TRAK ACL: Development of a self-management Digital Health Intervention to support optimal care in ACL rehabilitation: Scoping Review, Qualitative Study and Feasibility RCT.

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Declaration

I, Emma Dunphy, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

The following work was carried out at University College London, under the supervision of Dr Fiona Hamilton (Department of Primary Care and Population Health) and Professor Elizabeth Murray (Department of Primary Care and Population Health) and with Dr Kate Button from Cardiff University.

This thesis has not been submitted, in whole or in part, for any other degree, diploma or qualification at any other University. My work was funded by the National Institute for Health Research, Clinical Doctoral Research Fellowship.

This thesis does not exceed the limit of 100,000 words specified by the Degree Committee.

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Abstract

Background

Outcomes vary after Anterior Cruciate Ligament (ACL) reconstruction surgery and many patients do not return to previous levels of activity. This may be related to variations in evidence based rehabilitation care. It is NHS policy to avoid inappropriate variations in healthcare and to use digital health interventions (DHI) to improve access and outcomes.

Aim

This thesis explored causes of variability in care and the feasibility of a DHI to overcome them.

Objectives

1. To identify resources used in trials of optimal ACL rehabilitation;
2. To explore stakeholder views around criteria for optimal care and reasons for variation.
3. To explore opinions of digital tools in evolving care models.
4. To determine the feasibility of undertaking a definitive randomised controlled trial (RCT) to determine effectiveness and cost-effectiveness of a specific DHI to support ACL rehabilitation.

Methods

Methods were selected to match objectives: Objective 1 was addressed with a systematically conducted scoping review; Objectives 2 & 3 through qualitative interviews with orthopaedic surgeons and physiotherapists; and Objective 3 by a randomised feasibility trial comparing a specific DHI plus Treatment as Usual (TAU) with TAU.

Results

The scoping review established that ACL rehabilitation in RCTs includes specialist equipment, a gym environment and an experienced physiotherapist. Interviews revealed that practitioners were committed to evidence-based care, but were sometimes limited by systemic factors, including lack of resources, infrequent appointments or ambiguous pathways of care. Interviewees cautiously welcomed DHIs to support care but identified concerns. Feasibility results showed 86% recruitment rate, 78% retention rate and 100% completion rate on 4 out of 5 outcomes including the primary outcome of a future trial, the Knee Osteoarthritis Outcome Score. Fidelity to the DHI showed user engagement was heavily skewed.

Conclusion

This work provides evidence to explain observed unacceptable variations in care for this patient group and suggests that a digital health intervention could help address these. A definitive trial is both warranted and feasible.

Impact Statement

This thesis has identified unwarranted variations in ACL rehabilitation care that may negatively impact patient outcomes. I developed an evidence based digital health intervention that reflects the expertise of physiotherapy led ACL rehabilitation. This digital health intervention, TRAK ACL, could go some way to overcoming the variations in care at a national level and improving access to the information, exercises and benchmarks that are needed at all stages of ACL rehabilitation.

Following the closure of outpatient services nationally due to the COVID19 pandemic, the Chartered Society of Physiotherapists created a resource of digital health interventions on its website. TRAK ACL was accepted and was the only ACL focused intervention. I set up an email address to manage any requests and I created an infographic that could be circulated on social media. As a result, six NHS Trusts took up TRAK ACL for their patients and I continue to get new emails each week. In my clinical capacity I added over 100 patients to TRAK ACL during the pandemic and received feedback with their immense gratitude for the quality of care that TRAK ACL delivers.

Results from this thesis have been disseminated via workshops, presentations, conference posters and peer reviewed publication. The thesis led to 2 international clinical collaborations with renowned persons in my field at LaTrobe University in Melbourne, Australia and at Yale University, USA. During my PhD I won grant awards from University College London and the Chartered Society of Physiotherapy to fund international collaborations and from the Society for Primary Care Research to continue to develop as a clinical physiotherapist in digital health.

