of the reasons for selecting this specific trial for appraisal, was its long-term follow-up for the participants who chose to manage their ruptured ACL without going for a reconstructive surgery. Participants in this trial were followed between 2-12 years for the outcomes of non-surgical management of ACL. A subgroup of 109 patients was evaluated for at least 5 years (mean 8.5 years) on a PROM [i.e. International
Knee Documentation Committee (IKDC). In addition, all participants were evaluated on their levels of activities that were pre-defined by the authors as strenuous, moderate, light and sedentary activities. Findings to this trial had suggested an inverse relation between the occurrence time of ACL injury and its impact on the individual who had sustained it. i.e. a total of 78% of the individuals included had reported a decrease in their levels of activities at the time of injury, 57% participants after less than 5-year and only 17% between 5-8 year. Moreover, when participants of this trial were assessed by IKDC, 82.4% of them had been reported to achieve normal or near to normal category. In addition to the PROMs all participants in the latter trial were compared on the objective measures including range of motion and knee laxity with a prospective matched group who had undergone ACL reconstruction. It was reported in this trial that 19% of the participants had a limited range of motion in knee joint and 32% of all participants had near to normal laxity in the knee joint. In short, authors in the latter trial have endorsed the effectiveness of conservative management of ACL within a group of participants who were classified as low-demand athletes. However, the participants who managed ACL rupture conservatively did not achieve some aspects of ACL reconstruction (decreased laxity in knee joint).

1.10 REHABILITATION PROGRAMME FOLLOWING ACL RECONSTRUCTION

A general agreement to follow an extensive rehabilitation programme following ACL reconstruction might be seen in the literature (Kruse et al. 2012, Risberg et al. 2004). However, controversies still exist in the duration of rehabilitation programme in general and the way of implementing it in particular (Hohmann et al. 2011, Feller
et al. 2004, Beard and Dodd 1998). Therefore, various programmes of either having shorter durations in the form of accelerated rehabilitation programmes (Shelbourne and Nitz 1990, Shelbourne et al. 1992) or having various implementation modes such as the delivery of rehabilitation programme in the hospital or in the community settings might be seen in the literature (Hohmann et al. 2011, Grant and Mohtadi 2010, Ugutmen et al. 2008, Grant et al. 2005, Feller et al. 2004). The first part of controversies in the rehabilitation programme (accelerated rehabilitation) following reconstruction of ACL is beyond the scope of this research and only a detailed critical overview of the available literature on the implementation modes of the rehabilitation programme following ACL reconstruction has been focussed in the next chapter (systematic review of community-based rehabilitation programme, chapter 2). Before critically analysing the available literature on the controversies in implementation modes, a summary of key features of the contemporary rehabilitation programme following ACL reconstruction has been discussed in this section. The word “contemporary” rehabilitation following ACL is used to outline the current trends in the nature of rehabilitation programme following reconstruction of ACL. The contemporary rehabilitation programme has seen drastic changes since 1990s in the form of emphasis on early mobilization of the patients, achieving the full range of motion in knee joint during the early phase of rehabilitation, allowing patients to start early partial and then full weight bearing on knee joint and starting some functional activities that are essential for the patients to carry out their normal activities of daily living (Wilk et al. 2012). A complete template of the contemporary rehabilitation programme followed at Robert Jones and Agnes Hunt Orthopaedic, Hospital after ACL reconstruction may be found as an appendix (please see appendix III) of this
thesis. Apart from these evident changes seen over time in managing ACL reconstruction, a trend of reduced supervision from the health care team might be observed in the literature on the ACL rehabilitation programmes i.e. the study by Treacy et al. (1997) which to the author’s knowledge is the first published clinical trial on the effectiveness of the supervised and less supervised rehabilitation programmes following ACL reconstruction had reported sixty physiotherapy sessions in contemporary practice during the initial six months. The authors of the latter study had compared the patients in the control group (in which patients attended 60 physiotherapy sessions in the first six months) with the patients in two further subgroups; the non-compliant groups where patients had attended an average of 1.7 physiotherapy sessions and the minimally compliant group in which patients had attended an average of 12 physiotherapy sessions during the same duration of the rehabilitation period. No differences were reported in the latter trial, when patients in the control group were compared to the patients in minimally compliant group on the Lysholm score and range of motion in knee joint. Similar findings of ACL reconstruction have been reported in some other trials carried on the effectiveness of unsupervised or minimally-supervised rehabilitation programmes following the same surgery.

1.11 FACTORS INFLUENCING OUTCOMES OF ACL REHABILITATION PROGRAMME

Rehabilitation programmes following ACL reconstruction are multifaceted and might be influenced by a variety of factors. In a systematic review carried out on the outcomes of ACL rehabilitation for the patients aged ≥ 40 years, it was suggested that the outcomes of the rehabilitation were adversely associated with increasing ages
of the clinical population (Legnani et al. 2011). The fact that reconstruction of the ACL with increased age could lead to a variety of complications (stiffness, arthrofibrosis, infections, wound healing problems and thromboembolic disease), might be one of the reasons to associate middle-aged and older populations achieving poor outcomes of rehabilitation (Noyes et al. 1997, Shelbourne et al. 1992). Moreover, onset of degenerative changes during middle-age may be another significant factor contributing to achieving poor outcomes of rehabilitation. However, controversies in the form of achieving the same goals of rehabilitation by the patients with different age groups warrant further research in this area (Barber et al. 2010, Brandsson et al. 2000). Apart from the controversial role of age on the outcomes of ACL rehabilitation, the role of other orthopaedically-relevant factors has not been well established for ACL reconstruction. However, these factors have been found influential for other musculoskeletal injuries. Evidence associated with back disorders involving injuries to the spinal cord, have shown that a ‘long waiting time to surgery’ was associated with adverse outcomes of rehabilitation (Braybrooke et al. 2007, Derrett et al. 1999). A plausible explanation for this might be given by the fact that a ‘long waiting time to surgery’ may be associated to physiological de-conditioning in the involved musculature. Although, robust evidence in the form of systematic or meta-analytic reviews for the effects of a ‘long waiting time to surgery’ on recovery from injuries to the knee joint are not yet available in the literature, nevertheless, evidence from other musculoskeletal injuries suggest that such influences might also transfer to the issues of rehabilitation involving injuries to the knee.
1.11.1 EFFECTS OF LEVELS OF HABITUAL PHYSICAL ACTIVITIES

The term physical activity or levels of habitual physical activity are often described as a set of unplanned and unstructured bodily movements produced by the skeletal muscles, resulting in energy expenditure. The effects of the levels of habitual physical activity are often differentiated from exercise (being planned, structured, repetitive and purposeful) in the sense that improvement and maintenance of physical fitness are always associated with the latter (Myers et al. 2004). However, evidence from the literature suggested that levels of habitual physical activity were significantly associated with preventions of coronary artery diseases, type 2 diabetes, osteoporosis, obesity and depression (Knowler et al. 2002, Vuori 2001, Pollock 2001). The exact mechanisms and phenomena of how levels of habitual physical activity help the human body in preventing these conditions remain debatable in the literature. However, there is a consensus that performing physical activity while using large muscles group (such as walking, running or swimming) produce adaption to the vital physiological systems (Thomson et al. 2003). Recent investigations revealed that individuals being fit and active were associated with a greater than 50% reduction in risk to different medical conditions (Myers et al. 2004). An increase in energy expenditure from physical fitness of 1 MET was associated with a mortality benefit of about 20%. In contrast, physical inactivity in middle-aged women was reported to provoke a 52% in all-cause mortality, a doubling of cardiovascular-related mortality and a 29% increase in cancer-related mortality compared to the women who were classified as ‘active’ (Hu et al. 2004). Similarly, improvement in indicators of health status was associated with increasing physical activity levels in
the absence of changes in aerobic fitness. This was particularly evident in elderly populations where regular physical activity could lead to a reduction in risk factors for chronic diseases and disability without markedly changing traditional physiologic performance markers (for example, cardio output and oxidative potential). Furthermore, routine physical activity was associated with improvement in musculoskeletal fitness. There is increasing evidence that enhanced musculoskeletal fitness is associated with an improvement in overall health status and a reduction in the risk of chronic disease and disability. This research has led to a shift in focus in research related to the health benefits of activities that tax the musculoskeletal system. Despite this evidence, the role of the levels of habitual physical activity on specific musculoskeletal conditions such as ACL injury has not been established fully in the literature. Further research in this area might offer answers to some of the questions revolving around the potential role of physical activity on the outcomes of rehabilitation.

1.11.2 ROLE OF PRE-SURGERY FUNCTIONAL LEVEL ON THE FINAL OUTCOMES OF THE ACL REHABILITATION

A contemporary ACL rehabilitation programme may take, on average, 6-9 months before the discharge and return of a patient to pre-injury levels of activity. In general, the rehabilitation programme consists of sequenced phases that focus on different aspects of the rehabilitation. The early phases of rehabilitation (up to 12th week following surgery) are regarded as important junctures in which some of the largest relative gains in physiological and physical performances have been reported to occur (Gleeson et al. 2008). This has long been held as a potentially important
clinical ‘gauge-point’ for identifying successful ‘triage’ within the routine treatment of patients under the constraints of limited financial and logistical resources. Efficiency of clinical treatment might be enhanced if it could be shown that there was a robust correlation between early responses to treatment and functional and physical status at the end of treatment and that it was possible to predict with reasonable error, those patients whose performances might resist attaining those associated with MCIDs within the usual formal period of rehabilitation. Available clinical resources would be apportioned more effectively based on patients’ needs under such circumstances.

**Reasons for carrying out this specific research**

One of the reasons for conducting a research in this specific area was the background of the author who belongs to Khyber Pakhtunkhwa, Pakistan where less than two dozen physiotherapists are responsible for providing rehabilitation services to 22 million population. Implementation of such rehabilitation programmes in which patients are actively involved without supervision from rehabilitation team (physiotherapists) would be one of the reasonable solutions to utilising expertise of the these clinical physiotherapists in the latter mentioned situation. Moreover, the recent marked changes in emphasis of policy for the funding of health care which had driven a ‘shift of rehabilitation service to the community’ and patients’ centred rehabilitation programme for achieving appropriate outcomes in a cost effective manner (Grant et al. 2005) was another reason for designing this research. Effectiveness of similar approach for managing rehabilitation programmes in the community have been endorsed for some of the medical conditions having a low-risk characterises (Kennedy et al. 2007). However, management of rehabilitation
programme by the patients in the community for musculoskeletal injuries such as ACL rupture has received little attention in the literature. The characteristics of rehabilitation programme following ACL reconstruction might be categorised into a ‘low-risk category’ where patients in the latter category can successfully achieve optimal outcomes of rehabilitation without being supervised by rehabilitation team (Myer et al. 2006). For the latter purpose, literature review was undertaken and prospective clinical trials were designed to address the questions that had been identified. The next chapter of this thesis is a ‘systematic review’ on the effects of community-based rehabilitation programme following ACL reconstruction.

1.12 AIMS OF THIS THESIS

The aims of this thesis were:

- To systematically evaluate the available evidence associated with the outcomes of ACL rehabilitation programme deployed in two different environments (hospital and community) [this aim was addressed in chapter 2].

- To identify the areas of weak evidence associated with the community-based rehabilitation programmes that might be usefully addressed by the prospective trials carried out during this PhD research programme (this aim was addressed in chapter 2).

- To critically appraise the evidence associated with clinimetrics characteristics of the tools assessing subjectively and objectively performances of the knee joint following ACL reconstruction (this aim was addressed in chapter 3).
• To investigate the effects of the environment (hospital and community) on the outcomes of rehabilitation assessed by the selected PROMs amongst the patients receiving rehabilitation programme in the hospital and in the community (this aim was addressed in chapter 5).

• To explore the effects of the levels of supervision on the outcomes of rehabilitation assessed by the selected PROMs amongst the patients receiving rehabilitation programme in the hospital environment being fully-supervised and minimally supervised by rehabilitation team (this aim was addressed in chapter 6).

• To investigate the role of the levels of supervision on objectively measured outcomes amongst the patients receiving rehabilitation programme in the hospital environment being fully-supervised and minimally-supervised by the rehabilitation team (this aim was addressed in chapter 7).

• To assess the influence of anthropometric characteristics and orthopaedically-relevant factors on the final outcomes of rehabilitation programme following ACL reconstruction (this aim was addressed in chapters 5, 6 and 7).

• To explore the association amongst the change scores of PROMs during early phase of rehabilitation with their respective scores at 24th week following ACL reconstruction (this aim was addressed in chapters 5 and 6).

• To critically evaluate the findings of chapter 5, 6 and 7 of this thesis by comparing them with the findings of the previous clinical trials carried on ACL rehabilitation (this aim was addressed in chapter 8).
1.13 RESEARCH HYPOTHESIS

Based on the literature the following hypotheses were adopted for this research

Hypothesis 1 (Chapter 5)

\( H_0; \) There would be no statistically differences amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes for knee function and pain on PROMs across 24 weeks following ACL reconstruction.

\( H_1; \) (Non-directional, two-tailed hypothesis); There would be statistically significant differences amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes for knee function and pain on PROMs across 24 weeks following ACL reconstruction.

Hypothesis 2 (Chapter 6)

\( H_0; \) There would be no statistically differences amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for knee function and pain assessed on PROMs across 24 weeks following ACL reconstruction.

\( H_1; \) (Non-directional, two-tailed hypothesis); There would be statistically significant differences amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for knee function and pain assessed on PROMs across 24 weeks following ACL reconstruction.

Hypothesis 3 (Chapter 7)

\( H_0; \) There would be no statistically differences amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation
groups for knee function assessed by objectively measured outcomes across 24 weeks following ACL reconstruction.

$H_1$; (Non-directional, two-tailed hypothesis); There would be statistically significant differences amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for knee function assessed by objectively measured outcomes across 24 weeks following ACL reconstruction.
2 CHAPTER: A SYSTEMATIC REVIEW OF COMMUNITY-BASED REHABILITATION PROGRAMMES FOLLOWING ACL RECONSTRUCTION
OUTLINES OF THIS CHAPTER

This chapter set out to appraise critically the available evidence from the literature in order to identify the efficacy and clinical effectiveness of community-based rehabilitation programme following ACL reconstruction. For the latter purpose, a systematic review was carried out and areas of weak evidence were identified that would be usefully addressed by the prospective trials carried out during this PhD research programme.

Section 2.1 Introduction

Section 2.2 Methods

Section 2.2.1 Search strategy

Section 2.2.2 Inclusion and exclusion

Section 2.2.3 Quality assessments

Section 2.3 Results

Section 2.4 Discussion

Section 2.4.1 Objectively measured outcomes

Section 2.4.2 Subjectively measured outcomes

Section 2.4.3 Functionally measured outcomes

Section 2.5 Conclusion and implications for clinical practice
2.1 INTRODUCTION

People with long-term medical conditions are regarded as being amongst the largest consumers of facilities for health care due to a heavy demand for home care, increasing volume and frequency of visits to the health care team and intermittent periods of hospital-based care (Anderson and Horvath 2004). Long-term medical conditions not only affect the demand on health care facilities but may also result in an increased burden on the community due to compromised availability of individuals for productive activities including work (Lopez and Murray 1998, Weingarten et al. 2002). This effect might be prominent just at the time when the overall economic austerities in most countries are having an impact on the amount of funds available for health care facilities (Karanikolos et al. 2013). There have been marked changes in emphasis of policy for the funding of health care that has driven a ‘shift of rehabilitation services to the community’ and patient-centred rehabilitation programmes that might achieve appropriate outcomes in a cost effective manner (Grant et al. 2005). The clinical and economical effectiveness of community-based rehabilitation programmes in the form of National Health Service (NHS) lay-led and self-care support programmes for some of the long-term medical conditions have been endorsed by Kennedy et al. (2002). The latter research comprised a randomized controlled trial carried out in all 28 Strategic Health Authorities (SHA) in England (Kennedy et al. 2007). According to this research, patients with long-term medical conditions (70 to 80 % of which may classified as a low-risk category) can effectively self-manage their rehabilitation programmes in the community with minimum or no supervision from the health care team. In addition, a
systematic review carried out by Barlow et al. (2002) on 145 research studies from different countries and with clearly defined inclusion criterion, further endorsed this approach for long-term conditions such as arthritis, stroke and asthma. Similar benefits were noted for psychological health in terms of improved patient-reported outcomes such as physical, psychological and social health status in the latter review. To the authors’ knowledge, no study to date has provided a systematic evaluation of the effectiveness of community-based rehabilitation programmes designed for patients with musculoskeletal injuries, while the latter affects a large proportion of the population every year (Segui-Gomez and MacKenzie 2003, Van Grinsven et al. 2010). It is clinically plausible that due to the relatively low-risk characteristics associated with the rehabilitation of such injuries in general, injury to the ACL in particular, might have the potential for effective self-management by patients within the community and with minimum supervision from rehabilitation team. Moreover, the surgical reconstruction of a ruptured ACL is a frequent occurrence and offers an example of a well-established pathway of post-surgical rehabilitative care (Marx et al. 2003, Mirza et al. 2000, Vadala et al. 2007). Therefore, in this part of the thesis evidence available in the literature on community-based rehabilitation programme following ACL reconstruction was evaluated systematically.

2.2 METHODS

2.2.1 SEARCH STRATEGY

A systematic search for literature was undertaken (Jan 2003 until December 2013). Searches in electronic database including AMED, BNI, CINAHL, EMBASE, Health
Business Elite, HMIC, Medline, and PsycINFO were carried out for the outcomes of randomised controlled trials involving the community-based rehabilitation programmes following ACL reconstruction. Keywords used to search for the literature were entered into the databases under four themes:

Theme 1: community-based, home-based, hospital-based, unsupervised, unstructured, supervised, structured, self-management

Theme 2: anterior cruciate ligament, ACL

Theme 3: rehabilitation, physiotherapy

Theme 4: reconstruction, reconstructive surgery

Keywords in each theme were grouped with the word ‘OR’ operator while the results of all four themes were combined using the word ‘AND’ operator to get the final number of published articles in this area. Each of the final identified manuscript was reviewed manually and its reference list was checked for additional and relevant information that might also be usefully included in this review. The keyword searches and their results are shown in Table 2.1. The remaining process of scrutinizing trials for inclusion in this review is shown in a flow chart, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), in Figure 2.1.

2.2.2 INCLUSION AND EXCLUSION CRITERIA

The inclusion criterion was limited to randomised controlled trials carried out on community-based rehabilitation programmes following ACL reconstruction. The search
was limited to articles published in the English language from the year 2003 until the year 2013. Review studies were not included within this systematic review as according to the author’s knowledge no review has been reported in the available literature on the community-based rehabilitation programmes following ACL reconstruction. Initially, all abstracts were reviewed by two independent reviewers [HD (author) and AA (colleague)] and were grouped into “relevant”, “irrelevant” or “unsure” categories. In cases where the abstracts were not helpful, full manuscripts were reviewed before consensual allocation into the three categories of relevance.

2.2.3 QUALITY ASSESSMENT

Quality assessment of all four included studies was done by using the Physiotherapy Evidence Database rating scale (PEDro). The PEDro is based on 10 items: random allocation, concealed allocation, similarity at baseline, subject blinding, therapist blinding, assessor blinding, > 85% follow-up for at least one key outcome, intention-to treat analysis, between-group statistical comparison for at least one key outcome, and point and variability measures for at least one key outcome (De Morton 2009). The methodological quality of the studies that have been included in this review ranged from 4 to 8 on the PEDro. Two of the trials achieved a score of 8 (Grant and Mohtadi 2010, Grant et al. 2005) while another trial scored 7 (Hohmann et al. 2011) and the final trial that had been included in this review scored 4 (Ugutmen et al. 2008) on the latter scale.
2.3 RESULTS

The initial search produced a total number of sixty-five studies of which thirty were removed as duplicates. Keeping in mind the inclusion and exclusion criteria for this review, abstracts of the remaining thirty-five studies were further reviewed carefully to judge on the final appropriateness of the studies to be included in this review. Out of thirty-five studies, thirty studies were excluded as those trials typically did not reflect comparisons of responses for the community- and the hospital-based populations while one of the remaining five studies was excluded due to non-randomisation in that trial. Only four studies fulfilled the inclusion criteria for this review. Each manuscript was then reviewed manually and its reference list was checked for additional and relevant information that might also be usefully included in this review. A total of 377 patients in the included trials for this review were randomly allocated into the hospital- and the community-based rehabilitation groups and were assessed on functional, objective and patients' reported outcome measures. In all four trials no differences amongst the group mean scores for the patients in the hospital- and the community-based rehabilitation programmes were reported in functional (single-leg hop), objectives (quadriceps and hamstrings peak force) and subjective (IKDC, Lysholm, ACL quality of life, Tenger Scale) outcome measures. As only four studies have been included in this review therefore, in this section of the review an introduction to each study and findings of each individual study have been discussed. A collective interpretation of subjectively and objectively measured outcomes across all of the four studies has been discussed in the
discussion part of this review. A summary of the results of the trial included in this review is given in Table 2.2.

Figure 2.1: Figure showing PRISMA flow chart for the systematic review.
Table 2.1: Table showing database searches for the systematic review

<table>
<thead>
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<th>key words for searching in databases</th>
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</tr>
<tr>
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</tr>
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<td>12</td>
</tr>
<tr>
<td>5</td>
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<td>17</td>
</tr>
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</tr>
<tr>
<td>7</td>
<td>supervised</td>
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<tr>
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<td>157358</td>
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<td>1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8</td>
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</tr>
<tr>
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<td>anterior cruciate ligament</td>
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</tr>
<tr>
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<td>ACL</td>
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<tr>
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</tr>
</tbody>
</table>

The first trial included in this review

The first study included in this review is a randomised controlled trial carried out by Grant et al. (2005) on 145 patients. A strategy of stratification and blocked randomisation was used to assign participants into either the hospital- or the community-based rehabilitation groups with the main aim of comparing the outcomes of the hospital- and the community-based rehabilitation programmes following ACL reconstruction. The study was designed a single-blinded randomised controlled trial in which participants were kept aware of their allocation into either groups (hospital- or
community-based rehabilitation groups). However, the assessor was kept blinded throughout the whole process by patients being asked by researchers not to disclose group membership to the assessor. Baseline measurements for this clinical trial were taken before ACL reconstruction and all participants attended a pre-surgery educational session. This clinical trial was presumably carried out on recreational athletes because of previous patterns of athletic behaviour and adherence to regular conditioning. It has been established in the literature that individuals with similar experience of managing physical activities (i.e. athletes) are deemed more likely to adhere to the prescribed exercise programmes compared to non-athletic counterparts (Shaw 2002). Non-adherence of patients to long-term therapeutic programmes in the community and the transfer of responsibility for guiding care from the health care team to patients remains an obvious challenge faced by health care providers during the community-based rehabilitation programmes (Brand 2008, Di Matteo et al. 2007). In the first trial included in this review, the authors have reported a comparison of the hospital- and the community-based rehabilitation groups during the acute phase of rehabilitation programme (initial three months). In order to compare the hospital- and the community-based rehabilitation groups, range of motion was used as the primary outcome in the latter trial. It is noteworthy, that no previous trials carried out on the hospital- and the community-based rehabilitation programmes had compared these groups on range of motion (Grant et al. 2005). Achieving full or acceptable range of motion in the knee joint is deemed an important milestone in the knee rehabilitation programmes especially following ACL reconstructive surgery (Viswanathan and Kidd 2010). Moreover, activities of daily living including sitting down, rising from the sitting position,
squatting, going upstairs and down stairs cannot be performed properly having limited range of motion in the knee joint (Huang et al. 2005). Secondary clinical outcomes including knee laxity, the quadriceps and the hamstrings peak force were used for comparing both the hospital- and the community-based rehabilitation groups in the trial. The authors alluded to a higher percentage of patients with an acceptable range of motion in the community-based rehabilitation group compared to the patients in the hospital-based rehabilitation group (flexion, 67% versus 47%; extension, 97% versus 83%; community- and hospital-based rehabilitation groups, respectively). However, this finding was not confirmed statistically. Furthermore, no differences were reported between the groups on secondary outcomes.

The rehabilitation following ACL reconstruction is multi-faceted and might be implemented in a variety of ways (Van Grinsven et al. 2010). The extent and the nature of conditioning programme play an important role that could be simply matched in clinical setups by individuals’ attendance to their physiotherapy sessions (Fischer et al. 1998). However, this matching process could not be simply monitored in the community setups where individuals have more choices of adopting or modifying conditioning programme according to their own preferences. Therefore, a reliable and validated tool must be used to measuring patients’ adherence to rehabilitation programme in the community. In the aforementioned research, a consistency in rehabilitation programme for the hospital- and the community-based rehabilitation groups can be observed by providing a 12 weeks rehabilitation protocol sheet to them. Moreover, attendance of these patients to their respective clinics had been used as a tool
to monitoring patients’ adherence to contemporary rehabilitation programme. However, the use of proper tools to measure the extent and the nature of conditioning programme followed by the patients in the community had not been used which shows a need to evaluate the amount and extent of the latter following ACL reconstruction.

Sample size for this clinical trial was based on the expected number of patients within each group (frequency) to achieve a satisfactory range of motion in the knee joint at the 3-month follow-up period. Data from a previously carried out similar trial, suggested that 95% of the clinic-based patients would achieve an acceptable range of motion at 3-months after surgery. It was estimated that a difference of 20% in the number of patients attaining an acceptable range of motion would be clinically important. A total of 118 (59 patients per each group) were required within the experimental design in order to offer to have a power of 80% and an α-level of 0.05. Moreover, a dropout rate of 15% was incorporated while calculating sufficient number of patients for this clinical trial. The study seemed well-powered to detect difference between the outcomes of the hospital and the community-based rehabilitation groups.

**The second trial included in this review**

The second study included in this review is a randomised controlled trial carried out by Ugutmen et al. (2008) on 104 patients. This clinical trial had focused on two different clinical issues; the effectiveness of ACL reconstruction while using otogeneous hamstrings graft and the comparison of the hospital- and the community-based rehabilitation programmes following ACL reconstructive surgery. The mean time of surgery in this research had been reported 2 to 144 months. More than a half of the
clinical population included in this clinical trial had associated injuries along with ACL rupture [i.e. medial (n = 46), lateral (n = 8) and or both meniscal injuries (n = 10) and chondral injuries (n = 8)]. In addition, patients with previous knee surgical procedures problems such as arthroscopic meniscectomy (16 individuals) had also been included in this research. Despite the fact that all reconstructive surgeries had been carried out by one surgeon, a variety of techniques were reported during reconstructive surgery. The latter factors potentially contributed enormous experimental diversity to the condition of knee of the clinical population that were also likely to produce corresponding and inflated diversity in the final outcomes of the rehabilitation. It was reported in this trial that the patients in the hospital- and the community-based rehabilitation groups had shown statistically similar responses to rehabilitation programme as measured by outcomes that had included objectively measured variables such as range of motion, Lachman and Pivot Shift tests and PROMs included Lysholm, Hospital of Special Surgery (HSS) and IKDC.

When quality of this trial was assessed by PEDro, this trial had obtained a relatively lower score (PEDro score = 4) compared to the other trials included in this review. The reason for relatively lower score compared to other trials was lack of blindness in many places in this trial. i.e. blindness of participants, blindness of physiotherapists and blindness of assessors. Moreover, during randomization a strategy of ‘concealed randomization’ was not reported in the trial that would otherwise have improved the quality of this trial while assessing by the PEDro scoring system.
The third trial included in this review

The third study included in this review is from Grant and Mohtadi (2010). It is one of the very few studies investigating the long-term effects of the community-based rehabilitation programmes on clinical outcomes of the patients following ACL reconstruction surgery. The main aim of the study was to assess the long-term effects of the community-based rehabilitation programme on indices of quality of life, knee laxity and muscular strength (knee extensors and flexors) of the patients after more than 2 years following ACL reconstruction. The significance of this study’s findings is that they offer potentially a greater correspondence in time compared to those of the other studies. It had been well documented in the literature that ACL graft might need at least a 3-year duration to be fully matured after the reconstructive surgery (Rougraff et al. 1993, Risberg et al. 1999). In addition, it had been demonstrated that the corresponding re-establishment of the quadriceps’ and the hamstrings’ pre-injury strength might take two or more than two years following reconstruction of the latter ligament (Carter and Edinger 1999). PROM [ACL quality of life questionnaire (ACLQoL)] was the primary outcome in the third study included in this review. Moreover, both groups had been compared by the quadriceps’ and the hamstrings’ peak forces after a period of more than 2 years of rehabilitation. The significance of the muscular power around knee joint in preventing ACL injuries is obvious from the fact that these muscles (the quadriceps and the hamstrings) have the potential to support varus and valgus movements at the knee joint (William et al. 2001, Hewett et al. 2006). According to the trial carried out by William et al. (2001) dynamic stability in the knee joint, which plays an important role
in the ACL injuries prevention, is resulted from the bones geometry, the soft tissue restraints and the response of the musculature around the knee joint. The first two factors mentioned in this trial are non-modifiable by nature. However, the third factor, muscular strength around the knee joint, had been reported to show improvement to the conditioning programmes (Hewett et al. 2006). Moreover, Eitzen et al. (2009) had reported that pre-operative quadriceps muscle strength deficits had significant negative effects on the long-term functional outcomes of ACL reconstruction. It had been reported in this trial (Grant and Mohtadi. 2010) that the patients in the community-based rehabilitation group had shown 14% ($Cohen's\ d = 0.52$) more improvement than the patients in the hospital-based rehabilitation group on ACLQoL. However, it had not been reported in the trial whether this difference between both groups was statistically significant or not. Moreover, no differences amongst the group mean scores for the patients in the community- and the hospital-based rehabilitation groups had been reported in the latter trial when participants in both groups were assessed by secondary outcomes including bilateral difference in the knee joint range of motion, the knee laxity and the muscular strength around the knee joint.

Despite the fact that patients included in this trial had been assessed on long-term outcomes of the ACL reconstruction, still a dropout of the 32 % of patients for long-term assessments cast doubts in the difference of levels of motivation amongst the participants in the latter trial. Moreover, although, patients in this trial were assessed by the subjectively and objectively measures, still the use of any functional test such as single-leg hop, timed up and go or triple-hop had not been reported in this trial.
Power analysis for this clinical trial was performed following a conservative opinion-based clinically important difference between groups of 15 points. The ACL-QoL database information, collected locally from previous non-study patients at a minimum of 1-year follow-up, was used to perform a priori power analysis.

The fourth trial included in this review

The fourth study included in this review is a prospective randomized controlled trial carried out by Hohmann et al. (2011) on 40 participants who had undergone ACL reconstruction. The study had clearly defined its aim, to compare supervised (hospital-based) and unsupervised (community-based) rehabilitation programmes following ACL reconstructive surgery. Data collection and data analysis for this study was done by an independent examiner who was blinded to group allocation of the participants. All the participants in both the hospital- and the community-based rehabilitation groups were guided to same rehabilitation programme. However, the patients in the community-based rehabilitation group followed the rehabilitation programme at their local environment without supervision from the health care team. All participants were tested before surgery for a baseline measurement and later on 3rd, 6th, 9th and 12th months following ACL reconstructive surgery. A detailed comparison amongst the patients in the hospital- and the community-based rehabilitation groups had been reported in this trial using subjective (Lysholm, Tegner), objective (muscular strength) and functional outcomes (single-leg hop, timed hop and vertical jumps). The study indicates a well-powered designed trial where power calculation for the number of participants was done based on previously completed randomized controlled trial by Grant et al. (2005). The
final outcomes of the above mentioned trials had revealed that the patients in both groups (the hospital- and the community-based rehabilitation groups) improved significantly over the period of 12 months when assessed on the subjective, objective and functional measured variables. In this trial, the pre- and post-op scores on the Lysholm for the hospital- and the community-based rehabilitation groups had been reported 57-94 and 60-97, respectively, indicating that both groups had improved 37 units on the Lysholm over a period of 12 months. The community-based rehabilitation group had shown better functional outcomes compared to the hospital-based rehabilitation group. i.e the community-based rehabilitation group had shown 6% (Cohen’s d = 0.17) more improvement than hospital-based rehabilitation group on timed hop symmetry index. However, no differences between both the hospital- and the community-based rehabilitation groups had been reported on single-leg hop symmetry index (Cohen’s d = 0.01). Similar results of having non differences amongst the patients in the hospital- and the community-based rehabilitation groups had been reported when both groups were assessed by the variables that can be assessed objectively. However, the hospital-based rehabilitation group had improved 7% (Cohen’s d = 0.38) and 4% (Cohen’s d = 0.50) more than the community-based rehabilitation groups on isometric knee flexion and extension symmetry indexes, respectively. Moreover, the patients in the hospital-based rehabilitation group had improved 4% (Cohen’s d = 0.16) and 6% (Cohen’s d = 0.22) more than community-based rehabilitation groups when assessed by isokinetic concentric and eccentric strength, respectively. The only variable in this trial on which the patients in the community-based rehabilitation group had outperformed (although not statistically) the
hospital-based rehabilitation was timed hop symmetry index in which the patients in the community-based rehabilitation group had shown 6% ($Cohen’s \ d = 0.17$) more improvement than the hospital-based rehabilitation group.

The authors in the latter trial had use terms supervised and unsupervised for the rehabilitation programmes followed by the patients in the both groups in the clinical trial. However, the characteristics of supervised and unsupervised rehabilitation programmes had not been clearly differentiated in the latter trial. According to author’s knowledge, supervision during rehabilitation programme has not been clearly defined in the other trials in literature. The physiotherapists guide the patients coming for the rehabilitation programme to the rehabilitation activities and the presence of physiotherapists in these physiotherapy sessions had been termed as ‘supervision’ (Gram et al. 2014). Similar approach had been adopted in the trial carried out by the Hohmann et al. (2011) and the patients with high number of supervised rehabilitation sessions in the hospital have been categorised ‘supervised’ while the patients having low number of supervised rehabilitation programme in the hospital have been labelled ‘unsupervised’. However, during the clinical trials reported in thesis, a regular interaction amongst the physiotherapists and the patients in the form of feedback, modification in the intensity and volume of dose were observed during the physiotherapy sessions supervised in the hospital. Based on the evidence from the literature and observation during this clinical trial, operationally supervision might be defined the process of monitoring and direction of physiotherapists during physiotherapy sessions in which the patients activities are closely monitored and altered according to the his/her needs and preferences (an
alteration in intensity and volume of exercises suggested by the physiotherapists supervising the rehabilitation session). The latter had not been reported in the clinical trial reported by Hohmann et al. (2011).

Power calculation for this clinical trial was performed while using a web-based calculator. The power calculation was based on a previous clinical trial carried out on the effects of the hospital- and the community-based rehabilitation programmes. Based on a power of 80% and a significance level of 0.05, the sample size was calculated. Based on the power calculation, a total of 32 patients (16 patients in each group) were required for this clinical trial. The authors of this clinical trial had recruited a total of 40 patients (20 in each group), indicating that this clinical trial as well-powered.
Table 2.2: Table showing summary of the outcomes of the trials included in the systematic review

<table>
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<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Follow-up Time</th>
<th>Outcomes</th>
<th>Measuring Tools</th>
<th>PEDro Scoring</th>
<th>Results</th>
<th>Conclusion</th>
<th>Comments</th>
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</thead>
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<tr>
<td>Grant et al. 2005</td>
<td>RCT</td>
<td>145</td>
<td>3 months</td>
<td>Quadriceps Strength</td>
<td>ACLQoL dynamometer</td>
<td>8</td>
<td>More patients in the community-based rehabilitation groups attained the acceptable range of motion Hospital-based group showed a high proportion of acceptable Ligament laxity compared to community-based group All patients achieved acceptable peak flexion than peak extension values</td>
<td>Community-based rehabilitation is an effective rehabilitation programme both clinically and economically</td>
<td>Detailed assessment method discussed in the article Follow-up time is shorter as on average ACL rehab takes six months</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Hamstrings Strength</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td>Range of motion of Knee</td>
<td></td>
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</tr>
<tr>
<td>Ugurmen et al. 2008</td>
<td>RCT</td>
<td>104</td>
<td>31.1 months on average</td>
<td>Muscles atrophy</td>
<td>IKDC HSS</td>
<td>4</td>
<td>No differences were observed between the outcome of rehabilitation in both groups No differences were reported between both groups in the combined Lysholm, IKDC, Hospital of Surgery Special scores Both group of patients improved significantly from pre-surgery level 82.7 % of the patients had no complaint at the final evaluation 5.8 % of the patients reported knee pain after physical activities</td>
<td>Community-based rehabilitation is an effective rehabilitation programme both clinically and economically</td>
<td>Patients with associated injuries have been included in this trial The researchers have focused on two clinical outcomes, surgery type and rehabilitation programmes implementation mode</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Crepitation</td>
<td>Lysholm arthrometer</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Oedema</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Grant and Mohtadi 2010

RCT 88 2-4 years Quadriceps Strength Hamstrings Strength Range of motion Knee laxity IKDC 8 ACL-QoL arthrometer Biodex System 3 Goniometer

Community-based rehabilitation group demonstrated better disease specific quality of life on ACL Quality of life questionnaire. No differences were observed between these two groups based on secondary outcomes of the trial and IKDC.

Community-based rehabilitation group demonstrated better long-term clinically outcomes of the rehabilitation programme on some of the outcome measures used in the trial.

Details of rehabilitation programme after three months have not been mentioned.

Hohmann et al. 2011

RCT 40 12 months Quadriceps strength Hamstrings strength Single-leg hop vertical jump timed-hop IKDC 7 BiodexTM Isokinetic Lysholm score Dynamometer Tegner Scale

Based on single-leg hop no differences between both groups were observed.

Both groups significant improved on timed up at 12 month. Both groups improved significant in symmetry index at the final assessment.

There was no difference between two groups rehabilitated in hospital and community.

Details of variables have been well documented and reported in tables.
Table 2.3: Table showing the effect sizes and % difference amongst the outcomes of the community- and the hospital-based rehabilitation groups reported in the clinical trial included in this review

<table>
<thead>
<tr>
<th>Authors</th>
<th>Outcomes</th>
<th>ES</th>
<th>%difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant et al., 2005</td>
<td>Quadriceps Strength</td>
<td>0.08</td>
<td>10</td>
<td>0.23</td>
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<tr>
<td></td>
<td>Hamstrings Strength</td>
<td>0.07</td>
<td>9</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Knee Flexion</td>
<td>0.34</td>
<td>5</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>Knee Extension</td>
<td>0.27</td>
<td>4</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Anterior Tibio-femoral Displacement</td>
<td>0.21</td>
<td>4</td>
<td>0.34</td>
</tr>
<tr>
<td>Ugutmen et al., 2008</td>
<td>Range of Motion</td>
<td>0.21</td>
<td>3</td>
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<td>Pivot shift test</td>
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<td>IKDC</td>
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<td>HSS</td>
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<td>Lysholm</td>
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<td>Grant et al., 2010</td>
<td>ACL-QoL</td>
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<td>0.09</td>
</tr>
<tr>
<td></td>
<td>Quadriceps Strength</td>
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<td>8</td>
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</tr>
<tr>
<td></td>
<td>Hamstrings Strength</td>
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<td>Hohmann et al., 2011</td>
<td>IKDC</td>
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<tr>
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<td>Tegner</td>
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<tr>
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<td>Single-leg Hop</td>
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<tr>
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<td>Quadriceps Strength</td>
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</tr>
<tr>
<td></td>
<td>Hamstrings Strength</td>
<td>0.46</td>
<td>8</td>
<td>n/a</td>
</tr>
</tbody>
</table>

2.4 DISCUSSION

The main purpose of this review was to undertake a systemic review of the literature on the effects of the community-based rehabilitation programmes following ACL reconstruction. Various terminologies have been used by researchers to describe the community-based rehabilitation programme followed by patients post-surgically. Authors had termed it both as ‘community-based’ or ‘home-based’ rehabilitation but with a common approach involving individuals undertaking rehabilitation
programmes in their community without supervision from a rehabilitation specialist (Grant and Mohtadi 2010, Grant et al. 2005, Ugutmen et al. 2008). Other authors had labelled the process as ‘unsupervised rehabilitation’ but nonetheless it has offered the same characteristics of the patients receiving minimal or no supervision from the rehabilitation team (Hohmann et al. 2011, Feller et al. 2004). A decreased levels of supervision for the patients can be seen as the most common factor in all the above mentioned clinical trials that might provide autonomy to an individual in the form of his/her capability to self-modify the programmes according to the individuals’ preferences and needs. It is reported in the literature that allowing more independence in rehabilitation programmes might improve self-confidence of the patients (Chan et al. 2009) that could ultimately provide an opportunity for the individuals to start early activities and diminish the adverse effects of immobilization (Beynnon et al. 2005). A collective interpretation of subjectively and objectively measured outcomes across all of the four studies included in this review has been discussed in the coming section.

2.4.1 OBJECTIVELY MEASURED OUTCOMES

Range of motion is highly important to the capability for normal function of the knee joint and to achieving the normal activities of daily living (Viswanathan and Kidd 2010, De Carlo and Sell 1997). Three out of four trials included in this review, had compared the patients in the community-based rehabilitation group with the patients in the hospital-based rehabilitation group on range of motion (Grant and Mohtadi 2010, Grant et al. 2005, Ugutmen et al. 2008). The patients in the community-based rehabilitation group had achieved the same or even a better, but not statistically
different, range of motion in the knee joint when were compared to the patients in the hospital-based counterparts following ACL reconstruction (Grant et al. 2005, Ugutmen et al. 2008). Factors such as patients' autonomy and motivation in the community-based rehabilitation programmes might be associated to achieving better results in such rehabilitation programmes (Chan et al. 2009). It was reported in one of the trials included in the review, that a high percentage of the patients in the community-based rehabilitation group, although not statistically different, had achieved an acceptable range of motion compared to hospital-based rehabilitation group [97% versus 83% for extension; 67% versus 47% for flexion amongst the patients in the community- versus the hospital-based groups, respectively] (Grant et al. 2005). Similar findings of no significant difference in range of motion in knee joint between the hospital- and community-based rehabilitation groups had been reported by Fischer et al. (1998). Moreover, in one of the trials (Grant and Mohtadi 2010), a significant decreases in the pre- and the post-surgical range of motion in the patients in both the hospital- and the community-based rehabilitation groups was reported, even after more than two years following reconstruction of ACL. However, the extent of the raw or relative effect size had not been reported in the latter trial. Similar results of decreased range of motion in the knee joint following ACL reconstruction had been reported by Risberg et al. (1999b) with a reduction in an extension of 0.4° at the end of two years of rehabilitation following reconstruction of ACL. However, the trial carried out by Ugutmen et al. (2008) had shown no significant difference amongst the patients in the hospital- and the community-based rehabilitation groups at the end of rehabilitation programmes following reconstruction of the latter ligament.
Laxity in the knee joint is an important objectively measured variable that is used to evaluate knee joint stability. KT-1000 or KT-2000 arthrometers are commonly used to evaluate ACL laxity in the knee joint (Kupper et al. 2007, Lee et al. 2007). The validity and the reliability of both KT-1000 and KT-2000 arthrometers has been endorsed in clinical studies carried out on patients undergoing ACL reconstruction (Hanten and Pace 1987, Khan et al. 2007). One of the trials included in this review, revealed that the hospital-based rehabilitation group had outperformed the community-based rehabilitation group in terms of maintaining normal knee laxity scores when assessed by the KT-2000 arthrometer (Grant et al. 2005). However, the authors in the latter trial had not reported the extent by which the hospital-based rehabilitation group had outperformed the community-based rehabilitation group when assessed by KT-2000 for the knee laxity. In contrast, no significant difference in knee laxity had been reported when same patients were assessed by the KT-1000 arthrometer in another trial carried out by Grant and Mohtadi (2010) comparing the long-terms effects of the community- and the hospital-based rehabilitation programmes.

Another important objectively measured variable which had been reported by three out of four trials included in this review is the peak force of the quadriceps’ muscles. Final outcomes of the latter three trials had revealed no significant difference amongst the patients in the hospital- and the community-based rehabilitation groups when assessed for peak force of the quadriceps muscles for both the surgical and the non-surgical legs (Hohmann et al. 2011, Grant and Mohtadi 2010, Grant et al. 2005). For example, in a clinical trial by Grant et al. (2005), the relative performance of the quadriceps peak force between the surgical and non-surgical legs of the community-
and the hospital-based rehabilitation groups was statistically similar (61% to 60%, respectively).

### 2.4.2 SUBJECTIVELY MEASURED OUTCOMES

A variety of subjective measuring tools have been developed to evaluate the knee joint function following ACL reconstruction (Bjorklund et al. 2009). One of the commonest of the latter is International Knee Documentation Committee (IKDC) that is considered to be responsive to patients’ symptoms, function and sports activity following different knee problems (Irrgang et al. 2006) [please see chapter 3, section 3.1.1, for detailed description of IKDC]. Three out of four trials included in this review, have used the IKDC scores to compare the community- and the hospital-based rehabilitation groups (Grant and Mohtadi 2010, Ugutmen et al. 2008, Hohmann et al. 2011). No significant difference in IKDC scores were observed ($X^2 = 0.44, p = 0.8$) amongst the patients in the community- and the hospital-based rehabilitation groups in the clinical trial carried out by Grant et al. (2005). Similarly, no significant differences amongst the patients in the community- and the hospital-based rehabilitation groups had been reported in the trials carried out by Ugutmen et al. (2008) and Hohmann et al. (2011) when both these groups were assessed by the same PROM (IKDC).

Two out of the four trials had used Lysholm score for comparing patients in the hospital- and the community-based rehabilitation groups (Hohmann et al. 2011, Ugutmen et al. 2008). Lysholm is another widely used questionnaire, which has been cited 500 times in the PubMed during a recent five years period (Briggs et al. 2009), for evaluating function associated with different clinical conditions of the
knee. A significant interaction of subject groups with the test occasion for Lysholm scores has been reported by Hohmann et al. (2011) while assessing the community- and the hospital-based rehabilitation groups. According the authors of this trial between-test-occasion post hoc contrast had indicated that both subject groups improved significantly between test occasions in the postoperative period. However, no significant difference between both groups on Lysholm had been reported in the trial. Similar findings of having a no significant difference amongst the patients in the hospital- and the community-based rehabilitation groups, had been reported by Ugutmen et al. (2008) when these groups were assessed on the same measuring tool after 12 months of reconstructive surgery of ACL.

Two out of four studies included in this review had used ACL quality of life (ACL-QoL) as patient-reported measuring tool for comparing the patients in both the community- and hospital-based rehabilitation groups (Grant and Mohtadi 2010, Grant et al. 2005). However, only one of the two trials, Grant and Mohtadi 2010 had reported the detailed scores of the ACLQoL in which the patients in the community-based rehabilitation group had shown 14% (Cohen’s $d = 0.53$) more improvement than the hospital-based rehabilitation group when assessed after 2- to 4-year of ACL reconstruction.

2.4.3 MEASURES OF FUNCTIONAL OUTCOME

An interesting point to highlight is that only one out of the four clinical trials included in this review had used functional tests to compare the outcomes of the community- and the hospital-based rehabilitation programmes following ACL reconstruction (Hohmann et al. 2011). Single-leg hop, timed hop and vertical jump
had been used as functional outcome measures in the latter trial. Similar evidence of using more than one functional test following ACL injuries had been reported in the literature (Gustavsson et al. 2006). In the latter clinical trial it had been established that the use of a combination of functional tests could offer a better differentiation between affected and non-affected legs following ACL reconstruction. However, the use of only one functional test such as single-leg hop had been reported reliable to predict the likelihood of successful and unsuccessful outcomes following reconstruction surgery in a clinical trial carried out on a cohort of 85 patients (Logerstedt et al. 2012). In order to compare the outcomes of the hospital- and the community-based rehabilitation programmes following ACL reconstruction on functional outcomes repeated measures ANOVAs had been used by Hohmann et al. (2011). The final functional outcomes in the latter trial on repeated measures had shown a significant improvement of both groups from 3 to 12 months on single-leg hop test. Moreover, a significant improvement had been reported in the trial for both groups at 12 months on timed hop test and vertical jump. However, no differences on achieving functional outcomes between both the hospital- and community-based rehabilitation groups had been reported in the trial. The patients in the community-based rehabilitation group had shown better functional outcomes, although statistical similar, compared to the patients in the hospital-based rehabilitation group. i.e the patients in the community-based rehabilitation group had shown 6% ($Cohen’s d = 0.17$) more improvement than the patients in the hospital-based rehabilitation group on timed hop symmetry index. However, no differences amongst the patients in the hospital- and the community-based rehabilitation groups had been reported on single-leg hop symmetry index ($Cohen’s d = 0.01$).
2.5 CONCLUSION AND IMPLICATIONS FOR CLINICAL PRACTICE

This review suggests that the community-based rehabilitation programme is clinical-efficient in terms of achieving similar outcomes by the patients in the community to the outcomes achieved by the patients in the hospital-based rehabilitation programme at 24\textsuperscript{th} week following ACL reconstruction. This rehabilitation programme might be cost-effective to both the patients and the health service providers in the form of decreased number of patients’ visits to the rehabilitation team. However, the apparent clinical-efficacy and cost-effectiveness of the community-based rehabilitation programmes might be reversed if these programmes are followed imprecisely (i.e. variation in dose and response characteristics) by the individuals or insufficient guidance is provided by the health service providers to the individuals. Therefore, patients must be guided properly to the rehabilitation programmes. Moreover, the levels of supervision and minimum rehabilitation sessions might be designed according the patients’ capacity of self-managing the rehabilitation programme in the community.
3 CHAPTER: CLINIMETRICS OF THE SELECTED OUTCOME MEASURES
OUTLINES OF THIS CHAPTER

In this part of the chapter, a review of literature on tools assessing performance of the knee joint for the patients who have undergone ACL reconstruction, was offered. For the latter purpose, PROMs (IKDC, KOOS, K-SES and Lysholm), estimates of physical performance (peak force, rate of force development, sensorimotor performances, and electromechanical delay), musculoskeletal performances (ATFD), functional measure (single-leg hop) and their clinimetrics were included in this chapter.