TRAK ACL has the potential to improve access to optimal care across the NHS. Technical work to increase its functionality will be a part of its ongoing impact. The uptake of TRAK ACL during COVID19 creates an argument for the policy and implementation of digital health interventions in routine physiotherapy clinical practice

Publications and Presentations

Dunphy, E. (2018). The Development and Feasibility of TRAK ACL for ACL rehabilitation management. Homerton University Hospital NHS Trust Research & Development Conference. (Platform Presentation)

Dunphy, E (2017) TRAK ACL: The Protocol of a Feasibility Study. The International Society for Research on Internet Interventions, Berlin (Poster)

Dunphy, E. (2018) A scoping review of the resources needed to deliver Anterior Cruciate Ligament physiotherapy rehabilitation in randomised controlled trials. Sports Medicine Australia Conference, Perth, (Poster)

Dunphy E (2018) TREK for TRAK, Incorporating clinical knowledge translation into a website for ACL rehabilitation. LaTrobe University School of Allied Health, Melbourne (Invited Speaker / Workshop)

Dunphy, E. (2019), Digital Health Interventions in the management of ACL rehabilitation. Yale Hospital New Haven, (Invited Speaker)

Dunphy, E. (2019), Tele-rehabilitation and ACL rehabilitation. Yale Hospital New Haven, (Workshop)

Dunphy, E Hamilton, F.L., Button, K. and Murray, E., 2020. A scoping review of the resources needed to deliver anterior cruciate ligament physiotherapy rehabilitation in randomised controlled trials. *Physical Therapy Reviews*, pp.1-15.

Dunphy, E and Gardner E. (2020) Acceptability of tele-rehabilitation to address the 'Rehabilitation Gap' in Anterior Cruciate Ligament care: An on-line survey of patients who have had ACL Reconstruction." Submitted to JMIR Formative Research

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Abbreviations

ACL	Anterior Cruciate Ligament
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
CDRF	Clinical Doctoral Research Fellowship
CR	Critical Realism
DHI	Digital Health Intervention
HCI	Human Computer Interaction
HRA	Health Research Authority
IDLM	Interaction Design Lifecycle Model
IRAS	Integrated Research Application System
LSI	Limb Symmetry Index
MRC	Medical Research Council
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health Research
NLR	National Ligament Registry
NMES	Neuromuscular Electrical Stimulation
NPT	Normalisation Process Theory
OKC/CKC	Open Kinetic Chain/Closed Kinetic Chain
PBA	Person Based Approach
PPI	Patient and Public Involvement
PRISMA-ScR	Preferred Reporting Items for Systematic reviews extension for Scoping Reviews
RCT	Randomised Controlled Trial
RTP/RTS	Return to Play/Return to Sport
TRAK ACL	Taxonomy for the RehAbilitation of Knee conditions – Anterior Cruciate Ligament
UCL	University College London
VAS	Visual Analogue Scale
WHO	World Health Organisation

Glossary of Terms

Behaviour Change	Attempts to change people's personal habits to improve health outcomes.
Biomechanics	Study of body movement.
Digital Health	The coming together of digital tools and technologies with healthcare.
Dynamic Valgus	When, during movement, a person cannot control the knee from drifting medially into valgus stress in the coronal plane.
Femur	The thigh bone
Mechanoreceptors	A sensory neuron that responds to mechanical changes such as pressure or touch in the joint and function to relay information to the brain regarding joint position sense.
Neuromuscular Control	An unconscious function of the nervous system and muscles, where information about joint position and forces within the joint result in optimal muscle firing patterns.
Plyometric	Jump and hop exercises where strength is exerted in the quickest time possible for maximum efficiency.
Proprioception	The ability to know where one's joints are in space
Rehabilitation	A set of interventions delivered when a person is limited in everyday functioning.
Self-management	Identifies and facilitates the knowledge, skill and confidence that people have to manage their own healthcare
The coronal plane	Divides the body into front and back slices
The sagittal plane	Divides the body into left and right slices
Tibia	The shin bone
Valgus stress	Lateral pressure on the knee towards the midline of the body
Varus Stress	Lateral pressure on the knee away from the midline of the body

Thesis Outline

Chapter 1: Introduction

This chapter presents brief background information and context relevant to this thesis.

Chapter 2 A literature review of Anterior Cruciate Ligament Reconstruction

This chapter presents a summary of the anatomy and epidemiology of ACL injury and then summarises and synthesises the evidence for rehabilitation.

Chapter 3: A scoping review

This chapter presents a scoping review study that examined the resources needed to deliver Anterior Cruciate Ligament physiotherapy rehabilitation in randomised controlled trials.

Chapter 4: A qualitative study.

This chapter presents a qualitative study of stakeholder opinion on the characteristics of optimal care in ACL rehabilitation and explores barriers and facilitators in current practice.

Chapter 5: The development of TRAK ACL

This chapter describes the development process of the TRAK ACL website. It reflects on previous related research and then describes the application of the Behaviour Change Wheel framework for the intervention design.

Chapter 6 A feasibility study of TRAK ACL plus treatment as usual or treatment as usual.

This chapter details the process of a randomised feasibility trial to evaluate the possibility of a future trial to determine the effectiveness and cost-effectiveness of TRAK ACL.

Chapter 7 Discussion

This chapter synthesizes the findings of this thesis and reflects on the strengths and weaknesses of each methodological approach. It summarises the key implications of this work for clinical practice, research and policy.

Chapter 1 – Introduction

1.1 Chapter outline

This chapter outlines the thesis, providing a brief introduction to subsequent chapters. It starts by a very brief introduction to the clinical problem I observed in practice and why I thought it would be a good subject for a PhD; provides a concise summary of some of the key terms and concepts elaborated in the main body of the thesis; and ends with a statement of the aims and objectives and how the studies in the thesis address these objectives.

1.2 The problem in brief

I am an experienced physiotherapist, with a particular clinical interest in rehabilitation after injury or accident. At the time I was developing my ideas for a PhD, much of my clinical work involved rehabilitation after surgery for rupture of the Anterior Cruciate Ligament (ACL) in the knee. My experience and that of many of my colleagues suggested that different physiotherapy clinics, even within the same NHS Trust, had varied levels of resources at their disposal for rehabilitation. There were identifiable variations in the experience of clinical staff who managed ACL patients, the access to equipment that they used or the frequency with which they could see patients. I wanted to explore these variations in relation to the rehabilitation evidence base and impact on clinical practice. I thought that clinicians in particular would have insights into the questions I was posing about variability in care.

I was concerned that the variations that might exist in care meant that some patients had more access to evidence based care at each phase of ACL rehabilitation than others did and that this may contribute to suboptimal functional outcomes. I wondered if a digital health intervention that was specifically designed to reflect physiotherapy led ACL care could go some way to reducing observed variability and improving outcomes. This thesis was designed to address these questions.

There are some key concepts and terms which need to be introduced to enable the general reader to understand the body of this thesis. These include: the anterior cruciate ligament and key terminology of biomechanics; rehabilitation, supported self-management, digital health and behaviour change interventions such as TRAK ACL (Taxonomy for the RehAbilitation of Knee conditions – Anterior Cruciate Ligament). These concepts are briefly described here and are explored in detail in subsequent chapters.

1.3 **The Anterior Cruciate Ligament (ACL)**

The Anterior Cruciate Ligament in health and injury is described at length in Chapter 2. Approaches to rehabilitation are fully discussed in Chapters 2, 3 and 4. The following terminology is used in this thesis to describe the anatomy and position of the knee in relation to injury and rehabilitation (Table 1.1).

Term	Description
Femur	The thigh bone
Tibia	The shin bone
Anterior translation (of the tibia)	Forward movement of the shin bone relative to the thigh bone. Creating a 'drawer' effect at the knee joint
Valgus stress	Lateral pressure on the knee towards the midline of the body
Varus Stress	Lateral pressure on the knee away from the midline of the body
The sagittal plane	The sagittal plane divides the body into left and right slices
The coronal plane	The coronal plane divides the body into front and back slices
Dynamic Valgus	When, during movement, a person cannot control the knee from drifting medially into valgus stress in the coronal plane.

Table 1.1. Terminology of biomechanics of the knee

The anterior cruciate ligament is the primary stabilising ligament of the knee. Its function is to prevent excessive anterior translation of the tibia under the femur in the sagittal plane during dynamic activity, described in Figure 1.1 (1). It also functions to resist tibial rotation and varus and valgus stress in the coronal plane, shown in Figure 1.2 (2). Injury is common in sport and activities that involve jumping, landing and changing direction (3). Loss of control of the knee medially during active movements is known as dynamic valgus and is correlated with ACL injury (4).

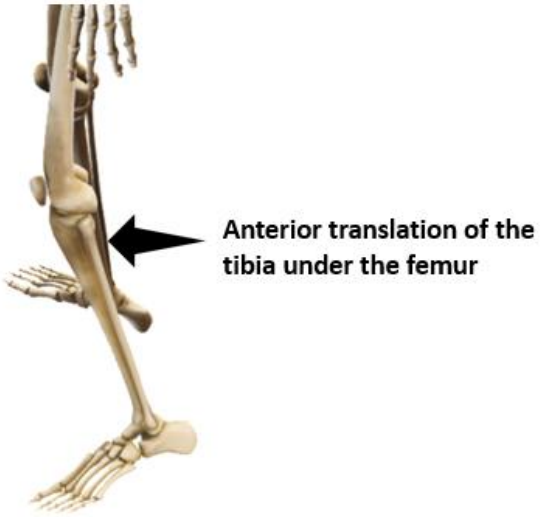

Figure 1.1. The tibia is the shin bone and the femur is the thigh bone.