Section 3 Clinimetrics
Section 3.1 PROMs
Section 3.1.1 IKDC
Section 3.1.2 KOOS
Section 3.1.3 Lysholm
Section 3.1.4 K-SES
Section 3.1.5 7-Day Physical Activity Recall
Section 3.2 Objective measures
Section 3.2.1 Peak torque
Section 3.2.2 Rate of force development
Section 3.2.3 Electromechanical delay
Section 3.3 Knee laxity
Section 3.3 Functional tests
3. CLINIMETRICS

The current focus on health care has resulted in a virtual explosion of health measurement scales used to measure phenomena such as quality of life and physical and psychological limitations associated with medical conditions (Marx et al. 1999). A wide range of instruments are available to measure components of quality of life and limitations associated with physical and psychological levels of the patients suffering from different medical conditions. Even when focusing on a specific aspect of functioning or a specific category of patient, the clinician is typically confronted with a disturbing wide range of options (Dekker et al. 2005).

Clinimetrics is a methodological discipline that focuses on the quality of clinical measurements (de Vet et al. 2003). Different clinimetric properties such as reproducibility and reliability have been reported as important aspects in both the development and evaluation of the instruments of measurement used in clinical practices. It is important to report that clinimetrics in rehabilitation medicine has undergone extensive advancement. However, several issues such as selection of an instrument out of the wide range available, using an instrument in a variety of diagnostic groups, using an instrument in the assessment of individual patients and the use of instruments in clinical practice, have remained debatable in the literature (Dekker et al. 2005). The aim of this chapter was to assess the quality of the assessment tools that would be deployed in the clinical trials carried out in this PhD thesis.
3.1 PROMS

It is imperative to monitor function and physical performance capabilities of the patients by PROMs and objective outcome measurements following ACL reconstruction. However, controversies associated with clinimetric utilities of PROMs used for evaluation of the knee joint following ACL reconstruction, have resulted in developing different rating scales (Hambly and Griva 2010). In this section of the thesis, clinimetric utilities such as minimal detectable changes (MDC), minimally clinically importance differences associated with the selected PROMs and objectively measured outcomes have been critically appraised.

It is evident from the literature that patients’ satisfaction and the way patients perceive about the outcomes of a treatment including functional capabilities, has become very important to the clinician (Jette 1989). The obvious reason for this is an increasing emphasis on ‘commercialization’ in the health services focussing on the satisfaction of patients alongside the clinical effectiveness of a treatment (Nemec and Kolisnichenko 2006). The inclusion of PROMs in routine clinical care has the potential to add valuable information about the impact of the disease and its treatment and to promote effective self-management of patients’ care (Santana and Feeny 2013). The subjective assessment tools had been reported to having clinical and economic significance with broad application, including the assessment of general health status, the development of health care model and improvement health care delivery (Greco et al. 2010).
3.1.1 IKDC

The IKDC is an assessment tool developed to specifically evaluate knee joint injuries. The purpose of developing this tool was justified by the fact that a variety of assessment tools were used with the incumbent logistical challenges for patient-assessment in the past for quantifying the disability caused by the knee conditions (Hefti and Muller 1993). One of the associated problems with PROMs was their inability to measure patients’ health related status in a quantifiable manner. The system of numerical values was adopted for evaluating the patients’ health status in the latter. To assess the patients’ knee status on a quantifiable manner, a committee known as IKDC was formed in 1987. The latter name was given to the PROM developed by latter committee. Quantification was anchored against verbal terms such as ‘normal’, ‘nearly normal’, ‘abnormal’, or ‘severely abnormal’ rather than quantified on an ordinal or other scoring scale.

The first IKDC evaluation form had been reported by Hefti and Muller (1993). After four years, the AOSSM revised the IKDC and a new subjective component ‘general health assessment’, similar to SF-12, was added. The inclusion of a general health assessment section in the IKDC was suggested due to the impact of knee joint injuries on the general health of an individual. A final version of the IKDC was drafted in March 1998 for further evaluation following three revisions of the subjective components of the IKDC form by the committee. The current version of IKDC consists of 18 items related to symptoms, function and sporting activities. This instrument has been designed to report a differentiation between the patients with higher levels of knee symptoms and lower levels of function (Anderson et al. 2006). The current version of IKDC consist of six sections; demographic form,
current health assessment form, subjective knee evaluation form, knee history form, surgical documentation form and knee examination form. The subjective knee assessment subsection of IKDC is getting popularity among the clinician for assessment of knee related conditions (Delcogliano et al. 2002, Higgins et al. 2007). A detailed overview of scoring this section has been discussed in this thesis.

**Scoring the IKDC subjective section**

A variety of methods of scoring the IKDC subjective knee evaluation form have been reported (Hefti and Muller 1993, Collins et al. 2011). The patients’ perceived outcomes are recorded in terms of their responses to each individual item in the assessment form. These responses are recorded at an ordinal method levels where each item has multiple options. i.e. the lowest levels of function is represented by a lowest score starting from ‘1’. As the relation of symptoms and function remains inversely related, the lower score for symptoms represent higher symptoms in this form. i.e scoring any option by ‘1’ represents the lowest levels of function; the same score represents the highest levels for symptoms. Moreover, ‘1’ which is used to indicate the highest levels of activity without significant pain is scored by assigning a score of ‘1’ to the response “Unable to perform any of the above activities due to pain in knee” and a score of ‘5’ to the response “Very strenuous activities like jumping or pivoting as in basketball or soccer”. For item ‘2’, which is related to the frequency of pain over the past 4 weeks, the response “Constant” is assigned a score of ‘1’ and “Never” is assigned a score of 11.

The IKDC subjective knee evaluation form is scored by summing the scores for the individual items and then transforming the score to a scale that ranges from 0 to 100. In the first step to evaluating the knee condition of an individual, as previously
discussed and involving the relativisation of the raw score to the lowest and highest capability for function and symptoms, respectively. All items responses are combined by adding them with the exception of the response to the item 10 ‘function prior to the knee injury’ and finally these score are transformed according the formula reported by Irrgang et al. (2001).

\[
\text{IKDC score} = \left( \frac{\text{Raw score} - \text{lowest possible score}}{\text{Range of score}} \right) \times 100
\]

The final transformed score is interpreted as a measure of function and symptoms. A higher score represents higher levels of function and lower levels of symptoms. A score of 100 is interpreted to mean no limitation with activities of daily living or sports activities and the absence of symptoms. The IKDC subjective knee score can still be calculated if there are missing data, as long as there are responses to at least 90% of the items (i.e. responses have been provided for at least 16 items). To calculate the raw IKDC score when there are missing data, the average score of the items that have been answered is substituted for the missing item score.

**Reliability and validity of IKDC**

The term reliability depicts the overall consistency of a measure or absence of error in the bio-statistical measurement. All measuring tools will demonstrate some error and operationally, reliability might be defined as the maximum amount of error deemed acceptable for the practical use of the tool in a given assessment settings (Bialocerkowski et al. 2010, Safrit and Wood 1989). On the other hand, the term validity reports the extent of an assessment tool to measure what it claims to measure. IKDC had been reported to be a reliable and valid tool for measuring patients’ perception toward the function and symptoms of a rehabilitation
programme following injuries to the ligaments of knee joints (Schmitt et al. 2010, Greco et al. 2010, Kocher et al. 2011, Higgins et al. 2007). Evidence from a clinical trial carried out by Higgins et al. (2007), which include participants from different ages, has been included for critical appraisal regarding the reliability and validity of IKDC. The latter trial was carried out on 1531 participants having African, Asian, Caucasian and Hispanic background. Chronbach’s Alpha reliability coefficients were computed for each subscale. Instrument validity of the IKDC subjective section had been assessed by correlating it to the SF-12 physical and mental component. In the latter trial, the IKDC subjective section had been separated into two distinct sections. Symptoms and knee articulation (11 items), and activity levels [4 items (a further 3 items were deemed to be too complex and omitted from this analysis)]. A significant correlation between symptom and knee articulation ($r = 0.45$, $p = 0.0001$) and activity levels ($r = 0.50$, $p = 0.0001$) had been reported with the total SF-12. The clinimetric characteristics of IKDC such as reliability, MDC and MCID are given in Table 3.2.

### 3.1.2 KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)

The development of the IKDC was criticized by some of the authors because of the involvement of an observer while filling some sections of the latter outcome measures (Roos et al. 1998). Moreover, the controversy that different assessment tools that is used for evaluation of the same condition might provide different results lead to the development of other subjective assessment tool that encompasses the overall condition of knee joint. Roos et al. (1998) developed another assessment
tool, the Knee injury and Osteoarthritis Outcome Score (KOOS), for assessing the knee joint function based on patients’ perceptions of capability but which didn’t involve an administrator of the inventory to aid its completion. The KOOS comprises a total of 42 items within five sections; pain (9), symptoms (7), activities of daily living (17), sport and recreation function (5) and knee related quality of life (4) and is based on an extension of Western Ontario and MacMaster Universities (WOMAC) Osteoarthritis Index (Hambly and Griva 2010). The content validity of questionnaire had been justified by including questions from the WOMAC Osteoarthritis Index. That is one of the reasons that why the KOOS score can be transformed into WOMAC scores. The process of developing KOOS is shown in Figure 3.1.

**Scoring KOOS**

In contrast to IKDC in which the items are aggregated to produce a single index, the KOOS had separate scores for different health dimensions, with lower scores signifying worse functioning in these areas. Each question in KOOS consists of five options that are scored from 0-4. As mentioned above, this PROMs consists of five sections, the collective score of each section is calculated separately. A detailed overview of how to score KOOS can be found in the study carried out by Roos et al. (1998).

Formulas used to calculate scores for each section of KOOS:

\[
\begin{align*}
\text{Pain} &= 100 - \frac{\text{Total score } P1 - P9 \times 100}{36} \\
\text{Symptoms} &= 100 - \frac{\text{Total score } S1 - S7 \times 100}{28} \\
\text{ADL} &= 100 - \frac{\text{Total score } A1 - A17 \times 100}{68} \\
\text{Sport and recreation} &= 100 - \frac{\text{Total score } SP1 - SP5 \times 100}{20} \\
\text{QOL} &= 100 - \frac{\text{Total score } Q1 - Q4 \times 100}{16}
\end{align*}
\]
Figure 3.1: Figure showing the process of KOOS development. (adapted from Roos and Lohmander 2003)

**Transforming KOOS score into WOMAC**
As mentioned above, KOOS has been adopted from the WOMAC, hence, the developer of KOOS had reported a formula that can transform KOOS scores into equivalent WOMAC scores. For the latter purpose, KOOS form is scored as mentioned in the above section about scoring KOOS. A sum of all items in each section is calculated and WOMAC scores be computed using the expression below:

$$\text{Transformed scale} = 100 - \frac{\text{actual raw scores} \times 100}{\text{maximum score}}$$

**Reliability and validity of KOOS**

The KOOS has been used extensively by researchers working on the assessment of knee joint. It is obvious from the fact the KOOS had been adopted in many languages and has been validated. The KOOS assessment form has been validated in different languages such as English (Roos et al. 1998a), Swedish (Roos et al. 1998b), Chinese (Xie et al. 2006), Japanese (Nakamura et al. 2011), Persian (Salavati et al. 2008), French (Ornetti et al. 2008), Dutch (De Groot et al. 2008), Polish (Paradowski et al. 2013) and Portuguese (Gonçalves et al. 2009). The first reliability and construct validity of the KOOS had been reported by Roos et al. (1998). For this purpose, a total of 21 patients who had undergone ACL reconstruction were recruited. All patients included in the trial, followed a well-controlled rehabilitation programme. Thirteen of the 21 participants, filled the KOOS twice within 9 day time interval before the ACL reconstruction. The random effects of intra-class correlation coefficient (ICC) had been reported as 0.85 for pain, 0.93 for symptoms, 0.75 for activities of daily living, 0.81 for sport activities of daily living, 0.81 for sport and recreation function and 0.86 for knee related quality of life. Please see Table 3.2 for details of the clinimetrics of the KOOS.
3.1.3 LYSHOLM KNEE SCORING SCALE

Lysholm Knee Scoring Scale is a well-known subjective measuring tool used for the assessment of individuals following variety of problems related to their knee joint. The first version of Lysholm Knee Scoring Scale was by Lysholm and Gillquist (1982) which was modified in 1985, in order to extend its scope of assessment to meniscal injuries. For the latter purpose, its modification was achieved by introducing the domain of locking in this subjective assessment tool. The focus of this scoring evaluated instability of the knee joint and was intended to correspond to the patient’s own opinion of function and signs of stability (Briggs et al. 2009). Every option in each question has been given a score which represent intensity of the levels of activity to be reported. i.e. regarding the first question which is asking about limp three options have been given. I have no limp when I walk (5), I have a slight or periodical limp when I walk (3) and I have a severe and constant limp when I walk (0). By ‘ticking’ the option 1, 2 and 3, it enables the participants to get a score of 5, 3 and 0, respectively. Patients’ symptoms are reported by an aggregate score across all questions is used to represent patients’ symptoms and higher scores (maximum 100) are associated with fewer symptoms.

Reliability of the Lysholm Knee Scoring Scale

Over the past 25 years, researchers have continued to use the Lysholm Knee Scoring Scale extensively for evaluating knee joint conditions, especially following the ACL reconstruction (Briggs et al. 2009). In the last 5 years, over 500 articles cited in PubMed, have reported outcomes using the Lysholm score of perceived symptoms associated with knee injuries. For the reliability of Lysholm results of clinical trial
carried by Briggs et al. (2010) on group of clinical population is appraised in this section. This clinical trial was carried out on 1783 patients who had undergone ACL reconstruction between 1997 and 2005. Patients with multiple ligamentous injuries in the latter trial were excluded. All the patients in the latter trial filled Lysholm Knee Scoring Scale twice with a difference of 4 weeks’ time between them. An acceptable ICC>0.70 had been reported for the overall Lysholm Knee Scoring Scale (ICC = 0.94). There was an acceptable test-retest reliability for instability (ICC = 0.92), pain (ICC = 0.87), stair climbing (ICC = 0.75), limping (ICC = 0.86), locking (ICC = 0.77), swelling (ICC = 0.80) and squatting (ICC = 0.78). The MDC of 8.9 units based on the Lysholm Knee Scoring Scale had been reported in this trial.

Table 3.1: Table showing the number of participants for psychometric analysis of Lysholm

<table>
<thead>
<tr>
<th>Psychometric analyses</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>test-retest reliability</td>
<td>50</td>
</tr>
<tr>
<td>minimal detectable change</td>
<td>940</td>
</tr>
<tr>
<td>internal consistency</td>
<td>1783</td>
</tr>
<tr>
<td>content validity</td>
<td>1783</td>
</tr>
<tr>
<td>criterion validity</td>
<td>170</td>
</tr>
<tr>
<td>construct validity</td>
<td>1783</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>1075</td>
</tr>
</tbody>
</table>

3.1.4 KNEE SELF EFFICACY SCALE (K-SES)

A patient’s perceived self-efficacy of function plays a vital role in achieving optimal clinical outcomes for a rehabilitation programme following soft issue injuries (Crossman 2001). The same principle of maintaining high self-efficacy may be necessary to obtain optimal clinical outcomes for rehabilitation of a patients who has undergone ACL reconstruction (Evans and Hardy 2002). Moreover, it has been
reported in a randomised controlled trial that patients’ well-being following ACL reconstruction can be influenced by their perception to the clinical outcomes (Brewer et al. 2000). The K-SES was first reported in 2006 by Thomee et al. (2006) and was developed on the same principles of patients’ perception to their knee condition. The development of this new instrument was justified due to the fact that no instruments had previously been available to evaluate perceived self-efficacy for prognostic and outcomes expectations in patients with an ACL injury. This instrument consists of four sections; A (daily activities, seven items), B (sports activities, five items), C (physical activities, six items) and D (perceived future knee function, four items). The first three sections reports the present levels of perceived certainty for successfully participation of patients within the activities mentioned in those sections, while the fourth section reports the patients’ future perception of likely capability within the activities mentioned in the relevant section. The initial step in the development of this assessment tool comprised an extensive search of the literature that was followed by a brainstorming session amongst 12 physiotherapists, two orthopaedic doctors and two general practitioners to ensure good face validity. The development of K-SES is shown in Figure 3.2. The K-SES has been reported as being statistically responsive to the patients’ condition following ACL reconstruction. The findings of Thomee et al. (2006) had reported that a significant difference among test occasions was observed when patients with ACL reconstruction were assessed at present, 4 and 6 months of surgery. However, the authors in the later trial had reported no significant difference between 6 and 12 months.
Scoring the K-SES

The present K-SES comprised of four sections having a total of 22 items. The first three parts that measures the perception of patients’ present condition, has 7, 5, 6 items, respectively, while the fourth section, which measures patients’ perception of knee status in the future, has 4 items. Patients categorized their perceived ability to perform the tasks mentioned in these 22 items, by using an 11-point likert scale. The options provided in the questionnaires range from 0 to 10 whereas 0 means that the individual who is scoring his/her abilities is not certain at all about his/her ability to perform the task and 10 means that he/she is very certain about their ability to perform the task. The sum of item scores is then calculated and divided by the total number of items (Brand and Nyland 2009).
Reliability and validity of the K-SES

According to author’s knowledge, only one trial has reported reliability and validity of the K-SES. The reason for having limited evidence with regards to the reliability of validity of this assessment tool might be justified by the fact that it had been developed recently compared to other assessment tools used to for the knee joint. i.e. Lysholm in 1982, IKDC in 1987. In this section, evidence available from the latter trial had been critically appraised. According to authors of the latter trial the construct validity of the K-SES had been assessed by comparing its correlation with the Multidimensional Health Locus of Control (MHLC) (Wallston et al. 1978), the Coping Strategy Questionnaires (Rosenstiel and Keefe 1983) and the SF-36 (Ware and Sherbourne 1992). Moreover, its convergent validity (the fact that two measuring tools with similar constructs are closely correlated) was assessed by comparing it to the KOOS. To assess the test-retest reliability and internal consistency of the K-SES, a total of 18 and 104 participants were recruited, respectively, in the latter trial. The overall internal consistency of the form had been reported 0.94 by calculating Chronbach’s Alpha. In the latter trial, Chronbach’s Alpha scores of 0.94, 0.91, 0.92 and 0.78 were reported for daily activities, sports activities, knee functional activities and your knee function in the future, respectively.

3.1.5 7-DAY PHYSICAL ACTIVITY RECALL

The 7-Day Physical Activity Recall is an interviewed-administered inventory that estimates an individual’s time spent in physical activity, strength and flexibility activities for 7 days prior to the interview (Sallis et al. 1993). This interview-
administered measuring tool was designed to collect data regarding physical activity at the population level with low cost and in an easy way. Moreover, generally acceptable and easy understandable questions capturing physical activity of the participants were included in the 7-Day Physical Activity Recall. Physical activity is basically the behaviour that results in any bodily movement produced by the skeletal musculature which ultimately cost energy expenditure in the human body (Casperson 1985). Physical activity of an individual includes functioning of all large muscles’ group needed for any performing any purposeful movement in day-to-day life (Bauman et al. 2006). It has been observed that physical activity of an individual varies from day to day, therefore, several days records are needed to provide a representative sample of the amount of activities carried out by an individual (Blair et al. 1985). While filling this inventory, the patients are asked to report specific activities with the perceived intensity. For example, participants are asked to estimate the number of hours spent during the last week in sleep, moderate, hard and very hard physical activity. This method is applicable for an estimate of energy expenditure according to the guideline reported in the literature. The physical-recall interview might be conducted in person by asking the patients to report the amount of physical activity performed during the last week (Hayden-Wade et al. 2003). Moreover, in case of unavailability of the patients in person, the seven-day physical recall may be completed by collecting information from the patients by any other sort of communication: telephone, emails etc.

**Calculations of Metabolic Equivalents (METs) from 7-day Physical Activity Recall**

The number of hours spent during different activities reported in seven-day physical recall was obtained. Time spent in sleep (1 MET), light (1.5METs), moderate (4
METs), hard (6 METs), and very hard (10 METs) activities for the past 7 days were multiplied by their respective MET values and then summated (Sallis et al. 1993). An estimate of total kilocalories of energy expenditure per day was calculated, as in the following example.

Example (adapted from Sallis et al. 1993)

*Data from the 7-Day physical activity recall:*

Sleep: 60.0 h X 1 MET = 60 kcal/kg

Light: 99.5 h X 1.5 METs = 149 kcal/kg

Moderate: 3.5 h X 4 METs = 14 kcal/kg

Hard: 2.5 h X 6 METs = 15 kcal/kg

Very Hard: 2.5 h X 10 METs = 25 kcal/kg

Total weekly energy expenditure = 263 kcal/kg/wk

Total daily energy expenditure = 263 kcal/kg/wk ÷ 7 d/wk = 37.8 kcal/kg/d

For a 70-kg individual: 37.8 kcal/kg/d × 70 kg = 2646 kcal/d

*Validity and reliability of the seven-day physical recall*

The 7-Day Physical Activity Recall has been reported valid and reliable (Gross et al. 1990). Its validity has been previously tested against objective measures, the doubly-labelled water technique and accelerometers in small sample trials (Adams et al. 2005, Dubbert et al. 2004). Findings of these trials have suggested that the 7-Day Physical Activity Recall was a valid mean for measuring physical activity of an individual. In this section of thesis, findings of a recent large scale cross-sectional trial by Zuazagoitia et al. (2012) was appraised for validity and reliability of the of
the 7-Day physical activity recall. The latter clinical trial was carried out on 260 participants who had already participated in the physical activity promotion during from March 2008 to May 2009. Participants who were involved in swimming or cycling or such activities that could not be measured by accelerometer were excluded from this trial. The 7-Day Physical Activity Recall was used to assess the time spent by participants on leisure and occupational physical activity, in bouts of more than 10-minutes, and the intensity of that activity, for the 7 days prior to the interview. The total amount of energy expenditure subjectively reported through 7-Day Physical Activity Recall was computed using the guidelines reported in the literature (Sallis et al. 1992). Objective data regarding physical activity, during the period when subjective data was collected, was acquired from the RT3 tri-axial accelerometer. The RT3 tri-axial accelerometer had been reported a reliable measuring tool for collecting minute-by-minute data on three orthogonal axes and providing one total movement score from all planes of movement. Moreover, the accelerometer provided sum of total amount of calories burnt for every minute while performing physical activity. Findings of this trial has suggested that the subsections regarding mild, moderate and vigorous activities has been reliable (ICC: 0.92, 0.92 and 0.96, respectively). Moreover, a significant correlation between the METs computed from 7-Day Physical Activity Recall and accelerometer scores, confirmed convergent validity of the 7-Day Physical Activity Recall. This indicated that the 7-Day Physical Activity Recall was a valid and reliable source for assessing the amount energy expenditure for the physical activity.
Table 3.2: Table showing clinimetric characteristics of the selected PROMs for knee conditions

<table>
<thead>
<tr>
<th>measure</th>
<th>patients cohort evaluated</th>
<th>internal consistency</th>
<th>ICC</th>
<th>MDC</th>
<th>SEM</th>
<th>effect size</th>
<th>MCID</th>
</tr>
</thead>
<tbody>
<tr>
<td>IKDC</td>
<td>Knee injuries (ACL, meniscal, chondral) Cohort of mixed knee pathologies</td>
<td>0.77-0.91 0.92-0.97</td>
<td>0.90-0.95 0.87-0.99</td>
<td>8.8-15.6 6.7</td>
<td>3.2-5.6 2.4-4.6</td>
<td>2.11 at 12 months 0.76 at 6 months</td>
<td>6.3 at 6 months 16.7 at 12 months 1.13 at 6-28 months 11.5 at 6-28 months</td>
</tr>
<tr>
<td>KOOS</td>
<td>Knee injuries</td>
<td>pain = 0.84-0.91 symptom = 0.25-0.75 ADL = 0.94-0.96 sport/rec = 0.85-0.89 QoL = 0.64-0.90</td>
<td>0.85-0.93 0.83-0.95 0.75-0.91 0.61-0.89 0.83-0.91</td>
<td>6.0-6.1 5.0-8.5 7.0-8.0 5.8-12.0 7.0-7.2</td>
<td>2.1 3.2 2.9 2.1 2.6</td>
<td>1.11 0.93 0.67 0.9 1.15</td>
<td></td>
</tr>
<tr>
<td>KOOS</td>
<td>Knee OA</td>
<td>pain = 0.65-0.94 symptom = 0.56-0.83 ADL = 0.78-0.97 sport/rec = 0.84-0.98 QoL = 0.71-0.85</td>
<td>0.80-0.97 0.74-0.94 0.84-0.94 0.65-0.92 0.60-0.91</td>
<td>13.4 15.5 15.4 19.6 21.1</td>
<td>7.2-10.1 7.2-9.0 5.2-11.7 9.0-24.6 7.8-10.8</td>
<td>1.08 0.97 1.07 0.79 0.78</td>
<td></td>
</tr>
<tr>
<td>Lysholm</td>
<td>Knee injuries (ACL, meniscal, chondral)</td>
<td>0.65-0.73</td>
<td>0.88-0.97</td>
<td>8.9-10.1</td>
<td>3.2-3.6</td>
<td>1.01</td>
<td></td>
</tr>
<tr>
<td>K-SES</td>
<td>ACL</td>
<td>daily activities = 0.94 sport activities = 0.91 knee functional activities = 0.92 knee function in future = 0.78</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.2 OBJECTIVE MEASURES

A variety of tools and procedures that can measure patients’ generic and disease-specific conditions subjectively and objectively have been reported in the literature (Asadi-Lari et al. 2004). The use of these assessment procedures and tools might be regarded essential for the patients who are actively involved in sporting activities and who sustain ACL-injury. A comprehensive assessment of these patients is crucial before advocating their safe return to their specific sporting activities. A comprehensive appraisal of subjective assessment tools used for the assessment of patients who have undergone ACL reconstruction has been given in the previous sections of this thesis. In this part of the thesis, factors that can be assessed objectively following ACL reconstruction have been considered and critically-appraised.

3.2.1 PEAK FORCE

The ability of muscles around the knee joint to respond to an internal or an external stimulus in the form of activation and inhibition enable the latter to play a vital role in the stability of knee joint (Shultz and Perrin 1999). It has been established in the literature that the main role of the ACL, is to restrain the anterior translation of the tibia relative to the femur, and is supported by the combined action of flexor musculature of the knee in protecting the ACL as well as the compensation for the loss of stability in the ACL-deficient knee (Ageberg 2002). Similarly, weakness or low coactivity of the latter musculature in reaction to quadriceps activation is associated with a high-risk of ACL injuries (Ageberg et al. 2009). Moreover, conflicting data regarding voluntary deficit in the peak force of knee muscles
especially of the quadriceps had been reported in the literature (Stevens et al. 2003). Assessment of estimates of strength such as peak force or peak force of muscles around the knee joint for the patients who have undergone ACL reconstruction is commonly used before advocating the safe return of these patients to high demanding activities (Gleeson and Mercer 1996, Minshull et al. 2009, Risberg et al. 2004). To justify the inclusion of peak force strength assessment for flexors and extensors muscle groups of the knee joint in this prospective clinical trial, a critical appraisal of the literature on the role of these muscles within the ACL-injuries has been discussed in this section. For the latter purpose, the work of Beynnon and colleagues has been critically appraised as it examined ACL in vivo through a series of studies (Beynnon and Fleming 1998, Beynnon et al. 1995, Fleming et al. 2001, Fleming et al. 2003). In 1998 a detailed overview of the mentioned authors was reported where they had arthroscopically implanted transducers onto the anterior bundle of the intact ACL’s of volunteers who already were candidate for diagnostic arthroscopic surgery (Beynnon and Fleming 1998). Following the latter process of implantation, evaluation of ACL in-vivo strain while volunteers performed various rehabilitation activities including isolated and combined contraction of the flexors and the extensors musculature of the knee joint, had been reported. It was found that ACL had sustained high strain at any position of the knee joint when the angle of flexion was less than 30°. Moreover, the highest ACL strain produced due to the isometric muscle contraction of quadriceps (4.4%), was reported at 15° of the knee flexion. The latter action was followed by co-contraction of hamstrings muscle group and resulting in a decreased ACL strain to (2.8%). In the latter trial, it was reported that contraction of the quadriceps especially at low flexion knee angle (less
than 30°), increased the ACL strain to such an extent that it might become an ultimate cause of its rupture. In previous trials, an inverse relation of strain to ACL caused by hamstrings strain with flexion angle of knee joint had been reported. i.e. greater strain due to the hamstrings is caused in smaller angle of flexion in the knee joint and vice versa. However, the contraction of these muscles around the knee joint sometimes might be beneficial by increasing stiffness in the knee joint which play important role in protective mechanism of ACL injuries by reducing the percentage of external force to be resisted by the ACL and other knee structures during movement (Wojtys et al. 2002). It has been documented that patients with ACL injuries or even reconstruction have shown inferior results on peak force to body mass ratio when compared to the non-injured population (Pinciviero et al. 2002). Moreover, there is plethora in the literature, suggesting bone-patellar bone-tendon graft (BPBT) for ACL reconstruction had shown inferior results in extensors muscle of knee and patients with hamstrings tendon graft had shown inferior results in the flexor group of muscle of the knee joint (Dauty et al. 2005). In prospective clinical trial within this thesis (chapter 7), peak torques of both flexor and extensor muscle groups of knee joint have been assessed using dynamometry. The clinimetric utility of using estimates of strength in adult populations is relatively well-established (Gleeson et al. 2008, Minshull et al. 2009). A recent trial of the single-measurement reliability and reproducibility of patients with ACL-injury undergoing surgery and rehabilitation (appendix I) endorses the assessment of strength in this thesis (ICC>0.87; V %< 4.5% (68% confidence limits) since it is likely to offer appropriate MDC and responsiveness.
3.2.2 RATE OF FORCE DEVELOPMENT

Rate of force development measures how fast the force or force output rise in movements of muscle group in specific duration of time (Aagaard et al. 2002). It is an important strength parameter which plays a vital role in determining functional capabilities of patients (Angelozzi et al. 2012). For instance, one of the criteria for assessing someone’s readiness is the ability to reach at least 80-85% of the maximal strength of the uninjured knee side. In terms of explosive muscle actions, the duration of activating maximal muscle strength (300 milliseconds) is longer than the duration required for muscle to develop muscular strength (0-200 milliseconds) in either daily functional activities or sporting activities (Angelozzi et al. 2012). If delayed, the shorter time required in RFD for muscular contraction may have serious consequences and compromises the stability of joint which ultimately contribute to the cause of neuromuscular injury (Mebes et al. 2008). Similarly, the important role of rate of force development of both hamstrings and quadriceps in athletic and non-athletic population following ACL injuries might be explained in how this estimate is responsible for producing explosive and non-explosive type of muscle action. For this purpose the research of Hoff et al. (2002) has been appraised in this section. This trial was carried on the 19 cross-country skiers which were allocated to two groups; control group and high resistance training group. Participants in the control group were advised to follow a contemporary strength programme while participants in high resistance training group followed same strength training programme with added activities designed to improve endurance that were believed to improve the rate of force development. All participants of the latter trial received 8 weeks training programme. Participants were tested two days before and after the training
Participants in this trial were aware of the training programme however, they were kept blinded to the hypothesis of the trial. Findings of this trial had revealed that participants who attended endurance training along with resistance training extra resistive programme had significantly improved in 1 repetition maximum and rate of force development. Authors in the latter trial had used ‘time to peak force’ for the rate of force development. These findings might be generalised for other activities where rapid rather than maximal production of force is required. The inclusion of this variable therefore might contribute to the robustness of the criteria used in determining patient’s readiness to resume normal daily and functional activities.

Different methods had been reported regarding measuring rate of force development. i.e. rate of force development is based on 25%-75% peak force (Gleeson et al. 2008), rate of force development determined from 0-30, 0-50, 0-100 and 0-200 ms (Aagaard et al. 2002). Despite variation in selecting different zones for calculating rate of force development in both the above mentioned trials, rate of force development is calculated based on the moment-time curve (moment/time). In this prospective trial, the method used by Gleeson et al. (2008) has been used to evaluate rate of force development. A detailed method on how to calculated rate of force development has been discussed in ‘methods’ section of chapter 7 of this thesis.

3.2.3 ELECTROMECHANICAL DELAY

The electromechanical delay refers to time delay between the onset of muscle activation and external force development in the skeletal muscles (Zhou et al. 1998). It had been reported that electromechanical delay comprised of two important
processes; electro-chemical and mechanical processes (Lacourpaille et al. 2013). According to authors of the later trial the electro-chemical process consists of series of changes that results from alteration in the concentration of certain chemicals at cellular level. These changes results into synaptic transmission, propagation of the action potential and excitation contraction coupling. On the other hand, the mechanical process might be seen in the form of force transmission along with active and passive part of the series of components. The concept of electromechanical delay had been reported in the early 1950 when Inman et al. (1952) observed a delay of 80 ± 20 ms between the peak muscle force and the apparent peak in the rectified and smoothed Electromyography (EMG) from cineplastic amputees while performing isometric contraction. In 1974 Corser recorded surface EMG,s from the flexors and extensors of the forearm during various forearm movement and reported a delay of 25 to 75 ms between the onset of EMG and the onset of movement. In 1979 Norman and Komi reported electromechanical delay for biceps and triceps and it was found that electromechanical delay for these groups of muscles might range from 41 ± 13 and 26 ± 11, respectively. The significance of assessing electromechanical delay in knee rehabilitation programme following ACL reconstruction is obvious from its association with neuromuscular performances (Minshull et al. 2012). As a neuromuscular performance and a component of the stretch reflex, electromechanical delay can play an important role in neuromuscular reaction time which is required during forces of unrestricted development and sufficient magnitude capable of damaging ligamentous tissue in synovial joints (Gleeson et al. 2002). Following ACL reconstruction, harvesting of either muscle the hamstrings or the quadriceps results in development of scar tissue around the
graft-harvested area. Previous studies had shown that the scar tissue development might prolong the reaction time of muscles fibres to sudden stimulus and might result a prolong electromechanical delay (Kaneko et al. 2002). This prolonged reaction time to stimulus is believed to be due to many factors (Georgoulis et al. 2005). i.e., impaired proprioception in knee joint after ACL reconstruction, increased elasticity in series elastic component of the muscle harvested for the surgery and prolonged processing interval in central nervous system. A wide range of absolute electromechanical delay (30 and 100 milliseconds) had been reported for the same muscles under different physiological conditions (Gleeson et al. 2008, Zhou et al. 1998). Similarly, the impact of ACL surgery in electromechanical delay prolongation is controversial. Two examples have been discussed in the regard.

The first example included is a clinical trial which was carried out by Georgoulis et al. (2005) on seventeen participants who had undergone ACL reconstruction. All these participants were divided into two groups; group ‘A’ and group ‘B’. Classification of these patients into two groups was done based on the injury to surgery time of the participants. Similar method has been reported by in other clinical trials carried out on the ACL reconstruction (Moebius et al. 2001). All participants in this trial underwent the same surgical procedure carried out by the same orthopaedic surgeon. Moreover, the same rehabilitation programme was followed by all participants following reconstructive surgery. Injured and non-injured legs of the participants were evaluated for electromechanical delay differences between both groups. No significance differences between injured and non-injured legs in electromechanical delay was observed in the trial. Another example included in this section is case control trial carried out by Ristanis et al.
(2009) on clinical population who underwent ACL reconstructive surgery. According to the authors of the latter trial 12-control participants who underwent ACL reconstruction were matched with 12 reconstructed patients for gender, age, height, mass and physical activity. All patients had undergone similar surgical technique and had followed the same rehabilitation programme. All participants in both groups were assessed by same clinician. Final findings of this trial had suggested that all patients in ACL reconstruction group were satisfied with the outcomes of the surgery and had returned to their previous athletic activities. Findings of this trial had revealed that electromechanical delay of muscles around the operated knee joint was significantly higher compared to the muscles around the intact contralateral knee. This increased in electromechanical delay had been hypothesised due to the harvesting of the muscles for reconstruction of ACL graft. Similar finding of an increase in electromechanical delay has been reported by Kaneko et al. (2002) in a clinical trial when electromechanical delay for the extensor musculature of both injured and non-injured knee was compared in a clinical population who had undergone ACL reconstruction. Evidence from clinical trials carried out on medical conditions other than knee joint has reported similar response of an increase in electromechanical delay following surgical intervention. Electromechanical delay of the knee musculatures may be associated with a variety of intrinsic and extrinsic factors including the time course of propagation of action potential on muscle membrane, the excitation-contraction coupling process and the stretching of the series elastic component by the contractile element (Cavanagh et al. 1979). In case of ACL reconstructive surgery, as either the hamstrings or the quadriceps muscles being a donor site are subjected to harvesting, scar tissue around
the graft-harvested might be responsible for prolonging the reaction time, resulting into an increase in the electromechanical delay in the effected musculature. Moreover, the adverse effects of deconditioning in the effected musculature might be another factor causing an increase in electromechanical delay in the knee musculature following ACL reconstruction.

3.2.4 KNEE LAXITY

It has been established that ACL limits anterior translation of the tibia on the femur and the assessment of anterior posterior knee laxity is often considered the gold standard in determining outcomes of the ACL reconstruction (Paterno et al. 2012). Moreover, due to individual variations reported in the knee laxity assessment, side-to-side difference in anterior posterior knee laxity is considered more reliable for the surgeons to evaluate the outcomes of the reconstruction (Bizzini et al. 2006, Ferrari et al. 2001). Despite the latter preference of surgeons’ choices controversies regarding the difference between laxity of right and left legs of an individual had been reported in the literature (Daniel et al. 1985). In this part of thesis a review by Paterno et al. (2012) has been critically appraised regarding the laxity of the knee joint following ACL reconstruction. The latter review had been designed to answer some of the key questions with regards to laxity of the knee joint following ACL reconstruction. i.e. to report side-to-side difference between both right and left legs, difference between the laxity of knee joint of males and female, difference between the knee laxity among clinical population whose ACLs have been reconstructed by using either of the two grafts (BPBT or hamstring). Out of the 11 studies included in the review, six trials had reported laxity of the knee joint in clinical populations who
had undergone the ACL reconstruction with hamstrings or bone-patella bone tendon graft, three of the included trials had reported the outcomes of BPBT graft between the males and females and two of the trials had reported a comparison between males and females who had undergone ACL reconstruction using the hamstrings graft. Four of the studies included in this trial had reported that females who underwent the hamstrings graft had shown a significant side-to-side difference while there was no side-to-side difference for the counterpart males who had undergone the same surgical method. None of the six studies had found a significant side-to-side difference between males and females when BPBT was used as graft for the ACL reconstruction. However, a significant difference in knee laxity of males and females population had been reported when hamstrings graft was used during ACL reconstruction. Similar findings of increased knee laxity following ACL reconstruction by hamstrings graft had been reported in the literature (Biau et al. 2009). These findings underpin an important point that asymmetries in the anterior posterior knee laxity are greater following a hamstrings graft for ACL reconstruction than with a BPBT graft in female population. These findings might be interested for the clinician while deciding about the graft choice for female population. The authors of this review had suggested that a difference of 2-5 mm of side-to-side in anterior-posterior knee laxity might be still used to day to define that arthrometric failure of the surgery.

**Reliability of the of objective measures**

Frequent use of dynamometers for data acquisition of the indices of neuromuscular and sensorimotor performances of the knee joint has been reported in the literature (Gleeson and Mercer 1996). These indices which include peak force, rate of force
development and electromechanical delay, are regarded reliable indicators for the assessment of the dynamic capabilities in knee joint (Minshull et al. 2009, Hartmann et al. 2009). Precise quantification of the latter indices by means of reliable measures is considered extremely important for clinical evaluation, decision making and prediction of functional capabilities of the knee joint (Gagnon et al. 2005). Some of the above mentioned indices such as peak force for both the flexor and extensor musculatures around knee joint, assessed by isokinetic dynamometers, have been reported critical for investigating functional status in different plural (Hartmann et al. 2009). Extensive scrutiny of the latter in the scientific literature of for their characteristics of reproducibility and reliability had been carried out in previous clinical trials (Gleeson and Mercer 1992, Gleeson and Mercer 1996, Minshull et al. 2009, Gleeson et al. 2002). However, many of them, such as electromechanical delay, rate of force development and sensorimotor performance still need comprehensive scrutinising due to the availability of limited evidence regarding the reliability and reproducibility of these indices. This was the principal reason for justifying the inclusion of a section of the thesis detailing the reproducibility and reliability of outcome measures (please see appendix I).

3.3 FUNCTIONAL TESTS

A consensus regarding the importance of using a variety of functional tests following ACL reconstruction might be seen in the literature (Hopper et al. 2003). It is believed that these tests assess an individual ability to tolerate the physical demands inherent to their specific sporting activities or activities of daily living (Clark 2001). A variety of functional tests assessing the present knee condition following the ACL
injuries had been reported. i.e. squatting, jumping and duck waddling (Marshall et al. 1977), hopping and duck waddling (Jensen et al. 1985), Figure of eight, hop for distance, spiral staircase run, and indoor slope run (Lysholm and Gillquist 1982). Despite the fact that a large number of these tests might be useful for assessing the present condition of knee joint, nevertheless, the use of valid and reliable functional tests for clinician is important in assessing functional capabilities including strength, flexibility, power, balance, change of direction and motor control of an individual to be assessed (Clark 2001). To appraise the available literature on the use of functional test for knee joint following ACL injuries, the study of Noyes et al. (1985) had been highlighted in the coming section. In the latter clinical trial a total of ninety three patients were evaluated for assessment of five functional tests included single-leg hop for distance, single-leg hop vertical jump, single-leg timed hop, shuttle run (no pivot), and shuttle run (pivot). For single-leg hop, patients were asked to stand one leg and hop as far as possible and land on the same leg. Each limb was tested twice for single-leg hop. Limb symmetry index for single-leg hop was calculated by the dividing mean of hop of affected leg by mean of hop of unaffected leg and by multiplying the outcome by 100. For single-leg vertical hop, patients were asked to stand on one leg and touch the wall by jumping off the ground. Chalks were applied to the fingers of the patients to measures the distance. For single-leg timed hop, patients were asked to run through a distance of 6 meter as fast as possible by hoping on one leg. The time taken by patients to run the latter distance was recorded to the nearest one hundredth of a second. The shuttle run test was performed with or without pivot. Patients in shuttle run without pivot were asked to run a distance of 6 meters course. Cones were place at both ends of the course. Patients were asked to
keep the designated limb towards inside of the course. Each patients completed a one-half-speed trial run for both injured and non-injured leg. Patients then completed two laps on each limb. For the shuttle run with pivot patients were asked to run through the same distance from point ‘A’ to ‘B’ while they were supposed to perform a sudden deceleration, turning back, pivoting and accelerated movement to reach back to point ‘A’. Findings of this trial had suggested that two of the hop tests (single-leg hop for distance and single-leg hop for time) achieved an 85% (15 ± difference between both injured and non-injured limbs) symmetry index for 92% and 93%, respectively, of the population in the trial. In contrary single-leg vertical hop, showed inferior results whereas only 69% of the population achieved a limb symmetry index of 85%.

**Reliability of single-leg hop test**

It is obvious from the literature that single-leg hop for distance had been used extensively for assessing patients with ACL injuries. In this section of reliability of single-leg hop for distance, the study of Reid et al. (2007) has been appraised. The latter trial was carried out on 42 participants who had undergone ACL reconstruction. Each participants in the trial performed 4 single-leg hop tests for distance and then completed self-reported questionnaires. Subjects were kept blinded to their hop test scores. Patients were tested three times within 16 weeks following reconstruction of ACL. A minimum of 24 hours between 2 test occasions were allocated. The purpose of first test occasion was to allow participants to learn the motor skills while the second and third occasions were intended to evaluate test-retest reliability of the hop test. The final occasion (fourth occasion) took place 6 weeks later and was used to evaluate longitudinal validity. It was reported in this
trial, that single-leg hop for distance had achieved a reliable functional assessment test with an Intraclass correlation coefficient ranged from 0.82 to 0.93, standard error of measurement 3.04 % to 5.59%. The minimal detectable changes (at 95% confidence level) for single-leg hop test on the operative leg had been reported significantly higher than non-operative leg (5.05% to 12.96%, respectively). Authors in this trial had used four types of hop tests; single-leg hop, 6-meter hop, triple hop and crossover hop test. Clinimetrics associated with the latter hop tests is shown in Table 3.3.

Table 3.3: Table showing reliability of hop tests

<table>
<thead>
<tr>
<th>Limb symmetry index</th>
<th>ICC (95% CI)</th>
<th>SEM (%) (95% CI)</th>
<th>Error in individual’s score (%)</th>
<th>Minimal detectable change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-leg hop</td>
<td>0.72-0.92</td>
<td>2.61-4.37</td>
<td>±5.72</td>
<td>±8.09</td>
</tr>
<tr>
<td>6-m timed hop</td>
<td>0.58-0.82</td>
<td>4.17-7.01</td>
<td>±9.17</td>
<td>±12.96</td>
</tr>
<tr>
<td>Triple hop</td>
<td>0.72-0.88</td>
<td>3.12-5.41</td>
<td>±7.08</td>
<td>±10.02</td>
</tr>
<tr>
<td>Cross over hop</td>
<td>0.64-0.84</td>
<td>3.94-6.62</td>
<td>±8.66</td>
<td>±12.25</td>
</tr>
<tr>
<td>combination of hop</td>
<td>0.85-0.93</td>
<td>2.27-3.81</td>
<td>±4.99</td>
<td>±7.05</td>
</tr>
</tbody>
</table>

ICC    Intra-class correlation coefficient
SEM    Standard error of measurement
4 CHAPTER: METHODS
OUTLINES OF THIS CHAPTER

This chapter set out to report generic methodology adopted during this research. Ethical approvals, inclusion criteria, exclusion criteria, recruitment of participants for this research, general overview about the number of the participants and information about the data protection were discussed in this chapter.

Section 4.1 Research design
Section 4.2 Recruitment of participants
Section 4.3 Inclusion criteria
Section 4.4 Exclusion criteria
Section 4.5 Ethical Approval
Section 4.6 Informed consent
Section 4.7 Data protection
Section 4.8 Indemnity
4.1 RESEARCH DESIGN

Specific methodologies adopted for each trial has been given in ‘methods’ section of each trial. The focus of this chapter was to report a generic overview of the methods adopted for all trials included in this thesis. To evaluate the effects of the environment and the levels of supervision from rehabilitation team on the final outcomes of rehabilitation following ACL reconstruction, two prospective clinical trials [trial I; (chapter 5) and Trial II (Chapters 6 and 7)] were designed. In the first clinical trial, a comparison between the hospital- and the community-based rehabilitation programmes was carried out on PROMs amongst the clinical population who had undergone ACL reconstructive surgery at the Robert Jones and Agnes Hunt Orthopaedic hospital, NHS trust Oswestry. For the latter purpose, all the patients who were willing to participate in this research self-allocated themselves into the hospital- and the community-based rehabilitation groups. This method of self-selection was adopted due to geographical location of the hospital. The hospital is situated in a small town and due to its well reputation with regards to ACL treatment patients are referred from distant areas within the UK. Following this criterion of self-selection in this part of trial has resulted a quasi-experimental design in the first prospective trial. The quasi-experiment is a clinical trial that includes a manipulated independent variable but lacks the important controls (random allocation of participants into groups) or a study that lacks a manipulated independent variable but includes important control. In the first trial, randomization of the patients into the hospital- and the community-based rehabilitation programmes has not been done due to the logistical infeasibility and ethical issue related to the random allocation of the patients into either of both the groups. The quasi-
experimental design, except random allocation or control, ensures every characteristic of randomised controlled trial. Despite some obvious limitations such as lack of randomisation in this design, still in many circumstances where randomisation is not logistical feasible or not ethical, designs like quasi-experimental had been reported a preferred method for evaluation of clinical populations (Glasziou et al. 2007, Harris et al. 2004). Moreover, it is well known fact that to get robust findings often in a research, a combination of randomized and non-randomised controlled trials had been reported in the literature (Panter and Sterba 2011). In the first trial of this thesis, the patients in the hospital-based rehabilitation programme followed a well-established rehabilitation programme in the hospital under the supervision of physiotherapists, while the patients in the community-based rehabilitation were guided to self-manage the same rehabilitation programme in the community without supervision from the physiotherapists. To ensure that the patients in the community-based rehabilitation programme have access to full information regarding the contemporary rehabilitation programme at the hospital, a template containing comprehensive guidance regarding the latter rehabilitation programme was provided to each participants in the community-based rehabilitation programme. Moreover, every participants in the community-based rehabilitation programme attended a supervised physiotherapy sessions before surgery and on 6th and 12th and 24th weeks following reconstructive surgery. During these sessions, patients were provided comprehensive guidance regarding self-managing of conditioning programme in the community until the next supervised physiotherapy session. From ethical point of view, the patients in this group had been informed that they had the rights to attend more supervised physiotherapy sessions any time during
the rehabilitation, if they wanted to continue the contemporary rehabilitation programme in the hospital rather than the community-based rehabilitation programme.

In the second clinical trials of this thesis, all participants in the hospital-based rehabilitation group were randomly allocated into two further subgroups (please see Figure 4.1). One of the latter two groups within the hospital was named ‘fully-supervised rehabilitation group’ while the other rehabilitation group was named ‘minimally-supervised rehabilitation group’. According to author’s knowledge, supervision during rehabilitation programme has not been clearly defined in the literature. The patients coming to the hospital for rehabilitation programme are guided by the physiotherapists to the rehabilitation activities and the presence of physiotherapists in these physiotherapy sessions had been termed as ‘supervision’ (Gram et al. 2014). However, during discussion with the rehabilitation team in the hospital it was revealed that regular interaction amongst the physiotherapists and the patients in the form of feedback, modification in the intensity and volume of dose were integral parts of fully-supervised physiotherapy sessions in the hospital. Based on the evidence from the literature and after discussion with the physiotherapists in the hospital, full supervision during the rehabilitation sessions (supervised physiotherapy sessions) was operationally defined as the process of monitoring and directing from physiotherapists during physiotherapy sessions in which the patients activities are closely monitored and altered in term of intensity and volume of exercises, if needed. The latter approach during the supervised rehabilitation sessions was adopted for all the patients in the fully-supervised rehabilitation group. On the other hand, the patients in the minimally-supervised rehabilitation group were
guided to the same exercises (suggested to the patients in the fully-supervised rehabilitation group) and were advised to continue these activities in the hospital gymnasium without being provided feedback from the physiotherapists is in the hospital.

Figure 4.1: Figure showing design for the clinical trials reported in this thesis.

4.2 RECRUITMENT OF PARTICIPANTS

Initially, a list detailing potential participants and contact details was extracted from the hospital database. The list was compiled using ‘Bluespier’ software that allowed registered clinical users access to the hospital operation theatre listings. Only patients waiting for ACL reconstruction were included in this initial list. All
potential participants were invited to participate in this research by making them phone calls or sending them emails. Relevant information about the research either were given during discussion on the phone or were sent by emails to the potential participants. For the latter purpose, a ‘standardised invitation email’ containing detailed information about this clinical trial was forwarded to all potential participants. Moreover, an information pack that contains the participants’ information sheet, protocol sheet and informed consents was sent to potential participants electronically or were handed over during their visits to the hospital. All potential participants had at least one week in which to decide to participate or not participate in this research study. A total of 100 patients were contacted for this clinical research. Out of the 100 patients contacted for this trial, 24 were unwilling to participate in this trial. The most often cited reason for a patients not being willing to participate was personal commitments preventing his/her complete availability for the programme of assessments. Moreover, as this hospital is specialised in ACL reconstructive surgery, therefore, patients were coming for far long distances and a regular follow-up of the rehabilitation programme at this hospital was not feasible for some of them. Nevertheless, a recruitment rate of 76% represented a robust response for this research. Out of 76 patients who showed their willingness to participate this trial, 48 (64% of the willing patients) self-allocated themselves into the hospital-based rehabilitation group while the remaining 28 (36%) patients preferred to follow the same rehabilitation programme in the community without supervision from the rehabilitation team. The patients in the hospital-based rehabilitation group (n = 48) were randomly allocated into further two subgroups; fully-supervised rehabilitation group (n = 24, 50% of the hospital-based rehabilitation group) and minimally-
supervised rehabilitation group (n = 24, 50% of the hospital-based rehabilitation group) (please see Figure 4.2).

Figure 4.2: Figure showing recruitment of patients for this clinical trial.
4.3 **INCLUSION CRITERIA**

All willing participants fulfilling the below criteria were included in this research.

- Aged 16 and above to ensure the musculoskeletal maturity
- Participants who were able to attend all prearranged physiotherapy sessions.
- Both genders (male and female) were eligible for this research
- No limits to race
- Participants who had no other physical or mental impairment that would have limited their participation in a physical rehabilitation programme
- Participants who had the capability to fully understand the implications of the research study and had volunteered to take part on the understanding that they may leave the study at any time without giving a reason and without this affecting their treatment in any way

4.4 **EXCLUSION CRITERIA**

Subjects were excluded from the trial following into one the below categories.

- Participants who don’t meet the surgeon’s criteria for ACL reconstruction
- Aged below 16 years (due to concerns with regards to biological immaturity of musculoskeletal systems)
- Participants with mental or physical immaturity that might limit or alter the standard post-operative rehabilitation
- Participants who could not attend all the stipulated physiotherapy session within his/her rehabilitation programme
4.5 ETHICAL APPROVAL

This study was reviewed and given a favourable ethical opinion by the National Health Service Staffordshire Research Ethics Committee (Research Ethics Committee No; 11/WM/0418) (please see appendix IV) and Research and development Robert Jones and Agnes Hunt Orthopaedic Hospital, NHS trust, Oswestry (R&D/CLRN Reference; RL1 509) (please see appendix V).

4.6 INFORMED CONSENT

Participation in this research was entirely on voluntary basis. Written informed consents were obtained from all participants before recruiting them into this research. All participants were told that they could withdraw at any point from this research without giving any reason and it will not affect their contemporary rehabilitation programme (please see appendix VI).

4.7 DATA PROTECTION

A 'master copy' of individual identification numbers unique to each participants was stored in a safe place on site and was accessible only to the named key investigators/collaborators. This identification number corresponded with the participant’s personal details and any participants information material and consent forms. This number was used throughout the research of the study to correspond with any scientific data collected, no personal and identifying information were used. All data was collected by the chief investigator throughout the study, access to data was only to the key investigators and associated collaborators.
Data was collated and stored electronically on the designated research laptop hard drive and back-up discs. The laptop and back-up discs were password protected, including the master copy of participants identification numbers (stored in a separate secure location within the physiotherapy clinic). Patients’ confidentiality was paramount during the dissemination of findings and submission of manuscripts for publication. The published literature did not include any names other than basic demographic data e.g. subject number, age, sex, height etc. Written documentation and data were also stored in a paper format in the participant’s medical notes as per normal clinical practice.

The storage and subsequent destruction of data are compliant with the Data Protection Act 1998. Written documentation and data have been stored in a paper format in the participants’ medical notes as per normal clinical practice. These will be destroyed after 8 years following discharge as per the health care records policy at Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry. All forms of data were securely kept in locked cabinets within locked rooms. Only the principal investigators and associated members had permission to use and access. All information that was collected during the course of the research were kept strictly confidential. Any information that could leave the hospital, patients name and addresses were removed to ensure to ensure anonymity.

4.8 INDEMNITY

Queen Margaret University, Edinburgh as an academic sponsors for this PhD programme has taken responsibility and offered indemnity cover (Confirmation of Insurance, Marsh Ltd, Queen Margaret University, Edinburgh and Subsidiary
Companies; Insurer: RSA, Insurance Certificate RTT153481, Public Liability 20M) for any harm that might come to a participants as a result of the design and management of each day. Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry foundation have taken similar responsibility for issuers arising from the conduct of research including the supervision of PhD candidate and any harm that might come to them while they are working with the hospital patients. Furthermore, Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry have taken the responsibility for the patients’ welfare in the all other aspects of their routine care.
5 CHAPTER: TRIAL I

COMPARISON OF THE HOSPITAL- AND THE
COMMUNITY-BASED REHABILITATION
PROGRAMMES ON PROMS IN A COHORT OF
PATIENTS WHO HAD UNDERGONE ACL
RECONSTRUCTION
SUMMARY OF THIS CHAPTER

The available literature is limited in some aspects of the community-based rehabilitation programmes following ACL reconstruction. The role of habitual levels of physical activities in the community (which go parallel with the conditioning programme in the hospital), orthopaedically-relevant factors (potentially influencing the final outcomes of the rehabilitation programme) and determinants of rehabilitation programme (that can be used as predictors for the final outcomes) following ACL reconstruction have received little attention amongst the patients receiving rehabilitation programmes at two different environments (hospital and community). Therefore, this clinical trial was designed to compare the effects of the hospital- and the community-based rehabilitation programmes in the patients undergoing ACL reconstruction on PROMs. A total of 76 patients undergoing ACL reconstruction, consented for this clinical trial and self-selected themselves into the hospital- and the community-based rehabilitation programmes (hospital- and community-based rehabilitation programme; n = 48 and 28, respectively). The patients in the hospital-based rehabilitation programme received contemporary rehabilitation in the hospital where they were seen more frequently by the physiotherapists compared to the patients in the community-based rehabilitation (physiotherapists’ supervised rehabilitation sessions for the patients in the hospital- and community-based rehabilitation programme; 14.4 ± 4.5; mean ± sd and 3.7 ± 0.7, respectively). The patients in the community-based rehabilitation were guided to manage the same rehabilitation programme in the community without the supervision from the rehabilitation team. All the patients in both the hospital- and the community-based rehabilitation programmes were assessed at four different
occasions (pre-surgery, 6th, 12th and 24th week following ACL surgery) on PROMs. The patients in the hospital-based rehabilitation programme showed statistical superior results on 10 out of 24 interactive comparison spread across responses at 12\textsuperscript{th} [8 out of 12; IKDC, KOOS (all five subsections) and K-SES (two subsections; sport and leisure, physical activities)] and 24\textsuperscript{th} week [2 out of 12 K-SES (subsection; physical activities) and KOOS (subsection; sport and recreation)] following ACL reconstruction. In contrast, the patients in the community-based rehabilitation programme showed statistically similar results to the patients in the hospital-based rehabilitation programme on the remaining 14 out of 24 interactive comparison spread across responses at 12\textsuperscript{th} and 24\textsuperscript{th} week. Changes in PROMs within early phase of rehabilitation showed weak association with their final outcomes at 24\textsuperscript{th} week. Based on the findings of this clinical trial it can be concluded, that despite some differences amongst the group mean scores for the patients in the hospital- and the community-based rehabilitation programme, the overall responses of the patients to both treatment approaches were similar in many aspects. Therefore, community-based rehabilitation programme is an efficient rehabilitation approach for post-surgical care of ACL reconstruction.
5.1 INTRODUCTION

The increasing burden of long-term medical conditions and the limited funding available for rehabilitation in the hospitals, demand the need for a ‘shift of rehabilitation services to the community’ (Anderson and Horvath 2004, Grant et al. 2005). Some of the long-term medical conditions such as asthma, diabetes, stroke and hypertension have been reported to be effectively managed by the patients in the community (Barlow et al. 2002, Kennedy et al. 2007). However, community-based rehabilitation for musculoskeletal injuries including ACL following reconstruction have not received robust attention in the literature and warrants further investigation to see whether this environment for care might offer equivalent or even better clinical efficacy.

The systematic review reported in chapter 2 of this thesis suggested that community-based rehabilitation programme had produced similar outcomes to the rehabilitation programme deployed in the hospital following ACL reconstruction (Hohmann et al. 2011, Grant and Mohtadi 2010, Ugutmen et al. 2008, Grant et al. 2005). The patients in the community-based rehabilitation programmes achieved similar or even better outcomes of rehabilitation (in some cases reaching statistical significance) compared to the outcomes achieved by the patients in the hospital-based rehabilitation programme. Despite the fact that the included trials were carried out on the effectiveness of the community-based rehabilitation programmes, all of them used different measuring tools for the assessment of the patients in the hospital- and the community-based rehabilitation programmes. The literature review carried out on different tools assessing function of knee in chapter 3 of this thesis suggested that
each of these measuring tools possessed different clinimetric characteristics (please see chapter 3, Table 3.2). The capabilities of some of the frequently used tools assessing knee function such as IKDC, Lysholm and HSS to detect changes in a patient’s perception of his/her functional performance capability (MDC) has been reported as 8.8 (Collins et al. 2009), 8.9 (Briggs et al. 2009) and 10.1 units (Narin et al. 2014) based on 68% confidence limits, respectively. Similarly, clinimetric responsiveness is thought to vary amongst this type of PROMs (Risberg et al. 1999a), making it more likely that depending on the extent of responses of patients to a given dose of conditioning, different PROMs of function would detect different patterns of changes in functional capability. The issue that different assessment tools possess different capabilities has been considered carefully in this trial and a variety of selected PROMs including IKDC, KOOS, K-SES, VAS and Lysholm have been used for comparing the outcomes of the hospital- and the community-based rehabilitation programmes.

Outcomes of rehabilitation following musculoskeletal injuries are influenced by a variety of factors (Riseberg 2004, Renstrom et al. 2008, Hewett et al. 2006). Individual’s anthropometric characteristics (height, body mass), orthopaedically-relevant factors (BMI, age, gender, waiting time to surgery, habitual levels of physical activity) have been reported being influential on the outcomes of the rehabilitation programme following injuries the musculoskeletal system of individuals (Smith et al. 2012a, Vincent et al. 2006, Lohmander et al. 2004). The mechanisms associated with these effects are not well determined in the literature (Holla et al. 2013, Braybrooke et al. 2007, Derrett et al. 1999). However, degenerative changes associated with old age and physiological de-conditioning
associated with long time to surgery may be some of the reasons that adversely affect the outcomes of rehabilitation. The effects of these factors on the final outcomes were assessed in this clinical trial by taking into account the influences of factors such as waiting time for surgery that couldn’t be experimentally-controlled within the scope of this study’s design. Moreover, significant changes in the form of the largest relative gains in physiological and physical performances during the early phase of rehabilitation (up to 12 weeks following surgery) were evaluated amongst the outcomes of the hospital and the community-based rehabilitation programmes by comparing the early outcomes during this phase of rehabilitation. This might be helpful in offering an important juncture in which the influence of early ‘dose-responses’ associated with both hospital and community environments and the likelihood of achieving favourable clinical status might be determined.

In short this trial was designed to compare the effects of altered environments for the delivery of rehabilitation (hospital- and community-based rehabilitation programmes) on PROMs (IKDC, KOOS, K-SES and Lysholm) and pain (VAS) in a cohort of the patients undergoing ACL reconstruction. Moreover, the relative effects of anthropometric characteristics and orthopaedically-relevant factors on outcomes of rehabilitation amongst the patients and the outcomes during the early phase of rehabilitation were assessed amongst the outcomes of both these group. Finally, this trial was designed to investigate whether changes in PROMs within early phase of rehabilitation could be used as predictors for the outcomes at 24th week.
5.2 METHODS

A total of 76 patients [hospital- and community-based rehabilitation programmes [n = 48 (♂=43, ♀=5) and 28 (♂=21, ♀=7), respectively] self-selected themselves into the hospital- and the community-based rehabilitation programmes (please see table 5.1 for the demographic details of the patients). The reasons for having non-randomised allocation to groups in this clinical trial were related to both logistical infeasibility and issues of ethics. The clinical trial was necessarily placed in a specialised NHS Foundation Trust orthopaedic research hospital of international repute. Due to the nature of the esteem in which this institution and its surgeons and clinical teams are held by peers, patients sustaining ACL injuries are routinely referred from distant areas within the UK and often, internationally. The composition of any serial cohort of patients meeting the inclusion criteria would inevitably have involved a considerable geographical spread with commensurate time- and financial-stresses for patients attending for hospital-based clinical treatment. To have required patients who were remote to the hospital but allocated to hospital-based rehabilitation by randomisation, to travel excessively without the necessary financial support associated with the funding of a major clinical trial, was deemed not to be feasible or desirable under ethical review (Research Ethics Committee No; 11/WM/0418 and Research and Development/CLRN Reference; RL1 509). Such an imposition on patients’ time and finances might also have influenced clinical behaviours unfavourably to such an extent that the nature of the experimental comparison might have been compromised. Thus, the design of this clinical trial might be categorised as quasi-experimental. The quasi-experiment is a study that includes a manipulated independent variable but lacks some important
controls (for example, random allocation of the participants into groups) or a study that lacks a manipulated independent variable but includes important controls (Reichardt 2009). This type of design has been reported to be a preferred method for the evaluation of clinical populations when randomisation is not feasible (Glasziou et al. 2007, Harris et al. 2004). In addition, robust findings are often achieved using a combination of randomised and non-randomised controlled trials (Panter and Sterba 2011). Importantly in terms of controls used within this trial, patients in the hospital-based rehabilitation group followed a well-established rehabilitation programme at the hospital that has been characterised as ‘long-standing (> 10 years), successful (0.01% failure rate associated with >300 ACL-reconstructions per year), regularly research audited, and incorporating many of the latest approaches to care (Bailey et al. 2003). It offered a well-established ‘benchmark’ and control against which the potential differences associated with the community-based rehabilitation could be compared. To ensure that the patients in the community-based rehabilitation had full access to the detailed information contained within the contemporary hospital-based rehabilitation care pathway (please see Appendix III) and could potentially undertake iso-volumetric levels of conditioning (compared to that undertaken in the hospital-environment), a comprehensive guidance package (booklet) was provided to every patients self-selecting community-based rehabilitation. Patients self-managing rehabilitation in the community were advised to attend the hospital on four occasions across the 24 weeks of rehabilitation in which they were able to review progress and modify the patterns of conditioning dose in consultation with the clinical team. From an ethical perspective, access to guidance and advice from the clinical teams by
means of telephone or internet-based communications was freely-available and equivalent for community- and hospital-based patients.

Table 5.1: Table showing demographic details of the participants

<table>
<thead>
<tr>
<th></th>
<th>hospital-based</th>
<th>community-based</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in yr</td>
<td>31.5 ± 12.1</td>
<td>34.5 ± 9.9</td>
<td>0.23</td>
</tr>
<tr>
<td>height in m</td>
<td>1.74 ± 0.06</td>
<td>1.71 ± 0.07</td>
<td>0.42</td>
</tr>
<tr>
<td>body mass in kg</td>
<td>78.2 ± 10.8</td>
<td>75.2 ± 12.4</td>
<td>0.51</td>
</tr>
<tr>
<td>waiting time in months</td>
<td>37.3 ± 33.7</td>
<td>31.1 ± 26.7</td>
<td>0.48</td>
</tr>
</tbody>
</table>

yr years m meter kg kilogram

Participants’ characteristics

The majority of the patients recruited for this clinical trial had elective surgery involving a hamstring graft (92%) and a small number of the patients had a BPTB graft (8%) for their reconstructive surgeries. Most of the patients had been previously involved in recreational/non-professional athletic activities (90% of the patients had recreational athletic background) while the remaining 10% had non-athletic backgrounds and had sustained injury to ACLs while falling from height (5%) and direct hits on the knee joint during road traffic accident (5%). A big proportion of the patients had injured ACL of their right knees (84%) while the rest (16%) had injured the ACL of their left knees. Interestingly, all the patients had injured ACL of their preferred leg. The most cited mechanism of injury to the ligament was ‘non-contact’ (75%) while the rest (25%) had resulted from direct blow or ‘not sure’ into the knee joint.
5.2.1 OUTCOME MEASURES

The outcomes of rehabilitation amongst the patients in the hospital- and the community-based rehabilitation programmes were measured on function assessed by PROMs (IKDC, KOOS, K-SES and Lysholm) and pain (VAS). The anthropometric characteristics of the patients were measured by objective measures and one of the orthopaedically-relevant factors, the levels of habitual physical activities, was measured by interview-based inventory. A summary of these measures is given below (for more details on PROMS, please chapter 3).

5.2.1.1 PROMS MEASURING FUNCTION

IKDC

The IKDC was developed by an international committee in an attempt to provide a uniform system of evaluating the outcomes of the knee ligamentous injuries (Gleeson et al. 2008). It is a multipage inventory includes demographic, current health assessment and subjective knee evaluation. The latter include evaluation of subjective assessment of symptom, capability for participation in sports activities and functionality associated with the knee joint. In the symptom section for example, patients are asked to state the highest levels at which he/she could use his/her knee without having one significant symptom (for example pain, swelling, partial giving-way, complete giving-way) even if he/she does not actually perform those activities. IKDC has been reported a reliable PROM (ICC; 0.90 -0.95) for assessment of knee following injuries. The MDC and MCID for IKDC have been reported 8.8 and 11.5 units (68% CI), respectively, at 12th months.
KOOS

The KOOS is an inventory that aims to assess patient’s perception about the status of knee both in short and long term duration following injuries to the latter joint (Collins et al. 2011). The KOOS instrument assesses the symptoms of knee joint in five distinctive subscales; pain, symptom, function of sports and recreation, activities of daily living and quality of life. The subsections of KOOS have shown differences in test-retest reliability (ICC) [subsections; pain (ICC; 0.83-0.93), symptoms (ICC; 0.83-0.95), function of sports and recreation (ICC; 0.61-0.89), activities of daily living (ICC; 0.75-0.91) and quality of life (ICC; 0.83-0.95)] (Collins et al. 2011). The MDC for the KOOS has been suggested 6.6 points (68% CI) at the 6th months of rehabilitation following surgical intervention to the knee joint.

Lysholm Knee Scoring Scale

Lysholm Knee Scoring Scale was originally developed to allow orthopaedicians to assess and measure the knee function (physician-administered) for patients with ACL reconstruction and other knee-related conditions (Briggs et al. 2009). Patients in this inventory are asked to compare the pre-surgical scores with the follow-up scores in eight sub-domains (limp, squatting, pain, swelling, stair climbing, locking, instability and support) which are considered important determinants for normal function of the knee joint. The Lysholm has been reported reliable (ICC; 0.88 – 0.97). The MDC for the latter PROM has been reported 8.9 points during the initial year of injuries to the knee joint.
**K-SES**

The K-SES is a psychometric measuring inventory that assess patients’ present knee status and provide an opportunity to the patients to predict their knee function in the future. This instrument consists of four subsections; daily activities, sports activities, physical activities and your knee function in the future. The first three subsections of the K-SES evaluate subjectively patients’ present condition conditions while the fourth subsection evaluate patients’ future expectation related to their knee joint. The internal consistence for the subsections of this inventory has been reported 0.94 for daily activities, 0.91 sports activities, 0.92 physical activities and 0.78 your knee function in the future.

**5.2.1.2 PROM MEASURING PAIN**

**VAS**

VAS is a self-reported psychometric response scale that is used to measure subjective characteristics of pain associated with any specific medical condition (Reilly et al. 1999). When using VAS, a person is asked to indicate, on a 10-cm visual scale, the levels of pain he/she experiences for any specific condition. Alternatively, the scale can be used as a sliding scale in which in one end of a paper the word ‘no pain’ will be written while the word ‘maximum pain’ is written on the other end of the paper. VAS has been reported less responsive to knee condition during the initial 12 months of surgery to the knee joint (Risberg et al. 1999a).
5.2.1.3 ANTHROPOMETRIC CHARACTERISTICS

*Height and body mass*

The heights of the patients were measured by stadiometer that is a portable instrument composed of vertical measuring board and a horizontal headboard. The patients whose height was to be taken were asked to take their shoes off and stand against the vertical board with knees straight and heels touching each other. Patients were asked to keep their head in normal anatomical positions. The latter was achieved by asking them to look forward in a straight line.

The weight of the participants were measured on a weighing scale of range suitable to the participants’ sizes. It was endured that the scales were at zero. Accuracy of the scale was checked using standard weights. The participants were asked to remove shoes and outer clothing prior to weighing. Weight of the participants was recorded in kilograms.

5.2.1.4 ORTHOPAEDICALLY-RELEVANT FACTOR

*7-Day Physical Activity Recall*

7-Day Physical Activity Recall is an interviewed-administered inventory that estimates an individual’s time spent in physical activity, strength and flexibility activities for 7 days prior to the interview (Sallis et al. 1993). It has been observed that physical activities of an individual varies from day to day, therefore, several days records are needed to provide a representative sample of the amount of activities carried out by an individual (Blair et al. 1985). The patients are asked to report specific activities with the perceived intensity. For example, participants are asked to estimate the number of hours spent during the last week in sleep, moderate,
hard and very hard physical activities. This method is applicable for an estimate of energy expenditure. The 7-Day Physical Activity Recall has been reported reliable (ICC 0.90) (Gross et al. 1990) [please see detailed information about the 7-Day Physical Activity Recall in chapter 3, section 3.1.5].

**Ethical approvals for clinical trial**

This study had received ethical approval by the Shropshire area NHS Ethics Committee and had received scientific merit approval from the Research Committee of Robert Jones and Agnes Hunt Orthopaedic Hospital, District Hospital Foundation NHS Trust, UK (Research Ethics Committee No; 11/WM/0418, Research and Development /CLRN Reference; RL1 509, respectively). A detailed overview of the inclusion and exclusion criteria for all the participants in this clinical trial has been given in chapter ‘Methods’ (chapter 4) of this thesis.

**5.2.2 STATISTICAL ANALYSIS**

Anthropometric characteristics, orthopaedically-relevant factors and baseline measurements of PROMs amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation were assessed for normal distribution by using Shapiro-Wilk test of normality. Initial assessment of the data showed no differences amongst anthropometric characteristics, orthopaedically-relevant variables and baseline measurement on PROMs, suggesting similar variance amongst the patients in the hospital- and the community-based rehabilitation programmes. The data was collected through selected PROMs, which recorded data
in a continuous manner. The data was shown to have fulfilled criteria that were pre-
requisites for employing parametric analysis in this trial.

The clinical efficacy of the hospital- and the community-based rehabilitation
programmes was assessed using separate Analysis of Variance (ANOVAs) for each
of primary outcome measures of PROMs (IKDC, KOOS, K-SES, Lysholm) and pain
(VAS). The ANOVA model involving factors of group (the hospital- and the
community-based rehabilitation groups) by test occasions (pre-surgery and at the 6th,
12th and 24th weeks post-surgery) with repeated measures on the latter factor, was
used to test the null-hypothesis of no statistical interaction between the group mean
responses for the patients undertaking conditioning programme in the hospital and
the community. The reason for deploying this statistical model was to compare the
outcomes of the hospital- and the community-based rehabilitation programmes
across a sequenced phase 24-weeks rehabilitation programme following ACL
reconstruction. The timings of these assessment sessions were chosen based on the
evidence from previous trials carried out on the effects of the hospital- and
community-based rehabilitation programmes. Moreover, a priori comparisons rather
than posterior (post-hoc) were included in the statistically analysis in order to
compare differences between the outcomes of the hospital- and the community-based
rehabilitation programmes at specific time intervals. This comparison can be
labelled as a “planned comparisons” based on the expectations that large changes
would be observed during the suggested phases of rehabilitation. The advantage of
including a priori comparisons rather than posterior (post-hoc) was merits associated
with the inclusion of the former in the form of its ability to eliminate the chance that
a researcher might mistake a false hypothesis for a true one and vice versa.
Moreover, _a priori_ comparisons are time saving in a sense to plan before the data is collected that allow a researcher to compare only the control and treated.

The effects of anthropometric characteristics, orthopaedically-relevant factors and baseline outcome scores that were not capable of being controlled experimentally (due to logistic, feasibility or cost implications), on the outcome measures of function on PROMs changes in the dependent variable (treatment programmes: hospital- and community-based rehabilitation programmes) were investigated using ANCOVA. An ANCOVA model involving a single candidate covariate and group (hospital-based, community-based rehabilitation programmes) by test occasions (pre-surgery and at the 6th, 12th and 24th week post-surgery) with repeated measures on the latter factor was used to test the null hypothesis of no statistical interaction of group mean scores between experimental groups and across time, for each outcome measurement.

**Power of the study**

The experimental design offered an approximate 0.80 power of avoiding type 2 error when employing a ‘least detectable difference’ [a minimum extent of difference between the effects of experimental interventions (hospital- versus community-based rehabilitation programmes)] that might be considered clinically and biologically meaningful in selected PROMs of function (Sport Science 2006). The sample size was also justified based on the findings of previous studies where an improvement of 33% and 42% the selected PROMs was reported for the patients in the hospital- and the community-based rehabilitation programmes, respectively (Grant et al. 2005). The improvement achieved by the patients in the both the rehabilitation programmes...
was reported clinically relevant. Moreover, clinical knowledge suggested that the standard deviation of the improvement in selected PROM with both treatment programmes could be undertaken as 10%. Based on this information, an internet-based sample size calculator that has been scientifically verified (Glazier et al. 2010), was used to estimate sample size of this study. It was estimated that 60 participants (after allowance for potential ‘losses-to-follow-up’ volunteering-rates had been accounted for) in total would be needed across hospital- and community-based rehabilitation groups for appropriate experimental design sensitivity and statistical power.

5.3 RESULTS

There were no differences amongst the group mean scores for the patients in the hospital- and the community-based rehabilitation groups for anthropometric factors [height (hospital versus community; mean ± SD; 1.74 ± 0.06 versus 1.71 ± 0.07 m, respectively, \( p=0.50 \)), body mass ( 78.2 ± 10.8, versus 75.2 ± 12.4 kg, respectively, \( p=0.23 \)), orthopaedically-relevant factors [ BMI (25.5 ± 3.0 versus 25.3 ± 3.2 kg/m\(^2\), respectively, \( p=0.52 \)), waiting time for surgery (37.3 ± 33.7 versus 31.1 ± 26.7 months, respectively, \( p=0.21 \)) and the levels of habitual physical activities (2088.3 ± 191.1 versus 1976.9 ± 174.2 Kcal/day, respectively, \( p=0.35 \))]. Similarly, the patients in the hospital- and the community-based rehabilitation programmes showed similarities at baseline on PROMs (IKDC, KOOS, K-SES, VAS and Lysholm; please see Table 5.2). This confirms that the self-selection to groups (hospital versus community), produced similarities at baseline amongst the patients in the latter groups for anthropometric, clinical-relevant factors and PROMs for function. The
latter suggested that the lack of randomisation in this study had not intruded unduly.

As expected, group mean scores for the number of formal sessions attended involving systematic physiotherapy conditioning in the hospital was significantly higher for the patients in the hospital-based rehabilitation programme compared to the patients in the community-based rehabilitation programme (hospital versus community; \(14.4 \pm 4.5\) versus \(3.7 \pm 0.7\), respectively, \(p=0.01\)). The latter offered conformational evidence that the patients in both groups had received significantly different opportunities for the supervision of structured rehabilitation and thus potentially, for the precise management of conditioning dose. None of the participants included in this clinical trial had any post-surgical complication which otherwise would had required special supervision from the rehabilitation team.

Table 5.2: Table showing group mean responses at baseline on the selected PROMs for the patients in both the hospital- and the community-based rehabilitation programmes

<table>
<thead>
<tr>
<th></th>
<th>HB</th>
<th>CB</th>
<th>(p)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IKDC</td>
<td>63.7 ± 11.3</td>
<td>69.3 ± 13.4</td>
<td>0.71</td>
</tr>
<tr>
<td>Lysholm</td>
<td>61.6 ± 15.3</td>
<td>71.0 ± 15.2</td>
<td>0.52</td>
</tr>
<tr>
<td>VAS</td>
<td>3.4 ± 2.0</td>
<td>3.3 ± 2.6</td>
<td>0.23</td>
</tr>
<tr>
<td>KS—daily activities</td>
<td>37.2 ± 15.9</td>
<td>40.9 ± 14.0</td>
<td>0.07</td>
</tr>
<tr>
<td>KS—sport activities</td>
<td>21.0 ± 11.9</td>
<td>19.5 ± 10.8</td>
<td>0.10</td>
</tr>
<tr>
<td>KS—physical activities</td>
<td>22.5 ± 11.3</td>
<td>26.7 ± 11.3</td>
<td>0.23</td>
</tr>
<tr>
<td>KS—your knee function in the future</td>
<td>23.6 ± 8.2</td>
<td>19.0 ± 9.5</td>
<td>0.12</td>
</tr>
<tr>
<td>KO—symptom and stiffness</td>
<td>13.5 ± 3.4</td>
<td>12.1 ± 3.6</td>
<td>0.09</td>
</tr>
<tr>
<td>KO—pain</td>
<td>10.4 ± 6.0</td>
<td>7.6 ± 5.7</td>
<td>0.31</td>
</tr>
<tr>
<td>KO—function, daily activities</td>
<td>14.5 ± 11.8</td>
<td>8.5 ± 9.6</td>
<td>0.24</td>
</tr>
<tr>
<td>KO—sport and recreation</td>
<td>11.2 ± 4.2</td>
<td>9.3 ± 4.0</td>
<td>0.09</td>
</tr>
<tr>
<td>KO—quality of life</td>
<td>10.8 ± 2.7</td>
<td>10.3 ± 3.4</td>
<td>0.42</td>
</tr>
</tbody>
</table>

HB hospital-based
CB community-based
KS K-SES
KO KOOS
5.3.1 OUTCOMES ACROSS 24 WEEKS (PROMS)

An ANOVA using factors of group (the hospital- and the community-based rehabilitation groups) by test occasion (pre-surgery, 6th, 12th and 24th weeks following ACL reconstruction) with repeated measures on the latter factor suggested statistically significant group by assessment occasion interaction for the subsection ‘physical activities’ of the K-SES ($F_{(3,0.87)}^{GG} = 3.9, p=0.03$). This suggested that while the patients in both the hospital- and the community-based rehabilitation groups improved significantly compared to baseline, these changes were more prominent in the patients who had received rehabilitation programme in the hospital compared to the patients who managed their rehabilitation programme in the community. Compared to the baseline, an increase of 52% and 36% on subsection ‘physical activities’ of the K-SES was observed for the patients in the hospital- and the community-based rehabilitation groups, respectively; [hospital- and community-based rehabilitation programmes; 22.5 ± 11.3 versus 46.6 ± 11.1 and 26.7 ± 11.3 versus 41.7 ± 13.0, respectively (baseline versus 24th week)]. The group mean responses over time for the patients in the hospital- and the community-based rehabilitation are shown in Figure 5.1.

Similarly, a statistically significant group × testing occasion interaction was observed for the ‘sport and recreation’ subsection of the KOOS ($F_{(3,0.183)} = 5.4, p=0.04$). The latter suggested that while the patients in both the hospital- and the community-based rehabilitation groups improved significantly compared to the baseline, these changes were more prominent in the patients who had received rehabilitation programme in the hospital compared to the patients who managed their rehabilitation programme in
the community. Compared to the baseline, an increase of 63% and 56% on subsection ‘sport and recreation’ of the KOOS was observed for the patients in the hospital- and the community-based rehabilitation groups, respectively; hospital- and community-based rehabilitation programmes [11.2 ± 11.3 versus 4.2 ± 3.5 and 9.3 ± 4.0 versus 4.6 ± 4.2, respectively (baseline versus 24th week)]. The group mean responses over time for the patients in the hospital- and the community-based rehabilitation are shown in Figure 5.2.

No interaction amongst the group mean scores for the patients in the hospital- and the community-based rehabilitation programmes were observed for IKDC (F(2.5, 157.8)\(\text{GG} = 2.5, p=0.31\)), Lysholm (F(2.5,154.8)\(\text{GG} = 1.8, p=0.44\)) and VAS (F(2.2,135.4)\(\text{GG} = 1.5, p=0.22\)) (Please see Table 5.3 for group mean responses for the patients in the hospital- and the community-based rehabilitation groups for IKDC, VAS and Lysholm and all subsections of KOOS and K-SES). The latter suggested that the recovery of function as measured by PROMs (IKDC and Lysholm) and pain as measured by VAS, was similar for the patients in both the hospital- and the community-based rehabilitation.
Figure 5.1: Figure showing interaction effect for the K-SES (physical activities) across 24 weeks period following ACL reconstruction. The pattern of improvement for the patients in both the hospital- and the community-based rehabilitation programme was different during the 24 weeks rehabilitation programme.

Figure 5.2: Figure showing interaction effect for the KOOS (sport and recreation). The patients in both groups (hospital- and community-based rehabilitation programmes) showed different pattern of improvement.
Table 5.3: Table showing group mean responses for the patients in the hospital- and the CB rehabilitation groups at four different occasions on selected outcome measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2,215.4) GG = 1.5, p=0.22)</td>
</tr>
<tr>
<td>HB</td>
<td>3.45±2.07</td>
<td>3.9±1.72</td>
<td>2.65±1.79</td>
<td>0.9±1.19</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>3.3±2.64</td>
<td>3.22±1.62</td>
<td>1.43±1.65</td>
<td>0.74±1.51</td>
<td></td>
</tr>
<tr>
<td><strong>IKDC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2,215.4) GG = 1.2, p=0.31)</td>
</tr>
<tr>
<td>HB</td>
<td>63.71±11.77</td>
<td>58.55±9.55</td>
<td>76.51±7.89</td>
<td>87.4±12.89</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>69.35±13.41</td>
<td>59.05±9.05</td>
<td>74.7±11.45</td>
<td>88.04±9.25</td>
<td></td>
</tr>
<tr>
<td><strong>Lysholm</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2,215.4) GG = 0.8, p=0.44)</td>
</tr>
<tr>
<td>HB</td>
<td>61.68±15.38</td>
<td>67.59±15.08</td>
<td>82.65±10.43</td>
<td>87.4±15.25</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>71.09±15.23</td>
<td>66.41±19.21</td>
<td>85.5±10.89</td>
<td>91.35±9.82</td>
<td></td>
</tr>
<tr>
<td><strong>KOSS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(3.0,160.0) = 1.1, p=0.51)</td>
</tr>
<tr>
<td>CB</td>
<td>12.13±3.63</td>
<td>11.23±2.33</td>
<td>10.12±2.69</td>
<td>9.91±2.41</td>
<td></td>
</tr>
<tr>
<td><strong>KOP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(3.0,160.0) = 1.2, p=0.43)</td>
</tr>
<tr>
<td>HB</td>
<td>10.46±6.07</td>
<td>11.4±4.37</td>
<td>5.59±2.26</td>
<td>3.88±4.06</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>7.61±5.79</td>
<td>10.81±5</td>
<td>6.33±5.13</td>
<td>3±3.12</td>
<td></td>
</tr>
<tr>
<td><strong>KOF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.5,154.8) GG = 1.8, p=0.31)</td>
</tr>
<tr>
<td>HB</td>
<td>14.5±11.9</td>
<td>16.4±10.22</td>
<td>5.22±4.45</td>
<td>3.98±7.37</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>8.52±9.65</td>
<td>12.31±10.96</td>
<td>5.99±6.37</td>
<td>2.48±4.15</td>
<td></td>
</tr>
<tr>
<td><strong>KOSR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.6,151.3) GG = 1.6, p=0.33)</td>
</tr>
<tr>
<td>HB</td>
<td>11.22±4.26</td>
<td>10.77±6</td>
<td>6.73±3.75</td>
<td>4.22±3.57</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>9.35±4.01</td>
<td>13.8±4.79</td>
<td>9.99±5.27</td>
<td>4.7±4.24</td>
<td></td>
</tr>
<tr>
<td><strong>KOQoL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.3,124.1) GG = 1.9, p=0.14)</td>
</tr>
<tr>
<td>HB</td>
<td>10.84±2.71</td>
<td>9.64±3.32</td>
<td>7.63±3.09</td>
<td>4.7±3.19</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>10.35±3.49</td>
<td>10.09±3.09</td>
<td>9.44±3.32</td>
<td>5.17±2.21</td>
<td></td>
</tr>
<tr>
<td><strong>KSDA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.6,150.1) GG = 1.2, p=0.39)</td>
</tr>
<tr>
<td>HB</td>
<td>37.29±15.91</td>
<td>29.29±13.06</td>
<td>45.27±10.59</td>
<td>61.42±10</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>40.91±14.07</td>
<td>26.54±10.15</td>
<td>43.02±11.69</td>
<td>58.78±10.68</td>
<td></td>
</tr>
<tr>
<td><strong>KSSA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.4,151.9) GG = 1.3, p=0.51)</td>
</tr>
<tr>
<td>HB</td>
<td>21.03±11.91</td>
<td>16.19±7.7</td>
<td>27.1±8.47</td>
<td>38.07±9.79</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>19.52±10.81</td>
<td>14.3±9.91</td>
<td>19.48±6.78</td>
<td>34±11.56</td>
<td></td>
</tr>
<tr>
<td><strong>KSPA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2.3,154.0) GG = 1.1, p=0.24)</td>
</tr>
<tr>
<td>HB</td>
<td>22.53±11.38</td>
<td>17.98±8.82</td>
<td>31.98±10.18</td>
<td>46.69±11.14</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>26.74±11.36</td>
<td>14.12±6.84</td>
<td>25.18±10.23</td>
<td>41.78±13.06</td>
<td></td>
</tr>
<tr>
<td><strong>KSKF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(F(2,2,141.5) GG = 1.7, p=0.37)</td>
</tr>
<tr>
<td>HB</td>
<td>23.65±8.27</td>
<td>26.98±7.97</td>
<td>27.16±5.39</td>
<td>32.49±7.08</td>
<td></td>
</tr>
<tr>
<td>CB</td>
<td>19±9.59</td>
<td>20.89±8.74</td>
<td>19.8±7.16</td>
<td>25±10.66</td>
<td></td>
</tr>
</tbody>
</table>

HB: hospital-based
CB: community-based
KOSS: KOOS (symptom and stiffness)
KOP: KOOS (pain)
KOF: KOOS (function, daily living)
KOSR: KOOS (sports and recreational activities)
KOQoL: KOOS (quality of life)
KSDA: K-SES (daily activities)
KSSA: K-SES (sport activities)
KSPA: K-SES (physical activities)
KSKF: K-SES (your knee function in future)
5.3.2 OUTCOMES ACROSS 24 WEEKS (PROMS) FOLLOWING
STATISTICAL ADJUSTMENTS FOR ANTHROPOMETRIC
CHARACTERISTICS AND ORTHOPEDICALLY-RELEVANT
FACTORS

By adjusting the levels of habitual physical activities at pre-surgery, a significant

\( F(3.0, 180.0) = 3.4, p=0.03 \) for subsection ‘pain’ of KOOS

showed that while both groups improved significantly over time, the group mean
responses from baseline to 24\(^{th}\) week for the patients in the hospital-based
rehabilitation were superior compared to the patients managing rehabilitation
programme in the community. Compared to the baseline, an increase of 63% and
60% on the subsection ‘pain’ of the KOOS was observed for the patients in the
hospital- and the community-based rehabilitation groups, respectively; hospital- and
community-based rehabilitation programmes \([10.4 \pm 6.0 \text{ versus } 3.8 \pm 4.0 \text{ and } 10.4 \pm
6.0 \text{ versus } 3.6 \pm 3.1, \text{ respectively (baseline versus } 24^{th}\text{ week})\]. No differences
amongst the group mean responses for the patients in the hospital- and the
community-based rehabilitation programmes were observed for the remaining four
subsections of KOOS while adjusting for the remaining orthopaedically-relevant
factors or all anthropometric characteristics (please see Table 5.4 for group mean
responses for the patients in hospital- and the community-based rehabilitation
programmes for the remaining subsections of the KOOS at four different occasions).
Table 5.4: Table showing group adjusted mean responses on subsections of the KOOS for the patients in the hospital- and the community-based rehabilitation groups at four different occasions

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
</tr>
</thead>
<tbody>
<tr>
<td>KOSS</td>
<td>HB</td>
<td>13.5 ± 3.4</td>
<td>12.4 ± 3.1</td>
<td>10.0 ± 3.0</td>
<td>9.8 ± 2.7</td>
</tr>
<tr>
<td></td>
<td>CB</td>
<td>13.5 ± 3.4</td>
<td>11.2 ± 2.3</td>
<td>10.1 ± 2.7</td>
<td>9.9 ± 2.4</td>
</tr>
<tr>
<td>KOQoL</td>
<td>HB</td>
<td>10.8 ± 2.7</td>
<td>9.6 ± 3.3</td>
<td>7.6 ± 3.0</td>
<td>4.7 ± 3.2</td>
</tr>
<tr>
<td></td>
<td>CB</td>
<td>10.8 ± 2.7</td>
<td>10.0 ± 3.0</td>
<td>9.4 ± 3.3</td>
<td>5.2 ± 2.2</td>
</tr>
<tr>
<td>KOF</td>
<td>HB</td>
<td>14.5 ± 11.9</td>
<td>16.4 ± 10.2</td>
<td>5.2 ± 4.5</td>
<td>4.0 ± 7.4</td>
</tr>
<tr>
<td></td>
<td>CB</td>
<td>14.5 ± 11.9</td>
<td>12.3 ± 11.0</td>
<td>6.0 ± 6.4</td>
<td>3.5 ± 4.2</td>
</tr>
<tr>
<td>KOSR</td>
<td>HB</td>
<td>11.2 ± 4.3</td>
<td>10.8 ± 6.0</td>
<td>6.7 ± 3.7</td>
<td>4.2 ± 3.6</td>
</tr>
<tr>
<td></td>
<td>CB</td>
<td>11.2 ± 4.3</td>
<td>13.8 ± 4.8</td>
<td>10.0 ± 5.3</td>
<td>4.7 ± 4.2</td>
</tr>
</tbody>
</table>

HB    hospital-based
CB    community-based
KOSS  KOOS (symptom and stiffness)
KOP   KOOS (pain)
KOF   KOOS (function, daily living)
KOSR  KOOS (sports and recreational activities)
KOQoL KOOS (quality of life)

5.3.3 OUTCOMES UP TO 12TH WEEK (EARLY PHASE OF REHABILITATION)

The rehabilitation programme followed at the Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry focuses on frequent physiotherapy visits of the patients to the hospital during the initial three months of rehabilitation following ACL reconstruction. On average the patients who have undergone ACL reconstruction are advised to attend a supervised physiotherapy session each week for the initial three month following ACL reconstruction and then once a month during the last two months of rehabilitation programme. This indicates that in the latter, patients, receive more supervised physiotherapy sessions in the hospital during
the initial three months of rehabilitation compared to the last three months following ACL reconstruction. One of the aims of this clinical trial, was to consider early responses to the rehabilitation for analysis as patients undertake the highest proportion of visits and dosage of conditioning during the latter. Therefore, testing of a priori ‘interaction’ between the outcomes of the hospital- and the community-based rehabilitation programme at 12th week was included in the statistical analysis of this trial.