The ACL prevents excessive anterior translation movement and can be torn if excess force is applied in this sagittal plane. (Figures from Microsoft PowerPoint (5))

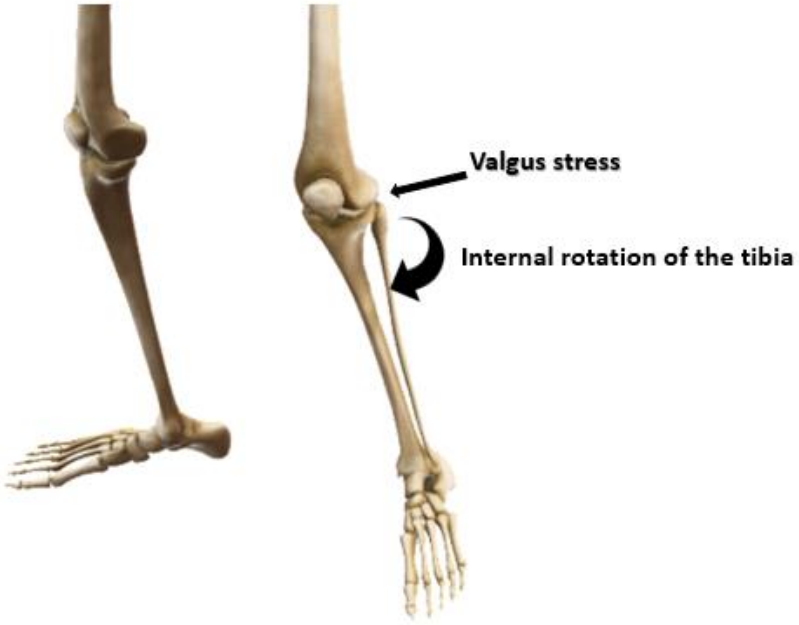

Figure 1.2. Lateral force in the valgus (midline) direction in the coronal plane is a common cause of ACL injury, often when combined with internal tibial rotation. (Figures from Microsoft PowerPoint (5)).

1.3.1 Rehabilitation

Rehabilitation is standard post ACL reconstruction surgery. This thesis refers often to the language of rehabilitation and the control of movement that is part of this process. Table 1.2 describes some of the common terms that are part of this process.

Rehabilitation	"Rehabilitation is a set of interventions needed when a person is experiencing or is likely to experience limitations in everyday functioning due to ageing or a health condition, including chronic diseases or disorders, injuries or traumas" WHO (6)
Neuromuscular Control	Describes an unconscious function of the nervous system and muscles, where information about joint position and forces within the joint result in optimal muscle firing patterns to increase dynamic joint stability and decrease risk to the joint. These responses are trainable with neuromuscular control exercises (7, 8).
Proprioception	The ability to know where one's joints are in space (joint position sense), based on feedback from the vestibular, visual and mechanoreceptors (9).
Mechanoreceptors	A sensory neuron that responds to mechanical changes such as pressure or touch in the joint and function to relay information to the brain regarding joint position sense (10).

Table 1.2. Understanding rehabilitation and control of movement

The NHS commissioning guidance on rehabilitation includes a definition of rehabilitation that reflects the values of biopsychosocial healthcare (11); "Rehabilitation is a personalised, interactive and collaborative process, reflecting the whole person. It enables an individual to maximise their potential to live a full and active life within their family, social networks, education/training and the workplace where appropriate." (12) This model views rehabilitation a lengthy process from acute care to community based self-management where multiple phases could be supported by digital health. Figure 1.3 shows a modification of the NHS England model to depict ACL rehabilitation.