Testing of a priori ‘interaction’ hypothesis of different rates of progression in an increases of IKDC scores (maximum score, 100) associated with the comparison of the hospital- versus the community-based rehabilitation programmes suggested a statistically significant interaction ($F_{(1.0, 97.1)}^{GG} = 3.5$, $p=0.01$) at 12th week following ACL reconstruction. The group mean scores for the IKDC between 12th week compared to previous assessment at pre-surgery and 6th week following ACL reconstruction were 76.5 ± 7.9 versus 63.7 ± 11.7 and 58.5 ± 9.5 for the patients in the hospital-based rehabilitation group and 75.8 ± 9.2 versus 69.3 ± 13.4 and 59.0 ± 9.0 for the patients in the community-based rehabilitation programme. The latter suggested that the recovery of function as measured by IKDC up to 12th week, was superior for the patients in the hospital-based rehabilitation compared to the patients in the community-based rehabilitation. Similar patterns of significant interaction amongst the mean scores for the patients in the hospital- compared to the community-based rehabilitation programmes, were observed for the subsections ‘sport and leisure’ and ‘physical activities’ of the K-SES, ‘symptom and stiffness’, ‘pain’, ‘function, daily living’, ‘function, sports and recreational activities’ and ‘quality of life’ of the KOOS (please see Table 5.5 for the mean scores). In contrast,
the Lysholm, VAS and the subsections of K-SES (daily activities and you knee function in future) did not show interaction amongst the patients in the hospital- and the community-based rehabilitation programmes in the early phase of rehabilitation following ACL reconstruction.
Table 5.5: Table showing group mean responses up to 12th week for the patients in the hospital- and the community-based rehabilitation groups for two subsections of K-SES and KOOS

<table>
<thead>
<tr>
<th></th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>F ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>3.45±2.07</td>
<td>3.9±1.72</td>
<td>2.65±1.79</td>
<td>(F(1,61.0) = 2.1, p=0.34)</td>
</tr>
<tr>
<td>CB</td>
<td>3.3±2.64</td>
<td>3.22±1.62</td>
<td>1.43±1.65</td>
<td></td>
</tr>
<tr>
<td><strong>IKDC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>63.71±11.77</td>
<td>58.55±9.55</td>
<td>76.51±7.89</td>
<td>(F(1,61.0) = 1.9, p=0.43)</td>
</tr>
<tr>
<td>CB</td>
<td>69.35±13.41</td>
<td>59.05±9.05</td>
<td>74.7±11.45</td>
<td></td>
</tr>
<tr>
<td><strong>Lysholm</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>HB</td>
<td>61.68±15.38</td>
<td>67.59±15.08</td>
<td>82.65±10.43</td>
<td>(F(1,61.0) = 1.1, p=0.40)</td>
</tr>
<tr>
<td>CB</td>
<td>71.09±15.23</td>
<td>64.61±19.21</td>
<td>85.5±10.89</td>
<td></td>
</tr>
<tr>
<td><strong>KOSS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>13.53±3.42</td>
<td>12.43±3.1</td>
<td>9.99±2.99</td>
<td>(F(1,61.0) = 3.9, p=0.02)</td>
</tr>
<tr>
<td>CB</td>
<td>12.13±3.63</td>
<td>11.23±2.33</td>
<td>10.12±2.69</td>
<td></td>
</tr>
<tr>
<td><strong>KOP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>10.46±6.07</td>
<td>11.4±4.37</td>
<td>5.59±2.26</td>
<td>(F(1,61.0)=10.3, p=0.01)</td>
</tr>
<tr>
<td>CB</td>
<td>7.61±5.79</td>
<td>10.8±5</td>
<td>6.33±5.13</td>
<td></td>
</tr>
<tr>
<td><strong>KOF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>14.54±11.9</td>
<td>16.44±10.22</td>
<td>5.22±4.45</td>
<td>(F(1,61.0) = 1.3, p=0.53)</td>
</tr>
<tr>
<td>CB</td>
<td>8.52±9.65</td>
<td>12.31±10.96</td>
<td>5.99±6.37</td>
<td></td>
</tr>
<tr>
<td><strong>KOSR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>11.22±4.26</td>
<td>10.77±6</td>
<td>6.73±3.75</td>
<td>(F(1,61.0) = 4.0, p=0.04)</td>
</tr>
<tr>
<td>CB</td>
<td>9.35±4.01</td>
<td>13.84±4.79</td>
<td>9.99±5.27</td>
<td></td>
</tr>
<tr>
<td><strong>KOQoL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>10.84±2.71</td>
<td>9.64±3.32</td>
<td>7.63±3.09</td>
<td>(F(1,61.0) = 4.1, p=0.01)</td>
</tr>
<tr>
<td>CB</td>
<td>10.35±3.49</td>
<td>10.09±3.09</td>
<td>9.44±3.32</td>
<td></td>
</tr>
<tr>
<td><strong>KSDA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>37.29±15.91</td>
<td>29.29±13.06</td>
<td>45.27±10.59</td>
<td>(F(1,61.0) = 1.5, p=0.32)</td>
</tr>
<tr>
<td>CB</td>
<td>40.91±14.07</td>
<td>26.54±10.15</td>
<td>43.02±11.69</td>
<td></td>
</tr>
<tr>
<td><strong>KSSA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>21.03±11.91</td>
<td>16.19±7.7</td>
<td>27.14±8.47</td>
<td>(F(1,61.0) = 7.1, p=0.01)</td>
</tr>
<tr>
<td>CB</td>
<td>19.52±10.81</td>
<td>14.3±9.91</td>
<td>19.48±8.78</td>
<td></td>
</tr>
<tr>
<td><strong>KSPA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>22.53±11.38</td>
<td>17.98±8.82</td>
<td>31.98±10.18</td>
<td>(F(1,61.0) = 6.0, p=0.02)</td>
</tr>
<tr>
<td>CB</td>
<td>26.74±11.36</td>
<td>14.12±6.84</td>
<td>25.18±10.23</td>
<td></td>
</tr>
<tr>
<td><strong>KSKF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB</td>
<td>23.65±8.27</td>
<td>26.98±7.97</td>
<td>27.16±5.39</td>
<td>(F(1,61.0) = 1.9, p=0.35)</td>
</tr>
<tr>
<td>CB</td>
<td>19±9.59</td>
<td>20.89±8.74</td>
<td>19.8±7.16</td>
<td></td>
</tr>
</tbody>
</table>

**HB** hospital-based

**CB** community-based

**KOSS** KOOS (symptom and stiffness)

**KOP** KOOS (pain)

**KOF** KOOS (function, daily living)

**KOSR** KOOS (function, daily living)

**KOQoL** KOOS (quality of life)

**KSDA** K-SES (daily activities)

**KSSA** K-SES (sport activities)

**KSPA** K-SES (physical activities)

**KSKF** K-SES (your knee function in future)

**KOQoL** KOOS (quality of life)

HB  | hospital-based
CB  | community-based
KOSS | KOOS (symptom and stiffness)
KOP  | KOOS (pain)
KOF  | KOOS (function, daily living)
KOSR | KOOS (sports and recreational activities)
KOQoL | KOOS (quality of life)
KSDA | K-SES (daily activities)
KSSA | K-SES (sport activities)
KSPA | K-SES (physical activities)
KSKF | K-SES (your knee function in future)
KOQoL | KOOS (quality of life)
5.3.4 OUTCOMES OF EARLY PREDICTION

The expectation that changes in PROMs within early phase of ACL rehabilitation programme might predict the final outcomes for the rehabilitation programme was based on the evidence from the previous clinical trials where physical performances including strength for the quadriceps had been reported as a significant predictor for PROMs at two year follow-up (Eitzen et al. 2009, Liu Ambrose et al. 2003). In this section of chapter 5, a correlation between the changes in PROMs within early phase of rehabilitation (acute; pre-surgery to 6th week, sub-acute; 6th to 12th week) were correlated with their respective scores at 24th week following ACL reconstruction.

A statistically significant correlation between changes in IKDC within early phase of rehabilitation with outcomes at 24th week was observed for the group mean response for the patients in the community-based rehabilitation programme (r = 0.5; p=0.02). Similarly, a statistically significant correlations were observed amongst changes within early phase of rehabilitation and the final scores at 24th week for the subsections ‘symptom and stiffness’ and ‘pain’ of the KOOS (r = 0.4 and 0.5, respectively; p=0.02,0.01, respectively), VAS (r = 0.5; p=0.04) and subsection ‘daily activities’ of the K-SES, (r = 0.6; p=0.01). Although, change scores within early phase of rehabilitation and final scores at 24th week for the patients in the community-based rehabilitation programme showed statistically significant correlation, still the association has not achieved consistent levels that can be used by the clinician to predict the outcomes of rehabilitation at 24th week based on the changes within early phase of rehabilitation. Similar findings were observed for the patients in the hospital-based rehabilitation programme where association between
changes in PROMs within early phase of rehabilitation and outcomes at 24th week of rehabilitation had not achieved consistent levels for prediction the outcomes of rehabilitation. These finding suggested that changes in PROMs within early phase of rehabilitation might not be good predictors for the outcomes of rehabilitation programme at 24th week following ACL reconstruction.

5.4 DISCUSSION

The main aim of this trial was to compare the effects of altered environments for the delivery of rehabilitation (hospital- and the community-based rehabilitation programmes) on PROMs (IKDC, KOOS, K-SES and Lysholm) and pain (VAS) in a cohort of the patients undergoing ACL reconstruction. The secondary aim of this trial was to assess the relative effects of anthropometric characteristics and orthopaedically-relevant factors on the outcomes of rehabilitation amongst the patients in the latter two groups. In addition, this clinical trial was designed to assess the outcomes of the hospital- and the community-based rehabilitation programmes across early phase of rehabilitation (up to 12 weeks). Finally, this clinical trial was designed to investigate the extent and robustness of relationships between change scores of the PROMs within the early phase of rehabilitation and final outcomes at the 24th week following ACL reconstruction.

In summary, the primary findings of this clinical trial suggested achieving of statistically superior outcomes by the patients in the hospital-based rehabilitation programme compared to the patients in the community-based rehabilitation programme on some aspects of PROMs assessing function in knee joint; subsection ‘physical activities’ of the K-SES ($F_{(3,0,87)} = 3.9, p=0.03$) and ‘sport and
recreation’ of the KOOS ($F_{(3.0, 183)} = 5.4, p=0.04$). The patients in the hospital-based rehabilitation programme showed 9-12% better outcomes compared to the patients in the community-based rehabilitation programme on the latter two aspects of PROMs when group mean responses for the patients in the hospital- and the community-based rehabilitation programmes were compared across 24 weeks following ACL reconstruction. In contrast, no differences were observed between the outcomes of the latter two programmes over time on IKDC ($F_{(2.5, 157.8)} GG = 2.5, p=0.31$), Lysholm ($F_{(2.5, 154.8)} GG = 1.8, p=0.44$), VAS ($F_{(2.2, 135.4)} GG = 1.5, p=0.22$), for the remaining subsections ‘symptom and stiffness’ ($F_{(3.0, 160.0)} = 1.1, p=0.51$), ‘pain’ ($F_{(3.00, 160.0)} = 1.2, p=0.43$), ‘quality of life’ ($F_{(2.3, 124.1)} GG = 1.9, p=0.14$) and ‘function, daily living’ ($F_{(2.5, 154.8)} GG = 1.8, p=0.31$) of the KOOS and ‘daily activities’ ($F_{(2.6, 150.1)} GG = 1.2, p=0.39$), ‘sport activities’ ($F_{(2.4, 151.9)} GG = 1.3, p=0.51$), and ‘your knee function in the future’ ($F_{(2.2, 141.5)} GG = 1.7, p=0.37$) of the K-SES. The latter suggested that on most aspects of the rehabilitation, the patients in both the hospital- and the community-based rehabilitation groups had achieved similar levels of function.

The second finding of this clinical trial suggested that the patients’ anthropometric characteristics and orthopaedically-relevant factors may not influence outcomes of rehabilitation programme following ACL reconstruction. By adjusting for the levels of habitual physical activities, the patients in the hospital-based rehabilitation programme statistically showed superior outcomes to the patients in the community-based rehabilitation programme on subsection ‘pain’ of the KOOS. The group mean response for the patients in the hospital-based rehabilitation groups showed 3% more improvement than the patients in the community-based rehabilitation programme, however, based on the MCID reported for the KOOS (10%), this result may not be
clinically important. No differences between the outcomes of the hospital- and the community-based rehabilitation programmes were observed by adjusting for the remaining orthopaedically-relevant factors and all anthropometric characteristics included in this trial. The latter suggested that, the outcomes of the rehabilitation programmes (hospital- and community-based rehabilitation programmes) were not intruded by the anthropometric characteristics and orthopaedically-relevant factors.

Another finding of this clinical trial suggested that the patients in the hospital-based rehabilitation programme possessed superior outcomes to the patients in the community-based rehabilitation programme at early phase of rehabilitation (up to 12 week) on IKDC ($F_{(1.0, 61.0)} = 1.9, p=0.43$), subsections ‘sport and leisure’ ($F_{(1.0, 61.0)} = 7.1, p=0.01$) ‘physical activities’ ($F_{(1.0, 61.0)} = 6.0, p=0.02$) of the K-SES and ‘symptom and stiffness’ ($F_{(1.0, 61.0)} = 3.9, p=0.02$), ‘pain’ ($F_{(1.0, 61.0)}=10.3, p=0.01$), ‘function, daily living’ ($F_{(1.0, 61.0)} = 10.1, p=0.03$), ‘sports and recreational activities’ ($F_{(1.0, 61.0)} = 4.0, p=0.04$) and ‘quality of life’ ($F_{(1.0, 61.0)} = 4.1, p=0.01$) of the KOOS. These findings suggested due the better management of dose in the patients in the hospital-based hospital programme compared to the patients in the community-based rehabilitation programme within early phase of rehabilitation, the patients in the former group might have achieved better outcomes of rehabilitation compared to the patients in the community-based rehabilitation programme.

Finally, this clinical trial suggested that change scores in PROMs within the early phase of rehabilitation may not be good predictors for their respective outcomes at 24th week. Change scores within the early phase of rehabilitation in IKDC, subsections ‘symptom and stiffness’ and ‘pain’ of the KOOS, ‘daily activities’ of the
K-SES and VAS showed significant correlation with their respective score at 24th week. However, the association in the latter may explain only 16-36% of the variance ($r = 0.4$ to $0.6$; $p = 0.03$) which might not be sufficient for the clinician to predict the final outcomes of the rehabilitation from the changes within early phase of rehabilitation.

The main finding of achieving superior outcomes of rehabilitation by the patients in the hospital-based rehabilitation to the patients in the community-based rehabilitation is in contrast to what was previously reported in the literature (Grant and Mohtadi 2010, Ugutmen et al. 2008, Hohmann et al. 2011). In the latter three trials, no differences were reported amongst the patients in the hospital- and the community-based rehabilitation programmes when assessed at 2-4 years (Grant and Mohtadi 2010), 12th months (Ugutmen et al. 2008) and 12th month (Hohmann et al. 2011) following ACL reconstruction. In this clinical trial, the outcomes of the hospital- and the community-based rehabilitation were assessed across 24 weeks following ACL reconstruction. On average, the structured rehabilitation programme following ACL reconstruction formally ends at 24th week of reconstruction of ACL in the hospital where this clinical trial was deployed. The latter hospital offers an example of a 'long-standing (> 10 years), successful and regularly research audited post-surgical rehabilitation programme that incorporates many of the latest approaches to care (Bailey et al. 2003). Similar duration for the end of formal rehabilitation programme has been reported in a systematic review (Risberg et al. 2004). The finding of this clinical trial may be a good example of comparison the outcomes of the hospital- and the community-based rehabilitation programmes as both the groups were assessed in such a time where the patients in the hospital-based rehabilitation programme have
not started self-managing rehabilitation activities in the community with supervision from rehabilitation team.

Despite the fact that statistically superior results were observed for the patients in the hospital-based rehabilitation on some aspects of PROMs assessing knee function, still on other aspects the patients in the community-based rehabilitation programme achieved similar levels of function on PROMs to the patients in the hospital-based rehabilitation group (i.e. no differences were observed between the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes on IKDC, VAS and Lysholm). The latter findings between the outcomes of the hospital- and the community-based rehabilitation programmes are in agreement with the available literature where no differences amongst the patients receiving rehabilitation programmes in the hospital- and the community following ACL reconstruction were reported (Grant et al. 2005, Beard and Dodd 1998, Schenck et al. 1997).

Although the community-based rehabilitation programme was not audited by the rehabilitation team, still achieving similar outcomes of rehabilitation by the patients in the community to the patients in the hospital-based rehabilitation might have been influenced by some factors. Motivation of patients towards their rehabilitation might be one of the factors due to which the patients in the community-based rehabilitation have achieved similar levels of function to the patients in the hospital-based rehabilitation programme on PROMs. Availability of familiar environment and support from the family members during rehabilitation in the community are some of the determinants that have been reported to enhance patients’ motivation towards
their rehabilitation in the community (Papalia et al. 2013). Similarly, independence in rehabilitation is another factor, which has been reported to positively influence achieving successfully the outcomes of a rehabilitation programme in the community (Chan et al. 2008). The latter allows patients to modify rehabilitative activities according to their needs and preferences that might be helpful in achieving optimal outcomes of rehabilitation programme.

On balance, equivalent outcomes for a wide variety of functional capacities and pain (IKDC, Lysholm and VAS) tend to suggest that the dose of conditioning experienced over time by both hospital- and community-based rehabilitation programmes had been similar. Thus, by inference, it is plausible that community-based patients managed successfully the requisite levels of intensity and volume for conditioning without full supervision and only relying on up to four interim consultation visits to modify the levels of conditioning.

An inconsistent pattern of the detected differences between hospital- and community-based patients groups amongst PROMs of function (IKDC, KOOS, K-SES and Lysholm) was an interesting finding given that all PROMs purported to focus attention on the same measurement outcome. Given the variance in the clinimetric characteristics that has been noted for these PROMs (please see chapter 3, Table 3.2), it is possible that differences amongst the PROMs in their responsiveness to changes in the patients’ perceptions of functional capability during the rehabilitative care pathways might correlate with the study’s pattern of significant findings. For example, the MDC scores for IKDC, KOOS and K-SES have been reported 8.8 (Collins et al. 2009), 6.1 (Roos and Lohmander 2003) and 6.0 units
(Thomee et al. 2007), respectively, suggesting that these PROMs possess varied capabilities for detecting changes over time. Furthermore, in a trial carried out previously on the clinimetric characteristics of PROMs in ACL-injured patients, results suggested that assessing pain using a VAS and the IKDC assessing function were less responsive to changes during the first year of recovery following surgery (Risberg et al. 1999a). By contrast, KOOS (for patients undergoing meniscectomy or with osteoarthritis) and K-SES (in patients with ACL injuries) have been reported to be responsive during the same period of clinical care (Roos and Lohmander 2003). Observing statistically significant findings amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes on the subsections ‘physical activities’ of the K-SES and ‘sport and recreation’ of the KOOS in this clinical trial confirms the latter interpretation that K-SES and KOOS are more responsive than IKDC and VAS.

The likelihood of bias associated with non-randomisation in this trial was not proved from the baseline results of anthropometric characteristics, orthopaedically-relevant factors and PROMs of this clinical trial. Baseline measurements of the latter three measures showed similarities amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes. The latter indicated that the lack of randomisation in this study had not intruded unduly on the design of this clinical trial.

In previous trials carried out on musculoskeletal injuries, age, BMI and time to surgery were reported being influential on the outcomes of rehabilitation (Smith et al. 2012, Vincent et al. 2006, Braybrooke et al. 2007). The possible reasons for the
influence of the latter may be physiological adoption, degenerative changes and deconditioning of musculature associated with the latter factors. The effects of the latter anthropometric measures and orthopaedically-relevant factors have not received robust attention in the previous trials carried out on the effects of the hospital- and community-based rehabilitation programmes following ACL reconstruction. One of the novelties of this clinical trial was statistically adjustments for the latter two factors at baselines amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes. By adjusting for the levels of habitual physical activities at baseline, a statistically significant interaction was observed for subsection ‘pain’ of the KOOS. The patients in the hospital-based rehabilitation programme showed 3% more improvement compared to the patients in the community-based rehabilitation programme on the latter subsection of the KOOS across 24 weeks rehabilitation when adjusted for the levels of habitual physical activities. It is interesting to report that the patients in the hospital-based rehabilitation group showed superior levels of habitual physical activities compared to the patients in the community-based rehabilitation programmes during the early phase of rehabilitation programme (levels of habitual physical activities amongst the patients in the hospital- versus community-based rehabilitation programmes at 12th week following ACL reconstruction; 2645.2 ± 267.2 and 2012.4 ± 176.0 Kilocalories/day, respectively; \( p=0.04 \). The latter might have intruded the final outcomes of rehabilitation amongst the group responses of the patients in the latter two groups. Although, by adjusting for the levels of habitual physical activities a significant interaction was observed for one subsection of the KOOS, still the per cent improvement is lower than what would be regarded as
clinically important (MCID for KOOS; 10%). In general, it might be suggested that the effects of the anthropometric characteristics and orthopaedically-relevant factors may not be influential on the final outcomes of rehabilitation. Moreover, the latter reaffirmed that the design of this clinical trial has not been influenced by non-randomisation in the trial. By adjusting for the levels of habitual physical activity, a statistically significant interaction was observed for subsection ‘pain’ of the KOOS. The patients in the hospital-based rehabilitation programme showed 3% more improvement compared to the patients in the community-based rehabilitation programme on the latter subsection of the KOOS across 24 weeks of rehabilitation when adjusted for the levels of habitual physical activity. It is interesting to report that the patients in the hospital-based rehabilitation group showed superior levels of habitual physical activity compared to their counterparts in the community-based rehabilitation programme. This occurred during the early phase of the rehabilitation programmes (levels of habitual physical activity amongst the patients in the hospital-versus community-based rehabilitation programmes at 12th week following ACL reconstruction: 2462.2 ± 167.2 Kilocalories/day versus 2172.0 ± 98.0 Kilocalories/day: p=0.03). It is interesting to report that using ANCOVA (by adjusting for levels of habitual physical activity) similar findings to ANOVA were observed: the patients in the hospital-based rehabilitation programme showed superior results compared to the patients in the community-based rehabilitation programme. By comparison to the findings of ANOVA, statistically significant result was still observed by adjusting for levels of habitual physical activity. The results for the sub-section of KOOS still favoured hospital-based rehabilitation. This
indicated that the effects of levels of habitual physical activity were not influential significantly on this selected outcome of rehabilitation.

The designed rehabilitation programme for ACL reconstruction in the hospital where this clinical trial was deployed is based on the current scientific and clinical evidences from the literature. An emphasis on more supervised physiotherapy sessions in the hospital during the initial three months of rehabilitation following ACL reconstruction has led the author to speculate that the patients in the hospital-based rehabilitation will show superior outcomes of rehabilitation at during the early phase of rehabilitation compared to the patients in the community-based rehabilitation programme. One of the aims of this clinical trial was to assess the outcomes up to 12th week of rehabilitation amongst the patients in the hospital- and the community-based rehabilitation programmes following ACL reconstruction. It is interesting to report that a significant interaction favouring the patients in the hospital-based rehabilitation over the patients in the community-based rehabilitation programme was observed for IKDC ($F_{(1.0, 61.0)} = 3.5, p=0.03$), subsections ‘sport and leisure’ ($F_{(1.0, 61.0)} = 7.1, p=0.01$) and ‘physical activities’ ($F_{(1.0, 61.0)} = 6.0, p=0.02$) of the K-SES and ‘symptom and stiffness’ ($F_{(1.0, 61.0)} = 3.9, p=0.02$), ‘pain’ ($F_{(1.0, 61.0)}=10.3, p=0.01$), ‘function, daily living’ ($F_{(1.0, 61.0)} = 10.1, p=0.03$), ‘sports and recreational activities’ ($F_{(1.0, 61.0)} = 4.0, p=0.04$) and ‘quality of life’ ($F_{(1.0, 61.0)} = 4.1, p=0.01$) of the KOOS. Similar findings of more improvement by the patients with more supervision compared to the patients with minimal supervised rehabilitation programme were reported in a 3-year longitudinal prospective trial carried out on clinical population who has undergone ACL reconstruction (Ageberg et al. 2001). These findings suggests that the hospital offers better environment compared to the community for managing dose of
exercises during the initial three months of rehabilitation. Moreover, similar expectations might be made about the outcomes at 24\textsuperscript{th} week of rehabilitation if the intensity of dose is monitored and regulated in the last three months of rehabilitation similar to the management of dose during the initial three months of rehabilitation following ACL reconstruction.

Relying on PROMs for the assessment of patients’ general health status and disease-specific symptoms are increasingly getting popularity among clinician due to commercialisation in the health care system (Nemec and Kolisnichenko 2006). It has been reported that, on average, the majority of the patients receive improvement on the PROMs following surgical intervention in the knee joint. However, an important minority of the patients has been reported to sustain no improvement of their symptoms on the PROMs (Lingard et al. 2004). It is important to identify patients at a risk of poor outcomes within the early phase of rehabilitation, such that rehabilitation team may modify the volume and the intensity of conditioning programme for the latter to achieving the optimal outcomes of rehabilitation (Judge et al. 2012). One of the aims of this chapter was based on the assumption that changes within early phase of rehabilitation might be used to predict final outcomes of rehabilitation at 24\textsuperscript{th} week following ACL reconstruction. Findings of this trial had suggested ‘low to medium’ correlation (‘r’ range; 0.4-0.6) between changes in early phase of rehabilitation and final outcomes of rehabilitation at 24\textsuperscript{th} week for the patients in the community-based rehabilitation programme. Similarly, changes in early phase of rehabilitation and final outcomes of rehabilitation showed medium (‘r’ range; 0.5-0.6) correlation for the patients in the hospital-based rehabilitation programme. These findings explain the 16-36\% of variance and suggest changes in
PROMs within early phase of rehabilitation might not provide confidence to the clinician to predict the outcomes of rehabilitation programme at 24\textsuperscript{th} week following ACL reconstruction.

5.5 LIMITATIONS

One of the limitations of this clinical trial was the non-randomisation which was not possible due to logistical and ethical issues. Moreover, due to the nature of this clinical trial, the amount of energy expenditure was only reported on PROMs (seven day physical activities recall). The amount of energy expenditure based on conditioning programme was not reported due to the fact that the latter was not monitored in the community by rehabilitation team. In addition, this clinical trial was carried out on the patients receiving rehabilitation programme at two different environments (hospital and community settings). The effect of surroundings (support and motivation from family members) and difference in the control might be some of the important issues influencing outcomes of a rehabilitation programme.

5.6 CONCLUSION

Despite showing inferior outcomes at early phase of rehabilitation (at 12\textsuperscript{th} week) by the patients in the community-based rehabilitation programme, the latter achieved similar levels of function on PROMs to the patients in the hospital-based rehabilitation at the end of rehabilitation. The latter suggested efficacy of the community-based rehabilitation programme for the achieving outcomes of rehabilitation following ACL reconstruction. The patients receiving rehabilitation programme following ACL reconstruction may be evaluated on regular basis as
outcomes of one stage (early) of rehabilitation may not predict the outcomes at another stage (late) of rehabilitation.
6 CHAPTER: TRIAL II (PART A)

DO THE LEVELS OF SUPERVISION DURING A STANDARDISED POST-SURGICAL REHABILITATION PROGRAMME INFLUENCE PROMs ASSESSING FUNCTION?

A RANDOM-ALLOCATION, CONTROLLED TRIAL INVOLVING ISO-VOLUMETRIC EXERCISE STRESS
SUMMARY OF THIS CHAPTER

There is no consensus in the literature about the effects of supervision from physiotherapists on the outcomes of rehabilitation programme following ACL reconstruction. This clinical trial was designed to compare the outcomes of the fully-supervised and the minimally-supervised rehabilitation programme following ACL reconstruction. For this purpose, a total of 48 patients who consented for this clinical trial were randomly allocated into the fully-supervised (n=24) and the minimally-supervised (n=24) conditioning programmes. The patients in the fully-supervised conditioning programme received contemporary rehabilitation in the hospital where they were fully monitored/supervised by the physiotherapists during the whole session of physiotherapy. The patients in the minimally-supervised conditioning programme followed a novel approach to the rehabilitation and self-managed their rehabilitation activities in the hospital without supervision from the physiotherapists. In the latter approach information about the rehabilitation activities that were to be undertaken by patients were provided to each patients in the minimally-supervised rehabilitation group at the beginning of each physiotherapy session by a physiotherapist. From an ethical prospective, the patients in the minimally-supervised rehabilitation programme were guided to the same rehabilitation programme received by the patients in the fully-supervised rehabilitation programme. The number of physiotherapy sessions in the hospital attended by the patients in the fully-supervised and the patients in the minimally-supervised rehabilitation groups were observed 14.3 ± 4.9 (mean ± sd) and 14.5 ± 4.3, respectively; p=0.01, indicating that the patients in both the latter groups have attended similar number of physiotherapy sessions in the hospital. All the patients in
both these groups were evaluated at four different occasions (pre-surgery and at the 6th, 12th and 24th weeks post-surgery) on PROMs (IKDC, KOOS, K-SES, Lysholm and VAS). Findings of this trial suggested, a statistically significant group × time interaction for subsections physical activities’ of the K-SES (F (3,0,114) = 2.6, p=0.02) of the K-SES. No difference were observed for the remaining three subsections of the K-SES, all five subsections of the KOOS, IKDC, Lysholm and VAS, suggesting that the patients in minimally-supervised rehabilitation group can achieve the same levels of function to the patients in the fully-supervised rehabilitation groups. Based on the findings of this trial, it can be concluded that the outcomes of the rehabilitation following ACL reconstruction may not be influenced by the levels of supervision from the rehabilitation team.
6.1 INTRODUCTION

The limited facilities available within healthcare systems have led to the increasing development and use of unsupervised rehabilitation protocols (Pappalia et al. 2013). Patients are often advised to share the responsibility for the delivery of care by self-managing programmes of exercise in the community (Judge et al. 2012). One possible advantage of such an approach is the manoeuvring of the time and place in which care is delivered to that which is convenient to the needs and preferences of the patients. The effects on PROMs of function and pain following ACL reconstruction surgery and rehabilitation that had taken place in the environment preferred by the patients (hospital versus community) were reported in chapter 5. Patients preferring to undergo rehabilitation in the community environment necessarily followed self-managed rehabilitation activities and at times, little supervision of conditioning activities by rehabilitative specialists. Evidence from the literature has suggested that due to some factors (independence, familiar environment and support from family member) associated with self-management of rehabilitation in the community, patients can achieve optimal outcomes of rehabilitation without supervision from rehabilitation specialists. However, the effects of self-managing rehabilitation programme within an environment where certain aspects such as familiar environment and family members support are lacking, have not received robust attention for the musculoskeletal injuries.

In this chapter, the effects of post-surgical rehabilitation delivered in an environment in which patients are fully-supervised and minimally-supervised by rehabilitation specialists are compared on PROMs of function and pain. The manipulation of the
amount of supervision is undertaken in a hospital-based environment that offered a consistent and controlled settings in which the influence of the levels of clinical supervision could be assessed experimentally.

The reason for choosing a hospital environment for assessing the effects of supervision on the outcomes of rehabilitation was the associated merits of a greater experimental control (less ‘noise’ from factors that couldn’t be controlled) in the latter environment compared to that associated with a community settings. The patients, who are self-regulating rehabilitation programmes in the community, have more choices in how they might manipulate the intensity and the volume of the training exercises (with corresponding variations to the ‘dosage’ of conditioning) according to their perceived needs and preferences. By contrast, rehabilitation experts are closely monitoring the intensity and the volume of the training conditioning programme in the hospital environment, theoretically facilitating optimised conditioning dosage for each patients (Pappalia et al. 2013).

Accumulating evidence from the literature suggests that post-surgical care of ACL injury might not always necessitate fully-supervised programmes of rehabilitative conditioning and patients with the latter injury might achieve optimal outcomes of rehabilitation (Hohmann et al. 2011, Grant and Mohtadi 2010, Feller et al. 2004).

In the previous clinical trials carried out on the effects of the supervision on the outcomes of rehabilitation following ACL reconstruction, various methods have been adopted to differentiate the levels of supervision (Hohmann et al. 2011, Grant and Mohtadi 2010, Feller et al. 2004). For example, in the clinical trial reported by Feller et al. (2004), the patients were classified into the ‘minimal-supervised’ and ‘fully-
supervised’ rehabilitation groups according to the number of physiotherapy attendances during the initial six months of ACL reconstruction; the patients with three or less than three attendances of physiotherapy sessions in the hospital were categorised into the ‘minimally-supervised’ rehabilitation group while the patients with more than 12 attendances of physiotherapy sessions in the hospital were categorised into the ‘fully-supervised’ rehabilitation group. In contrast, in the clinical trials carried out by Hohmann et al. 2011 and Grant and Mohtadi 2010, the levels of supervision have been differentiated on the basis of environment where the conditioning programme was delivered; the patients receiving rehabilitation programme in the hospital were categorised into ‘fully-supervised’ rehabilitation group while the patients receiving rehabilitation programme in the community were categorised into the ‘minimally-supervised’ rehabilitation group. The approaches adopted in the above three trials (Hohmann et al. 2011, Grant and Mohtadi 2010, Feller et al. 2004) are limited to provide an equal opportunity to the patients to receive an iso-volumetric conditioning programme in the same environment. The latter might have influenced the final outcomes of rehabilitation by allowing patients to follow a hypo- or hyper-dosing conditioning programme. In this clinical trial, a novel approach to rehabilitation was adopted and the patients in both the fully-supervised and the minimally-supervised rehabilitation groups were provided equal opportunities to receive an iso-volumetric rehabilitation programme in the same environment regardless being subjected to different levels of supervision from rehabilitation team.

It is important to report that the characteristics associated with full-supervision and minimal-supervision during rehabilitation are complex and have received little
attention in the literature. Characteristics such as presence of physiotherapists (Gram et al. 2014), monitoring (Puente-Maestu et al. 2000) and evaluation (Celis et al. 2003) during rehabilitation have been reported integral parts of full-supervision during rehabilitation sessions in the hospital. The rehabilitation programme following ACL reconstruction in the hospital where this clinical trial was deployed, offers distinctive feature of interaction amongst physiotherapists and the patients during rehabilitation sessions delivered in the hospital. The latter provides an opportunity to physiotherapists to closely monitor the intensity and the volume of the conditioning programme during supervised rehabilitation sessions and alter the latter two according to the needs of the patients. Based on the evidence from the literature and observations during this clinical trial, operationally supervision (full) during rehabilitation was defined as the process of monitoring and direction from physiotherapists during physiotherapy sessions in the hospital in which patients’ activities are closely monitored and altered according their needs and preferences. In contrast, the minimal-supervision for this clinical trial was defined a rehabilitation approach during which patients are guided to self-manage the proposed rehabilitation activities in the hospital without being provided feedback from physiotherapists (please see Figure 6.1 for the components of the fully-supervised and the minimally-supervised rehabilitation sessions). From ethical perspectives, the patients who were allocated into the minimal supervised rehabilitation group in this trial, had an equal opportunity to follow the exact dose of exercises in the same environment suggested to the patients in the fully-supervised rehabilitation group. Moreover, the patients in the latter group were guided to the same contemporary rehabilitation programme followed by the patients in the fully-supervised rehabilitation groups.
In the previous trial reported in chapter 5 of this thesis, randomization of participants was not done due to the logistical and ethical issues related to the design of the trial. Patients were allowed to self-select themselves into the hospital- and the community-based rehabilitation programmes. In order to minimise the possibility of bias in the results, this study has been designed as a prospective randomised controlled trial in which patients undergoing post-surgery rehabilitation have been subjected to different levels of supervision during the hospital-based conditioning programme. Due to the associated merits of same environment and randomisation in this clinical trial some aspects of potential bias may have been controlled. However, other uncontrolled determinants for rehabilitation in this trial including anthropometric characteristics and orthopaedically-relevant factors might still have the potential to intrude the final outcome of this clinical trial. The assumption that the latter might affect the final outcomes of rehabilitation has been addressed in this trial and separate analysis following statistically adjustments for anthropometric characteristics and selected orthopaedically relevant factors has been undertaken to compare the outcomes of function and pain of PROMs between the outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes. The designed rehabilitation programme for ACL reconstruction in the hospital where this clinical trial was deployed, is based on the current scientific and clinical evidences from the literature. It was observed that more supervised physiotherapy sessions were provided to the patients during the initial three months of rehabilitation compared the last three months of rehabilitation following ACL reconstruction. Based on the latter, it was speculated that the patients receiving the fully-supervised rehabilitation programmes will achieve superior outcomes at early phase of
rehabilitation compared to the patients receiving the minimal supervision. The variation associated with clinimetric characteristics of different PROMs reported in the literature and observed in chapter 4 of this thesis led the author to adopt similar strategy adopted in the latter chapter of this thesis and more than one PROMs were used in this trial.

Figure 6.1 Figure explaining the full-supervision and the minimal-supervision in the hospital. The solid lines represent elements, which were common in both types of supervision. In contrast, the dotted lines represent those elements, which are only present in the full supervision during supervised rehabilitation sessions.

### 6.2 METHODS

A total of 48 patients [ fully-supervised group n=24; (age; mean ± sd, 32.2 ± 11.1 yr, height; 1.73 ± 0.07 m, body mass 75.8 ± 10.7 kg, waiting time; 35.8 ± 29.4 months), the minimally-supervised group n=24; (age; mean ± sd, 31.0 ± 13.2 yr, height; 1.75 ± 0.06 m, body mass 80.6 ± 10.7 kg, waiting time; 28.8 ± 25.1 months)] who consented for this trial were randomly allocated to the fully-supervised and the
minimally-supervised rehabilitation groups. To get equal number of the patients in each group an approach of ‘blocked randomization’ was adopted which allowed the recruiter to use varying size of blocks for the randomization. The two fundamental characteristics associated with concealment in randomization reported in the previous clinical research were ensured (Vickers 2006); researcher was not allowed to predict the group allocation of the next patient and researcher was not allowed to change the allocation of the patients after being allocated to any of the two groups. The inclusion of these two characteristics during the allocation of the patients into either of the two groups has resulted the allocation to be classified as ‘concealed allocation’. Moreover, all the patients in this clinical trial were blinded to their group allocation. However, being an educational project having limited funding and time, blinding of physiotherapists and assessors was not plausible. The whole process of assessment of the participants was carried out by the author of this thesis and a PhD colleague who was blinded to the group allocation of the participants. The patients in the fully-supervised rehabilitation group received contemporary conditioning programme in the hospital where they were fully-supervised by the physiotherapists in the hospital throughout the physiotherapy sessions while the patients in the minimally-supervised rehabilitation group were advised to self-manage the same rehabilitation activities in the hospital suggested to the patients in the fully-supervised rehabilitation group. To report adherence of the patients to the prescribed exercises, a sheet containing the exact number and duration for each exercise were recorded by these patients. Similarly, to ensure that the patients in both groups are guided to an iso-volumetric rehabilitation programme, physiotherapists were advised to guide them to the same conditioning programme which has been continuously
used in the hospital for the last decade. All the patients were assessed on four different occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction surgery) for function and pain on PROMs including IKDC, KOOS, K-SES, VAS and Lysholm (the same cohort was tested for functional and objective outcomes as well, which have been discussed in the next chapter of this thesis). In this chapter, we have analysed data of 40 patients (20 in each group) as 17% of the total recruited patients were lost during follow-up. Details of the patients’ recruitment, allocation and loss to follow-up have been given in a Consolidated Standards of Reporting Trials (CONSORT) Figure 6.2. Selection bias associated with loss to follow-up was assessed by comparing baseline (pre-op) PROMs and other relevant anthropometric and orthopaedically clinically relevant factors for self-excluded and contributing patients.
Figure 6.2: Figure showing allocation of the patients into the fully-supervised and the minimally-supervised rehabilitation groups.

**Quantification of exercise programme**

According to author’s knowledge, none of the clinical trials carried out on the effects of the levels of supervision following ACL reconstruction, have reported the influence of dose (rehabilitative activities in the hospital and the levels of habitual physical activities) on the final outcome of rehabilitation. One of the aims of this clinical trial was to investigate the effects of the latter two on the final outcomes of rehabilitation programme following ACL reconstruction. The conditioning programme received by the patients in both these groups was reported in the form of repetitions, sets, weight lifted and duration during which these exercises were
performed. The total amount of work done during one session was computed using the latter mentioned information which was then converted into Kilocalories/minute. Similarly, the amount of levels of habitual physical activities was computed from a validated inventory, seven day physical activities recall, which was then converted into Kilocalories/minute. Guidelines reported in the literature were used to compute amount of levels of habitual physical activities (Sallis et al. 1993). A detailed overview how to compute Kilocalories/minute from the structured conditioning has been attached as appendix (please see appendix VIII).

6.2.1 STATISTICAL ANALYSIS

The clinical efficacy of the fully-supervised and the minimally-supervised rehabilitation programmes was assessed using separate ANOVAs for each of primary outcome measures of PROMs (IKDC, KOOS, K-SES, Lysholm) and pain (VAS). The ANOVA model involving factors of group (the fully-supervised and the minimally-supervised rehabilitation groups) by test occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction) with repeated measures on the latter factor was used to test the null-hypothesis of no statistical interaction between the group mean responses for the patients undertaking conditioning programme in the hospital with fully-supervision and minimally-supervision from the rehabilitation team. The effects of anthropometric characteristics and orthopedically-relevant factors on the clinical efficacy of the latter two rehabilitation programmes (fully-supervised and minimally-supervised rehabilitation programmes) were assessed by using a separate ANCOVAs for each of primary outcome measures of PROMs (IKDC, KOOS, K-SES, Lysholm) and pain (VAS) following a statistical adjustment
for anthropometric characteristics and orthopedically-relevant factors. The ANCOVA model involving factors of group (the hospital- and the community-based rehabilitation groups) by test occasions (pre-surgery and at the 6th, 12th and 24th post-surgery) with repeated measures on the latter factor was used to test the null-hypothesis of no statistical interaction between the group mean responses for the patients undertaking fully-supervised and minimally-supervised rehabilitation programmes in the hospital. Pearson product-moment correlation coefficients were used to assess the association between changes in the early phase of rehabilitation in PROMs with the final outcomes of the latter at 24th week following ACL reconstruction. A priori alpha level was set at p< 0.05. Greenhouse-Geisser adjustment of the degrees of freedom associated with experimental and error variances were used where selected assumption underpinning ANOVAs had not been met.

6.3 RESULTS

There were no differences amongst the group mean scores for the patients in the fully-supervised (♂=3, ♀=17) and the minimally-supervised (♂=2, ♀=18) rehabilitation groups for anthropometric characteristics [(height: mean ± sd: 1.73 ± 0.07 m and 1.76 ± 0.07 m, respectively, p=0.50 ) and (body mass: 75.8 ± 10.7 kg and 80.6 ± 10.7 kg, respectively, p=0.32)] and orthopaedically relevant factors [(body mass index: 25.2 ± 3.3 kg/m² and 25.9 ±2.8 kg/m² , respectively, p=0.45), (age: 32.20 ± 11.20 yr and 31.00 ± 13.25 yr , respectively, p=0.33), (waiting time for surgery: 45.8 ± 39.4 and 28.8 ± 25.1 months, respectively, p=0.42) and (levels of habitual physical activity at baseline: 2173.9 ± 197.4 Kilocalories/day and 1994.4 ±
185.5 Kilocalories/day, respectively, \( p=0.46 \)], suggesting that the patients in both groups were similar on the latter factors. Similarly, the patients in the fully-supervised and the minimally-supervised rehabilitation groups showed similarities at baseline on PROMs (IKDC, K-SES, KOOS, VAS and Lysholm) [please see Table 6.1]. The latter findings indicated that the groups were matched well on these parameters at the baseline and that the process of randomly-allocating patients to groups had been successful. None of the participants included in this clinical trial had any post-surgical complication which otherwise would had demanded special supervision from the rehabilitation team.

Table 6.1: Table showing group mean responses on PROMs for the patients in the fully-supervised and the minimally-supervised rehabilitation groups

<table>
<thead>
<tr>
<th></th>
<th>FS</th>
<th>MS</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IKDC</td>
<td>65.9 ± 11.4</td>
<td>61.6 ± 12.1</td>
<td>0.41</td>
</tr>
<tr>
<td>Lysholm</td>
<td>63.6 ± 14.1</td>
<td>59.8 ± 16.7</td>
<td>0.19</td>
</tr>
<tr>
<td>VAS</td>
<td>3.5 ± 2.0</td>
<td>3.5 ± 2.2</td>
<td>0.43</td>
</tr>
<tr>
<td>KS-daily activities</td>
<td>37.5 ± 14.9</td>
<td>37.0 ± 17.1</td>
<td>0.09</td>
</tr>
<tr>
<td>KS-sport activities</td>
<td>18.1 ± 10.6</td>
<td>22.9 ± 13.0</td>
<td>0.11</td>
</tr>
<tr>
<td>KS-physical activities</td>
<td>18.2 ± 9.3</td>
<td>26.8 ± 11.7</td>
<td>0.14</td>
</tr>
<tr>
<td>KS-your knee function in the future</td>
<td>22.6 ± 8.1</td>
<td>24.6 ± 8.4</td>
<td>0.21</td>
</tr>
<tr>
<td>KO-symptom and stiffness</td>
<td>23.0 ± 3.7</td>
<td>14.0 ± 3.1</td>
<td>0.09</td>
</tr>
<tr>
<td>KO-pain</td>
<td>9.9 ± 6.0</td>
<td>11.0 ± 6.1</td>
<td>0.21</td>
</tr>
<tr>
<td>KO-function, daily activities</td>
<td>13.8 ± 10.1</td>
<td>15.2 ± 13.6</td>
<td>0.18</td>
</tr>
<tr>
<td>KO-sport and recreation</td>
<td>12.0 ± 3.3</td>
<td>10.3 ± 4.9</td>
<td>0.24</td>
</tr>
<tr>
<td>KO-quality of life</td>
<td>11.1 ± 2.7</td>
<td>10.5 ± 2.7</td>
<td>0.31</td>
</tr>
</tbody>
</table>

FS = fully-supervised
MS = minimally-supervised
KS = K-SES
KO = KOOS
6.3.1 OUTCOMES ACROSS 24 WEEKS (PROMS)

An ANOVA using factors of group (the fully-supervised and the minimally-supervised rehabilitation groups) by test occasion (pre-surgery and at the 6th, 12th and 24th weeks post-surgery) with repeated measures on the latter factor suggested a statistically significant group by assessment occasion interaction for subsection ‘physical activities’ of the K-SES (F(3.0,114) = 2.6, p=0.02), suggesting that while patients in both the fully-supervised and the minimally-supervised rehabilitation groups had improved significantly by the 24th week of rehabilitation compared to pre-surgery (group mean scores for the patients in the fully-supervised and minimally-supervised rehabilitation groups at pre-surgery versus 24th week were 18.3 ± 9.4; mean ± sd, versus 48.0 ± 9.2 and 26.8 ± 11.8 versus 45.4 ± 12.9, respectively), these changes were more prominent in the patients who were in the fully-supervised rehabilitation group (Figure 6.3). The relative effect size (from baseline to 24th week) for the patients in the fully-supervised rehabilitation programme was 3.02, which represents a ‘large’ effect, corresponding an improvement of 61% from baseline to 24th week. Similarly, the relative effect size (from baseline to 24th week) for the patients in the minimally-supervised rehabilitation group was observed 1.5, corresponding to an improvement of 41% from the baseline to 24th week for the patients in the latter group. In this clinical trial, subsection ‘physical activities’ of the K-SES was the only PROM where a statistically significant interaction between the group mean responses for the patients in the fully-supervised and minimally-supervised rehabilitation groups, was observed. In contrast, no interactions were observed for subsections ‘daily activities’(F(3.0,114) = 0.8, p=0.21), ‘sport activities’(F
(2.5,110.2) \( GG = 1.3, p=0.34 \) and ‘your knee function in the future’ \( (F_{(3,0,114)} = 2.0, p=0.56) \) of the K-SES, IKDC \( (F_{(2.3,113.1)} \ GG = 0.9, p=0.45) \), Lysholm \( (F_{(3,0,114,0)} = 1.4, p=0.56) \), VAS \( (F_{(2.1,111.4)} = 1.3, p=0.33) \) and all five subsections ‘symptom and stiffness’ \( (F_{(3,0,114)} = 1.4, p=0.54) \), pain \( (F_{(3,0,110)} \ GG = 2.1, p=0.35) \), ‘function, daily activities’ \( (F_{(3,0,114)} = 1.6, p=0.71) \), ‘sport and recreation’ \( (F_{(3,0,114)} = 1.9, p=0.43) \), and ‘quality of life’ \( (F_{(3,0,114)} = 2.1, p=0.44) \) of the KOOS. The inconsistencies in the findings of different PROMs at 24\(^{th}\) week following ACL reconstruction suggested that in most aspects, the patients in both the fully-supervised and the minimally-supervised rehabilitation groups had achieved similar levels of function of PROMs.

Figure 6.3: Figure showing interaction for the K-SES (physical activities) amongst the group means scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups across 24 week rehabilitation following ACL reconstruction.
6.3.2 OUTCOMES ACROSS 24 WEEKS (PROMS) FOLLOWING STATISTICAL ADJUSTMENTS FOR ANTHROPOMETRIC CHARACTERISTICS AND ORTHOPAEDICALLY RELEVANT-FACTORS

By adjusting age, a statistically significant group × time interaction was observed for subsection ‘daily activities’ of the K-SES (F(3.0, 114.0) = 2.6, p=0.02). The group mean responses (adjusted means) for the patients in the fully-supervised rehabilitation group and the minimally-supervised rehabilitation group at pre-surgery versus 24th week were 37.5 ± 14.9; mean ± sd, versus 64.2 ± 4.2 and 37.5 ± 14.9 versus 58.6 ± 13.0, respectively, indicating the patients in the fully-supervised rehabilitation group possessed superior outcomes compared to the patients in the minimally-supervised rehabilitation group (Figure 6.4). The relative effect sizes from pre-surgery to 24th week for the patients in the fully-supervised and the minimally-supervised rehabilitation groups were 2.5 and 1.6, corresponding to an improvement of 41% and 37%, respectively. The latter indicated that the patients in the fully-supervised rehabilitation group had shown 4% more improvement at the end of rehabilitation programme compared to the patients in the minimally-supervised rehabilitation group. Similarly, a statistically significant group × time interaction amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups were observed for ‘physical activities’ of the K-SES (F(3.0,114.0) = 2.7, p=0.02) by adjusting age, (F(3.0,114.0) = 3.0, p=0.01) by adjusting levels of habitual physical activities at 6th week, (F(2.3,111.2) GG = 2.9, p=0.02) by adjusting levels of habitual physical activities at 12th week and (F(3.0,114.0) = 2.5, p=0.01) by adjusting levels of
habitual physical activities at 24th week. In contrast, no interactions were observed amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for the remaining two subsections of the K-SES [sport activities ($F_{(3.0,114.0)} = 1.7$, $p=0.21$), you knee function in the future ($F_{(3.0,114.0)} = 1.2$, $p=0.32$)] and all five subsections of KOOS [symptom and stiffness ($F_{(2,1,113.1)} GG = 0.7$, $p=0.29$), pain ($F_{(3,0,114.0)} = 1.1$, $p=0.42$), function, daily activities ($F_{(2,5,113.2)} GG = 1.1$, $p=0.43$), sport and recreation ($F_{(3,0,114.0)} = 1.4$, $p=0.28$), quality of life ($F_{(2,4,113.5)} GG = 1.2$, $p=0.35$), IKDC ($F_{(2,8,111.2)} GG = 0.9$, $p=0.19$), Lysholm ($F_{(3,0,114.0)} = 1.1$, $p=0.44$), and VAS ($F_{(3,0,114.0)} = 1.7$, $p=0.11$) by adjusting anthropometric characteristics and orthopedically-relevant factors. The latter findings indicated that no differences amongst the outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes were observed on majority of the PROMs following statistical adjustments for anthropometric characteristics and orthopedically-relevant factors.
Figure 6.4: Figure showing interaction for the K-SES (daily activities) amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups across 24 weeks rehabilitation period following ACL reconstruction following statistical adjustment for age.

6.3.3 OUTCOMES UP TO 12TH WEEK (EARLY PHASE OF REHABILITATION)

Testing of a priori ‘interaction’ hypothesis of different rates of progression in increases of the subsection ‘function, sports and recreational activities’ of the KOOS associated with the comparison of the fully-supervised and the minimally-supervised rehabilitation programmes suggested a statistically significant interaction ($F_{(1.0, 38)} = 8.6, p=0.03$). The mean scores for the subsection ‘function, sports and recreational activities’ of the KOOS between 12th week following ACL reconstruction compared to previous assessment at pre-surgery and 6th week following ACL reconstruction for the patients in the minimally-supervised rehabilitation groups were 24.7 ± 7.0 versus
19.2 ± 10.6 and 16.4 ± 7.0, and 29.5 ± 9.3 versus 22.9 ± 13.1 and 16.0 ± 8.9, respectively, suggesting the patients in the fully-supervised rehabilitation group showed superior results to the patients in the minimally-supervised rehabilitation group. In contrast to the findings observed for the subsection ‘sport and recreation’ of KOOS, no interactions were observed for IKDC ($F_{(1,0,38,0)} = 0.9, p=0.43$), Lysholm ($F_{(1,0,38,0)} = 1.6, p=0.42$), VAS ($F_{(0.9,37.7)} GG = 0.8, p=0.29$), all subsections of the K-SES [daily activities ($F_{(1,0,38,0)} = 1.4, p=0.14$), physical activities ($F_{(0.8,36.9)} GG = 1.7, p=0.24$), sport activities and you knee function in future ($F_{(1,0,38,0)} GG = 1.8, p=0.49$)] and the remaining four subsections of the KOOS [symptom and stiffness ($F_{(1,0,38,0)} = 1.5, p=0.16$), pain ($F_{(1,0,38,0)} = 1.4, p=0.53$), function, daily living ($F_{(0.9,37.1)} = 0.9, p=0.41$), quality of life ($F_{(1,0,38,0)} = 1.5, p=0.22$)]. These findings indicated that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups had shown similar responses at early phase of rehabilitation on majority of PROMs and the expectations that patients with more supervision will show better outcomes at early phase of rehabilitation, have not been proven.

### 6.3.4 OUTCOMES OF EARLY PREDICATION

Statistically significant correlations were observed between changes within early phase of rehabilitation and 24th week for subsections ‘sport and leisure activities’ and ‘you knee function in the future’ of the K-SES (r = 0.4 and 0.5, respectively; p=0.01) and subsection ‘quality of life’ of the KOOS (r = 0.3; p = 0.01) in the patients in the minimally-supervised rehabilitation group. In contrast, no correlations were observed between the changes in early phase of rehabilitation and the outcomes at 24th week for remaining subsections of the K-SES, remaining subsections of the
KOOS, IKDC, VAS and Lysholm. Similarly, no correlations were observed between the changes in acute phase of rehabilitation and the outcomes at 24\textsuperscript{th} week for the patients in the fully-supervised rehabilitation programme for all PROMs. This indicated that changes in early phase of rehabilitation may not be good predictors for the outcomes at 24\textsuperscript{th} week following ACL reconstruction. These findings were similar to the findings reported in chapter 5 of this these, where change within early phase of rehabilitation showed weak correlation with the outcomes at 24\textsuperscript{th} week of rehabilitation.

\textbf{6.4 DISCUSSION}

The main aim of this prospective single-blinded randomised controlled trial was to investigate the influence of the levels of supervision from physiotherapists on PROMs of function amongst the patients receiving the fully-supervised and the minimally-supervised rehabilitation programmes in the same environment (hospital) following ACL reconstruction. The second aim of this trial was to assess the role of anthropometric characteristics and orthopaedically relevant factors on the final outcomes of rehabilitation. Moreover, this clinical trial was designed to compare the outcomes of rehabilitation up to 12\textsuperscript{th} week following ACL reconstruction amongst the patients receiving the fully-supervised and the minimally-supervised rehabilitation programmes. Finally, one of the aims of this clinical trial was to investigate whether changes in PROMs within early phase can be used as predictors for the outcomes at 24\textsuperscript{th} week.

The main finding of this clinical trial suggested that the patients in the fully-supervised rehabilitation group had achieved statistically superior results compared
to the patients in the minimally-supervised rehabilitation group on one subsection ‘physical activities’ of the K-SES (F (3.0,114) = 2.6, p=0.02). In contrast, no interactions were observed for subsections ‘daily activities’ (F (3.0,114) = 0.8, p=0.21), ‘sport activities’ (F (2.5,110.2) GG =1.3, p=0.34) and ‘your knee function in the future’ (F (3.0,114) =2.0, p=0.56) of the K-SES, IKDC (F (2.3,113.1) GG =0.9, p=0.45), Lysholm ((F (3.0,114.0) \leq 1.4, p=0.56), VAS (F (2.1,111.4) =1.3, p=0.33) and all five subsections ‘symptom and stiffness’ (F (3.0,114) =1.4, p=0.54), pain (F (3.0,110) GG =2.1, p=0.35), ‘function, daily activities’ (F (3.0,114) =1.6, p=0.71), ‘sport and recreation’ (F (3.0,114) =1.9, p=0.43), and ‘quality of life’ (F (3.0,114) = 2.1, p=0.44) of the KOOS. The latter suggested that the patients in the fully-supervised and the minimally-supervised rehabilitation groups had achieved similar levels of function on most of the PROMs and the levels of supervision from physiotherapists had not being influential during rehabilitation programme following ACL reconstruction.

The second finding of this clinical trial suggested that following statistically adjustments for age or levels of habitual physical activities, statistically significant interaction favouring patients in the fully-supervised rehabilitation was observed between the mean group responses of the patients in the fully-supervised and the minimally-supervised rehabilitation groups for subsections ‘daily activities’ (F (3.0, 114.0) = 2.6, p=0.02) and ‘physical activities’ (F (3.0, 114.0) = 2.7, p=0.02) of the K-SES. The average improvement observed following statistical adjustments for age or levels of habitual physical activities was 5%, which may be not be clinical important (MCID for similar PROMs; 10-16%). In contrast, no differences were observed between the mean group responses of the patients in the fully-supervised and the minimally-supervised rehabilitation groups following statistical adjustments for the
remaining orthopaedically-relevant factors and anthropometric characteristics, endorsing the fact that these factors might not be influential on the outcomes of rehabilitation following ACL reconstruction.

The third finding of this clinical trial suggested, no difference of function on PROMs up to 12\textsuperscript{th} week of rehabilitation amongst the mean group responses of the patients in the fully-supervised and the minimally-supervised rehabilitation groups; IKDC (F(1.0,38.0) =0.9, p=0.43), Lysholm (F(1.0,38.0) =1.6, p=0.42), VAS (F(0.9,37.7) GG =0.8, p=0.29), all subsections of the K-SES [daily activities (F(1.0,38.0) =1.4, p=0.14), physical activities (F(0.8,36.9) GG =1.7, p=0.24), sport activities and you knee function in future (F(1.0,38.0) GG =1.8, p=0.49)] and the remaining four subsections of the KOOS [symptom and stiffness (F(1.0,38.0) =1.5, p=0.16), pain (F(1.0,38.0) =1.4, p=0.53), function, daily living (F(0.9,37.1) =0.9, p=0.41), quality of life (F(1.0,38.0) =1.5, p=0.22). Subsection ‘function, sports and recreational activities’ (F(1.0, 38) = 8.6, p=0.03) of the KOOS was the only aspect of the selected PROMs where the patients in the fully-supervised rehabilitation group had shown superior outcomes compared to the outcomes of the patients in the minimally-supervised rehabilitation group up to 12\textsuperscript{th} week of rehabilitation. These findings suggested that the pattern of improvement up to 12\textsuperscript{th} week following ACL reconstruction, was the same for the patients in the fully-supervised and the minimally-supervised rehabilitation programmes.

The fourth finding of this clinical trial suggested that changes in PROMs within early phase of rehabilitation may not be good predictors for the outcomes at 24\textsuperscript{th} week following ACL reconstruction. Although changes in subsections ‘sport and leisure activities’ and ‘you knee function in the future’ of the K-SES (r = 0.4 and 0.5,
respectively, p=0.01) and ‘quality of life’ of the KOOS (r = 0.3; p= 0.01) showed significant correlation with the final outcomes of rehabilitation, still the amount of explained variance (9-25%) by the latter subsections of the K-SES and the KOOS may not be clinically important. Based on the latter, the clinician might not be confident to predict the final outcomes of rehabilitation on changes within the early phase of rehabilitation.

The finding of observing no differences of function and pain on PROMs amongst the patients in the fully-supervised and the minimally-supervised rehabilitation programmes is in agreement with what was previously reported for the patients who had received the ‘minimally-supervised’ and the ‘fully-supervised’ rehabilitation programmes in the hospital following ACL reconstruction (Feller et al. 2004). In the latter retrospective trial, the patients were classified into the ‘minimally-supervised’ and the ‘fully-supervised’ rehabilitation groups according to the number of physiotherapy attendances during the initial six months of ACL reconstruction (full-supervised \( \leq 12 \) physiotherapy attendances, minimal-supervised \( \geq 3 \) physiotherapy attendances). The latter indicates that the patients in the ‘minimal-supervised’ and the ‘fully-supervised’ rehabilitation groups had different opportunities to assess the hospital environment for rehabilitation following ACL reconstruction. In contrast, in this clinical trial, a novel approach to the manipulation of the amount of supervision was undertaken in a hospital-based environment that may offer a consistent and controlled settings to the patients in both the fully-supervised and the minimally-supervised rehabilitation groups (for details please see introduction of this chapter).
Despite the fact that the patients in the fully-supervised and the minimally-supervised rehabilitation groups showed no differences on majority of the outcomes, still the patients in the fully-supervised rehabilitation group showed superior outcomes on aspect of PROMs assessing knee function; ‘physical activities’ of the K-SES (F (3.0,114) =2.6, p=0.02). These findings are similar to the findings of the chapter 5 of this thesis where inconsistencies were observed between the function and pain on PROMs between the outcomes of the two rehabilitation programmes delivered at two different environments. As mentioned in the introduction of this chapter that the same PROMs, reported in chapter 5, were used in this trial and the likelihood of observing inconsistencies in the outcome of the latter were expected (please see discussion of the chapter 5 for further details on the clinimetric characteristics of these PROMs). Findings of this clinical trial endorses the fact the different PROMs possess different clinimetric characteristics that might show variation in their abilities to detect change.

Adherence to physiotherapy during rehabilitation programme had always remained a dilemma in the literature. In this clinical trial, the patients in the minimally-supervised conditioning programme were guided to the same rehabilitation programme in the same environment (hospital) where the patients in the fully-supervised conditioning programme were receiving rehabilitation services. Being provided same guidance and same environment to the patients in the minimally-supervised rehabilitation group during rehabilitation, led the author to speculate that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups will show similar adherence to the exercises programme deployed in the hospital. However, it is interesting to report that the patients in the minimally-
supervised rehabilitation group showed inferior levels of adherence to the rehabilitation programme compared to their counterpart patients in the fully-supervised rehabilitation group. The latter can be confirmed from the intensity of conditioning programme followed by the patients in both the fully-supervised and the minimally-supervised rehabilitation groups in early phase of rehabilitation (mean scores for the intensity of structured rehabilitation programme in acute phase and sub-acute phase of rehabilitation for the patients in the fully-supervised versus the minimally-supervised rehabilitation groups; mean ± sd ;11.2 ± 2.1 versus 8.3 ± 1.2 Kilocalories/minute and 9.2 ± 3.6 versus 5.2 ± 2.3 Kilocalories/minute, respectively; \( p=0.02 \)). The latter findings might be one of the reasons due to which the patients in the minimally-supervised rehabilitation group showed inferior results compared to the patients in the fully-supervised rehabilitation group on some aspects of PROMs during the early phase of rehabilitation (12\(^{th}\) weeks) and at 24\(^{th}\) week. Similar evidence of non-adherence to the rehabilitation programme in the patients with less supervision has been reported in a clinical commentary (Bassett 2003). In the latter commentary a big proportion (65 \%) of the patients, had shown either non-adherence or partial adherence to the rehabilitation programme when supervision was withdrawn from them. Exercises programmes that demand skilful techniques during its implementation may need a proper supervision during the implementation period and any withdrawal of the supervision has been reported to cause the patients to manipulate the exact amount of dose (Flynn et al. 1995). The latter will, ultimately, cause partial or non-adherence of the patients to the exercises programme.

Individuals’ anthropometric characteristics and orthopaedically-relevant factors have been associated with degenerative changes of the involved joint and deconditioning
of the musculature around it (Vincent et al. 2006, Lohmander et al. 2004). To control the influence of the latter factors on the outcomes of this clinical trial, statistically adjustments for the anthropometric characteristics and orthopaedically-relevant factors were performed in a separate analysis. By adjusting for age and levels of habitual physical activities significant interaction favouring the outcomes of the fully-supervised rehabilitation groups were observed for subsections ‘daily activities’ and ‘physical activities’ of the K-SES. The average difference in improvement of function on the latter subsections of the K-SES was 5% amongst the mean group responses of the patients in the fully-supervised and the minimally-supervised rehabilitation groups. Similar PROMs to K-SES have suggested that an improvement of 10-16% function on the PROMs may be clinically important for the patients following ACL reconstruction (Collins et al. 2011). It may be inferred that the anthropometric characteristics and orthopaedically-relevant factors were not influential on the outcomes of this clinical trial.

The baseline measurement for the patients in the fully-supervised and the minimally-supervised rehabilitation showed that the patients in both the groups were similar, suggesting that the process of randomisation had been successful by providing a balance among the covariate levels amongst the patients in both groups (please see Table 6.1 for details). Evidence from the literature suggested, that following randomisation, similar results of the no differences of individuals’ anthropometric characteristics and orthopaedically-relevant factors amongst the mean group responses of the patients in fully-supervised and the minimally-supervised rehabilitation programmes following ACL reconstruction (Ugutmen et al. 2008, Hohmann et al. 2011). Finding of this clinical trial endorse the latter by reporting that baselines measurements of
PROMs, anthropometric characteristics and orthopaedically-relevant factors were similar amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups following randomisation in this trial.

The third finding of this clinical trial suggested that the patients in the minimally-supervised rehabilitation group can achieve similar levels of function to patients in the fully-supervised rehabilitation on PROMs at early phase of rehabilitation. The expectation that the patients in the fully-supervised rehabilitation will achieve better function to the patients in the minimally-supervised rehabilitation group on patient-reported outcome was revisited in this trial. In previous trial (chapter 5), it was observed that the patients in the hospital-based programme showed consistently superior results compared to the patients in the community-based rehabilitation programme during the early phase of rehabilitation. Similar differences were expected for this trial and it was speculated that the patients in the fully-supervised rehabilitation group may show superior outcomes compared to the patients in the minimally-supervised rehabilitation group. However, the finding of this trial suggested that the patients in both groups were similar on function of PROMs and pain during the initial 12 weeks of rehabilitation programme following ACL reconstruction. This finding is in an agreement to what was reported a randomised controlled carried out on the effects of the supervision on the outcome of rehabilitation programme following ACL reconstruction (Grant et al. 2005). In the latter trial, the patients who had undergone ACL reconstruction, were randomly allocated into the fully-supervised (clinic-based) and minimally-supervised rehabilitation programmes (home-based). Patients in both the latter two groups showed similarities of function on IKDC and ACL-QoL at the end of 12th week.
following ACL reconstruction. Findings of showing similarities amongst the mean group response of the patients in the fully-supervised and the minimally-supervised rehabilitation programme at two different occasions (12\textsuperscript{th} week and 24\textsuperscript{th} week) endorse that the hospital provide equal opportunities to the patients to manage the exact amount of dose regardless differences in the levels of supervision.

One of the novelties of this clinical trial, was the investigation of the association between the changes in PROMs within the early phase of rehabilitation and the final outcomes at 24\textsuperscript{th} week following ACL reconstruction. As mentioned in the introduction of chapter 5, that efficiency of clinical treatment might be enhanced if a robust correlation exits between early responses to treatment and the outcomes of rehabilitation at 24\textsuperscript{th} week, then clinician might manipulate the rehabilitation programme according the needs of the patients. One of the findings of this clinical trial suggested that changes in early scores of PROMs may not be good predictors for the final outcomes of rehabilitation at 24\textsuperscript{th} week following ACL reconstruction. This finding is in agreement to what was reported in the literature where pre-surgery early health status was reported a weak predictor for the final outcomes of rehabilitation programme (Mahomed et al. 2002, Jones et al. 2003, Lingard et al. 2004 ). In the latter trials, 20\% of the variability in PROMs was explained. Based on the results of this clinical trial, up to 25\% of variability in the PROMs may be predictable. Although the predictable proportion in this clinical trial is more than the one reported in the literature, still due to a larger portion of unexplained variance (75\%) the predication may not be useful for the clinician.
6.5 LIMITATIONS

One of the limitations of this clinical trial was calculating the volume of exercises for
the whole period of rehabilitation programme following ACL reconstruction. The
total volume of exercises was computed only from structured exercises performed in
the hospital while exercises suggested to the patients in the community and levels of
habitual physical activity were not included in the total dose. The volume of
exercises was based on the number of sets, repetitions and loads lifted during specific
duration only. A more reliable way of calculating the intensity of exercises in terms
of comparing it with heart rate reserve (HRR) and maximal heart rate (HR max) or
oxygen uptake reserve (VO2R) was not deployed in this trial due to unavailability of
the equipment needed. A threshold exceeding maximal oxygen uptake (VO2max)
needed to sustain eight-hour work shift (33%-50% of VO2max), has been suggested to
gain the effects of exercise programmes which has not been considered during this
clinical trial. This highlighted the importance of the of the intensity exercises
compared to the total volume of exercises. The fact that intensity of exercise
programmes is correlated with improvement in performance have been endorsed by
previous trials carried out on the effects of high, moderate and low intensity exercise
programmes. The findings of these trials have led to a revival of intense interval-
type exercise training programmes. It is important to know the limits of tolerance of
an individual before prescribing any exercises programme that would need to
bringing changes in the muscular capabilities. This was not done in the clinical trial
reported in this chapter of the thesis that is one of the limitations of this clinical trial.
Moreover, the patients in both the fully-supervised and the minimally-supervised
rehabilitation programmes were advised to continue some of the exercise at home.
These exercises were not capable of being monitored by the physiotherapists in the community. Subjective information regarding those exercises and levels of habitual physical activity were relied on that is another limitation associated with computing the total amount of exercises.

6.6 CONCLUSION

Based on the findings of this clinical trial, it can be concluded that the patients in the minimally-supervised rehabilitation group can achieve similar function on PROMs to the patients in the fully-supervised rehabilitation group. Individuals’ anthropometric characteristics and orthopaedically-relevant factors may not be influential on the outcomes of the rehabilitation following ACL reconstruction.
7  CHAPTER: TRIAL II (PART B)

COMPARISON OF THE FULLY-SUPERVISED AND THE MINIMALLY-SUPERVISED REHABILITATION PROGRAMMES ON THE OBJECTIVE MEASURES FOLLOWING ACL RECONSTRUCTION
SUMMARY OF THIS CHAPTER

Commercialization and limitations in the availability of time and budget in the health system are some of the factors that have resulted in the frequent use of PROMs for assessing outcomes of a rehabilitation programme. The latter are based on self-assessment by the patients and had been reported to be limited in some aspects especially in providing comprehensive information on the assessment of the general and the disease-specific health status of the patients. To comprehensively evaluate outcomes of rehabilitation, a combination of patient-reported and objectively measured outcomes has been suggested. In this clinical trial, selected objectives, functional and physical performance-related outcomes of rehabilitation programme following ACL reconstruction have been reported in the same cohort of patients that had been assessed solely on PROMs in chapter 6 of this thesis. A total of 48 patients who were randomly allocated to the fully-supervised and the minimally-supervised rehabilitation groups (24 in each group) were evaluated at four different occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction) on functional (single-leg hop) and physical performances (peak force, rate of force development, sensorimotor performances, electromechanical delay) and musculoskeletal performance (ATFD) outcome measures. Using ANOVA, results showed no group × leg × time interaction for function [single-hop; \( F_{(2,0,76.0)} = 1.8, \) ns] and all selected physical performance outcomes [knee flexors and extensors musculatures; peak force; \( F_{(3,0,114.0)} = 0.9, \) ns] and \( F_{(3,0,114.0)} = 0.8, \) ns), rate of force development; \( F_{(3,0,114.0)} = 1.1, \) ns] and \( F_{(3,0,114.0)} = 1.4, \) ns), sensorimotor performances; \( F_{(3,0,114.0)} = 0.5, \) ns] and \( F_{(3,0,111.0)} = 1.9, \) ns), respectively, and ATFD; \( F_{(3,0,114.0)} = 0.5, \) ns]). This indicated that the fully-supervised and the minimally-supervised rehabilitation
groups showed statistically similar patterns of recovery over time as measured by most indices of function and physical performance. *A prior* testing analysis revealed that the patients in the minimally-supervised rehabilitation group showed superior outcomes on 5 out of 9 interactive comparisons compared to the patients in the fully-supervised rehabilitation group while the patients in the latter group showed superior outcomes over the former rehabilitation group on the remaining 4 interactive comparisons spread during the early phase of rehabilitation programme. Based on these findings, it can be concluded that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups have achieved similar levels of functional capabilities and physical performances regardless being subjected to different levels of supervision from the clinical team in the hospital.
7.1 INTRODUCTION

For over a decade, researchers have been expressing interest in the use of PROMs for evaluation patients’ general health and disease-specific status (Greco et al. 2010). One of the reasons for the use of these measuring tools has been reported to be their ability to detect physical or psychological problems related to the general health of clinical population that would otherwise be overlooked (Espallargues et al. 2000, McHorney 1999). Moreover, the use of PROMs has been reported to improve patient-clinician communication that would ultimately promote the model of shared decision-making process in the health system (Rothwell et al. 1997). Similarly, the recent changes in the health care system paradigm, especially a shift towards a ‘market model approach’ and an emphasis on patients’ satisfaction in evaluating the outcomes of a treatment, are some of the other reasons that PROMs have remained a vital source of evaluation for outcomes of a treatment (Nemec and Kolisnichenko 2006). The latter (PROMs including IKDC, KOOS, K-SES, VAS and Lysholm) were used as measuring tools in chapter 5 and 6 of this thesis for evaluating outcomes of rehabilitation programmes following ACL reconstruction. Despite the several benefits associated with the use of PROMs, the latter had been reported limited in some aspects of evaluating the patients’ generic and diseases-specific health conditions. It was interesting to note that although some sub-domains of the selected PROMs showed advantages for interventions focused on either placing patients in particular environments (chapter 5) or with differing levels of supervision (Chapter 6) for their rehabilitative care, there was an inconsistency of changes noted amongst PROMs, despite notionally measuring the same outcomes associated with functional capacity.
One of the biggest challenges associated with the use of PROMs is their limited ability to measure specific functional capabilities of patients (Greenhalgh and Meadows 1999). Moreover, the latter reporting measures provide information based on self-assessment of the patients rather than an assessment by an external observer or tools assessing patients’ capabilities objectively. Furthermore, there has been a lack of clinically-relevant association between PROMs and objective measures of function and physical performance capabilities noted in the literature (Kocher et al. 2002, Fitzgerald et al. 2001) and in pilot study (Appendix II), r <0.4. This suggests that as a favourable interpretation, PROMs and objectively measured outcomes are simply measuring different (unrelated) aspects of the same domain of function, and it might be helpful to include both types of measurements to accurately describe a patient’s current performance status. Alternatively, it is plausible that low correlation signifies ineffective scaling of perceived and actual capabilities amongst patients and a need routinely to assess both approaches separately wherever possible, to quantify the extent of patients’ mis-scaling. The purpose of this study was to evaluate the effects of the levels of supervision of post-surgery rehabilitation conditioning by physiotherapists on objectively measured outcomes of function and physical performance capabilities in patients who had undergone ACL reconstruction surgery. The participants in this study were those patients also reporting PROMs in chapter 6 of this thesis and so this study reflects their responses recorded within a standardised hospital environment. For the latter purpose, peak force, rate of force development, sensorimotor performance, electromechanical delay and ATFD were assessed for the same clinical population that was the subject of investigation in the
Chapter 6 of this clinical trial. A detailed overview of these objectively measured outcomes is available in chapter 3 of this thesis. This study offers novelty in that it focused attention on objectively measured outcomes of function (single-leg hop), physical performance (peak force) and musculoskeletal performance (ATFD) that have been frequently reported in the literature (Gleeson et al. 2013, Minshull et al. 2013). However, the study has combined patients’ responses to these outcomes with those from novel neuromuscular (rate of force development, electromechanical delay) and sensorimotor (force-matching tasks) assessments that have received less attention in the orthopaedic literature but which have been shown to be valid indicators of physiological changes that might underpin functional capability in the exercise-science literature (Gleeson et al. 2002, Gleeson and Mercer 1996). The objectively-measured outcomes used in this study have previously received favourable clinimetric scrutiny in the literature (Minshull et al. 2009) and have received further investigations of single-measurement reliability and reproducibility in patients undergoing ACL-reconstruction (Appendix I).

7.2 METHODS

As this clinical trial was carried out on the same cohort of patients that was the subject of investigations in chapter 6 of this thesis, the anthropometric characterises of the patients have been presented in section 6.2 (chapter 6, ‘Methods’). Specific methods relating to the design of this clinical trial are described in the forthcoming paragraphs. Details of random-allocation of patients to groups, manipulation of the independent variable (levels of supervision by physiotherapists of the patient’s conditioning), assessment protocols for outcomes (pre-surgery, 6th, 12th and 24th
week following ACL reconstruction surgery), assessment of anthropometric characteristics and orthopaedically-relevant factors are shown in sub-sections (chapter 6 ‘Methods’).

7.2.1 ASSESSMENT PROTOCOL

All participants were instructed to refrain from strenuous physical activities 24 hours prior to each testing occasion. Prior to each testing occasion, patients undertook a standardised warm-up. The warm session was consist of five minutes of cycle ergometry (90 watts for males, 60 watts for females) followed by further five minutes of static stretching of the musculature to be assessed on dynamometry (Figure 7.1). Any changes including excessive sweating or pain in the lower limb during the warm-up period were keenly observed. Testing of the patients with either of the symptoms were postponed to the next available slot for testing. Assessments and the order of testing legs were undertaken in a random sequence that had been determined from a computer-generated list of numbers before each assessment.
Figure 7.1: Figure showing warm-up session before testing the participants on the dynamometer. The warm session was consist of five minutes of cycle ergometry (90 watts for males, 60 watts for females) followed by further five minutes of static stretching of the musculature of knee joint to be assessed on dynamometry.

7.2.2 PATIENTS AND DYNAMOMETER ORIENTATION

Patients were secured in a seated position on a custom-built dynamometer following the standard warm-up session. This device has been extensively used in similar researches carried out previously on the evaluation of indices for physical performances and had been reported to be a reliable and valid means of assessment for these indices (Gleeson and Mercer 1992, Gleeson and Mercer 1996, Minshull et al. 2009). The lever-arm on the dynamometer was attached to the leg to be tested. Padded ankle-cuffs and adjustable strapping were used to avoid undesired movements during the period of assessment. The distal part of the lever-arm which had load cell for measuring the force produced during the volitional effort of participants was positioned above the lateral malleolus. The length of lever arm was recorded for each participants on the first testing occasion and the same length was ensured for commencing testing occasions. The dynamometer and knee joint’s axis of rotation were aligned in such a manner that a gap of no more than 10 mm was left
between them. This gap was allowed to avoid any restriction that can affect the smooth production of isometric flexion force in the knee joint. To ensure the production of localised volitional force produced by the knee flexor and extensor group of muscles, adjustable strapping across the mid-thoracic spine and pelvis were used (Figure 7.2). All patients were assessed using a functionally relevant knee flexion angle of 25 degrees (0.44 rad), (0° = full knee extension) which was maintained throughout the whole assessment period. This angle (25-degree flexion in the knee joint) was used during the assessment as the ACL is proven to the greatest mechanical strain at this angle (McGinty et al. 2000, Li et al. 1999). Prior to producing three maximal volitional efforts, all participants were required to perform a series of warm-up while seated on the dynamometer. This warm-up session consisted of 2 repetitions at each levels of increasing intensities of effort (25%, 50% and 75% of subjectively-judged maximal volitional peak effort). Each of the produced efforts was sustained for a period of 3 seconds and was separated from the next effort by 20 seconds. A period of approximately two minutes separated formal testing and warm-up procedures.

7.2.3 EXPERIMENTAL AND ASSESSMENT PROCEDURES

The experimental design examined group mean responses of all participants within four stages; before surgery, early where assessment was done on 6th, intermediate where assessment was done on 12th week and long-term where assessment was done at the end of the rehabilitation programme (on 24th week following the ACL reconstruction). These testing occasions were purposefully designed to correspond to and encompass the most rapid period of physical improvement and effect sizes
associated with the rehabilitation process. The experimental design comprised a longitudinal comparison of intra-session performances associated with the injured leg and the non-injured leg during the rehabilitation period. The first testing session was scheduled approximately two weeks before surgery. The first assessment session was longer compared to the remaining assessment sessions as it allowed the patients to familiarise with the lab, assessment procedures and protocols. During the initial and later on the remaining testing sessions, each patient was assessed for the indices of physical performance. These indices included peak force, rate of force development, sensorimotor performances and electromechanical delay associated with the knee flexors and extensors of the injured and the non-injured legs. Demographic details including age, date of injury, cause of injury and anthropometric measurements (height, body mass) were also recorded during the first session.
Figure 7.2: Figure showing custom-built dynamometer for the assessment of indices of physical performances. Patients in this diagram has been well protected from undesirable movements by using strappings across the mid-thoracic spine and pelvic region. (adapted from Gleeson et al. 2002)

7.2.4 PROCEDURES FOR RECORDING ELECTROMECHANICAL DELAY

The electromechanical delay during the knee flexion and extension was recorded from the hamstrings and the quadriceps muscles, respectively, for both the injured and the non-injured legs during each maximal volitional muscle contraction. Before allowing a patient to be comfortable seated on the dynamometer, rigorous skin
preparation was done by the testing team (Figure 7.4). This process of skin preparation included removing of hairs from the belly of muscles to be assessed, which was done by shaving those areas with the help of disposable razors. To ensure good conduction throughout the whole testing session, the site of muscles belly for electrodes was abraded by using fine sand paper. Finally, the skin was de-greased using an alcohol swab to help the electrodes in making a firm contact between skin and electrodes. The skin over the belly of the biceps femoris and the vastus lateralis was undertaken for recording electromechanical delay from knee flexor and knee extensor, respectively. Three self-adhesive bi-polar surface electrodes (AgCl) were placed in a triangular shape over the belly of the above mentioned muscles (Figure 7.3). Two of the electrodes were placed on the equidistant from the ischial tuberosity and the medial epicondyle of the femur with a fixed inter-electrode distance of 30 mm between them. The third electrode that worked as a ‘reference’ electrode was placed 30 mm lateral and equidistant from the recording electrodes parallel to the gap between the two detector electrodes. Electrode placement was standardised across assessment occasions, where appropriate, by means of mapping (using acetate paper) and measuring the position relative to anatomical landmarks and angiomas. Skin preparation quality was assessed using an impedance meter with a resistance of less than 5 KΩ being acceptable (Basmajian et al. 1985).
Figure 7.3: Figure showing placement of electrodes for recording electromechanical delay. The two electrodes are placed on the equidistant from the ischial tuberosity and the medial epicondyle of the femur with a fixed inter-electrode distance of 30 mm between them.
Figure 7.4: Figure showing skin preparation for recording EMG from the extensors and flexors muscles around the knee joint. A three-step approach was adopted to do skin preparation for the testing.
7.2.5 ASSESSMENT OF PHYSICAL PERFORMANCES

7.2.5.1 PEAK FORCE

Following a proper warm-up session of five minutes ergometry and five minutes static stretching, patients were secured on the custom-built dynamometer where they completed a dynamometer-specific warm-up consisting of 2 repetitions at each levels of increasing intensities of effort (25%, 50% and 75% of subjectively-judged maximal volitional peak effort. After a verbal cue, an auditory signal was given randomly within 1-4 seconds and the participants were instructed to activate their knee musculature as rapidly and forcefully as possible by attempting to extend or flex the knee joint as appropriate, against the immovable restraint offered by the apparatus (Figure 7.5). Patients were asked to maintain the maximal effort for 3 seconds and another auditory signal was given to relax the muscles contraction. Participants were asked to repeat the same process of producing maximal volitional effort for two more times. Each attempt within a specific trial, was separated by 10 seconds. A minimum of 10 second in between efforts had been suggested in previous similar research trials to allow the normal muscle glycogen and electrolyte concentrations to be re-established (Gleeson and Mercer 1996, Minshull et al. 2009).

Commercially available software (Spike 2 software, version 7.0, Cambridge Electronics Design Ltd., UK) was used for all data acquisition initially and then for data analysis later on. Volitional maximal peak effort was recorded by taking average of all three efforts exerted during specific testing session.

As it had been reported in the literature that the average rate of force increase are associated with the force-time response between 25% and 75% of the peak force calculated during each time (Gleeson et al. 2008), the latter (25 and 75 % of each
maximal volitional effort) was used for calculating rate of force development for the knee flexor and extensor musculatures.

Figure 7.5: Figure showing peak force recording position for both knee flexor and extensor musculature.

7.2.5.2 ELECTROMECHANICAL DELAY

Concomitant electromyographic activity was recorded from the biceps femoris and the vastus lateralis during the estimation of volitional peak force. The obvious reason for selecting these both muscles (biceps femoris and vastus lateralis) might be given by the fact that these muscles play vital role in competing any shearing effort made during the ATFD and lateral rotation of the femur relative to the tibia. The latter processes have been reported to make ACL prone to injuries (Gleeson et al. 1998). The raw electromyographic signals were passed through a differential amplifier (1902 Mk IV; Cambridge Electronic Design, UK). The signal, which incorporated minimal intrusion from induced currents associated with external electrical and electromagnetic sources and noise inherent in the remainder of the recording instrumentation, was analogue-to-digitally converted at 2.5 kHz sample
rate, ensuring a significant margin of reserve between the highest frequencies expected in the electromyographic signal and the Nyquist frequency (Gleeson et al. 2002). The index of electromechanical delay was computed as the mean response from three electromechanical delays observed during three maximally produced effort in a single testing session. Electromechanical delay is basically the time delay between the onset of electrical activity and the onset of force production. The onset of electrical activity was defined as the first point in time at which the electrical signal exceeded consistently the 95% confidence limits of the isoelectric line associated with the background electrical noise amplitude and quiescent muscle and which was the first deviation of the recorded electrical signal that was congruent with physiological activation of the muscle (Figure 7.6). Onset of muscle force was defined as the first point in time at which the force record exceeded consistently the 95% confidence limits associated with the electrical noise amplitude of the load cells.
Electromechanical delay was calculated as the time difference between the onset of electromechanical activity and the onset of force production. (adapted from Gleeson et al. 2008)

7.2.5.3 ASSESSMENT OF SENSORIMOTOR PERFORMANCE

Sensorimotor performance of the knee musculature for both the injured and the non-injured limbs was assessed by means of a force-matching task involving brief muscle actions. In this type of assessment of sensorimotor performance, the participants were required to reproduce a blinded prescribed ‘target’ force ten times, which was set to be 50% of their individual capability for maximal voluntary muscle action (peak force at the specified angle of joint flexion). The levels of sensorimotor performance was described by the extent of discrepancy observed between the mean
of prescribed target force and the mean of participant’s blinded reproduction of the target. Moreover, constant error for bias [CE%] for each attempt was calculated and was expressed as a percentage relative to the target force. i.e. error in performance was computed using the generic expression;

$$\text{Error} = \left( \frac{\text{Observed performance} - \text{target performance}}{\text{target performance}} \right) \times 100$$

The required pattern of response from the participants in this assessment is shown within Figure 7.7, where neuromuscular control assessment requires the participants to produce a sensorimotor performance consisting of 10 target-orientated and brief flickers of peak forces for the volitional activation of muscles. To match the target force as closely as possible patients were guided to learn the target force by providing them feedbacks to volitional efforts made during the familiarisation session that took place during each testing session. Participants received standardized and contemporaneous verbal feedback only from the test administrator to facilitate further improvements in performance precision. In this way, participants were blinded to both the absolute levels of the prescribed target force and the scale of measurement used to offer feedback. Participants were effectively learning to self-perceive the performance outcomes in an arbitrary scale of measurement without units. Feedback from the test administrator was offered in standardised terminology such as “25 high”, “20 high”, “15 high”, “10 high”, “5 high” and “25 low”, “20 low”, “15 low”, “10 low”, “5 low”, respectively, depending whether or not the outcome of a trial had been higher or lower than the target (i.e. an underestimation or overestimation of performance, respectively).
Figure 7.7: Figure showing raw scores recorded for sensorimotor performance of the knee flexor and extensors musculatures. The participants were required to reproduce a blinded prescribed ‘target’ force ten times, which was set to be 50% of their individual capability for maximal voluntary muscle action.

7.2.5.4 ASSESSMENT OF ATFD

Estimates of patients’ musculoskeletal responses were calculated from the ATFD of both legs (injured and non-injured legs) recorded by arthrometer system. This system had been used extensively for measuring the ATFD in similar trials and had been reported to be reliable and valid (Gleeson and Mercer 1996, Gleeson and Mercer 1992). The apparatus and patients orientation during the assessment is shown schematically in Figure 7.8. The arthrometer and knee joint’s axis of rotation were aligned along the fixed bar of arthrometer allowing the knee joint to maintain an angle of 25 degrees (0.44 radians) of flexion. Moreover, the ankle joint was positioned having an angle of 15 degrees (0.26 radians) of external rotation and 20 degrees (0.35 radians) of plantar flexion. During the assessment of ATFD, a gap of no more than 10 mm was ensured between the arthrometer seat and leg to be
assessed. This gap was allowed to avoid any external effort recorded by the instrumented force handle incorporating a load cell. The designed arthrometer which is used to measure ATFD, consists of two linear inductive displacement transducers (DCT500C, RDP Electronics Ltd., Wolverhampton, U.K.). The latter incorporated spring-loaded plungers that were adjusted accurately in three planes to provide perpendicular attachment to the patella and tibial tubercle. During measurements, both transducers were secured to the skin surface using tape. The transducers were able to move freely only in the anterior-posterior plane relative to the supporting framework. The instrument monitored only the relative motion between the patella and tibial sensors and so facilitated the exclusion of measurement artefacts caused by extraneous movements of the leg during the application of anterior displacement forces. Anterior force was applied in the sagittal plane and in a perpendicular direction relative to the tibia by an instrumented force handle incorporating a load cell (Model 31E500N0, RDP Electronics Ltd., Wolverhampton, U.K.). This device was positioned behind the leg at a level 0.02m inferior to the tibial tubercle. The transducers were interfaced to a computerized data acquisition system (Cambridge Electronic Design Ltd., U.K.). Calibrated data from all transducers were sampled at 2.5 kHz. Measurements on each knee were preceded by two practice trials. During each measurement, patients were instructed to relax the musculature of the involved limb. The latter was verified by inspection of on-line EMG records of the activity of the biceps femoris and the vastus lateralis. Rapid but gentle manual anterior-posterior drawer oscillations were used to facilitate relaxation and to establish a neutral tibio-femoral position from which all measurements were initiated. The same test administrator performed all measurements. Indices of ATFD were calculated as
the mean of three intra-session replicates of the net displacement of the patella and tibial tubercle transducers at an anterior tibial displacement force of 160N applied in the sagittal plane, at a rate of $67.0 \pm 7.0$ N·s⁻¹, and was tolerated well by symptomatic patients (Gleeson and Mercer 1992, Gleeson et al. 2008).

![Diagram of force measurement equipment](image)

Figure 7.8: Figure showing for assessing ATFD in the knee joint. Relative motion between the patella and tibia was recorded to calculate anterior tibio-femoral displacement.

### 7.2.6 STATISTICAL ANALYSIS

The clinical efficacy of the levels of supervised conditioning programme by physiotherapists during rehabilitation was evaluated using a separate ANOVAs for primary outcome measure of function (single-leg hop) and physical performance associated with secondary outcomes of peak force, rate of force development, sensorimotor performance, electromechanical delay and ATFD. An ANOVA model involving group (fully-supervised, minimally-supervised rehabilitation) by leg
(injured, non-injured) by test occasions (pre-surgery, 6th, 12th and 24th week) with repeated measures on the latter two factors was used to test the null hypothesis of no statistical interaction for group mean scores for each outcome measure. The outcome performances associated with the knee extensors and flexors of both the injured and the non-injured legs were assessed separately where appropriate.

The effects of anthropometric characteristics, orthopaedically-relevant factors and baseline outcome scores that were not capable of being controlled experimentally, on the primary outcome measures of function (single-leg hop) and physical performances associated with secondary outcomes of peak force, rate of force development, sensorimotor performance, electromechanical delay and ATFD under changes in the dependent variable (levels of supervision: fully-supervised and minimally-supervised rehabilitation programmes) were investigated using ANCOVA. An ANCOVA model involving a single candidate covariate and group (fully-supervised, minimally-supervised rehabilitation) by leg (injured, non-injured) by test occasions (pre-surgery, 6th, 12th and 24th week) with repeated measures on the latter two factors was used to test the null hypothesis of no statistical interaction of group mean scores for each outcome measurement. Pearson product-moment correlation coefficients were used to assess the association between the changes in the conditioning programme in the fully-supervised and the minimally-supervised rehabilitation groups during the early phases of rehabilitation programme (pre-surgery to 6th and 6th to 12th week following ACL reconstruction) and with the final function and physical performance status at 24th week following ACL reconstruction. A priori alpha levels was set at p <0.05. Greenhouse-Geisser adjustment of the
degrees of freedom associated with experimental and error variances were used where selected assumptions underpinning ANOVAs had not been met.

7.3 RESULTS
7.3.1 OUTCOMES ACROSS 24 WEEKS

7.3.1.1 CHANGES IN FUNCTIONAL OUTCOMES

An ANOVA using factors of group × leg × test occasion with repeated measure on the latter two factors showed no 3-factor interaction for single-leg hop (F(2.0,76.0) = 1.8, p=0.18), suggesting that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed similar patterns of gains during the 24 weeks of formal rehabilitation (Figure 7.9). A statistically significant leg (injured and non-injured) × test occasion (pre-surgery, 6th, 12th and 24th week following ACL reconstruction) interaction (F(2.0, 76.0) = 4.8, p=0.01) for single-leg hop suggested that the patterns of improvement in single-leg hop over time were different for the injured and non-injured legs. However, a statistically non group × test occasion interaction (F(2.0,76.0) = 0.5, p=0.23) for single-leg hop for the group means responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups suggested that the patterns of improvement were similar amongst the patients in the latter two groups.

The group mean scores for single-leg hop of the injured leg for the patients in the fully-supervised and the minimally-supervised rehabilitation groups at 24th week versus baseline were 113.5 ± 22.6 versus 113.3 ± 24.7 cm and 124.6 ± 26.1 versus 122.6 ± 25.0 cm, respectively. The relative effect sizes for single-leg hop for the injured leg were 0.08 and 0.01 for the patients in the fully-supervised and the
minimally-supervised rehabilitation groups, corresponding an improvement of 1% and 3%, respectively, from baseline to 24\textsuperscript{th} week. The effect sizes observed for the injured leg for the patients in the fully-supervised and the minimally-supervised rehabilitation programmes can be categorised as ‘negligible’.

Figure 7.9: Figure showing group response for single-leg hop for the injured and the non-injured legs for the patients in the fully-supervised and the minimally-supervised rehabilitation groups. No 3-way interaction ($F_{(2,0,76,0)} = 1.8, p=0.18$) was observed for single-leg hop amongst the group mean responses for the patients in fully-supervised and the minimally-supervised rehabilitation groups.

7.3.1.2 CHANGES IN PHYSICAL PERFORMANCES

Estimates of physical performance for the quadriceps

For reporting results regarding the estimates of physical performance for the quadriceps an example of peak force is explained in details and then summary for the rest of the estimates (rate of force development, electromechanical delay) is given.
An ANOVA using factors of group × leg × test occasion with repeated measure on the latter two factors showed no 3-factor interaction for peak force elicited from the knee extensor musculature \((F_{(2.0,76.0)} = 1.4, \ p=0.32)\), suggesting that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed similar patterns of improvement during the 24 weeks of formal rehabilitation. A statistically significant leg × test occasion interaction for peak force elicited from the knee extensor musculature \((F_{(3.0, 114.0)} = 16.8, \ p=0.01)\), suggested that the pattern of improvement in peak force overtime was different for the injured and the non-injured legs. However, a statistically non-significant group × test occasion interaction \((F_{(3.0, \ 114.0)} = 0.5, \ p=0.45)\) for peak force elicited from the latter musculature suggested a similar pattern of improvement for peak force amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups. The group mean scores for responses for the injured legs for the patients in the fully-supervised and the minimally-supervised rehabilitation groups at 24th versus pre-surgery were 411.2 ± 88.2 versus 397.7 ± 90.6 Newton (N) and 393.2 ± 83.3 versus 357.3 ± 84.4 N, respectively. The relative effect sizes for group mean responses for the injured leg in the fully-supervised and the minimally-supervised were 0.49 and 0.93, respectively, corresponding to decrease of 12% and 33%, respectively, from pre-surgery to 24th week for the patients in the latter two groups.

Similar to findings observed for peak force, statistically significant leg × test occasion interaction was observed for rate of force development \((F_{(3.0, 114.0)} = 14.2, \ p=0.02)\), sensorimotor performance \((F_{(3.0, 114.0)} = 10.3, \ p=0.01)\) and electromechanical delay \((F_{(3.0, 114.0)} = 9.3, \ p=0.04)\) of the knee extensor musculature, suggesting that the pattern of improvement for both legs overtime was different for latter three indices of
physical performance. However, statistically no group × time interaction for rate of force development ($F_{(3.0, 114.0)} = 2.3, p=0.56$), sensorimotor performance ($F_{(3.0, 114.0)} = 1.5, p=0.09$) and electromechanical delay ($F_{(3.0, 114.0)} = 1.2, p=0.34$) of the knee extensor musculature, suggested that the patients in both the fully-supervised and the minimally-supervised groups improved on similar pattern for the mentioned estimates physical performance. Group mean responses for peak force, rate of force development, electromechanical delay and sensorimotor responses is shown Table 7.1 and 7.2.

**Estimates of physical performance for the hamstring**

Similar to the strategy of reporting results regarding the estimates of physical performance for the quadriceps, an example of peak force is explained in details and then summary for the rest of the estimates (rate of force development, electromechanical delay) is given for reporting findings for the estimates of physical performance for the hamstrings.

An ANOVA using factors of group × leg × test occasion with repeated measure on the latter two factors showed no 3-factor interaction for peak force elicited from the knee flexor musculature ($F_{(2.0, 76.0)} = 2.1, p=0.34$), suggesting that the patients in both the fully-supervised and the minimally-supervised rehabilitation improved in similar pattern during the 24th week rehabilitation programme following ACL reconstruction. A statistically significant leg × test occasion interaction for peak force elicited from the knee flexor musculature ($F_{(3.0, 114.0)} = 11.3, p=0.01$) suggested that the injured and the non-injured legs showed different patterns of improvement in peak force overtime for latter musculature. However, a statistically non group × test
occasion interaction ($F_{(3.0, 114.0)} = 1.4, p=0.23$) for peak force elicited from the knee flexor musculature suggested that the pattern of improvement amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups was similar for peak force elicited from the latter musculature. Interestingly, the group mean scores of peak force for responses for the injured leg for the patients in the fully-supervised and the minimally-supervised rehabilitation groups at 24th versus pre-surgery were $232.8 \pm 57.2$ versus $224.7 \pm 66.7$ N and $224.3 \pm 53.7$ versus $228.6 \pm 65.1$ N, corresponding to improvement of 2 and 17 %, respectively. The latter suggested that the patients in the minimally-supervised rehabilitation group showed superior outcomes compared to the patients in the fully-supervised rehabilitation group.

Similarly, statistically significant leg × test occasion interaction was observed for rate of force development ($F_{(3.0, 114.0)} = 10.1, p=0.01$), sensorimotor performance ($F_{(3.0, 114.0)} = 7.5, p=0.02$) and electromechanical delay ($F_{(3.0, 114.0)} = 11.9, p=0.01$) of the knee flexor musculature. The latter suggested that pattern of improvement in the injured and the non-injured legs were not similar overtime for the latter three estimates of physical performance. In contrast, statistically no group × time interaction for rate of force development ($F_{(3.0, 114.0)} = 1.3, p=0.51$), sensorimotor performance ($F_{(3.0, 114.0)} = 1.5, p=0.29$) and electromechanical delay ($F_{(3.0, 114.0)} = 1.2, p=0.09$) of the knee flexor musculature was observed, suggesting the pattern of improvement was same for the patients in both the fully-supervised and the minimally-supervised rehabilitation groups.
Table 7.1: Table showing group mean scores for the patients in the fully-supervised group and corresponding per cent changes for estimates of physical performance elicited from the quadriceps (q) and the hamstring (h). The effect size and % changes were calculated from the interval pre-surgery and 24th week assessment.

<table>
<thead>
<tr>
<th></th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
<th>ES</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peak force (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>411.2±88.2</td>
<td>365.5±91.7</td>
<td>373.9±91.2</td>
<td>397.7±90.6</td>
<td>1.0</td>
<td>12</td>
</tr>
<tr>
<td>ninj</td>
<td>408.6±95.7</td>
<td>240.7±86.9</td>
<td>279.3±82.8</td>
<td>396.7±91.7</td>
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<tr>
<td><strong>Rate of force development (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>1621.0±1054.3</td>
<td>1296.8±460.4</td>
<td>1480.8±680.8</td>
<td>1428.3±378.2</td>
<td>0.2</td>
<td>18</td>
</tr>
<tr>
<td>ninj</td>
<td>2100.0±1018.8</td>
<td>2123.9±624.5</td>
<td>2308.6±923.3</td>
<td>2551.7±1173.8</td>
<td>0.4</td>
<td>2</td>
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<tr>
<td><strong>Electromechanical delay (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>inj</td>
<td>36.0±7.4</td>
<td>36.9±5.3</td>
<td>37.2±4.1</td>
<td>35.6±4.9</td>
<td>1.0</td>
<td>9</td>
</tr>
<tr>
<td>ninj</td>
<td>31.5±6.3</td>
<td>40.2±6.1</td>
<td>36±4.1</td>
<td>42.8±6.9</td>
<td>0.3</td>
<td>2</td>
</tr>
<tr>
<td><strong>Sensorimotor performance (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>17.5±42.1</td>
<td>15.3±34.0</td>
<td>14.5±17.2</td>
<td>8.2±51.5</td>
<td>0.3</td>
<td>60</td>
</tr>
<tr>
<td>ninj</td>
<td>25.7±36.1</td>
<td>17.1±34.5</td>
<td>25.7±28.1</td>
<td>19.6±41</td>
<td>0.2</td>
<td>14</td>
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<tr>
<td><strong>Peak force (h)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>232.8±57.2</td>
<td>223.5±55.3</td>
<td>224.3±53.7</td>
<td>224.7±66.7</td>
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<tr>
<td>ninj</td>
<td>169.7±54.5</td>
<td>135.9±48.9</td>
<td>150.2±45.7</td>
<td>145.1±56.4</td>
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<td><strong>Rate of force development (h)</strong></td>
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<td></td>
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<tr>
<td>inj</td>
<td>1062.2±838.6</td>
<td>947.3±537.2</td>
<td>937.9±296.8</td>
<td>1143.3±807</td>
<td>0.4</td>
<td>18</td>
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<tr>
<td>ninj</td>
<td>779.4±518.7</td>
<td>439.1±216.3</td>
<td>558.1±222.3</td>
<td>744.7±619.1</td>
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<tr>
<td><strong>Electromechanical delay (h)</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>37.3±8.1</td>
<td>36.3±5.6</td>
<td>36.7±4.6</td>
<td>34.3±6.1</td>
<td>0.5</td>
<td>40</td>
</tr>
<tr>
<td>ninj</td>
<td>29.2±3.4</td>
<td>39.4±5.0</td>
<td>37.8±3.4</td>
<td>41.5±4.3</td>
<td>0.3</td>
<td>8</td>
</tr>
<tr>
<td><strong>Sensorimotor performance (h)</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>9.4±20.8</td>
<td>6.0±13.0</td>
<td>20.1±16.1</td>
<td>8.7±15.4</td>
<td>0.3</td>
<td>39</td>
</tr>
<tr>
<td>ninj</td>
<td>12.4±28.2</td>
<td>8.1±13.6</td>
<td>7.6±24.8</td>
<td>-7.4±20.2</td>
<td>0.2</td>
<td>8</td>
</tr>
</tbody>
</table>

q | quadriceps  

h | hamstrings
Table 7.2: Table showing group mean scores for the patients in the minimally-supervised group and corresponding per cent changes for physical performances (peak force, rate of force development, sensorimotor performance and electromechanical delay) elicited from the quadriceps and the hamstrings. The effect sizes and % changes were calculated from the interval pre-surgery and 24th week assessment.

<table>
<thead>
<tr>
<th></th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
<th>ES</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peak force (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>393.2 ± 83.3</td>
<td>364.6±86.3</td>
<td>370.5±84.8</td>
<td>357.3 ± 84.8</td>
<td>1.0</td>
<td>33</td>
</tr>
<tr>
<td>ninj</td>
<td>333.8 ± 106.4</td>
<td>249.7±75.4</td>
<td>299.1±81.1</td>
<td>327.9 ± 98.9</td>
<td>1.1</td>
<td>15</td>
</tr>
<tr>
<td><strong>Rate of force development (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>2308.6 ± 923.3</td>
<td>2551.7±1173.8</td>
<td>2513.5±1360.9</td>
<td>2364.4 ± 1213</td>
<td>0.2</td>
<td>18</td>
</tr>
<tr>
<td>ninj</td>
<td>1480.8 ± 680.8</td>
<td>1428.3±378.2</td>
<td>1911.8±1141.6</td>
<td>1809.8 ± 1250.1</td>
<td>0.3</td>
<td>14</td>
</tr>
<tr>
<td><strong>Electromechanical delay (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>36.0 ± 4.1</td>
<td>35.6±4.9</td>
<td>33.9±3.7</td>
<td>31.4 ± 5.4</td>
<td>2.0</td>
<td>26</td>
</tr>
<tr>
<td>ninj</td>
<td>37.2 ± 4.1</td>
<td>42.8±6.9</td>
<td>36.2±5.1</td>
<td>34.3 ± 4.2</td>
<td>1.1</td>
<td>15</td>
</tr>
<tr>
<td><strong>Sensorimotor performance (q)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>14.5 ± 17.2</td>
<td>8.2±51.5</td>
<td>13.7±40.3</td>
<td>33.6 ± 26.6</td>
<td>0.2</td>
<td>81</td>
</tr>
<tr>
<td>ninj</td>
<td>25.7 ± 28.1</td>
<td>19.6±41</td>
<td>22.2±35.6</td>
<td>12.8 ± 30.7</td>
<td>1.3</td>
<td>50</td>
</tr>
<tr>
<td><strong>Peak force (h)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>224.3 ± 53.7</td>
<td>224.7±66.7</td>
<td>222.5±64.7</td>
<td>228.6 ± 65.1</td>
<td>1.2</td>
<td>17</td>
</tr>
<tr>
<td>ninj</td>
<td>150.2 ± 45.7</td>
<td>145.1±56.4</td>
<td>163.6±49.6</td>
<td>180.6 ± 52.4</td>
<td>1.1</td>
<td>17</td>
</tr>
<tr>
<td><strong>Rate of force development (h)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>937.9 ± 296.8</td>
<td>1143.3±807</td>
<td>887.8±512.9</td>
<td>1145.6 ± 751.2</td>
<td>1.1</td>
<td>44</td>
</tr>
<tr>
<td>ninj</td>
<td>958.1 ± 222.3</td>
<td>744.7±619.1</td>
<td>936.3±821.2</td>
<td>1003.8 ± 539.7</td>
<td>1.4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Electromechanical delay (h)</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>37.8 ± 3.4</td>
<td>34±6.1</td>
<td>35.8±5.2</td>
<td>34.1 ± 3.5</td>
<td>3.3</td>
<td>30</td>
</tr>
<tr>
<td>ninj</td>
<td>36.7 ± 4.6</td>
<td>41.5±4.3</td>
<td>37.9±3.3</td>
<td>35.7 ± 5.6</td>
<td>1.2</td>
<td>11</td>
</tr>
<tr>
<td><strong>Sensorimotor performance (h)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>7.6 ± 24.8</td>
<td>8.7±15.4</td>
<td>24.9±28.2</td>
<td>5.6 ± 21.2</td>
<td>3.0</td>
<td>29</td>
</tr>
<tr>
<td>ninj</td>
<td>20.1 ± 16.1</td>
<td>-7.4±20.2</td>
<td>17.1±25.5</td>
<td>14.4 ± 25.6</td>
<td>1.1</td>
<td>11</td>
</tr>
</tbody>
</table>

q  quadriceps
h  hamstrings
7.3.2 OUTCOMES ACROSS 24 WEEKS FOLLOWING STATISTICAL ADJUSTMENTS

7.3.2.1 CHANGES IN FUNCTIONAL OUTCOMES

Using an ANCOVA model involving statistical adjustments for each single anthropometric characteristics (height, body mass) or each single orthopaedically-relevant factors (age, sex, BMI, time to surgery, levels of habitual physical activities, structured rehabilitation programmes) and group (fully-supervised, minimally-supervised rehabilitation) by leg (injured, non-injured) by test occasions (pre-surgery, 6th, 12th and 24th week) with repeated measures on the latter two factors showed no 3-factor interaction for single-leg hop \( (F_{(3.0, 114.0)} = 1.6, p=0.33) \), suggesting that patients in the fully-supervised and the minimally-supervised rehabilitation groups improved in a similar pattern for single-leg hop by statistically controlling the potential intruders (anthropometric characteristics and orthopaedically-relevant factors) on the results. This finding is similar to the finding of ANOVAs, suggesting that results have not been influenced by the anthropometric characteristics and orthopaedically-relevant factors.

7.3.2.2 PHYSICAL PERFORMANCES

Estimates of physical performance for the quadriceps

Using an ANCOVA model involving adjustment for each single anthropometric characteristics (height, body mass) or each single orthopaedically-relevant factors (age, sex, BMI, time to surgery, levels of habitual physical activities, structured rehabilitation programmes) and group × leg × test occasions with repeated measures on the latter two factors showed no interaction for peak force \( (F_{(3.0, 114.0)} = 1.3, p=0.33) \).
rate of force development ($F_{(3, 114.0)} = 2.1, p=0.19$), electromechanical delay ($F_{(3, 114.0)} = 1.9, p=0.23$) and sensorimotor performance ($F_{(3, 114.0)} = 1.1, p=0.06$) for the knee extensor musculature. The latter suggested that patients in the fully-supervised and the minimally-supervised rehabilitation groups showed similar pattern of improvement overtime for the latter four estimates of physical performances by statistically adjusting uncontrollable factors in this trial. These results of ANCOVA for the selected estimates of physical performance for the quadriceps muscle are similar to the results reported for these estimates in ANOVA. This suggested that the anthropometric characteristics and orthopaedically-relevant factors have not been influential on the findings of this clinical trial.

**Estimates of physical performance for the hamstrings**

All estimates of physical performance selected in this clinical trial, except electromechanical delay, have shown similar results by using ANCOVA and ANOVA for the hamstrings as reported for ANOVA. Finding of the electromechanical delay is discussed in the next paragraph.

Using an ANCOVA model involving adjustment for levels of habitual physical activities and group × leg × test occasion with repeated measures on the latter two factors showed a statistically significant interaction for electromechanical ($F_{(3, 114.0)} = 6.3, p=0.03$) for knee flexor musculature, suggesting that the patients in the fully-supervised and the minimally-supervised rehabilitation groups showed different patterns of improvement for electromechanical delay for the knee flexors musculature (Figure 7.10). The group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for electromechanical
delay for the injured leg of knee flexor musculature at baseline versus 24\textsuperscript{th} week were 34.0 ± 6.1 versus 37.3 ± 8.1 ms and 35.7 ± 5.6 versus 36.7 ± 4.6 ms, respectively. The effect sizes for electromechanical delay for the injured legs of knee extensor musculature for the patients in the fully-supervised and the minimally-supervised rehabilitation programmes were observed 0.47 and 0.27, corresponding an increase of 9\% and 3\%, respectively, for electromechanical delay from baseline to 24\textsuperscript{th} week. The latter indicated that the patients in the minimally-supervised rehabilitation programme had possessed superior outcomes for electromechanical delay for the injured legs of knee extensor musculature compared to the patients in the minimally-supervised rehabilitation group (The higher score in electromechanical delay presents the inferior results).

Figure 7.10: Figure showing group mean response on electromechanical delay for the flexor musculature of the injured and the non-injured legs for the patients in the fully-supervised and the minimally-supervised groups. A statistically significant interaction ($F_{(3.0, 114.0)} = 6.3, p=0.03$) was observed by adjusting for levels of physical activities.
7.3.3 OUTCOMES UP TO 12TH WEEK (EARLY PHASE OF REHABILITATION)

7.3.3.1 EARLY CHANGES IN FUNCTIONAL OUTCOMES

Testing of *a priori* ‘interaction’ hypothesis of different rates of progression in an increases of single-leg hop associated with the comparison of the fully-supervised and the minimally-supervised rehabilitation programmes suggested a statistically significant group × leg × time 3-factor interaction \( (F(1.0, 37.0) = 4.5, p=0.02) \) at 12th week compared to the previous testing occasion (pre-op). The mean scores for single-leg hop for the injured leg for the patients in the fully-supervised and the minimally-supervised rehabilitation groups at 12th week versus pre-surgery were 116.9 ± 26.7 versus 122.6 ± 25.0 cm and 102.9 ± 20.5 versus 113.3 ± 24.7 cm. The effect sizes observed for the injured leg for the patients in the fully-supervised and the minimally-supervised rehabilitation groups from pre-surgery to 12th weeks were 0.23 and 0.47, respectively, corresponding to a decrease of 5% and 9% at 12th week for the patients in the fully-supervised and the minimally-supervised rehabilitation groups. The latter indicated that the patients in the fully-supervised possessed superior outcomes at 12th week compared to the patients in the minimally-supervised rehabilitation groups (small decrease). It is in contrast to the findings observed at 24th week of the rehabilitation programme where no difference for function (single-leg hop) were observed amongst the group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups.
### EARLY CHANGES IN PHYSICAL PERFORMANCE

*Estimates of physical performance for the quadriceps*

Testing of *a priori* ‘interaction’ hypothesis of different rates of progression in increases of peak force elicited from the knee extensors associated with the comparison of the fully-supervised and the minimally-supervised rehabilitation programmes suggested a statistically significant group × leg × test occasion interaction \( (F_{1.0, 37.0} = 4.5, p=0.03) \) at 12th week compared to the previous testing occasions (pre-surgery, 6th week). The group mean responses for peak force for the injured leg of knee extensor musculature for the patients in the fully-supervised and the minimally-supervised rehabilitation programmes at 12th versus pre-surgery and 6th were 279.3 ± 82.8 versus 333.8 ± 106.4 and 240.7 ± 86.9 N, and 299.1 ± 81.1 versus 343.2 ± 83.4 and 249.7 ± 75.4 N, respectively, suggesting superior rate of maintaining or re-establishing peak force capability in the knee extensors musculature of the injured leg from pre-surgery to 12th week following ACL reconstruction by the patients in the fully-supervised rehabilitation group compared to the patients in the minimally-supervised rehabilitation group. The corresponding improvement for the patients in the fully-supervised and the minimally-supervised rehabilitation groups were 16% and 13%, respectively. Similarly, statistically differences were observed up to 12th week amongst the group mean responses for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for rate of force development \( (F_{0.9, 36.3} GG = 3.2, p=0.01) \), electromechanical delay \( (F_{1.0, 37.0} =4.1, p=0.04) \) and sensorimotor performances \( (F_{0.7, 35.1} = 4.4, p=0.02) \) elicited from knee extensor musculature. These finding suggested that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed
different patterns of improvement during the initial phases of rehabilitation (up to 12\textsuperscript{th} week).

*Estimates of physical performance for the hamstrings (sensorimotor)*

Testing of *a priori* ‘interaction’ hypothesis of different rates of progression in increases of sensorimotor performance elicited from the knee flexors associated with the comparison of the fully-supervised and the minimally-supervised rehabilitation programmes suggested statistically group × leg × test occasion interaction ($F_{(1.0, 37.0)} = 7.0, p=0.02$) at 12\textsuperscript{th} week compared to the previous testing occasions (pre-surgery, 6\textsuperscript{th} week). The latter suggested that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed different patterns of improvement during the initial phases of rehabilitation. A statistically significant leg × test occasion interaction ($F_{(0.9, 36.3)} G = 3.4, p=0.03$) up to 12\textsuperscript{th} week of rehabilitation suggested that the patterns of improvement between the injured and the non-injured legs was not similar during the initial phase of rehabilitation. The group mean scores for the injured and non-injured legs for the patients in the fully-supervised rehabilitation groups at 12\textsuperscript{th} week versus pre-surgery and 6\textsuperscript{th} weeks were 20.1 ± 16.1 versus 9.4± 20.8 and 6.0 ±13.0, and 7.6 ± 24.8 versus 12.4 ± 28.2 and 8.1 ± 13.6, and for the patients in the minimally-supervised rehabilitation groups 24.9 ± 28.2 versus 7.6 ± 24.8 and 8.7 ± 15.4, and 17.1 ± 25.5 versus 20.1 ± 16.1 and 16.4 ± 20.2, respectively. The corresponding improvement for the injured and non-injured legs of the patients in the fully-supervised rehabilitation group were 80 % and 13 %, and for the patients in the minimally-supervised rehabilitation group were 70% and 7%, respectively. This suggested that the injured leg of the patients in both the fully-
supervised and the minimally-supervised rehabilitation groups showed more changes compared to the non-injured of the patients in the latter two groups. Similar responses of different patterns of improvement between the injured and the non-injured legs of the patients in the fully-supervised and the minimally-supervised rehabilitation groups during the early phases of rehabilitation were observed for electromechanical delay ($F_{(1.0, 37.0)} = 5.3, p=0.01$) and for peak force ($F_{(0.9, 36.5)} GG = 3.3, p=0.04$) of the knee flexor musculature.

Figure 7.11: Figure showing group mean responses on sensorimotor performance for flexor musculature for the patients who were fully-supervised and minimally-supervised in the hospital following ACL reconstruction. The patients in both these groups showed different pattern of improvement across 24-week rehabilitation programme.
Chapter 7

7.4 DISCUSSION

The primary aim of this clinical trial was to compare the outcomes of rehabilitation programme delivered within the same standardised environment (hospital) with different levels of supervision from rehabilitation team on functional (single-leg hop), physical performance and musculoskeletal measures over the 24 weeks of rehabilitation following ACL reconstruction. The second aim of this clinical trial was to assess the role of the individuals’ anthropometric characteristics and orthopaedically-relevant factors on outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes over 24 weeks rehabilitation following ACL reconstruction. Finally, this clinical trial was designed to assess the outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes during the early phases of rehabilitation (up to 12th week of rehabilitation) following ACL reconstruction.

The main finding of this clinical trial suggested no 3-factor interaction (group × leg× test occasion) amongst the group mean scores of the fully-supervised and the minimally-supervised rehabilitation programmes for function [single-leg hop ($F_{(2,0.76,0)} = 1.8, p=0.18$)], for physical performance measures [quadriceps and hamstrings; peak force; ($F_{(2,0.76,0)} = 1.4, p=0.32$) and ($F_{(2,0.76,0)} = 2.1, p=0.34$), rate of force development; ($F_{(3,0,114,0)} = 1.1, p=0.23$) and ($F_{(3,0,114,0)} = 1.4, p=0.33$), sensorimotor performances; ($F_{(3,0,114,0)} = 0.5, p=0.43$) and ($F_{(3,0,111,0)} = 1.9, p=0.54$), respectively] and musculoskeletal measures [ATFD ($F_{(3,0,114,0)} = 0.5, p=0.56$)]. The latter indicated that the pattern of improvement during the initial 24 weeks of rehabilitation following ACL reconstruction, was similar amongst the group mean
scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups. However, a 2-factor ANOVA involving factors of leg x time, showed significant interaction for single-leg hop, physical performance and musculoskeletal measures. The latter indicated that the pattern of improvement overtime was different for the injured and the non-injured legs. For example, the group mean scores for the patients in the fully-supervised rehabilitation group for peak force elicited from the knee extensor musculature showed 12 and 6 % improvement for the injured and the non-injured legs, respectively, over 24 weeks duration of rehabilitation following ACL reconstruction (please see Table 7.1 for details). Similarly, 33 and 15 % improvement for peak force elicited from the latter musculature for the injured and the non-injured legs was observed for the group mean scores for the patients in the minimally-supervised rehabilitation group (please see Table 7.2). This indicated that pattern of improvement between the injured and the non-injured legs was different in the patients in both the fully-supervised and the minimally-supervised rehabilitation groups. The finding of more improvement in injured leg compared to the non-injured leg was according to the expectations where more changes were expected to be observed in the injured leg compared to the non-injured leg.

Findings of lack of significant differences amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups on function and physical performances is in agreement with what was reported previously in the literature on the effectiveness of supervised (fully-supervised) and unsupervised (minimally-supervised) rehabilitation programmes following ACL reconstruction (Hohmann et al. 2011, Grant and Mohtadi 2010, Beard et al. 1998). For example,
Grant et al. (2005) in single-blinded prospective study assessed range of motion up to 3 months post ACL surgery in the patients who were receiving clinic- (fully-supervised) and home-based rehabilitation programmes. Findings of the latter trial suggested that the patients in both groups achieved similar outcomes of rehabilitation in the initial three months following ACL reconstruction. In addition, Beard et al. (1998) assessed function (single-leg hop) and physical performance measures (strength of the musculature around knee joint) amongst the patients receiving rehabilitation programme in the fully-supervised and the minimally-supervised rehabilitation groups. In the latter trial, no differences were reported between the outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes. Similarly, Schenck et al. (1997), at an average of 22 months follow up, reported achievement of similar outcome by the patients in the minimally-supervised rehabilitation group to the patients in the fully-supervised rehabilitation group. It was notable that the current study in chapter 7 endorses the previous findings but offers the novelty of having evaluated potential differences across a much wider selection of outcome measures, from objectively-measured indices of function to relatively sophisticated indices of neuromuscular performance measured using electrophysiology. One of the possible explanations of achieving successful outcomes of rehabilitation by the patients in the minimally-supervised group that matched those of the fully-supervised counterparts may have been their aspiration of returning to the pre-injury activity after ACL injuries. It is evident from the literature that majority of the ACL injuries are sustained during sporting activities at young age (Grannan et al. 2009, Risberg et al. 2004), indicating that these patients would be motivated to return to their sporting activities. Finding of this thesis endorse the
latter by reporting that out of 76 participants recruited for this trial, 70 (92%) have sustained ACL injuries during sporting activities. Moreover, the average age of the latter participants reported in this thesis was 32.2 ± 12.1 years that suggested that these participants were in an active age when their ACLs were injured.

The obvious explanations for the need to retain null hypotheses might be either that the levels of supervision delivered by the physiotherapists is truly not influential in the outcomes of rehabilitation, or that the potency of the experimental manipulation of the differential between fully-supervised and minimally-supervised programmes of rehabilitation had not been sufficiently large. Both possible explanations would seem to be plausible. The size of the relative effect associated with the difference between the two levels of ‘supervision’ might not have matched that expected prior to the experiment. This might have led to patients’ responses being muted compared to the background experimental ‘noise’ that had been present in the trial and associated with factors that it had not been possible to control in this clinical environment. Nevertheless, in order to contextualise this possibility, the experimental manipulations of the levels of supervision accurately reflected a pragmatic delivery of a continuum involving minimally acceptable levels of supervision from the perspective of clinical ethics and not withdrawing treatment, and maximum amounts of supervision reflecting a long-established, regularly-audited and well-respected NHS programme of rehabilitation. Therefore, if the experimental intervention in this chapter had not been sufficiently potent to elicit changes in the outcome measures, then it had been reasonably representative of the type of differences in the levels supervision that could be expected in a number of clinical environments within the UK and elsewhere. Thus, even with the possibility
of an elevated likelihood of Type-II error, the results in this clinical trial should be deemed representative of what might be expected from variations in the levels of supervision in the care pathways associated with ACL injury. The congruence of this study’s findings, albeit at an early juncture following surgery (up to 24 weeks post-surgery), with those in the wider clinical and scientific literature (up to 4-year follow-up), might suggest a lesser role for ‘supervision’ in the successful outcomes following ACL reconstruction surgery.

The latter issue associated with the timing of the assessment of the effects of supervision was a distinctive feature of this clinical trial. The current trial focused attention on the early responses (up to the 24 week of post-surgical care) of patients to altered levels of supervision associated with their rehabilitation, and this corresponded to the immediate efficacy of the intervention rather than legacy effectiveness. In the trials reported by Hohmann et al. (2011) and Grant and Mohtadi (2010), and in earlier trials by Beard et al. (1998) and Schenck et al. (1997), outcomes of the patients to equivalent categories of ‘fully-supervised’ and ‘minimally-supervised’ rehabilitation programmes were assessed over a longer period of rehabilitation and ‘follow-up’ (1-4 years). Thus, a realistic interpretation might be that neither immediate responses to altered levels of supervision nor longer-term effects on function and physical performance, which might be driven increasingly by influences such as unstructured conditioning effects and activities of daily living outside of formal rehabilitation, were substantive. The latter indicated that following a six months formal rehabilitation programme, the patients in both the fully-supervised and the minimally-supervised rehabilitation programmes were subjected to similar levels of independence of managing exercises programmes in the
Community. This might have resulted them to continue similar activities/exercises in the community without being supervised by rehabilitation specialist and ultimately the results may have been influenced.

The second aspects of this clinical trial that by adjusting for levels of habitual physical activities, a 3-factor statistically significant interaction (group × leg × test occasion) for electromechanical delay \( F_{(3.0, 114.0)} = 6.3, p=0.03 \) elicited from the knee flexor musculature of the injured and the non-injured legs of the patients in the fully-supervised and the minimally-supervised rehabilitation groups suggested that the patterns of improvement amongst the patients in the latter two groups were different for electromechanical delay overtime 24 weeks rehabilitation following ACL reconstruction. The group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups for electromechanical delay elicited from the injured leg of the knee flexor musculature showed that the patients in the minimally-supervised rehabilitation group showed 6% more improvement compared to the patients in the fully-supervised rehabilitation group for the latter estimate of physical performance (please see Table 7.2 for more details). Although, by adjusting for levels of habitual physical activities, both groups showed different patterns of improvement for electromechanical delay, still, the improvement may not be clinically important. Unfortunately, no specific cut-off points that determine a range for a decrease in electromechanical delay to be considered minimally clinical important, was found in the literature. However, PROMs used in this thesis (chapter 5 and 6) for the assessment of function of the knee joint suggested that an improvement of 10-16% might be clinically important (Collins et al. 2009, Roos et al. 2003). The per cent difference between the injured legs of the fully-supervised
and the minimally-supervised rehabilitation groups has not achieved the latter mentioned range of improvement that may be considered as clinically important. On balance, the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed similar pattern of improvement across 24 weeks rehabilitation following ACL reconstruction.

The final finding of this clinical trial suggested that the patients in the fully-supervised and the minimally-supervised rehabilitation groups showed different patterns of improvement during the initial 12 weeks of rehabilitation following ACL reconstruction. The patients in the fully-supervised rehabilitation group showed superior outcomes on electromechanical delay (knee extensor group), sensorimotor performance (knee flexor and extensor groups) and ATFD during the initial 12th week of rehabilitation period following ACL reconstruction. In contrast, the patients in the minimally-supervised rehabilitation group showed superior outcomes compared to the patients in the fully-supervised rehabilitation group on peak force (knee flexor and extensor groups), rate of force development (knee flexor and extensor groups) and electromechanical delay (knee flexor group). The estimates where improvement was observed for the patients in the fully-supervised and the minimally-supervised rehabilitation groups portrays an association with specific measures. For example, the patients in the minimally-supervised rehabilitation programme showed superior results to the patients in the fully-supervised rehabilitation groups on peak force and rate of force development, which are associated with the power/strength of the muscles. In contrast, the patients in the fully-supervised rehabilitation group showed superior results on sensorimotor performance and ATFD, which are associated with proprioception in the knee joint.
The possible reason for this specific pattern of improvement may be explained from the structural composition of rehabilitation programmes offered following ACL reconstruction (please see appendix III). In the latter rehabilitation programme, an emphasis is given on the exercise that are essential for increasing range of motion and proprioception in the knee joint during the initial three months of rehabilitation. Due to the associated challenges related to the implementation of complex exercises needed for improving proprioception, the patients in the fully-supervised rehabilitation groups had better chance of having been monitored by the rehabilitation specialists during these exercises compared to the patients in the minimally-supervised rehabilitation group who were supposed to have self-regulated exercises in the hospital. The latter might have contributed to the superior results shown by the patients in the fully-supervised rehabilitation programme on sensorimotor performance and ATFD. In a recent systemic review by Paterno et al. (2012), it was reported that independence of action by patients in rehabilitation programmes during the initial three months of rehabilitation, often produce increased laxity in the patients who had undergone ACL reconstruction. The possible explanation for increased laxity in less supervised rehabilitation programmes might be due to the reasons that patients in such programmes might be prone to hyper-dosing of exercises that would affect laxity in the knee joint. Findings of this clinical trial therefore, endorse those reported by Paterno et al (2012) where the patients with minimal-supervision during post-surgical rehabilitation were reported as having the worst knee laxity compared to that of the patients who had been fully-supervised in their rehabilitation.
It is well known that the human health condition is affected by a variety of factors. The structure and function of human body alongside participation level in physical activity have been reported to influence overall performance of human body. Malfunctioning of these factors not only affect health condition of human body but also expose an individual to a high-risk of disability. This model has been adopted by the WHO for most of the medical conditions that are regarded to making an individual prone to disability. The International Classification of Function, disability and health (ICF) provide reliable measuring assessment in this regard. The ICF model is based on outcomes of interaction between health conditions (diseases, disorder and injuries) and contextual factors. The list of domains in ICF is very important as it measures the presence and severity of a problem in functioning at the body, person and societal levels. In this clinical trial, functioning of an individual were assessed at ‘body’ and ‘person’ levels. Objectively-measured outcomes (single-leg hop, peak force, rate of force development, sensory motor performance, electromechanical delay) were used to assess the first part of ICF (functioning at ‘body’ level) while selected PROMs (IKDC, KOOS, K-SES, VAS and Lysholm were used to assess the second part of the ICF (functioning at ‘person’ level). Findings of functioning at ‘body’ level were reported in this chapter while findings of function at ‘person’ level were reported in chapter 6 of this thesis. Moreover, an association between the functioning at ‘body’ and ‘person’ levels was reported in an appendix (Please see appendix II). It is interesting to report that in this clinical trial, the patients in both the fully-supervised and the minimally-supervised rehabilitation groups showed similar responses of no differences on the selected PROMs of function, objectively measured function (single-leg hop) and several (but not all)
aspects of physical performance (peak force, rate of force development, electromechanical delay and sensorimotor performance). This indicated that the patients in both the fully-supervised and the minimally-supervised rehabilitation groups had achieved similar functioning at ‘body’ and ‘person’ levels. Moreover, these findings suggested that the perception of the patients had provided similar information about the function at ‘body’ level. Despite the latter fact, no strong association was observed between the selected PROMs and the selected objectively-measured outcomes (appendix II), suggesting that these assessment tools might assess different aspects of rehabilitation and inclusion of both the latter might be used for comprehensive assessment of patients.

7.5 CONCLUSION

Based on the findings of this clinical trial, it may be concluded that the patients in the minimally-supervised rehabilitation group can achieve similar levels of function to the patients in the fully-supervised rehabilitation group. The differences observe at 12th week may not be sustainable up to the formal end of rehabilitation. Assessment by PROMs may not be an alternative to the objective measures especially in those circumstances, where a comprehensive assessment of an individual is required.
8 CHAPTER: GENERAL DISCUSSION
8.1 DISCUSSION

This thesis was designed to make an original contribution to knowledge in relation to whether outcomes of rehabilitation programme following ACL reconstruction are influenced by the environment or by the levels of supervision from rehabilitation team. As outlined in the introduction and literature review chapter of this thesis, rehabilitation programmes following ACL reconstruction have seen drastic changes in terms of their contents, duration and mode of implementation in the last two decades. Recent rehabilitation following ACL reconstruction, is based on the early introduction of extensive exercises for the early return of the patients to their previous levels of activities. However, the role of the environment on the outcomes of rehabilitation had received little attention in the literature. In addition, according to the author’s knowledge, none of the clinical trials carried out previously, had reported effects of the levels of supervision on the outcomes of rehabilitation programme following ACL reconstruction. For this purpose, two clinical trials (findings of these two trials have been discussed in chapter 5, 6 and 7) were carried out during this research with the aims to address specific questions given below.

- Does the environment in which rehabilitation is delivered bring significant changes on patients’ perceived functional outcomes of rehabilitation programme following ACL reconstruction (chapter 5)?
- Do the levels of supervision from the clinical team influence patients’ perceived functional outcomes of rehabilitation programme delivered in the same environment (chapter 6)?
Do the levels of supervision from the clinical team influence objectively and functionally measured outcomes of rehabilitation programme delivered in the same environment (chapter 7)?

Do anthropometric characteristics and orthopaedically-relevant factors affect the outcomes of ACL rehabilitation?

Do the outcomes during the early phase of rehabilitation (at the 6th and 12th weeks post-surgery) predict the final outcomes at 24th week following ACL reconstruction?

The purpose of this chapter was to consider and synthesise the findings from the two clinical trials in greater depth and to evaluate these findings in the context of the existing literature. This chapter will also consider the limitations of the studies and discuss the implications of these empirical observations for future research. Finally, this chapter will make recommendations for investigators and policy makers regarding the effects of the environment and the levels of supervision from the clinical team on the final outcomes of rehabilitation programme following ACL reconstruction.

**Does the environment in which rehabilitation is delivered bring significant changes on patients' perceived functional outcomes of rehabilitation programme following ACL reconstruction (chapter 5)?**

The first clinical trial of this thesis was carried out on 76 patients, who self-selected themselves into the hospital- and the community-based rehabilitation programmes (48 and 28 in the hospital- and the community-based rehabilitation programmes, respectively). The reasons for allowing the patients to self-select themselves into the hospital- and the community-based rehabilitation programmes were logistical
constraints and ethical issues that have been discussed in chapter 5 (‘methods’ section; 5.2) of this thesis. The aim of the latter clinical trial was to investigate the effects of the environment (hospital and community) on the final outcomes of rehabilitation programme following ACL reconstruction. Findings of the latter clinical trial suggested, that the patients in the hospital-based rehabilitation programme showed statistical superior results on some aspects of PROMs of function [subsections ‘physical activities’ (\(F_{(2.9, 87.5)} G G = 3.9, p=0.03\)) of the K-SES and ‘sport and recreation’ (\(F_{(3.0, 183.0)} = 5.4, p=0.04\)) of the KOOS] across 24 weeks of rehabilitation programme following ACL reconstruction. The group mean scores for the patients in the hospital- and the community-based rehabilitation programmes suggested that the patients in the hospital-based rehabilitation programme had shown 9-12% better outcomes on the latter aspects of PROMs compared to the patients in the community-based rehabilitation programme. In contrast, the patients in both the hospital- and community-based rehabilitation programmes achieved similar levels of function and pain on IKDC, Lysholm, VAS and the remaining three and four subsections of the K-SES and KOOS, respectively. This finding is in agreement to what had been reported in the literature on the effects of the hospital- and the community-based rehabilitation programmes (Grant and Mohtadi 2010, Ugutmen et al. 2008). In the clinical trial reported by Grant et al. (2010), the patients in the community-based rehabilitation programme achieved similar levels of function on IKDC during 2- to 4-year follow-up following ACL reconstruction. Similarly, in the clinical trial reported by Ugutmen et al. (2008), the patients in the community-based rehabilitation programme achieved similar levels of function on IKDC and HSS at 12th month assessment following ACL reconstruction. It is noteworthy, that in both
the latter trials, the patients in the hospital- and the community-based rehabilitation programmes were assessed between 12 to 48 months following reconstruction of ACL while the formal rehabilitation programme of ACL routinely ends six months following ACL reconstruction. Usually, following a 6-month rehabilitation programme, patients in both the hospital- and the community-based rehabilitation programmes continue their activities in the same environment (community). In the latter environment, both sets of patients are required to follow the remainder of the rehabilitation activities in the community without being supervised by the rehabilitation team. During this longer-term period of post-surgical care (6 months onwards), the patients in the hospital-based rehabilitation programme follow the same approach of self-managing rehabilitation programme like the patients in the community-based rehabilitation programme.

It is interesting to report, that in chapter 5, the patients in the hospital-based rehabilitation programme showed superior results compared to the patients in the community-based rehabilitation programme on most aspects (IKDC, subsections ‘sport and leisure’ and ‘physical activities’ of the K-SES, ‘symptom and stiffness’, ‘pain’, ‘function, daily living’, ‘function, sports and recreational activities’ and ‘quality of life’ of the KOOS) of PROMs assessing knee function during the initial 12 weeks following ACL reconstruction. However, findings across 24 weeks in the latter trial suggested that patients in both rehabilitation groups had achieved similar levels of function on most of the PROMs. Rehabilitation programme in the hospital where this clinical trial was deployed, is designed in such a manner where patients are advised to attend more supervised physiotherapy sessions during the initial three months. In the latter programme, patients in the hospital-based rehabilitation
programme, attended rehabilitation session at least once a week for the first three months and later on, once a month (Bailey et al. 2003). This indicated that the amount of dose during the initial three months was closely monitored and regulated during the initial three months of rehabilitation programme following ACL reconstruction. The patients who had been more monitored (hospital-based) showed superior outcomes following rehabilitation compared to the patients whose rehabilitation programme was not closely monitored during the latter rehabilitation period. The complex nature of the rehabilitation programme following ACL reconstruction had always remained debatable in terms of types of exercises, duration and implementation mode (Biggs et al. 2009, Beynnon et al. 2011, Shaw 2002, Shelbourne and Nitz 1992, Shelbourne and Nitz 1990). A variety of exercises have been suggested during the latter rehabilitation. Although the exact role and to what extent these exercises may influence the outcomes of rehabilitation could not be verified from the literature (Wilk et al. 2012), nevertheless, an appropriate dose of exercise-related conditioning has been reported to favourably influence the outcomes of rehabilitation programmes for musculoskeletal injuries (Treacy et al. 1997). This latter might be one of the reasons which had favoured outcomes of the hospital-based rehabilitation programme over the outcomes of the community-based rehabilitation programme during the early phase of rehabilitation (up to 12th week) following ACL reconstruction. Apart from the conditioning programme in the hospital, the patients having their ACLs reconstructed are continuously involved in carrying out habitual physical activities which might range from very low to very high demanding activities. The influences of the latter on the outcomes of the rehabilitation following ACL reconstruction had not been reported in the literature. This was the case
especially in those trials which had been carried on the effects of environment on rehabilitation programme following ACL reconstruction (Grant et al. 2005, Grant and Mohtadi 2010, Feller et al. 2004, Hohmann et al. 2011, Ugutmen et al. 2008, Treacy et al. 1997, Beard and Dodd 1998). One of the novelties of the clinical trial reported in chapter 5 of this thesis, was quantifying the levels of habitual physical activities in the community. A validated and reliable interview-based PROM was used to assess the levels of habitual physical activities in the latter clinical trial. It is noteworthy, that the patients in the hospital-based rehabilitation programme showed superior levels of habitual physical activities compared to the patients in the community-based rehabilitation programme [habitual levels of physical activities for the patients in the hospital- and the community-based rehabilitation programme; 2645.2 ± 267.2 and 2012.4 ± 176.0 Kilocalories/day, respectively, $p=0.04$. The latter indicates that the patients in the hospital-based rehabilitation programme were performing 31% more unstructured rehabilitation activities compared to the patients in the community-based rehabilitation programme which might have contributed to their superior results on some aspects of rehabilitation. Being one of the novelties of this, the role of physical activity on the outcomes of rehabilitation following ACL reconstruction has not received robust attention in the literature and, therefore, it is no possible to compare the outcomes of the effects of levels of habitual physical activity with other trials carried out on ACL rupture. However, a validated model, ICF, suggested by WHO for a variety of medical conditions, was considered for comparing the effects of the levels of habitual physical activity on the outcomes ACL rehabilitation. In this model, the overall health status of an individual has been reported to be influenced by a variety of factors included ‘body function and
structure’ participation and contextual factors. The aim of all these three factors is to provide a stable and smooth environment to an individual for performing ADL. Malfunctioning of any of these factors can lead the individual to a restricted participation in the ADL and ultimately making him/prone to disability. Moreover, the principle of this model is based on ‘the more active, the better the health condition’. In the clinical trial, reported in chapter 5 of this thesis, the patients in the hospital-based rehabilitation programme showed higher level of habitual physical activity compared to the patients in the community-based rehabilitation programme, it is, therefore, suggested that this higher level of habitual physical activity might have contributed to the overall improved health status of patients in the former group.

Figure 8.1: Figure showing component of health condition based on ICF.

Although it was observed that the patients in the hospital-based rehabilitation group showed superior outcomes over the patients in the community-based rehabilitation
programme on some aspects of outcomes relating to function and pain, still, the question of whether these findings were meaningful to the patients cannot be determined by only reporting the significant interaction effect. To determine whether these results were or were not clinical meaningful to the patients, finding of both groups are plotted in a scattered diagram (please Figure 8.1) inserting lines for the MDCs and MCIDs. The term ‘MDC’ of a PROM represents its ability to accurately detect change overtime when it had occurred (Giordano et al. 2009) while the term ‘MCID’ represent the minimal change in the score of an assessment tool which is meaningful for the patients (Kovacs et al. 2008). These characteristics (MDC and MCID) for the assessment tools used for evaluation of the patients reported in chapter 5, have been summarised in chapter 3 of this thesis (please see Table 3.2). The results plotted in the scattered diagram showed that 80% (32 out of 40) and 70 % (16 out of 23) of the patients in the hospital and the community-based rehabilitation, respectively, had achieved ‘MCID’ status across 24 week rehabilitation. The latter indicated that majority of the patients in the hospital- and the community-based rehabilitation programmes had achieved clinical important outcomes of rehabilitation programme across 24 week following ACL reconstruction. In short, the role of the environment in which post-surgical rehabilitation takes place on the final outcomes of rehabilitation following ACL may not be significant. Patients in either hospital- or community-based rehabilitation programme can achieve similar levels of function on PROMs following ACL reconstruction. However, this chapter focused on PROMs which are highly-dependent on patients correctly scaling their self-perceptions of capability and could not answer the question of whether patients in both the hospital- and the community-based
rehabilitation may achieve similar levels of function if they are measured on objective measures.

Figure 8.2: Figure showing individual patient’s position in term of MICDs in the hospital and the community-based rehabilitation programme on function assessed by IKDC.

Figure 8.3: Figure showing individual patient’s position in term of MICDs in the hospital and the community-based rehabilitation programme on function assessed by K-SES.
Figure 8.4: Figure showing individual patient’s position in term of MICDs in the hospital and the community-based rehabilitation programme on function assessed by Lysholm.

Figure 8.5: Figure showing individual patient’s position in term of MICDs in the hospital and the community-based rehabilitation programme on function assessed by VAS.
Do the levels of supervision from the clinical team influence patients’ perceived functional outcomes of rehabilitation programme delivered in the same environment (chapter 6)?

The second clinical trial of this thesis was carried out on 48 patients who were randomly allocated into the fully-supervised and the minimally-supervised rehabilitation groups (24 patients in each group). The aim of this clinical trial was to evaluate the effects of the levels of supervision from physiotherapists amongst the patients of both the latter two mentioned groups. All the patients in the latter clinical trial were assessed by all those PROMs which were included in trial I (chapter 5 of this thesis). Findings of this clinical trial suggested superior results for the patients in the fully-supervised rehabilitation group compared to the patients in the minimally-supervised rehabilitation group on one aspect of PROMs (subsection ‘physical activities’ of the K-SES). In contrast, the patients in the fully-supervised and the minimally-supervised rehabilitation groups achieved similar levels of function on the remaining aspects of the selected PROMs (IKDC, Lysholm, VAS, all five subsections of the KOOS and the remaining three subsections of the K-SES). The finding of observing no differences of function assessed by PROMs in this trial, is in agreement to what was reported previously (Hohmann et al. 2010, Feller et al. 2004).

In the latter trials levels of supervision have been differentiated on the basis of number of supervised physiotherapy sessions in the hospital. For example, Feller et al. (2004) classified patients in the ‘minimally-supervised’ and ‘fully-supervised’ rehabilitation groups if there physiotherapy attendances were less than 3 and more than 12, respectively, during the initial six months of rehabilitation. The latter might be considered deficient in providing a controlled environment for the patients to
follow iso-volumetric rehabilitation programme following ACL reconstruction. In the clinical trial reported in chapter 6 of this thesis, a novel approach providing equal opportunities to the patients in both the fully-supervised and the minimally-supervised rehabilitation groups to follow iso-volumetric conditioning programme in the hospital, was adopted. The patients in the fully-supervised rehabilitation groups were monitored throughout the physiotherapy attendances in the hospital. Alteration in the intensity and volumes of exercises was suggested by the physiotherapists during these attendances. In contrast, the patients in the minimally-supervised rehabilitation programme were guided to the contemporary rehabilitation programme in the beginning of each physiotherapy attendance and were advised to continue the rest of physiotherapy activities in the hospital gymnasium without further supervision from the physiotherapists. This means that patients in the latter group were provided an equal opportunity to follow the exact volume of training (exact dose of exercise) which was not done in the previous trials that had been reported in the literature.

Results of chapters 5 and 6 showed that some of the PROMs (K-SES, KOOS) or certain aspects of the latter (‘physical activities’ of the K-SES, ‘sport and recreation’ of the KOOS), had detected differences amongst the outcomes of the patients assessed as in those chapters. In contrast, no differences were observed amongst the group mean scores for the patients in the hospital- and community-based rehabilitation programmes (chapter 5), and the patients in fully-supervised and the minimally-supervised rehabilitation groups (chapter 6) on IKDC, Lysholm and VAS. One of the possible reasons for this inconsistency amongst the outcomes of the different PROMs used in this clinical trial, might be due to their inherent clinimetric
characteristics. For example, the ability of the IKDC to detect change in the initial 12 months of rehabilitation following ACL reconstruction is considered to be relatively poor in comparison to KOOS (Collins et al. 2011, Roos and Lohmander 2003). In a clinical trial carried out by Risberg et al. (1999a) on the clinimetric characteristics of PROMs assessing knee injuries, it was reported that assessing pain using a VAS and assessing knee function using the IKDC, were less responsive to changes during the initial 12 month following surgical procedures in the latter joint. The MDC for the IKDC has been reported 8.8 % during the initial year following ACL reconstruction (Collins et al. 2009). In contrast, the MDC for the KOOS and K-SES has been reported 6.1 and 6.0%, respectively. Similarly, the MCIDs for the IKDC, KOOS and K-SES have been reported 16.5, 10.0 and 10%, respectively (Roos and Lohmander 2003, Thomee et al. 2007) (these characteristics have been discussed in chapter 3 and a summary may be found in Table 3.2). Findings of this thesis (chapter 5 and 6) endorse that the PROMs and even their subsections possess different capabilities to detect changes in the outcomes of rehabilitation programmes following ACL reconstruction. For research purposes in which limited budgets and resources are available, PROMs having a high responsiveness may be helpful to detecting change compared to their low responsiveness counterparts, when it had occurred.

One aspect of the fully-supervised and minimally-supervised rehabilitation programmes in the hospital revealed that the patients in the former group had achieved superior levels of dose of exercises-conditioning across 24 week rehabilitation programme. For example the intensities of exercise programmes for the patients in the fully-supervised and the minimally-supervised rehabilitation
groups were 9.2 ± 3.6 and 5.2 ± 2.3, and 11.2 ± 2.1 and 8.3 ± 1.2 Kilocalories/minute during the initial 6 and 12 weeks of rehabilitation programme, respectively ($p=0.03$), following ACL reconstruction. The latter findings indicated that the patients in the fully-supervised rehabilitation programme were closely monitored during the physiotherapy attendances their rehabilitation programme was altered according progress made by these patients. Evidence from the literature suggested that the patients with withdrawn supervision (minimal-supervision) are less likely to adhere to exercises programme especially to those which demand skilful techniques for implementation (Bassett 2003, Flynn et al. 1995). The exercise programmes deployed following ACL reconstruction, focused on the complex exercises (exercise for proprioception) during the initial 12 weeks compared to the last 12 weeks. One of the possible reasons for the differences observed in the intensity of exercises during the initial 12 week might the due the complex nature of the exercise programme. During this period, the patients self-managing their rehabilitation programmes, might not be able to judge the required dose of exercises. Despite the latter differences observed amongst the group mean score for the patients in the fully-supervised and the minimally-supervised rehabilitation groups, the patients in both groups achieved similar outcomes following the rehabilitation associated with ACL reconstruction. This indicates that the patients in the minimally-supervised rehabilitation groups were able to perform exercises with an intensity that led them to achieve similar outcomes of function and pain on PROMs to the patients in the fully-supervised rehabilitation group.

In short, the levels of supervision during physiotherapy attendances in the hospital may not be a significant contributor to the final outcomes of rehabilitation in the
patients following ACL reconstruction. However, the levels of supervision might influence patients’ abilities to maintaining intensities of exercises programme (the more in supervision, the better in maintaining exercise intensities).

*Do the levels of supervision from the clinical team influence objectively and functionally measured outcomes of rehabilitation programme delivered in the same environment (chapter 7)?*

Objectively-measured outcomes of the fully-supervised and the minimally-supervised rehabilitation programmes were reported in chapter 7 of this thesis. The clinical population in this trial was the same reported in chapter 6 of this thesis. However, the specific aim of this clinical trial was to compare the patients in the fully-supervised and the minimally-supervised rehabilitation groups on functional (single-leg hop), physical performance (peak force, rate of force development, sensorimotor performances, electromechanical delay) and musculoskeletal (ATFD) measures. For the latter purpose, all the patients in both the fully-supervised and the minimally-supervised rehabilitation groups were assessed for functional outcome measures, physical performance and musculoskeletal (ATFD) performance measures on four different occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction). Findings of this clinical trial suggested no differences amongst the group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups on functional and physical and musculoskeletal performances across 24 weeks rehabilitation following ACL reconstruction. However, statistically significant differences were observed during the initial 12 weeks of rehabilitation amongst the group mean scores for the patients in the fully-supervised and the minimally-supervised rehabilitation groups. The patients in the
fully-supervised rehabilitation group showed statistically superior outcomes compared to the outcomes of the patients in the minimally-supervised rehabilitation group on electromechanical delay (quadriceps), sensorimotor performance (hamstrings and quadriceps) and ATFD. In contrast, the patients in the minimally-supervised rehabilitation group showed statistically superior outcomes compared to the outcomes of the patients in the fully-supervised rehabilitation group during the latter period of rehabilitation on peak force (hamstrings and quadriceps), rate of force development (hamstrings and quadriceps) and electromechanical delay (hamstrings). The latter indicated that different aspects of rehabilitation were improved amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups during the initial 12 weeks of rehabilitation following ACL reconstruction. For example, the patients in the fully-supervised rehabilitation group showed superior results compared to the patients in the minimally-supervised rehabilitation group on the estimates associated with proprioception of knee joint (sensorimotor performance). In contrast, the patients in the minimally-supervised rehabilitation group showed superior outcomes on the estimates associated with strength (peak force, rate of force development). As mentioned in response to question II in this chapter, the contents of ACL rehabilitation during the initial 12 week focused on different aspects of rehabilitation compared to the contents of rehabilitation programme suggested during the last 12 week of rehabilitation. For example the conditioning programme during the initial 12 week, focuses on exercises associated with improving proprioception of knee joint while the focus of the latter during the last 12 weeks remains on the exercises associated with improving strength of the muscles around knee joint. The exercises associated with improving the
proprioception are more complex compared to the exercises performed for strength training. The patients in the fully-supervised rehabilitation group might have been guided and monitored to follow the exact dose of the complex exercises during the initial 12 weeks of rehabilitation programme. In contrast, the patients in the minimally-supervised rehabilitation group might have not attained the specific dose required for improving the proprioception in knee joint. Evidence from the literature suggested that if supervision is withdrawn from the patients, then exercise which need skilful techniques are not followed by the patients with required dose (Flynn et al. 1995). The latter might led the patients being fully-supervised to achieve better outcomes rehabilitation compare to the patients being minimally-supervised.

It is important to report that in chapter 6 and 7, same clinical population was assessed on PROMs and objectively measured outcomes, respectively. Findings of both the latter chapters suggested that the patients with minimal-supervision could achieve the same levels of function on PROMs and objective measures. Being showing similar patterns of findings, it was expected that these selected measure (PROMs and objective measures) might possess an association amongst them. However, it is interesting to report there was no correlation (or poor correlation) amongst the objective measures and the PROMs and the outcomes of one might not provide sufficient information about the other (please see chapter ‘correlation’, appendix II). Based on this, it may be suggested that these selected objective measures and PROMs might assess different aspects of rehabilitation and a multivariate approach may be adopted for assessing the outcome of rehabilitation programme following ACL reconstruction.
In short, the levels of supervision from the rehabilitation team in the same environment may not bring significant difference in achieving the outcomes of rehabilitation programme following ACL reconstruction. For comprehensive assessment, a combination of both objectives and PROMs may be used for the patients following ACL reconstruction.

*Do anthropocentric characteristics and orthopaedically-relevant factors affect the outcomes of ACL rehabilitation programme?*

One of the novelties of this thesis was assessing the influence of anthropometric characteristics (height, body mass) and orthopaedically-relevant factors (age, gender, body mass, BMI, habitual levels of physical activity) on the outcomes of rehabilitation programme following ACL reconstruction. For this purpose, the outcomes of the hospital- and the community-based rehabilitation (chapter 5) and the fully-supervised and the minimally-supervised rehabilitation programmes (chapter 6 and 7) were assessed following statistically adjustment for each of the anthropometric characteristics and orthopaedically-relevant factors. The justifications for doing the latter was based on the evidence from the clinical trials reported in the literature on musculoskeletal conditions (Smith et al. 2012a, Vincent et al. 2006, Lohmander et al. 2004, Braybrooke et al. 2007, Derrett et al. 1999). For example, in a prospective clinical trial carried out on the total hip replacement, age was shown to be influential on the outcomes of the rehabilitation following total hip replacement: being younger age favourable outcomes and vice versa (Smith et al. 2012a). Furthermore, the potential consequences associated with old age were reported with an increased clinical problems and increased cost of treatment for patients who had sustained injuries to the knee joint (Vincent et al. 2006, Lohmander et al. 2004). In addition, ‘long waiting time to surgery’ was reported to adversely affect the outcomes in the patients with back disorders involving injuries to the spinal cord (Braybrooke et al. 2007, Derrett et al. 1999).

By adjusting for the levels of habitual physical activity at pre-op, a significant group × time interaction ($F(3.0, 180.0) = 3.4, p<0.05$) favouring the outcomes of the hospital-based rehabilitation programme over the outcomes of the community-based
rehabilitation programme was observed for subsection ‘pain’ of the KOOS. However, following the statistical adjustment, the difference between the outcomes of the hospital- and the community-based rehabilitation programme was 3% (hospital- versus community-based rehabilitation: 63% versus 60 %, respectively) that might not be considered clinical important (MCID for the KOOS= 10%). Moreover, no differences amongst the group mean responses for the patients in the hospital- and the community-based rehabilitation programmes were observed for IKDC, VAS, Lysholm, the remaining 4 subsections of KOOS and all subsections of K-SES following statistical adjustments for the anthropometric characteristics and orthopaedically-relevant factors. This indicated that the latter factors were not influential on the outcomes of ACL rehabilitation for the patients receiving physiotherapy at the hospital and at the community. Similarly, in chapter 6 where the outcomes of the fully-supervised and the minimally-supervised rehabilitation groups were compared, a statistically significant group × time interaction was observed for subsection ‘daily activities’ of the K-SES (F (3.0, 114.0) = 2.6, p<0.05) following statistically adjustment for age. In the latter trial, the patient in the fully-supervised rehabilitation programme showed 4% better outcomes on subsection ‘daily activities’ of the K-SES at the end of ACL rehabilitation. Moreover, a statistically significant group × time interaction amongst the patients in the fully-supervised and the minimally-supervised rehabilitation groups were observed for ‘physical activity’ of the K-SES (F (3.0,114.0) = 2.7, p<0.05) by adjusting age, (F (3.0,114.0) = 3.0, p<0.05) by adjusting levels of habitual physical activity at 6th week, (F (2.3,111.2) GG = 2.9, p<0.05) by adjusting levels of habitual physical activity at 12th week and (F (3.0,114.0) = 2.5, p<0.05) by adjusting levels of habitual physical activity at 24th week. The patients in the fully-supervised and the minimally-supervised rehabilitation groups showed similar response for the rest of the PROMs (IKDC, VAS and Lysholm) following statistical adjustment for the each of the anthropometric characteristics and orthopaedically-relevant factors. In chapter 7 where the outcomes of the fully-supervised and the minimally-supervised rehabilitation groups were assessed on objective measures, group × leg × test statistically significant interaction for electromechanical (F (3.0, 114.0) = 6.3, p<0.05) for knee flexor musculature, favouring the outcomes of the minimally-
supervised rehabilitation programme was observed. The patients in the minimally-supervised rehabilitation programme showed 6% more improvement than the patients in the fully-supervised rehabilitation programme. Despite the fact that the patients in the minimally-supervised rehabilitation group showed statistically better outcomes for electromechanical delay, still, the improvement may not be classified clinically important. Following statistically adjustment for anthropometric characteristics and orthopaedically-relevant factors, significant differences between the outcome of the hospital- and the community-based rehabilitation programmes, and fully-supervised and the minimally-supervised rehabilitation programmes were observed, still, the improvement have achieved levels of clinical importance. Moreover, findings of ANCOVA were quite similar to the findings of ANOVA in the trials reported in the chapter 5, 6 and 7 of this thesis that endorsed the fact that these factors had not been influential.

*Can the final outcomes (at 24th week) of ACL rehabilitation be predicted from the outcomes during the early phase of rehabilitation (6th and 12th weeks)?*

The aim that the outcomes during the early phase of rehabilitation might be used to predict the outcomes at 24th week was one the subsidiary aims in chapter 5 and 6 of this thesis. The reason for including this aim in these two chapters was the assumption that the efficiency of clinical treatment might be enhanced if the outcomes during early phase of rehabilitation showed a robust correlation with the final outcomes at 24th week following ACL reconstruction. This might help the clinician to predict with reasonable error those patients whose performances might resist attaining those associated with MCIDs within the usual formal period of rehabilitation and help the clinician to apportioned clinical resources more effectively. For this purpose, a correlation between the changes in PROMs within early phase of rehabilitation (acute: pre-op to 6th week, sub-acute: 6th to 12th week) were correlated with their respective scores at 24th week following ACL reconstruction. A statistically significant correlation between changes in PROMs
[IKDC, KOOS (subsections: ‘symptom and stiffness’ and ‘pain’), VAS and K-SES (subsection ‘daily activities’)] within early phase of rehabilitation with outcomes at 24th week was observed for the group mean response for all the patients reported in chapter 5 of this thesis (r = 0.5, 0.4, 0.5, 0.5 and 0.6, respectively: p< 0.05). Similarly, statistically significant correlations were observed between changes within early phase of rehabilitation and 24th week for subsections ‘sport and leisure activities’ and ‘you knee function in the future’ of the K-SES (r = 0.4 and 0.5, respectively: p < 0.01) and subsection ‘quality of life’ of the KOOS (r = 0.3: p < 0.01) for the group mean response for the patients reported in chapter 6 of this thesis. Finding of having significant correlation amongst the outcomes of ACL rehabilitation within early phase of rehabilitation and 24th week is in agreement to what was reported in the literature where pre-op early health status was reported a predictor for the final outcomes of rehabilitation programme (Mahomed et al. 2002, Jones et al. 2003, Lingard et al. 2004). In the latter three trials, a weak correlation (‘r’ ranges from 0.3 to 0.4) explaining 9% to 16% of variability was reported amongst pre-op and final outcomes of rehabilitation programme for musculoskeletal injuries. In this thesis, the change scores in the outcomes at early phase of rehabilitation (pre-op to 6th week, 6th week to 12th week) were compared with the final outcomes. The association observed in chapter 5 and 6 may be categorised weak to moderate correlation (‘r’ ranges from 0.3 to 0.6) that may explain 9% to 36% of variance. Although the correlation observed amongst some aspects of PROMs was stronger than the reported one, still, the correlation has not achieved 50% of the explained variance. This indicates that changes score during the early phase of rehabilitation may not be good predictors for the final outcomes of
rehabilitation and clinician would not be confident in altering rehabilitative activities while considering the change scores at early phase of rehabilitation.

8.2 STRENGTH AND LIMITATIONS

8.2.1 STRENGTHS

8.2.1.1 QUANTIFICATION OF PHYSICAL ACTIVITIES IN THE COMMUNITY

The clinical trials carried out previously on the effects of the environment following ACL reconnection, are limited in some aspects. None of the clinical trial carried out on the latter, had quantified the levels of habitual physical activities performed by the patients in their leisure time. One of the strengths related to this thesis is, using of a validated interview-based PROM for quantifying the levels of habitual physical activities.

8.2.1.2 A NOVEL APPROACH TO REHABILITATION

In trial II (chapter 6 and 7 of this thesis), the effects of a novel approach to rehabilitation programme were evaluated on PROMs and objectively measured outcomes. In the latter approach, the patients who had undergone ACL reconstruction were allocated to the fully-supervised (contemporary) rehabilitation programme and minimally-supervised rehabilitation programmes. The latter approach consisted of guiding the patients to the desired rehabilitation activities which were then continued by the patients in the hospital gymnasium without further supervision from the rehabilitation team.
8.2.1.3 QUANTIFICATION OF CONDITIONING PROGRAMME

Similar to quantifying the levels of habitual physical activities, conditioning programme in the hospital had not been quantified in the previous trials carried out on the outcomes of the rehabilitation programme following ACL reconstruction. In trial II (chapters 6 and 7 of this thesis), conditioning activities performed by the patients in the hospital were quantified from the available information and the effects of the latter were evaluated on the final outcomes of rehabilitation programme.

8.2.1.4 RANDOMIZATION

In addition to the above strengths, the second trial of this thesis was a single-blinded randomised controlled trial in which the patients were kept blinded to their group allocation. Allocation of the patients was concealed in which the recruiter was not allowed to predict or change the group allocation of the participants.

8.2.2 LIMITATIONS

8.2.2.1 NON-RANDOMIZATION

The first clinical trial included in this thesis was a non-randomized controlled trial in which the patients were allowed to self-select themselves to the hospital- and the community-based rehabilitation groups. The reasons for allowing non-randomization in the clinical trial were due to logistical constraints and ethical issues. The hospital where this clinical trial was carried out is well-known for treating ACL injuries. The patients having the latter injuries are referred from far distant parts within the UK. As mentioned in the methods section of chapter 5 that this was an educational project with limited funding where provision of transportation to the patients to attend physiotherapy attendances in the hospital, was not possible.
Moreover, the patient’s own choice to continue rehabilitation programmes in the community cannot be withdrawn. These were some of the reasons where the patients in ‘Trial I’ were allowed to self-allocate themselves to the hospital and the community-based rehabilitation programmes.

8.2.2.2 QUANTIFICATION OF PHYSICAL ACTIVITIES IN THE COMMUNITY ONLY FOUR TIMES

As mentioned in the chapter 2 of this thesis, the previous clinical trial carried out on effects of the environment had not reported the amount of levels of habitual physical activities performed by the patients in their leisure time. In this clinical trial, an emphasis was given to quantify the levels of habitual physical activities and a validated questionnaire (seven-day physical activity recall) was used to quantify the latter. Ideally, all the patients were supposed to fill the latter PROM on weekly basis. However, due to poor response from the patients, data was only collected one week before the assessment sessions designed for this project.

8.2.2.3 BLINDING

Blinding is one of the limitations which was not achieved during this thesis. In the trials reported in the chapter 6 and 7 of this thesis, although, the patients were blinded to the treatment but due to an educational nature of this project associated with limited budget, blinding of physiotherapists and assessors was not done. Similarly, one (author) of the two persons (author and a colleague) who analysed the data was not blinded to some aspects of the data (testing occasion, group allocation).
8.2.2.4 SUBJECTIVE ASSESSMENT FOR THE PATIENTS IN THE COMMUNITY-BASED REHABILITATION PROGRAMME

Outcomes of the rehabilitation programme managed by the patients in the community following ACL reconstruction were only assessed by PROMs. Assessment of the patients in the latter group by objective measures was not possible due to limited funding for this research and unwillingness of the patients to come for the objectives testing.

8.3 CLINICAL IMPLICATIONS AND FUTURE RESEARCH

- Community-based rehabilitation programme is a feasible model for rehabilitation of ACL injuries. The patients in the community-based rehabilitation may achieve optimal levels of function and pain on PROMs.
- The mechanism for the successful management of community-based rehabilitation may include provision of information in the form of manual and CDs.
- Although patients in the community-based rehabilitation programme are not expected to attend regular physiotherapy attendances in the hospital, still, they will need to discuss their progress with members of rehabilitation team on regular intervals. This would help the rehabilitation members to offer suggestions about the volume and intensity of exercise programme needed for achieving optimal outcomes of rehabilitation.
- Supervision during the rehabilitation programme may bring some favourable effects on the outcomes of rehabilitation. However, once the levels of supervision are withdrawn the patients would not maintain those gains.
• Early outcomes of the rehabilitation might not be strong predictors for the final outcomes of rehabilitation. Patients’ progress may be monitored on regular basis.

• Outcomes of rehabilitation at early phase of rehabilitation may not be sustainable and patients may be advised to continue some parts of rehabilitation activities even completing the formal rehabilitation in the hospital.

• Patients following ACL reconstruction may be assessed by variety of PROMs and objectively measured variable as due the varied inherent clinimetrics characteristics of these, none of them alone provide sufficient information to capture the whole progress of the patients.

• While comparing the effect of the environment a strategy of random allocation of the patients to the hospital- and the community-based rehabilitation group might be considered.

• Physical activities carried out by the patients in the community might be carefully recorded on weekly basis for the patients in both the hospital and the community-based rehabilitation programmes.

• While designing clinical trial on the levels of supervision, aspects of the latter (time to demonstrate exercises to the patients, duration of the physiotherapists’ presence during the session, interaction amongst the patients and the physiotherapists during the physiotherapy session, dose modification) might be monitored during each physiotherapy session.

• Habitual levels of physical activities may be recorded by objective measures if possible (accelerometer).
REFERENCES


References


References


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References


References


References


Introduction
The use of sophisticated assessment tools and the comprehensive protocols cautiously designed are deemed integral parts of a clinical research (Robey 2005, Shein-Chung Chow et al. 2011). However, these measuring tools and procedures are almost always prone to a variety of errors, which ultimately, results into findings that might differ from the actual value (Bartlett and Frost 2008). The presence of some common factors observed during clinical trials such as learning effect, fatigue, insufficient recovery time, motivation, biological or mechanical variation and inconsistency in the measurement protocol make the outcomes vulnerable in terms of reliability and reproducibility (Coldwells et al. 1994). Moreover, in case of repeated test systematic bias which refers to a general trend for measurements to be different in a particular direction (either positive or negative) between repeated tests had been reported in the literature (Atkinson, Nevill 1998). Despite some definite limitations related to these measuring tools and protocols, it is still extremely important to adequately ensure reliability of these measuring tools and protocols used during the clinical research (Atkinson, Nevill 1998, Vaz et al. 2013). The reason for having an acceptable reliability in the latter is obvious from the fact that these characteristics in measurement are responsible for providing a strong base to the meaningfulness of evaluation and interpretation of the data acquiesced during the research (Mercer, Gleeson 2002). Hence, reliability of the indices for different measurements had been reported frequently in the literatures (Gleeson, Mercer 1996, Minshull et al. 2009, Hirano, Yamamoto 2013). The scope of this chapter is limited to evaluate reliability of indices of neuro-musculoskeletal and sensorimotor responses. For this purpose, initially, a generic overview of the literatures has been discussed in the coming paragraphs and then a comprehensive review of the literature relevant to the reliability of indices of neuro-musculoskeletal and sensorimotor has been given. The term reliability depicts overall consistency of a measure or absence of error in the measurement. Realistically some error might be related to any measuring tool and reliability might be defined as the amount of measurement error that has been deemed acceptable for the effective practical use of a measurement tools (Safrit, Wood 1989, Bialocerkowski et al. 2010). Irrespective of the type of reliability that is assessed (internal consistency, stability, objectivity), there are 2 components of variability associated with each assessment of measurement error. These are systematic bias and random error. The sum of these components of variation is known as total error (Chatburn 1996). Terms such as ‘repeatability’, ‘reproducibility’, ‘consistency’, ‘agreement’, ‘concordance’ and ‘stability’ might be seen interchangeably with ‘reliability’, in the literature. Two types of reliability relative and absolute had been reported in the literature (Baumgartner 1989). According to the latter authors relative reliability provides confidence to a measure to maintain its position in a sample with repeated measurements. While absolute reliability is confidence to which repeated measurement vary for the measures.
Reliability of a measure might be computed by variety of statistical methods. In case of relative reliability paired t-Test, analysis of variation for detection of systematic bias, Pearson’s correlation coefficient, intra-class correlation and regression analysis had been reported in the literature (Atkinson, Nevill 1998). While in case of absolute reliability, standard error of measurement and coefficient of variation had been reported. In overview of some of the commonly used statistical methods for relative reliability such as Pearson’s coefficient of correlation and intra-class correlation has been discussed in the section statistical analysis of this chapter. Moreover, a brief overview of the method such as standard error of measurement, coefficients has been discussed in the later section of this chapter.

Dynamometry, a sophisticated objectively measuring tool, might be seen frequently used in the available literature for data acquisition of the indices of neuromuscular and sensorimotor performances of knee joint (Gleeson, Mercer 1996). These indices which include peak force, electromechanical delay and rate of force development had been reported to provide reliable indicators to the dynamic capabilities of any particular joint (Minshull et al. 2009, Hartmann et al. 2009). Precise quantification of these indices by reliable measures is considered extremely importance for clinical evaluation, decision making and prediction of functional capabilities of the knee joint (Gagnon et al. 2005). Some of the above mentioned indices such as force of both flexor and extensor muscle groups around knee joint assessed by isokinetic dynamometers had been reported critical for investigating functional status in different population (Hartmann et al. 2009) and an extensive scrutiny of the latter in the scientific literature of for their characteristics of reproducibility and reliability had been carried out in previous clinical trials(Gleeson, Mercer 1992, Gleeson, Mercer 1996, Minshull et al. 2009, Gleeson et al. 2002). However, reliability of the peak force in latter trial had reported while using the isokinetic dynamometery. Moreover, many of them such as electromechanical delay, rate of force development and sensorimotor performances still need comprehensive scrutinising due limited availability of evidence reported in the literature. Therefore, in this chapter of thesis reliability of peak force, electromechanical delay, rate of force development, sensorimotor responses, knee laxity and single-leg hop test has been evaluated. Despite the fact that the inter-day reliability of single-leg hop had been reported in the literature, it is still plausible, to report intra-session reliability of this important functional outcomes. The latter reliability (intra-session) would be of the importance because in most circumstances three or more than three single-leg hop tests in one session had been reported in the literature.

**Why intra-session reliability was selected for this trial?**

A variety of methods such use of different raters, same measurements taken more than one time and different tools measuring same measures might be used to assess reliability of a measure. For this clinical research intra-session reliability of the indices of neuro-musculoskeletal performances such as peak force, rate of force development, sensory motor responses, knee laxity and electromechanical delay has been evaluated. Moreover, intra-session reliability for one of the functional outcome measures, single-leg hop, has been reported as well. Some of the characteristics related to different types of evaluating reliability were not logistical feasible and intra-session reliability for the above mentioned indices has been carried out in this
clinical trial. It had been reported in the literature the logistical constraint, time related pressure and cost associated with the replicates of same individual might considered while carrying out clinical trial (Gleeson, Mercer 1996).

Methods
Participants
Forty adults [ {men, 35 ; age 32.2 ± 12.2 (mean ± SD)years, ; height 1.76 ± 0.04 m, ; body mass; 80.2 ± 9.6 kg},{women, 05; age 29.6 ± 11.6 (mean ± SD) years,; height 1.62 ± 0.04 m; body mass; 64.2 ± 8.9 kg}] were selected from within a consecutive series of patients electing reconstructive surgery of the ACL at U.K. National Health Service Foundation Trust Hospital. Detailed information regarding the project was given and informed consents were obtained from them. Prior to recruiting these patients in this research, all patients were judged on the inclusion and exclusion criteria which have been explained in the ‗methods’ chapter of this thesis. All patients for this trial were treated by four different consultant orthopaedic surgeons using similar surgical procedures and having similar expertise. All forty participant followed a rehabilitation programme comprised of a standardised and established (>5 yr) programme of exercise conditioning used in current clinical practice focusing on progressive mobility, strength and endurance conditioning (please see appendix 8.A - RJAH ACL rehabilitation guide following ACL reconstruction). All participants were instructed to follow the exact rehabilitation programme regardless the levels of supervision from the rehabilitation team (As mentioned in chapter 4A half of the patients in the hospital-based rehabilitation group were further divided into two groups; contemporary and experimental). Patients were advised not to participate in strenuous exercise programme for at least 24 hours prior to the testing occasions. This study was reviewed and given a favourable ethical opinion by the National Health Service Staffordshire Research Ethics Committee and Research and development Robert Jones and Agnes Hunt Orthopaedic Hospital, NHS trust, Oswestry.

Experimental procedure
All participants completed a standard warm-up session consisting of five minutes cycle ergometry (900 Watts for male participants, 60 Watts for female participants). This five minutes ergometry was followed by five minutes static stretching of the involved musculature to be tested. All participants were secured on the custom-built dynamometer for evaluation of indices of neuro-musculoskeletal performances. A detailed method how to evaluated patients on dynamometer has been described in the ‘method’ chapter of this thesis. For this specific clinical trial a within session three estimates of neuro-musculoskeletal performances were obtained from all patients at four different testing sessions (pre-surgery, 6th, 12th and 24th weeks following ACL reconstruction).

Statistical Analysis
Indices of neuro-musculoskeletal performances were described by using the ordinary statistical procedures (mean ± standard deviation). To report systematic learning effects across trial within each testing occasion (intra-session) and amongst each four separate testing occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction) one way repeated measure analysis of variance (ANOVA) was
calculated. Single measurement reliability for indices of neuro-musculoskeletal performance was assessed by computing intraclass correlation coefficient and standard error of measurement. Intra-class correlation coefficient is one of the commonly used methods for reporting reliability of measures. The intra-class correlation coefficients quantify the confidence to which a measure with a fixed degree of resemble each other in term of quantitative trait. One of the distinctive characteristics of intra-class correlation coefficient is its ability to examine more than two measures simultaneously. Shrout and Fleiss (1979) had proposed three main considerations while applying intra-class correlation of coefficient for reliability. According to the latter the design should ensure reliability study rather than correlation. Secondly a proper statistical model either one way or two way random model might be selected. Finally, the number of measures conducted during the trial must be reported. i.e ICC (1,k) where ‘1’ denotes the one-way model and ‘k’ denotes the number of measures. Standard Error of Measurement (SEM) is one the commonly used for the evaluating absolute reliability of a measure in a trial. It is one of the useful tools used in statistics which provides a simple measure of the variability of actual scores that are helpful in providing overall measurement of assessment’s quality (McManus 2012) or in other words it estimates how repeated measures of a person on the same instrument tend to be distributed around his or her “true” score. Standard error of measurement has been calculated by the calculating standard deviation and intra-class correlation of coefficient.

\[
\text{Standard Error of Measurement} = SD \sqrt{1 - \text{reliability}}
\]

One of the limitations related to the expressing reliability in terms of SEM is that the true scores of measures are often unknown and no measurement can be constructed that provide perfect reflection of it. Generally, the larger SEM presents the inferior consistency of a measure. Since all measurements are prone to some definite limitations, it is highly unlikely that exactly similar findings might be yielded after repeating a test on same measuring tools and following the exact protocol designed for the test. An important distinction between the SEM and ICC might be seen as SEM is not influenced by the sample while ICC also depends on the total variation of an index in the population under consideration.

Coefficients of variation (V %) was used to compute variability of the indices across the three trials for each intra-session and the inter-session (pre-surgery, 6th, 12th and 24th weeks following ACL reconstruction). Coefficient of variation was calculated as \[
\frac{\text{Standard Deviation}}{\text{Mean}} \times 100
\] so that final results appear in percentage. It had been reported in the literature that Coefficients of variation is one of the easy calculation based method for computing the variability for any measurement across any number of trials (Shechtman 1999). Moreover, it provides useful information about the reliability of data in terms of considering standard deviation and mean of the data. The actual values of CV is independent of unit and it is deemed as dimensionless number. Just like other statistical measures the CV is also prone to some limitations such is CV is influenced by the mean values when it is close to zero. The CV will become infinite in the latter case and hence is very sensitive to small changes in the mean.

Results
None of the indices of neuro-musculoskeletal performances showed systematic or learning effects when intra-session and inter-session reliability was computed using one-way ANOVA. These finding suggests that changes in the latter indices might be attributed to the random technical or biological variation associated with equipment used for the assessment or individuals who were assessed for this trial.

Reliability of Electromechanical delay for the knee flexors and extensors
Electromechanical delay for the hamstring muscles of the non-injured limb had shown equalling or exceeding results in terms of reliability coefficients at pre-surgery and 24\textsuperscript{th} week following ACL reconstruction (ICC; 0.88, 0.81, 0.74 at 6\textsuperscript{th} and 12\textsuperscript{th} week respectively). However, same magnitude for ICC for the same limb was not achieved at 6\textsuperscript{th} and 12\textsuperscript{th} week following ACL reconstruction (ICC; 0.78, 0.74 at 6\textsuperscript{th} and 12\textsuperscript{th} week respectively). On the other hand electromechanical delay the injured limb had achieved relatively inferior results compared to the non-injured limb on the same indices of neuromuscular during each testing occasions. i.e (ICC; non-injured and injured limb, 0.88 vs 0.46, 0.78 vs 0.51, 0.74 vs 0.44 and 0.81 vs 0.53 on pre-surgery, 6\textsuperscript{th}, 12\textsuperscript{th} and 24\textsuperscript{th} weeks respectively following ACL reconstruction)
Electromechanical delay for the quadriceps muscles of both injured and non-injured limb had scored ICC 0.73 and 0.78, 0.71 and 0.67, 0.62 and 0.59, and 0.64 and 0.68 at pre-surgery, 6\textsuperscript{th}, 12\textsuperscript{th} and 24\textsuperscript{th} week respectively following ACL reconstruction.

Reliability for functional test (hop)
Results for the single-leg hop had shown a clinical acceptable reliability for both injured and non-injured limb at all thee testing occasions (ICC; injured vs non-injured, 0.92 vs 0.91, 0.91 vs 0.92, 0.92 vs 0.94 at pre-surgery, 12\textsuperscript{th} and 24\textsuperscript{th} week respectively following ACL reconstruction).

Reliability of Peak force for knee flexors and extensors
Peak force for the hamstring muscles is one of the other indices included in the trial that had achieved a clinical acceptable ICC during all four testing occasions for both injured and non-injured limb (ICC; injured vs non-injured, 0.97 vs 0.99, 0.98 vs 0.99, 0.92 vs 0.99 and 0.93 vs 0.98 at pre-surgery, 6\textsuperscript{th}, 12\textsuperscript{th} and 24\textsuperscript{th} week following ACL reconstruction.
Similar levels of reliability was achieved by peak force for the quadriceps muscles of both injured and non-injured limbs (ICC; injured vs non-injured, 0.96 vs 0.96, 0.95 vs 0.96, 0.94 vs 0.95 and 0.96 vs 0.93 at pre-surgery, 6\textsuperscript{th}, 12\textsuperscript{th} and 24\textsuperscript{th} week respectively following ACL reconstruction.

Reliability of Rate of force development for knee flexors and extensors
Results of this trial had shown that rate of force development for the hamstring of injured limb had achieved an acceptable clinical reliability during two occasions (ICC; 0.81 and 0.91 at pre-surgery and 12\textsuperscript{th} weeks respectively) while non-injured limb had achieved similar levels of reliability just at 24\textsuperscript{th} week following the ACL reconstruction (ICC; 0.81). However, knee extensors did not achieve an acceptable ICC during any test occasions.

Reliability of sensory motor responses of knee flexors and extensors
Results of this trial had shown that sensory motor responses for both the knee flexors and extensors had exceeded an acceptable levels of ICC at all four testing occasion for both injured and non-injured limb (ICC; hamstrings, injured vs non-injured 0.93 vs 0.92, 0.91 vs 0.92, 0.87 vs 0.89, 0.89 vs 0.91 and quadriceps, injured vs non-injured, 0.99 vs 0.99, 0.99 vs 0.99, 0.97 vs 0.98, 0.99 vs 0.99 at first, second, third and fourth testing occasions respectively).

**Reliability of knee laxity**

Results of our trial had shown that knee laxity for the non-injured had only achieved an acceptable levels of ICC at pre-surgery testing occasion while ICC for the laxity of the injured leg had not equalled an acceptable reliability coefficient at any testing occasion (please see table 9.2)
Table 9.1: Table showing mean scores for indices of neuro-musculoskeletal performances included emdh, emdq, pfh, pfq, rfh, rfq, smh, smph, smq, smpq, lax at pre-surgery, 6th, 12th and 24th week following ACL.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-Op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inj (mean±sd)</td>
<td>ninj (mean±sd)</td>
<td>ninj (mean±sd)</td>
<td>ninj (mean±sd)</td>
</tr>
<tr>
<td>emdh (ms)</td>
<td>29.94±3.81</td>
<td>35.22±7.96</td>
<td>35.14±5.91</td>
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<tr>
<td>emdq (ms)</td>
<td>31.79±6.19</td>
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<td>36.25±5.06</td>
<td>36.09±4.6</td>
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<tr>
<td>hop (cm)</td>
<td>117.94±24.96</td>
<td>131.61±27.22</td>
<td>109.91±24.56</td>
<td>121.57±24.94</td>
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<tr>
<td>lax (mm)</td>
<td>7.37±1.34</td>
<td>3.41±1.11</td>
<td>3.12±1.33</td>
<td>3.01±0.99</td>
</tr>
<tr>
<td>pfh (n)</td>
<td>179.09±54.07</td>
<td>232.29±61.64</td>
<td>140.5±52.31</td>
<td>224.1±60.51</td>
</tr>
<tr>
<td>pfq (n)</td>
<td>338.53±94.47</td>
<td>409.96±90.92</td>
<td>245.22±80.44</td>
<td>365.07±87.89</td>
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<td>rfh (n/s)</td>
<td>849.56±553.77</td>
<td>1110.11±758.61</td>
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<td>1045.28±683.88</td>
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<td>2376.25±1230.66</td>
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<td>smh (n)</td>
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<td>115.57±38.74</td>
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<td>smph (n)</td>
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<td>109.63±35.52</td>
<td>95.87±29.04</td>
<td>108.19±34.74</td>
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<tr>
<td>smq (n)</td>
<td>187.03±71.38</td>
<td>217.26±74.87</td>
<td>180.99±65.55</td>
<td>205.73±67.56</td>
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<tr>
<td>smpq (n)</td>
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<td>196.89±65.38</td>
<td>163.57±54.62</td>
<td>193.08±62.92</td>
</tr>
</tbody>
</table>
Table 9.2: Table showing intraclass correlation coefficient (ICC) and coefficient of variation for indices of neuro-musculoskeletal performances included emdh, emdq, pfh, pfq, rfh, rfq, smh, smph, smq, smpq, lax on pre-surgery, 6th, 12th and 24th week following ACL.

<table>
<thead>
<tr>
<th>variables</th>
<th>pre-op</th>
<th>6th week</th>
<th>12th week</th>
<th>24th week</th>
</tr>
</thead>
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<tr>
<td></td>
<td>ICC</td>
<td>CV%</td>
<td>ICC</td>
<td>CV%</td>
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<td>0.91</td>
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<td>5.75±3.05</td>
</tr>
<tr>
<td>lax</td>
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<td>0.84</td>
<td>10.11±8.2</td>
<td>12.35±9.44</td>
</tr>
<tr>
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<td>0.96</td>
<td>5.26±2.91</td>
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<td>rfh</td>
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<td>23.12±15.03</td>
</tr>
<tr>
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<td>0.92</td>
<td>11.01±5.03</td>
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</tr>
<tr>
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<td>0.97</td>
<td>4.96±2.19</td>
<td>5.15±4.44</td>
</tr>
<tr>
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<td>0.99</td>
<td>3.34±1.81</td>
<td>2.68±1.26</td>
</tr>
<tr>
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<td>0.93</td>
<td>8.49±3.67</td>
<td>8.37±3.68</td>
</tr>
</tbody>
</table>
Table 9.3: Table showing standard error of measurement and minimal detectable change for indices of neuro-musculoskeletal performances included emdh, emdq, pfh, pfq, rfh, rfq, smh, smph, smq, smpq, lax on pre-surgery, 6th, 12th and 24th week following ACL.

<table>
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<th>12th week</th>
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<td>SEM</td>
<td>MDC</td>
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<tr>
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<td>22.2 21.0</td>
<td>61 58</td>
</tr>
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<td>15 7</td>
<td>5.3 2.7</td>
<td>15 7</td>
</tr>
<tr>
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<td>15 12</td>
<td>7.4 4.9</td>
<td>20 14</td>
</tr>
<tr>
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<td>79 102</td>
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</tr>
<tr>
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<td>5.3 5.6</td>
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<tr>
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<td>11 10</td>
<td>3.7 3.3</td>
<td>10 9</td>
</tr>
<tr>
<td>smpq</td>
<td>7.7 8.8</td>
<td>21 24</td>
<td>7.5 8.7</td>
<td>21 24</td>
</tr>
</tbody>
</table>
Discussion
The purpose of this clinical trial was to assess reproducibility and single measurement reliability for the indices of performance included electromechanical delay, peak force, rate of force development, sensory motor responses, anterior tibio-femoral displacement (knee laxity) and single-leg hop for both injured and non-injured leg during four different testing occasions. Findings of this trial had suggested that none of the indices of neuro-musculoskeletal performances had shown systematic or learning effects when intra-session and inter-session reliability was computed using one-way ANOVA. Similar findings regarding the reproducibility of these indices had been reported by Minshull et al. (2009) when patients were assessed on the custom-built dynamometer. In the latter trial participants were assessed for these indices in prone position while in this clinical trial a more commonly used position (sitting position) was adapted for evaluating reliability and reproducibility of these indices. These findings suggests that changes in the indices for neuro-musculoskeletal performances might be attributed to the random technical or biological variation associated with equipment used for the assessment or individuals being assessed. One of the reasons for carrying out this trial was the findings of the available literature regarding the significant difference reported between the knee muscles peak force scores when muscle of the same group were assessed in two different positions (prone lying and supine lying position) (Barr and Duncan 1988). Despite the fact that sitting position was adapted during the assessment of performance indices, our findings endorses the results of clinical trial carried out by Minshull et al. (2009) whereas different (prone lying) position had been used to assess reliability and reproducibility for the indices of performances. Based on the ICC scores which had been reported as ‘moderate’ from 0.50 to 0.69, ‘high’ from 0.70 to 0.89 and ‘very high’ from 0.90 and above (Sole et al. 2007) findings of our trial had shown that single-leg hop, peak force for hamstring and quadriceps and sensory motor responses for both injured and non-injured limb had achieved ‘very high’ reliability on ICC during all testing occasions (pre-surgery, 6th, 12th and 24th week following ACL reconstruction). These results are in accordance to the available literature whereas the test-retest reliability for the quadriceps and the hamstring muscles had been reported as highly reliable with an ICC= 0.96 (for both hamstring and quadriceps) (Neil et al. 2013). The latter trial was carried out on healthy population while our results are based on the clinical population who had undergone ACL reconstruction. Moreover, in our clinical trial we have reported the reliability for the injured and non-injured leg and have observed them as reliable as for the healthy population. Similar to the results for the peak forces the hop test had achieved ‘very high’ reliability for both the injured and non-injured legs when intra-session class correlation coefficient was calculated. These findings are similar to the findings reported by Reid et al. (2007) when reliability of the hop was assessed amongst a clinical population who had undergone ACL reconstruction. The authors of the latter trial had reported reliability of the second and third hop test occasion as first hop was used for motor learning purposes and fourth occasion for the longitudinal validity. In our clinical trial we have reported outcomes of all three occasions amongst the clinical population who had undergone ACL reconstruction. Our findings confer the outcomes reported by Reid et al. (2007) for all testing occasions. Some of the indices for performance such as electromechanical delay and rate of force development had shown compromised reliability in our trial. The latter
finding underpins further research in this area and suggests the use of more than three estimates for this measure during a single assessment session. Findings of this trial had shown that indices of performances included electromechanical delay for both the hamstring and the quadriceps, peak force (the hamstring and the quadriceps) of the injured limb were associated with greater variability compared to non-injured limb during all testing occasions. The latter might be associated to the morphological changes occurred during the reconstruction surgery to the limb. However, some of the indices for performance included hop and sensory motor responses had not shown significant difference during all these sessions.

It had been observed that the indices for neuro-musculoskeletal performances such as electromechanical delay, peak force for both the quadriceps and hamstring muscles for the non-injured limb had shown superior measurement for reliability compared to injured limb. This variation in the reliability between both the injured and the non-injured limbs might be attributed to the biological and morphological changes resulted due the reconstruction.

**Conclusion**

It can be concluded that the indices of performances included peak force, rate of force development, electromechanical delay, sensory motor performances, knee laxity and hop are reproducible for both injured and non-injured limb. Some of these indices including electromechanical delay, rate of force development and knee laxity had shown comprised reliability. The relative superior reliability results of the non-injured limb over the injured limb in our clinical trial suggest that results of non-injured limb for indices of performance can be used as a ‘reference’ for comparing the effectiveness of a treatment.
Appendix II

Correlation

Introduction
The ultimate goal of ACL reconstruction for the athletic and the non-athletic population is to achieve an early and a safe return to their previous levels of functional capabilities (Jang et al. 2013). A variety of measuring tools evaluating knee related functional capabilities and perception of the patients towards the outcomes of rehabilitation programme following ACL reconstruction had been reported in the literature (Kocher et al. 2002). The use of the latter mentioned tools not only evaluate the effectiveness of a therapeutic intervention but are regarded significantly important in decision making processes for modification of clinical practices (Reid et al. 2007). The use of sophisticated tools to assessing the performance of knee joint following injuries had remained a focus during the last few decades and determinants for performance included peak force, rate of force development and electromechanical delay had been widely reported for assessment of the knee joint following injuries (Ristanis et al. 2009, Blackburn et al. 2009, Kaneko et al. 2002). However, the logistical constraints, availability of limited time from the patients or the health care team and limited budget for the researches had made it extremely difficult for the researcher to assess each individual patients on these objective and functional recording tools (Gleeson, Mercer 1996). Moreover, the recent changes in the health care system paradigm had seen a shift towards a ‘market model approach’ and an emphasis on patients’ satisfaction in evaluating the outcomes of a treatment had been reported in the literature (Nemec, Kolisnichenko 2006). Similar trend had been observed in the literature about the postsurgical evaluation of ACL and a variety of tools assessing patients’ perception towards the outcome of rehabilitation programme following ACL reconstruction had been reported in the literature (Sernert et al. 2002). The use of both sophisticated objectively measuring tools and patient-reported outcome measures might be advised in such conditions whereas both the patients and the health care team had sufficient time alongside the availability of these cutting edge technologies. However, in many conditions such as overburdened health care facilities, unavailability of these sophisticated tools and limited time from the patients or health care team demand an alternative in the form of relying patients-reported outcomes for getting information regarding the conditions of the patients. As mentioned above these both objective and patient-reported outcome measure are deemed to assess patients’ general health and disease specific condition, an expectation regarding an association between them would be likely expected. The latter issue had received little attention in the available literature and limited information regarding the association between the objectives and patient-reported outcome measures had been reported in the literature. In this part of this thesis an overview of clinical trial carried out on the association between the objective and patient-reported outcome measure has been given and then results of our clinical trial has been discussed later in the result and discussion section of this chapter.

In order to examine the evidence from the available literature regarding the association between the patient-reported and objectively measured outcomes
following ACL reconstruction a clinical trial carried out by Kocher et al. (2004) has been included. This clinical trial was carried out on a cohort of 202 patients who were assessed by three independent reviewers. No patients with other knee injuries were included in this trial. All patients included in this clinical trial were assessed by objective measures included instrumented knee laxity, pivot shift and Lachman test while subjective assessment included questionnaires for assessing pain, swelling, partial giving way, full giving way, locking, crepitus, stiffness and limping. Subjective functional assessment was done by evaluating walking, squatting, walking up and down stairs, running, cutting, jumping, twisting, activities of daily living and sport participation for all patients included in the trial. Findings of this trial had suggested weak and negative correlation between the instrumented knee laxity and subjective measures [instrumented knee laxity and, patients stratification (0.05), work levels (0.01), sports levels (0.05), activities of daily living (0.02) and Lysholm score (0.04)]. Similar findings of having weak and negative relation had been reported by Sernet et al. (1998) in a clinical population (527 patients) who had undergone ACL reconstruction. According to the latter trial poor or negative correlation between the patient-reported and objectively measure outcome measures (‘r′ for KT-1000 with Lysholm instability sub-score, Lysholm pain sub-score, Lysholm total, single leg-hop, patients’ subjective evaluation, patients’ subjective expectations and Tegner activity levels had been reported as -0.21, -0.12, -0.17, -0.18, -0.18, -0.20 and -0.06 respectively). However, functional outcomes measure had shown poor to good correlation (correlation coefficient between the single leg-hop and Lysholm instability sub-score, Lysholm pain sub-score, Lysholm total, patients’ subjective evaluation and IKDC final classification (0.28), (0.30), (0.36), (0.29) and (0.28) respectively. Apart from reporting correlation between the patient-reported and objectively measure outcomes strong association amongst the patient-reported outcomes measures had been reported in this trial. i.e IKDC had shown a strong correlation with Lysholm r=0.66. One important point worth mentioning here is the defining limits for a ‘good’ correlation in this trial. The limits for having good correlation in this trial are not accordance to the literature as measures having spearman r ≥ 0.28 amongst them had been considered as having ‘good’ correlation.

Similar to the findings of the above two mentioned trials conflicting results regarding the association between patient-reported and objectively measured outcomes had been reported in a clinical commentary by Fitsgerald et al. (2001). According to the latter trial correlation between hop and Cincinnati Knee scale had ranged from -0.11 – 0.48, hop and Lysholm from 0.02 – 0.36 and IKDC r= 0.28. One of the reason for having not a consistent correlation between the hop and patient-reported outcome measures had been explained as the non-responsiveness of hop test score to changes or the magnitude that would representing minimal clinically importance difference in these patients. Similarly, hop had not shown any significant correlation with the strength of the hamstring and the quadriceps muscles in the latter clinical commentary. Reflecting on the findings of these three trials (included in this introduction) it might be conceived that there is not a definite conclusion on the correlation between the patient-reported and objectively measured variables and further research in this area will contribute to the find an answer to the correlation between them.

Method
Forty adults male, 35 and women, 5 [age (years); mean±SD, 31.58±12.11, height (cm) 174.75±10.67, body mass (kg) 78.25±10.85] were selected from within a consecutive series of patients electing reconstructive surgery of the ACL at U.K. National Health Service Foundation Trust Hospital. Detailed information regarding the project was given and informed consents were obtained from them. Prior to recruiting these patients in this research, all patients were judged on the inclusion and exclusion criteria which have been explained in the ‘methods’ chapter of this thesis. All patients for this trial were treated by four different consultant orthopaedic surgeons using similar surgical procedures and having similar expertise. All forty participant followed a rehabilitation programme comprised of a standardised and established (>5 yr) programme of exercise conditioning used in current clinical practice focusing on progressive mobility, strength and endurance conditioning (Refer to Appendix III- RJAH ACL rehabilitation guide following ACL reconstruction). All participants were instructed to follow the exact rehabilitation programmes. Patients were advised not to participate in strenuous exercise programme for at least 24 hours prior to the testing occasions. All patients were assessed four times (pre-surgery, 6th, 12th and 24th week following ACL reconstruction) on patient-reported and objectively measured outcomes. A detail overview on how to assess these patients on the objectively measured outcomes had been discussed in the method chapter of this thesis.

Statistical Analysis
Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, version 20.0 for windows. To report correlation amongst the assessment tools (patients reported and objectively measuring outcome tools) used to evaluate knees of the participants in this trial across four testing occasions (pre-surgery and 6th, 12th and 24th week following ACL reconstruction) Pearson product-moment correlation coefficient was calculated. The Pearson product-moment correlation coefficient is a measure of the strength of a linear association between two variables (Pearson’s correlation coefficient). It is measured on a scale with no unites and can take a value from +1 to -1 whereas +1 mean possible strong positive correlation while -1 means possible strong negative correlation and 0 means no association amongst the variables. The strength of association is often reported small or low correlation having r=0.1-0.29 , medium correlation having r= 0.3 –0.49 and large or high having r ≥ 0.5.

Results
Correlation between objective and patient-reported outcomes measures
Hop vs patient-reported outcome measures
Findings of this trial had suggested a positive correlation between single-leg hop (injured and non-injured leg) and patient-reported outcomes measures included IKDC, Lysholm and K-SES on 12th and 24th weeks following ACL reconstruction (please see table 6.1). Statistically significant correlation was observed between the hop (non-injured) and both the Lysholm (r=0.421**) and the K-SES (r=0.357*) at 12th week assessment session. Moreover, a statistically significant correlation had been observed between the hop (injured) and Lysholm at 12th (r=0.374*) and 24th (r=0.327*) week assessment sessions. IKDC and hop (injured and non-injured) had a negative (weak) correlation during pre-surgery assessment session. Similarly,
Lysholm had shown negative (weak) correlation with hop (non-injured) at the latter assessment session.

Table 10.1: Table showing correlation between the patient-reported outcome measures and hop

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<th>hop inj24</th>
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</tbody>
</table>

*. Correlation is significant at the 0.05 levels (2-tailed).

**. Correlation is significant at the 0.01 levels (2-tailed).

**Peak force vs patient-reported outcome measures**

**Peak force quadriceps vs patient-reported outcomes measures**

Table 10.2 shows summary of the correlation between the peak force quadriceps muscle of the injured and non-injured leg with the patient-reported outcomes measures. Peak force of quadriceps for the injured leg had not shown statistically significant correlation with all patient-reported outcome measures except Lysholm at the 12th week assessment session (r= 0.363*). Moreover, IKDC and peak force quadriceps for the non-injured leg had negative correlation at the first three assessment occasion (r= -0.075, -0.104, -0.288 respectively) and positive r=0.117 (statistically not significant) correlation at 24th week assessment session. Similarly, K-SES and peak force quadriceps for the non-injured leg had negative correlation at 6th and 12th week assessment sessions (r= -0.096 and -0.063 respectively).

**Peak force hamstring vs patient-reported outcomes measures**

Peak force for hamstring muscles of the injured and the non-injured leg had shown a weak correlation with all patient-reported outcomes measures at all testing occasions (table 10.2). The only statistically significant correlation between the peak forces of injured leg was observed with K-SES at pre-surgery assessment session (r= 0.338*). Negative correlation was observed between the peak force for hamstring of the non-injured leg with IKDC at pre-surgery and 6th (r= -0.090 and -0.023 respectively) and with K-SES at 6th week assessment sessions (r= -0.096) while the injured leg had negative (weak) correlation with IKDC at pre-surgery assessment session (r= -0.014).

**Rate of force development vs patient-reported outcomes measures**

**Rate of force development for quadriceps muscles vs patient-reported outcomes measures**

Rate of force development for the quadriceps muscles of the injured leg had shown statistically significant correlation with K-SES at 24th week assessment session (r= 0.343*) while non-significant correlation with IKDC and Lysholm across all assessment session (table 10.3). Similarly, for the non-injured leg the rate of force development Quadriceps showed negative correlation with patient-reported outcomes measures.
Rate of force development for the quadriceps muscle had shown statistically significant correlation with IKDC at one occasion (6th week assessment session, r=0.341*) and statistically non-significant correlation for the rest of testing occasions for the IKDC. Lysholm and K-SES had not shown any statistically significant correlation with rate of force development for the quadriceps muscle of the non-injured leg across all four testing occasions (please see table 10.3).

**Rate of force development for hamstrings muscles vs patient-reported outcomes measures**

Rate of force development for the hamstring muscles of injured and non-injured had not shown statistically significant correlation with all patient-reported outcome measures at all testing occasions (table 10.3). IKDC had shown negative correlation with rate of force development for the hamstring muscle of injured leg at 6th and 12th week (r= -0.150 and -0.142 respectively), Lyshom at 6th and 12th (r=-0.073 and -0.288 respectively) and K-SES at 12th week assessment sessions (r=-0.171). Similarly, for the hamstring muscles of the non-injured leg IKDC had negative correlation during pre-surgery, 6th week and 12th week (r=-0.197, -0.230 and -0.021 respectively), Lysholm at pre-surgery and 6th week (r= -0.246 and -0.151 respectively) and K-SES at pre-surgery assessment session (r=-0.110).

Electromechanical delay vs patient-reported outcomes measures

A summary of correlation between the electromechanical delay for the quadriceps muscle of the injured and the non-injured legs with patient-reported outcome measures had been shown in table 10.4. No statistically significant correlation was found for the electromechanical delay of the injured leg with IKDC, Lysholm and K-SES at any testing occasion. However, statistically significant correlation between the electromechanical delay of quadriceps muscle was observed with K-SES at 24th week assessment session (r=0.383*).

Electromechanical delay for the hamstrings vs patient-reported outcomes measures

Findings of this trial had shown no statistically significant correlation between the electromechanical delay for the hamstrings muscle of both injured and non-injured legs with the patient-reported outcome measures at any testing occasions.

Knee laxity versus patient-reported outcomes measures

Table 10.5 shows correlation between knee laxity for the injured and the non-injured legs and patient-reported outcome measures. Knee laxity for both the injured and the non-injured legs had not shown statistically significant correlation with any of the patient-reported outcome measures used in the clinical trial at any testing occasion.
Table 10.2: Table showing correlation between the peak force (quadriceps and hamstring) muscle of both the injured and the non-injured legs with IKDC, Lysholm and K-SES

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* Correlation is significant at the 0.05 levels (2-tailed).

Table 10.3: This table show correlation of the rate of force development for the quadriceps and the hamstrings muscles of both injured and non-injured legs.

<table>
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<tr>
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<th>RF inj12</th>
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* Correlation is significant at the 0.05 levels (2-tailed).
Table 10.4: Table showing correlation of electromechanical delay for both quadriceps and hamstring muscle (injured and non-injured leg) with PROMs

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* Correlation is significant at the 0.05 levels (2-tailed).
Table 10.5: this table shows correlation between knee laxity (injured and non-injured leg) and patients reported outcome measures

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*Correlation is significant at the 0.05 levels (2-tailed).

**Sensory motor performance vs patient-reported outcome measures**

**Sensory motor performance of the quadriceps muscles vs patient-reported outcomes measures**

Sensory motor performance for the quadriceps muscles of both the injured and non-injured legs had not shown any statistically significant correlation with patient-reported outcome measures at any testing occasions (please table 10.6).

**Sensory motor performance of the hamstring muscles vs patient-reported outcomes measures**

A summary of correlation between the sensory motor performances for the hamstring muscles and patient-reported outcome measures has been given in table 10.6. Expect from the Lysholm at 12th week with non-injured leg, none of the patients reported and sensory motor performance had shown statistical significant correlation.

**Correlation amongst objective measures**

**Correlation between the hop and peak force of the quadriceps muscles**

A statistical significant correlation was observed between the hop (injured and non-injured legs) and PFq for both the injured and the non-injured legs at all three testing occasions (pre-surgery, 12th and 24th week following ACL reconstruction). The correlational between the latter two had ranged from 0.365 to 0.612. In other words the association between the hop and pfq had shown medium to high association.

Correlation between the hop and peak force for the hamstring muscles

Similar to the correlation between single-leg hop for both the injured and the non-injured and pfq, correlation between the hop and pfh for both injured and non-injured legs had achieved a statistical significant levels at all three testing occasions (pre-surgery, 12th and 24th week following ACL reconstruction) (please see table 10.5).

**Correlation between the hop and rate of force development**

**Correlation between the hop and rate of force development quadriceps muscle**

Single-leg hop for both the injured and non-injured leg, expect at pre-surgery, had not shown any statistical significant correlation with rate of force development of the quadriceps muscle of both injured and non-injured legs.
Correlation between the hop and rate of force development hamstring muscle
The hop test for both injured and the non-injured legs had not shown any statistical significant correlation with rate of force development with the hamstring muscle for both the injured and the non-injured legs at any testing occasion (please see table 10.7).

Correlation between the hop and electromechanical delay
Correlation between hop and electromechanical delay for the quadriceps muscle
The hop test for both the injured and the non-injured legs had not shown statistical significant correlation with electromechanical delay of the quadriceps muscle for both the injured and the non-injured legs (please see table 10.8). The correlation between the latter mentioned two had ranged from 0.002 to 0.253.

Correlation between the hop and electromechanical delay hamstring muscle
In contrary to the correlation between single-leg hop and electromechanical delay for the quadriceps muscle whereas significant correlation was not observed between them at any testing occasion, electromechanical delay for the hamstring muscles of the non-injured leg had shown statistical significant correlation with single-leg hop for the injured leg at 12th week assessment session \( r = -0.358^* \). The other occasion whereas single-leg hop for the non-injured leg had shown statistical significant correlation with EMD of the hamstring of the injured leg was 24th week assessment session \( r = .327^* \). However, both times the correlation between them had not achieved clinical significant level.
### Table 10.6: Table showing correlation between sensory motor performances of both the quadriceps and the hamstring muscles with PROMs

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<th>sm inj24 quads</th>
<th>sm inj24 hams</th>
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- Correlation is significant at the 0.05 levels (2-tailed).

### Table 10.7: Table showing correlation between single-leg hop for the injured and the non-injured legs and peak PF

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- Correlation is significant at the 0.01 levels (2-tailed).
- Correlation is significant at the 0.05 levels (2-tailed).
Table 10.7: Table showing correlation between single-leg hop and rate of force development

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**. Correlation is significant at the 0.01 levels (2-tailed).
* . Correlation is significant at the 0.05 levels (2-tailed).

Table 10.8: Table showing correlation between single-leg hop and electromechanical

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<td>-0.15</td>
<td>-0.1</td>
<td>-0.31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hop 24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>-0</td>
<td>-0.12</td>
<td>0.29</td>
<td>-0.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ninj</td>
<td>0.028</td>
<td>0.015</td>
<td>0.327*</td>
<td>-0.09</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 levels (2-tailed).
* . Correlation is significant at the 0.05 levels (2-tailed).
Correlation between single-leg hop and sensory motor performances

Table 10.9 shows summary of correlation between single-leg hop and the sensory motor performances for both the quadriceps and the hamstring muscles of the injured and non-injured legs. The quadriceps had shown statistically significant correlation with quadriceps at all three testing occasions. However, the correlation is not strong enough to reach to a levels of clinical significance \((r \geq 0.70)\). Sensory motor performances for the hamstring of the non-injured leg muscle had shown statistical significant correlation with the hop at pre-surgery and 24th week assessment session. However, this levels of significant was not achieved at 12th assessment session.

Correlation between hop and Knee laxity

A summary of correlation between single-leg hop for both the injured and the non-injured leg and anterior tibio-femoral displacement had been given in table 10.10. There was not statistically significant correlation between hop for the injured and non-injured leg and anterior tibio-femoral displacement for both the injured and the non-injured leg at any testing occasion.

Correlation amongst patient-reported outcome measures

Table 10.11 shows summary of correlation amongst the patient-reported outcome measures used in this clinical trial. Statistically significant association had been observed amongst these patient-reported outcomes measure at all, expect one IKDC and K-SES at pre-surgery testing session, occasions. This association had achieved a clinical significant between the IKDC and Lysholm at 6th week \((r= 0.732^{**})\), 24th week \((r=0.794^{**})\) and K-SES with both the IKDC and Lysholm at 24th week assessment sessions \((r=0.787^{**})\) and 0.764** respectively.

Table 10.9: Table showing correlation between single-leg hop and the sensory motor performances

<table>
<thead>
<tr>
<th></th>
<th>smq 00</th>
<th>smh 00</th>
<th>smq 12</th>
<th>smh 12</th>
<th>smq 24</th>
<th>smh 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hop</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>00</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>.62**</td>
<td>.64**</td>
<td>.43**</td>
<td>.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ninj</td>
<td>.57**</td>
<td>.65**</td>
<td>.60**</td>
<td>.36*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hop</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>12</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>.35*</td>
<td>.40**</td>
<td>.04</td>
<td>0.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ninj</td>
<td>.31*</td>
<td>.43**</td>
<td>0.12</td>
<td>0.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hop</td>
<td></td>
<td></td>
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<td>24</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>inj</td>
<td>.46**</td>
<td>.39*</td>
<td>.28</td>
<td>0.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ninj</td>
<td>.55**</td>
<td>.42**</td>
<td>.47**</td>
<td>.39*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 levels (2-tailed).
*. Correlation is significant at the 0.05 levels (2-tailed).
Table 10.10: Table showing correlation between single-leg hop and knee laxity

<table>
<thead>
<tr>
<th></th>
<th>ATFD 00</th>
<th></th>
<th>ATFD 12</th>
<th></th>
<th>ATFD 24</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>inj</td>
<td>ninj</td>
<td>inj</td>
<td>ninj</td>
<td>inj</td>
<td>ninj</td>
</tr>
<tr>
<td>hop 00</td>
<td>-0.068</td>
<td>0.101</td>
<td>0.071</td>
<td>0.164</td>
<td>-0.114</td>
<td>-0.096</td>
</tr>
<tr>
<td></td>
<td>-0.084</td>
<td>0.14</td>
<td>-0.006</td>
<td>0.25</td>
<td>0.089</td>
<td>-0.017</td>
</tr>
<tr>
<td>hop 12</td>
<td>inj</td>
<td></td>
<td>ninj</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.071</td>
<td>0.164</td>
<td></td>
<td>-0.114</td>
<td>-0.096</td>
</tr>
<tr>
<td>hop 24</td>
<td>inj</td>
<td></td>
<td>ninj</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.089</td>
<td>-0.017</td>
<td></td>
</tr>
</tbody>
</table>

Table 10.11: Table showing correlation amongst the patient-reported outcome measures

<table>
<thead>
<tr>
<th>K-SES00</th>
<th>Ly00</th>
<th>K-SES06</th>
<th>Ly06</th>
<th>K-SES12</th>
<th>Ly12</th>
<th>K-SES24</th>
<th>Ly24</th>
</tr>
</thead>
<tbody>
<tr>
<td>ik00</td>
<td>0.299</td>
<td>.349*</td>
<td></td>
<td>.630**</td>
<td></td>
<td></td>
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<tr>
<td>ly00</td>
<td>.689**</td>
<td>.732**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ik06</td>
<td></td>
<td>.528**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ly06</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ik12</td>
<td></td>
<td></td>
<td></td>
<td>.604**</td>
<td>.593**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ly12</td>
<td></td>
<td></td>
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<td>.409**</td>
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<td></td>
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<tr>
<td>ik24</td>
<td></td>
<td></td>
<td></td>
<td>.787**</td>
<td>.794**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ly24</td>
<td></td>
<td></td>
<td></td>
<td>.764**</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 levels (2-tailed).
*. Correlation is significant at the 0.05 levels (2-tailed).

Discussion
The aim of this trial was to evaluate association amongst the objectively measured and patient-reported outcome measures at four different testing occasions (pre-surgery, 6th, 12th and 24th week following the ACL reconstruction) amongst the clinical population who had undergone ACL reconstruction. For the latter purpose findings of this trial have been divided into three sections. In the first section correlation between the objectively measured and patient-reported outcome measures has been evaluated. While in the second part association between the hop and other objectively measured outcomes included peak force, rate of force development, electromechanical delay, sensory motor performances and anterior tibio-femoral displacement has been reported. Finally, in the third section association amongst the patient-reported outcomes measures (IKDC, Lyshom and K-SES) has been assessed. Association between objective and patient-reported outcomes measures

Findings of this trial had suggested ‘low to medium’ correlation between single-leg hop and patient-reported outcome measures. Single-leg hop test for the injured leg had shown low correlation with K-SES at pre-surgery, 12th and 24th week assessment sessions. Similarly, hop test for the contralateral leg (non-injured) had shown low correlation with the latter mentioned patient-reported outcome measure at pre-
Appendix II

surgery and 24th week assessment sessions. Both of the latter had shown medium correlation at 12th week assessment session. The association between single-leg hop for the non-injured leg and K-SES had achieved statistically significant levels (p<0.05) at 12th week assessment session. It is hard to compare our findings of correlation between single-leg hop and K-SES as according to our knowledge limited data is available regarding the correlation between the latter in the literature. The only trial which had reported correlation between single-leg hop and K-SES had divided the outcomes of the trial into acceptable and non-acceptable category (Thomeé et al. 2008). Achievement of ≥ 90% of the pre-surgery hop distance for the non-injured leg had been categorised as acceptable while achieving of ≤ 90% of the pre-surgery hop distance as non-acceptable. In our trial we have evaluated association between the hop and K-SES on the actual scores achieved during the trials. In the trial mentioned above statistically non-significant correlation between the hop and K-SES had been reported at pre-surgery assessment session. We had found similar correlation (statistically non-significant) between hop and K-SES at pre-surgery and 24th week assessment session. One of the distinctive features of our trial from the above mentioned trial is evaluating correlation for hop of both the injured and non-injured legs which had not been reported in the trial mentioned above. Despite these differences between our trial and the trial mentioned above still the association reported in both trials can be categorised into same levels of ‘low’ category (present knee function vs hop, and knee function in future vs hop, r= 0.0 and 0.25 respectively).

Another patient-reported outcome measure that we have evaluated for correlation in this clinical trial was IKDC which had not shown statistically significant correlation with hop (injured and non-injured) at all testing occasions (‘r’ between the hop and the IKDC ranges from 0.148 to 0.263, table; 10.1). These findings are in accordance to the previous literature whereas a low correlation (r=0.28) between single-leg hop and IKDC had been reported (Sernert et al. 1999). In our clinical trial Lysholm is the only patient-reported outcome measure which had shown statistically significant correlation with single-leg hop in more than one occasion; hop (injured) at two occasions 12th and 24th weeks assessment sessions and hop non-injured leg at one occasion 12th week assessment session. Our findings regarding correlation between Lysholm and single-leg hop are in accordance to the available literature whereas statistically significant correlation between single-leg hop and Lysholm had been reported (Baltaci et al. 2012). Despite the fact that single-leg hop test had shown statistically significant correlation with patient-reported outcome measures at different testing occasions, clinical significant was not observed between them in our clinical trial at any testing occasion. Similar to the findings of correlation between hop and patient-reported outcomes measures, none of the other objectively measured variables included peak force, rate of force development and electromechanical delay, sensory motor performances and anterior tibio-femoral displacement had shown clinical significant association with the IKDC, Lysholm and K-SES.

**Association between hop and other objectively measured outcomes**

In our clinical trial statistically significant correlation was observed between the hop (injured and non-injured legs) and peak force for both the quadriceps and the hamstring muscles of the injured and the non-injured legs at all three occasions.
Single-leg hop for the injured leg had shown high correlation with the peak force for quadriceps of the non-injured at the pre-surgery and at 24th week assessment session. However, the association had remained ‘medium’ at the 12th week assessment session. Single-leg hop had shown ‘medium’ correlation at all except one occasion with the hamstring muscle for both the injured and non-injured legs. Comparing our results with the available evidence from the literature is difficult as conflicting results had been reported regarding the correlation between single-leg hop and both the quadriceps and the hamstrings muscles (Fitzgerald et al. 2001). The correlation between hop and peak force for the quadriceps had been reported ‘medium to high’ by Wilk et al. (1992) (‘r’ ranges from 0.41-0.62) and by Petschnig et al. (1998) (‘r’ ranges from 0.45 to 0.51), ‘low to medium’ by Noyes et al. 1992 (0.26 – 0.49) and ‘low’ by Borsa et al. (1994) (r=0.06).

Correlation between hop and rate of force development for the both the quadriceps and the hamstrings muscle of the injured and the non-injured legs had not shown statistically significant association at all except one occasion (hop non-injured with rate of force development for the quadriceps non-injured at pre-surgery testing occasion). Similarly, statistically significant correlation between hop and electromechanical delay was observed at two testing occasion (hop injured and electromechanical delay for the hamstring muscle of the non-injured leg at 12th week, hop for the non-injured leg and electromechanical delay for the hamstring muscle of the injured leg at 24th week assessment session). Reflecting on the results of our trial and comparing it with the evidence from the available literature especially the notion that factors such as rate of force development and reactive strength capabilities are not influenced by the ACL surgery (Flanagan et al. 2008) it might be speculated that these measure might not play vital in correlation with the functional capabilities of an individual who had undergone ACL reconstruction.

**Association amongst patient-reported outcome measure**

All patient-reported outcome measures had shown statistically significant correlation amongst them at different testing occasions. The only statistically non-significant correlation was observed between IKDC and K-SES at pre-surgery testing occasion. The correlation between the IKDC and Lysholm had remained high throughout all four testing occasions. Correlation between the latter had achieved clinical significant at two testing occasion (at 6th and 24th week testing occasions). Similarly, clinical significant correlation had been observed between the Lysholm and K-SES at 24th week assessment session. As suggested in previous literature that patient-reported outcome measures are regarded valid way of assessing patients’ general and specific health, a strong association/correlation amongst the questionnaire assessing same medical conditions might be expected. Similar findings of having strong association amongst the patient-reported outcome measures had been reported by Hohmann et al. (2012) whereas clinical significantly correlation had been reported between IKDC and Lysholm for the patients who had undergone ACL reconstruction (Hohmann et al. 2012).

**Conclusion**

Based on findings of this clinical trial it can be concluded that correlations between the objective and patient-reported outcome measures had not shown clinical
significant at any testing occasion following ACL reconstruction and rehabilitation. We cast doubts that these patient-reported and objectively measured outcomes might possess distinct features which capture different aspect of physical performances and function of the patients. Moreover, as suggested in previous literature neither of these methods can stand alone as an adequate assessment of knee function and both types of measurements may be simultaneously required to precisely describe the patient's status of function and capabilities at any given point of time.
# Appendix III

<table>
<thead>
<tr>
<th>PHASE OF REHABILITATION</th>
<th>STAGE OF REMODELLING</th>
<th>'CURRENT'</th>
<th>PURPOSE/AIM</th>
<th>'PHASED-STRENGTH &amp; ENDURANCE'</th>
<th>ETHICAL CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHASE 1</td>
<td>Day 1: Discharge</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>The graft is at its</td>
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<td></td>
<td>strongest at this</td>
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<td></td>
<td>stage, with respect</td>
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<tr>
<td></td>
<td>to the soft tissue.</td>
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<tr>
<td></td>
<td>- Continuous Passive</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Motion (CPM)</td>
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<tr>
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<td>- Cryotherapy</td>
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<td>- Passive mobilizations</td>
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<td>- End of range extension mobilisations</td>
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<td></td>
<td>- Mobilisations as directed by physiotherapist</td>
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<tr>
<td></td>
<td>- Heat therapy</td>
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<tr>
<td></td>
<td>- Aftercare</td>
<td></td>
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<tr>
<td></td>
<td>- Passive F/f over edge of bed</td>
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<tr>
<td></td>
<td>- Static squats</td>
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<tr>
<td></td>
<td>- Co-contraction Q and H</td>
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<tr>
<td></td>
<td>- Avoid 'heavy' eccentric (ecc) Q</td>
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<tr>
<td></td>
<td>- Maintain the harvest site</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Prone H; concentric (con) eccentric (ecc)</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>- Prone straight leg raise (SLR)</td>
<td></td>
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<tr>
<td></td>
<td>- Partial weight bearing (PWB)</td>
<td></td>
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<tr>
<td></td>
<td>- Cricket (can be insted for first week)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Reduce ischamia and prevent compartment syndrome</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Can be removed for exercises and sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Mini squats</td>
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<td></td>
<td>- Heat therapy</td>
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<tr>
<td></td>
<td>- Weight transferring</td>
<td></td>
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</tr>
</tbody>
</table>

**PLEASE REFER TO APPENDIX 11 (A description of programmes of exercise used in current practice for rehabilitation associated with ACL reconstruction) FOR DETAILS**

- Reduce inflammation,
- Gain full terminal extension (E).
- Promote digital circulation.
- Gradually regain range of motion (ROM).
- Introduce early Quadriiceps (Q) and Hamstring (H) work.
- Promote early mobility.

As traditional

- The exercises, duration of each exercise session and the physiotherapist time is the same as the traditional.
- The various strength endurance exercises are performed concurrently in the traditional programme.
- The strength endurance emphasis separates the strength/endurance work, where clinically possible. Thus a non-concurrent rehabilitation programme will be followed.
- Consequently, the overall administration of the traditional programme is 'packaged' differently.
<table>
<thead>
<tr>
<th>PHASE OF REHABILITATION</th>
<th>STAGE OF GRAFT REMODELLING</th>
<th>‘CURRENT’</th>
<th>PURPOSE/AIM</th>
<th>‘PHASED STRENGTH &amp; ENDURANCE’</th>
<th>ETHICAL CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge – 10 Days</td>
<td>No initial blood supply to graft, results in avascularization of the soft tissue defect.</td>
<td>Static bike hollow seat, erg directed by physiotherapist. Gradually increase weight bearing. Start re-education (wear off splash and elbow crutches). Low step-touch-stance up. Active open kinetic chain (OKC) Q. 50° - 45°. Progress H-walk: Repetitions (Pace), Resistance (Resist), as directed by the physiotherapist. Other muscle groups not to be neglected.</td>
<td>Promote early function. Increase ROM. Encourage weight bearing. Improve muscular strength, endurance and control.</td>
<td>As traditional</td>
<td></td>
</tr>
<tr>
<td>PHASE OF REHABILITATION</td>
<td>STAGE OF GRAFT REMODELLING</td>
<td>‘CURRENT’</td>
<td>PURPOSE/AIM</td>
<td>‘PHASED STRENGTH &amp; ENDURANCE’</td>
<td>ETHICAL CONSIDERATIONS</td>
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<tr>
<td>-------------------------</td>
<td>---------------------------</td>
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<td>-------------------------------</td>
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</tr>
<tr>
<td>PHASE 3 Day 10 – Week 6</td>
<td>Avascularisation of graft leads to continued decrease in graft strength. The graft becomes encased in a synovial sheath.</td>
<td>Full weight bearing (FWB).</td>
<td>Progress functional activities.</td>
<td>As traditional, except alternate blocks of separate strength and endurance work. Each block to be separated from the other by at least 2 days of rest and maintenance.</td>
<td>Strength: Step ups forward and sideways holding dumbbells, 6 – 10 kg total &amp; 5 Reps.</td>
</tr>
<tr>
<td>IDEAL CRITERIA BEFORE COMMENCING</td>
<td></td>
<td>Goal with predictable changes in direction.</td>
<td>Prevent anterior knee pain.</td>
<td></td>
<td>Leg Press: 3 x 5 Reps (Weight = 5 Rep Max)</td>
</tr>
<tr>
<td>• Minimal discomfort.</td>
<td></td>
<td>Frame auto-overpress F – develop S stretch.</td>
<td>Prevent scar adhesions.</td>
<td></td>
<td>Rowing: Rests 5, 1000m Dist. x 6 min</td>
</tr>
<tr>
<td>• SLR with no leg.</td>
<td></td>
<td>Step ups (torso/sideways)</td>
<td>Prevent joint stiffness.</td>
<td></td>
<td>General leg and upper body weights set at 3 – 5 Rep Max.</td>
</tr>
<tr>
<td>• Active range of motion (AROM).</td>
<td></td>
<td>Weight/propulsion speed.</td>
<td>Restore normal gait pattern.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Full E – approx. 100° F.</td>
<td></td>
<td>Eg 10k slow paces, 10k fast paces.</td>
<td>Promote appropriate muscle strength, power and endurance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Leg press/propulsion speed.</td>
<td>Improve proprioception.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eg 2 x 10 Reps (10 Rep Max)</td>
<td>Maintain cardiovascular fitness.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Early plyometrics.</td>
<td>Encourage patient compliance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rowing – distal/propulsion.</td>
<td></td>
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<td></td>
<td></td>
<td>Eg Rests 3, (Concept K, sledging), 1500m Dist. x 10 min</td>
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<td></td>
<td></td>
<td>Progress proximal propulsion –resisted board.</td>
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<td></td>
<td></td>
<td>Ski/skateboard/marathon skills.</td>
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<td></td>
<td></td>
<td>Gym ball, Theraband work.</td>
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<tr>
<td></td>
<td></td>
<td>Hydrotherapy, swimming (AVOID breastroke leg until 3 months stage).</td>
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<td></td>
<td></td>
<td>Progress general leg exercises VMO, ab/adduction, glutes, etc.</td>
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<td></td>
<td></td>
<td>Upper body.</td>
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<td></td>
<td></td>
<td>Muscle balance as appropriate.</td>
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<td></td>
<td></td>
<td>Flexibility as appropriate.</td>
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</tbody>
</table>

*Rep Max = Maximum number of repetitions a particular weight can be lifted in a controlled manner (i.e. 10 Rep Max = a weight that can be lifted ten times, but is too heavy to lift an eleventh).

**Concept K = An indoor rowing machine.
<table>
<thead>
<tr>
<th>STAGE OF REHABILITATION</th>
<th>STAGE OF GRAFT REMODELLING</th>
<th>‘CURRENT’</th>
<th>PURPOSE/AIM</th>
<th>‘PHASED-STRENGTH &amp; ENDURANCE’</th>
<th>ETHICAL CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>From Week 6 – 12</td>
<td>• Progress above ankle, • Triampullaestrength • Treadmillwalking, incline, bokchat</td>
<td>Continue to promote specific function: Increase muscle work and control through range. Normal Q strength = 75 – 85%</td>
<td>Maintenance level training: Strength block</td>
<td>To maintain and improve limb function and prevent complications.</td>
</tr>
<tr>
<td>Ideal Criteria</td>
<td>Before commencing</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>PHASE OF REHABILITATION</td>
<td>STAGE OF GRAFT</td>
<td>‘CURRENT’</td>
<td>PURPOSE/AIM</td>
<td>‘PHASED-STRENGTH &amp; ENDURANCE’</td>
<td>ETHICAL CONSIDERATIONS</td>
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<tr>
<td>PHASE 5</td>
<td>From Month 3</td>
<td>IDEAL CRITERIA BEFORE COMMENCING:</td>
<td></td>
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<tr>
<td>30 min fast walk</td>
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<tr>
<td>Row 2000m within 15 min, moderate resistance</td>
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<tr>
<td>H=90° of contra-lateral side</td>
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<tr>
<td>Adequate dynamic proprioception</td>
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<tr>
<td>By month 4 complete re-vascularisation with the laying down of collagen occurs. A gradual increase in strength is gained as the graft remodels.</td>
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<tr>
<td>‘Iso-metric Q. E.g. 2 x 3 Reps 60°, 2 x 10 Reps 90°, 10-20 sec Recovery</td>
<td></td>
<td></td>
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<tr>
<td>OKC Q. → Hip Strengthening/ Endurance E.g. F/E 2 x 5 Reps (5 Rep Max), 1 x 3 Ecc Q.</td>
<td></td>
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<tr>
<td>Plyometrics, drops from 6-12” Bounding, etc.</td>
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<tr>
<td>Hoping → Single/Double/Hopping/ Speed</td>
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<tr>
<td>Jogging = Running</td>
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<tr>
<td>Surface = Distance</td>
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<tr>
<td>Progress to incorporate Agility, run/ sprint into multidirectional accelerated decelerate</td>
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<tr>
<td>Surface = Spring board Grass/ Track X 10 min Randomised</td>
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<tr>
<td>Maintenance level during Strength Phase</td>
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</tr>
<tr>
<td>Trail jogging 8 min duration, Walk x 1 min → Light jog x 1 min → Alternate 1 min jog / 1 min light jog (x 5 min total) → Walk x 1 min</td>
<td></td>
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</tr>
<tr>
<td>Running (Surface = Trail/Track/Grass) 15 min duration, 1 min Light jog → 2 min Jog → Alternate 1 min Run / 30 sec Sprint / 10 min Total → Jog x 1 min → Light jog / Fast walk x 1 min</td>
<td></td>
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<tr>
<td>Endurance</td>
<td></td>
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</tr>
<tr>
<td>Iso-metric Q. 1 x 20 Reps at 180°</td>
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<tr>
<td>OKC Q.</td>
<td></td>
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<tr>
<td>F/E 2 x 20 Reps (20 Rep Max)</td>
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<tr>
<td>Ecc. Q.</td>
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<tr>
<td>1 x 10 Reps (15 Rep Max)</td>
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<tr>
<td>Trail jogging 12 min duration, Walk x 2 min → Light jog x 2 min → Jog x 5 min → Light jog → 2 min → Walk x 1 min</td>
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<tr>
<td>Running (Surface = Trail/Track/Grass) 20-30 min duration, 1 min Light jog → 2 min Jog → 10-20 min Run → 5 min Jog → 2 min Jog</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

320

Appendix III
<table>
<thead>
<tr>
<th>PHASE OF REHABILITATION</th>
<th>STAGE OF GRAFT REMODELLING</th>
<th>‘CURRENT’</th>
<th>PURPOSE/aim</th>
<th>‘PHASED-STRENGTH &amp; ENDURANCE’</th>
<th>ETHICAL CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHASE 6</strong></td>
<td>From Month 6</td>
<td></td>
<td></td>
<td>Non-contact training.</td>
<td></td>
</tr>
<tr>
<td>IDEAL CRITERIA</td>
<td></td>
<td></td>
<td></td>
<td>Sport specific 1 – 2 hr duration combining strength and endurance where applicable for particular sport.</td>
<td></td>
</tr>
<tr>
<td>BEFORE COMMENCING</td>
<td></td>
<td></td>
<td></td>
<td>Non-contact sport.</td>
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<td></td>
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<td></td>
<td></td>
<td>Prepare physical and psychological ability for complete return to unrestricted function.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gradual organisation of collagen. At 1 year the graft resembles the appearance of a ligament with densely organised bundles. Graft strength is thought to range from 30-60% of the original. The laxity of the graft appears to be linked with muscle strength.</td>
<td>Earliest return to contact sport</td>
<td>Unrestricted confident function.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Non-contact training.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sport specific, with set time durations. Separating strength and endurance work (except maintenance levels) by at least 24 hrs.</td>
<td></td>
</tr>
</tbody>
</table>
Dear Mr. Haider Daran,

School of Health Sciences
Queen Margaret
University Musselburgh
Edinburgh
EH21 6UJ

Neuromusculoskeletal and psychophysiological outcomes of hospital- and community-based rehabilitation programmes following anterior cruciate ligament (ACL) reconstruction.

REC reference: 11/WM/0448

Protocol number:

Thank you for your letter of 03 May 2012, responding to the Committee’s request for further information on the above research and submitting revised documentation. The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

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

It is suggested that the research team give serious consideration to the points raised in the peer review relating to randomisation and retaining the expertise of a statistician on the study team.

Ethical review of research sites

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

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study:

A Research Ethics Committee established by the Health Research Authority
Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.nfcrnm.nhs.uk](http://www.nfcrnm.nhs.uk).

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

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

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

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>29 July 2011</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>17 November 2011</td>
</tr>
<tr>
<td>Other: Summary CV for supervisor - Professor Gleeson</td>
<td></td>
<td>01 March 2011</td>
</tr>
<tr>
<td>Other: Summary CV for supervisor - Dr Coutts</td>
<td></td>
<td>26 April 2011</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>2</td>
<td>01 April 2012</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>2</td>
<td>01 April 2012</td>
</tr>
<tr>
<td>Protocol</td>
<td></td>
<td>26 November 2011</td>
</tr>
<tr>
<td>Questionnaire: 2000 KDC Knee Forms (validated)</td>
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</tr>
<tr>
<td>Questionnaire: KOOS Knee Survey (validated)</td>
<td></td>
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<tr>
<td>Questionnaire: SF-12 Patient Questionnaire (validated)</td>
<td></td>
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<tr>
<td>Questionnaire: The Performance Profile (validated)</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: Seven-Day Physical Activity Recall (validated)</td>
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<tr>
<td>HEC application</td>
<td>IMAG 5.4</td>
<td></td>
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<tr>
<td>Referees or other scientific critique report</td>
<td></td>
<td>03 October 2011</td>
</tr>
<tr>
<td>Response to Request for Further Information</td>
<td></td>
<td>03 May 2012</td>
</tr>
<tr>
<td>Independent Peer Review</td>
<td>Prof. T Mercer</td>
<td>25 March 2012</td>
</tr>
</tbody>
</table>

Statement of compliance

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

A Research Ethics Committee established by the Health Research Authority
After ethical review

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

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

The NRES website also provides guidance on these topics, which is updated in the light of
changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National
Research Ethics Service and the application procedure. If you wish to make your views
known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

| 11/WM/0418 | Please quote this number on all correspondence |

With the Committee’s best wishes for the success of this project

Yours sincerely

[Signature]

Dr Kathryn Kinmond
Chair

Email: laura.brown@northwest.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Professor Nigel Olleson, Queen Margaret University, Edinburgh Ma,
Teresa Jones, Robert Jones & Agnes Hunt Orthopaedic Hospital NHS
Trust.
Appendix V

The Robert Jones and Agnes Hunt Orthopaedic Hospital
NHS Foundation Trust

Research Office
Oswestry
Shropshire
SY10 7AG
Telephone 01691 404143
Email: teresa.jones@rjah.nhs.uk

Mr Haider Darain
Physiotherapy PhD Student
Queen Margaret University, Edinburgh
c/o RJAH Orthopaedic Hospital
Physiotherapy dept.

5th July 2012

Confirmation of NHS Trust Approval of Research Study

Dear Mr Darain

I can confirm that approval has been granted by the Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust Research Management and Governance Office for the following research study, which falls under the requirements set out in the NHS Research Governance Framework.

<table>
<thead>
<tr>
<th>Title:</th>
<th>Comparison of Hospital and Community Based Rehabilitation Programmes</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D / CLRN Reference:</td>
<td>RL 1509</td>
</tr>
<tr>
<td>Ethics Reference:</td>
<td>11/WM/0416</td>
</tr>
<tr>
<td>Chief Investigator:</td>
<td>Mr Haider Darain</td>
</tr>
<tr>
<td>Principle investigator (RJAH):</td>
<td>Mr Haider Darain</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>QMU and RJAH</td>
</tr>
<tr>
<td>Funder:</td>
<td>QMU</td>
</tr>
<tr>
<td>Proposed local study end date:</td>
<td>1st July 2013</td>
</tr>
</tbody>
</table>

You may begin this research study within the Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust.

Please read carefully the following additional information that is applicable to this confirmation of approval.

Please note that your research study may be monitored or audited by this research office or other relevant authority as part of the requirements set out in the Research Governance Framework for Health & Social Care (2005).

T:\Approval letters\RL 1 509 Comparison of hosp and community based rehab physio (Haider)

INVESTORS IN PEOPLE
Delivering Outstanding Patient Care
In order for us to continue to meet the requirements for Research Governance you are requested to provide us with the following documents (electronic or paper) relating to this study:

- A copy of all NRES Annual progress report(s) (if applicable)
- A copy of the NRES End of Study Declaration
- A copy of the final report no more than 6 months after completion of the study

You are also requested to notify us about any of the following that are applicable:

- Amendments to any documents that require REC approval
- Changes to the study start and end dates
- Changes in personnel / members of the research team
- Changes to details of locations of the study
- Any serious adverse events (SAE, SUSAR) within the timescale specified on the NRES website.

Wishing you every success with the study.

Yours sincerely

[Signature]

Mr Andrew Roberts
Research Director.

6/1/2022
Appendix VI

Neuromusculoskeletal and psycho-physiological outcomes of hospital and community-based rehabilitation programmes following anterior cruciate ligament (ACL) reconstruction

(RJAH Research Reference: to be completed [example 05/Q2601/36])

RESEARCHERS & COLLABORATORS:

Haider Darain (Chief Investigator/PhD Candidate)        Prof. Nigel Gleeson (Professor in Rehabilitation Science)
Mr. Dai Rees (Consultant Orthopaedic Surgeon)                Dr. Fiona Coutts (Dean of the School of Health Sciences)
Prof. James Richardson (Professor of Orthopaedics)        Andrea Bailey (Clinical Specialist Physiotherapist)
Mr. Simon Roberts (Consultant Orthopaedic Surgeon)         Jane Leah (Senior Physiotherapist)

CONSENT FORM

Please initial box

1. I confirm that I have read and understand the information sheet provided for the above study. I have had the opportunity to consider the information, ask any questions, and have had these answered satisfactorily. □

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

3. I understand that data collected during this study may be looked at by responsible individuals from the NHS (being Robert Jones and Agnes Hunt Orthopaedic & District Hospital, Oswestry) and Queen Margaret University throughout the course of this study. □

4. I agree that the research team/physiotherapists may contact me by email, letter or telephone to discuss my rehabilitation progress should this be needed. □

5. I agree to take part in the above study: □

   Name of Participant          Date           Signature

   Name of Researcher          Date           Signature

If you would like some independent advice about whether you should take part in the study, please contact:

Prof. Tom Mercer (tm Mercer@qmu.ac.uk)
Professor of Exercise Physiology and Rehabilitation
School of Health Sciences
Queen Margaret University, Edinburgh
Queen Margaret University Drive
School of Health Sciences
Queen Margaret University Drive
Musselburgh, East Lothian
EH21 6UU

National Centre for Sport Injury Surgery
Gobowen, Oswestry
Shropshire
SY10 7AG

PROJECT TITLE:
Neuromusculoskeletal and psycho-physiological outcomes of hospital and community-based rehabilitation programmes following anterior cruciate ligament (ACL) reconstruction
(RJAH Research Reference: to be completed [example 05/Q2601/36])

RESEARCHERS & COLLABORATORS:

Haider Darain (Chief Investigator/PhD. candidate)
Mr. Dai Rees (Consultant Orthopaedic Surgeon)
Prof. James Richardson (Professor of Orthopaedics)

Prof. Nigel Gleeson (Professor in Rehabilitation Science)
Dr. Fiona Coutts (Dean of the School of Health Sciences)
Andrea Bailey (Clinical Specialist Physiotherapist)
PARTICIPANT INFORMATION SHEET

You are being invited to take part in the above titled research study. Before you decide to participate, it is important for you to understand why this research is being carried out and what it will involve. Please take your time to read the following information sheet and please feel free to ask any questions if there is anything that is not explained clearly. If you would like more information, please contact the research team (contact details are provided at the end of this information sheet).

WHAT IS THE PURPOSE OF THE STUDY?

This study is part of a doctoral research programme that is currently being undertaken at Queen Margaret University, Edinburgh. The research team are investigating whether we can enhance the rehabilitation that you will be receiving within or away from the hospital following your anterior cruciate ligament reconstruction surgery.

This rehabilitative programme is detailed in the ACL surgery and rehabilitation patients advice booklet you have already received. If you have not yet received this, please contact the physiotherapy team. This information guide provides you with examples of the physiotherapy programme you are to receive. This will include strength, endurance and other related techniques used within the field of physiotherapy. It is important that you follow the instructions given to you by the physiotherapy team as they will be important for your recovery following your surgery.

The purpose of this study is to compare the effectiveness of the hospital- and the community-based rehabilitation programmes in terms of clinical outcomes after ACL reconstruction at the National Centre for Sport Injury Surgery Robert Jones and Agnes Hunt Orthopaedic and District Hospital, Oswestry.

WHY HAVE I BEEN CHOSEN?

In this study, the research team will be investigating patients (like yourself) who have elected to undergo ACL reconstruction knee surgery and who are otherwise medically fit. The reason you are being invited to take part in this study is that you fit this description.
We are hoping to recruit 80 participants (40 in the hospital- and 40 in the community-based rehabilitation groups) for this trial that involves a self-selection allocation of participants to either the hospital- or the community-based rehabilitation group.

**DO I HAVE TO TAKE PART?**

Participation in this study is entirely voluntary and you are free to decline participation or to withdraw from the study at any time. You do not need to give any reasons if you decide to leave the study. If you do decide to withdraw, you will continue your rehabilitation as normal with no prejudice.

**WHAT WILL HAPPEN TO ME IF I TAKE PART AND WHAT WOULD I HAVE TO DO?**

The main purpose of this research is to compare hospital- and community-based rehabilitation programmes in terms of functional/clinical outcomes after ACL reconstruction. Participants (like yourself) will self-select themselves into either group (hospital- or community-based rehabilitation groups). It is important to note that no matter which group you select yourself into, you will follow the same standard rehabilitation programme that is routinely implemented for all patients after ACL reconstruction at Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry. All participants (both groups) of the research will be given a ‘seven day self-reporting’ diary where the volume and intensity of physical activities might be recorded on daily bases. Each participant will be tested on four different occasions (one prior and three after ACL reconstruction (on 6th, 12th and 24th weeks after surgery)).

The hospital-based rehabilitation group will follow physiotherapy programme in the hospital. They will be closely monitored by the chartered physiotherapists in the hospital. Participants in this group will come approximately 15-20 times over the 24 weeks rehabilitative period. It is important that you attend all scheduled appointments with your physiotherapist. However, if you cannot attend for whatever reason, the research team or physiotherapists might contact you by email, letter or telephone to discuss your rehabilitation progress. All participants in this group will be tested prior to surgery and then on 6th, 12th and 24th week following reconstruction.

The community-based rehabilitation group will be guided to follow the same rehabilitation programme in the community. Participants in this group will visit the hospital three to five times after ACL reconstruction. Their visits will be scheduled on 6th, 12th and 24th week of the ACL reconstruction. However, if they want to modify their rehabilitation programme and are interested to visit rehabilitation team in the hospital, they can schedule their visit any time.

During your rehabilitation programme, you will need to attend up to four assessment sessions (one prior and three after ACL reconstruction). The research team with gain the majority of the information required for the study from these assessment sessions,
and so it will be very important that you attend. These assessments sessions will last approximately one hour and will take place on the day that you would normally attend the physiotherapy clinic.

Within these assessment sessions, you will be tested using advanced computerised data acquisition equipment and software. The research team hope you will find these assessment sessions informative and interesting, providing you with additional time to ask questions and to learn more about your rehabilitation.

We will be monitoring aspects of knee joint performance such as:

(1) The strength of your leg muscles and your ability to repeat brief strength tasks accurately. This allows us to check how well the muscles can produce force to protect the joint efficiently.

(2) The ability of your leg to reach a target position with closed eyes that has been achieved by you 10-20 second before. This allows us to check the ability of your joint to recall/sense the previous position.

(3) The laxity/looseness of your knee will also be tested. This allows us to check how well the rehabilitation is affecting the stability of the knee joint.

You will also be asked to complete questionnaires about your knee, and keep a weekly diary of your rehabilitation. It is anticipated that entering information into the diary should take no longer than 10 minutes per week to complete, and recorded over the 24-week period.

**WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS, AND WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

No matter which rehabilitation group you select yourself into; there will be no extra clinical risks or disadvantages to yourself. This is because all participants in this study will be following the same exercise programme after ACL reconstruction. In addition, taking part might be more beneficial for yourself, the community and the health service provider as the information the research team gathers from this study might inform and improve future clinical practice.

**WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?**

The research findings may inform the research team that one way of rehabilitating patients is better than another or both are having similar clinical outcomes. This will then alter the way the physiotherapy team suggest patients rehabilitate in the future.
If you wish, after the research is complete, we can disseminate the findings from the study to you.

The findings may also be written and published in medical/scientific journals to aid other clinicians and patients elsewhere. Neither you nor your data will be identifiable in these publications.

**WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

The only purpose of this study is to assess the best way to rehabilitate patients after ACL reconstruction surgery. The research team will keep your name, age, sex and your results in a record that will be stored on a password-protected computer to ensure only persons involved in the study can access the information. The storage and subsequent destruction of your data is compliant with the Data Protection Act 1998. All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves this hospital will have your name and address removed so that you cannot be identified from it, and will subsequently be anonymous.

**COMPLAINTS**

If you believe you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the Queen Margaret University, Edinburgh and Robert Jones & Agnes Hunt NHS Orthopaedic Hospital, Oswestry, who are acting as the research sponsors. Details about this are available from the research team. Also, as an NHS patient, you have the right to pursue a complaint through the usual NHS complaints procedures. Please note that the NHS has no legal liability for non-negligent harm. However, if you are harmed as a result of someone’s negligence, you may have grounds for legal action against the NHS, but you may have to pay your legal costs.

**CONTACT DETAILS FOR FURTHER INFORMATION:**

We hope you will participate in this study, but if you have any questions or would like more information, please contact:
WHO HAS REVIEWED THE STUDY?

For you to have been offered participation in this study, it will have had to have been already given a favourable ethical opinion for conduct in the NHS by the Staffordshire Local Research Ethics Committee and by Queen Margaret University Edinburgh’s local Ethics Committee. It will also have been approved for scientific merit by the Research Panel at Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry.

If you would like some independent advice about whether you should take part in the study, please contact:

Prof. Tom Mercer  
Professor of Exercise Physiology and Rehabilitation (Physiotherapy)  
School of Health Sciences  
Queen Margaret University, Edinburgh  
Queen Margaret University Drive  
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Thank you for taking the time to read this information sheet and considering whether or not you’d like to participate.
Appendix VIII

Computation of energy from condition programme in the hospital.

Work done can be calculated by

\[ W = FD \]

For calculation \( F \), we need to calculate weight (weight and ‘\( F \)’ are same things)

weight = \( mg \)

(mass will be the total resistance in kilogram lifted during exercise) while \( g \) is acceleration due to gravity which is constant (9.8m/s\(^2\)). If a person lifts 10 Kg in one session the weight of that 10 kg would be equal to

w = \( mg \)

w = 10 \times 9.8 = 98 \text{ kg.m/s}^2

\text{kg.m/s}^2 \text{ is the unit of force so basically the } F \text{ would be 98N.}

For distance we need to calculate length of arc at specific angle

Length of arc for 90° angle (angle might change during each phase/session/exercise)

= \text{diameter} \times \pi \times \text{angle}/360

Diameter would be calculated from the height of the patients (height/shin ratio)

After calculating the length of arc and force we can compute the amount of work done which can be converted into Kilo-calories as

1 Joule = 0.000238 Kilo-calories.