The International Classification for functioning, disability and health (ICF) is the all-encompassing model for rehabilitation. This framework suggests that 'body structures and functions', 'activity' and 'participation' are the key outcomes of rehabilitation. Environmental factors, social and psychological context are noted as important contextual factors (13). The early stage of ACL rehabilitation is often labelled the impairment phase which pertains to the 'structures and functions' of the knee being limited by post-operative impairments such as the healing graft implant, the range of motion, swelling, muscle function and wound healing. The second phase of care is characterised by restricted 'activity'. The impairments may be reduced but a careful and often slow return to physical activity is indicated and patients are still faced with 'limitations' to many of their usual functions. Although the boundaries overlap somewhat, the transition to advanced and return to sport phases of care are analogous with

the ‘participation’ domain of ICF. Individuals are working within support networks (family and friends) and environment (i.e. football club or ballet class) to overcome restrictions to participation in premorbid levels of activity. As they progress through physical and psychological milestones each phase interacts with individual’s self-efficacy, their social support network and quality of life.

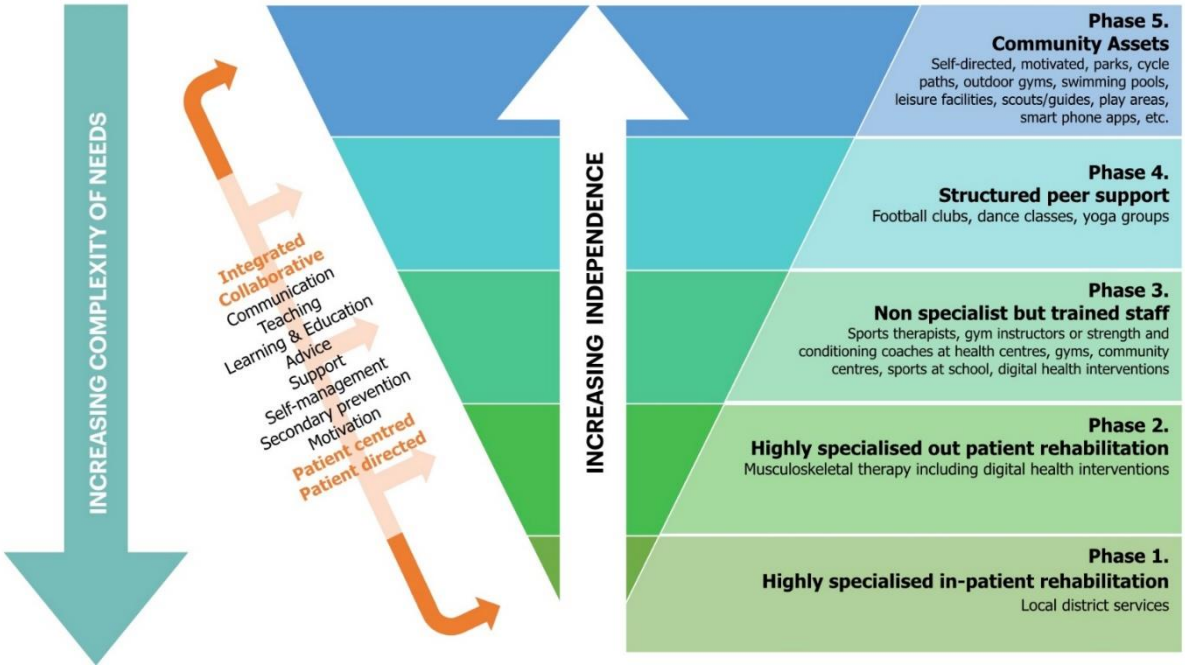

Figure 1.3. Rehabilitation model, modified from NHS England (12)

1.3.2 Supported self-management in rehabilitation

Self-management is discussed at length in Chapter 5 in relation to how digital health interventions can support patients to manage their own health. The World Health Organisation (WHO), UK Department of Health and Social Care (DHSC) and NHS England all emphasise the need for enablement of patients to engage in supported self-management of their rehabilitation (14-16). Self-management skills are commonly discussed in the context of management of long term conditions (17) which may not immediately appear relevant to ACL rehabilitation. However, anterior cruciate ligament rehabilitation commonly continues for over a year (18). Management of their knee is part of patients’ everyday life. Further, for many patients their rehabilitation plan is not the end of their knee care, which may go on to include, maintenance, prevention of further injury (19, 20) and management of more long term effects such as osteoarthritis of the knee (21). In this regard, ACL reconstruction and rehabilitation have many elements of long term condition management.

In 1989 Lorig et al defined 5 core self-management skills; problem solving, decision making, resource utilisation, developing a partnership with clinician and taking action (22) These ideas evolved into the

understanding that self-management is a complex intervention which incorporates multiple combinations of the patients' activities (23). Taylor et al identified that across a review of self-management interventions no single component stands out (23). They identified numerous strategies of supported self-management and synthesized findings into 5 common components. These included provision of education, psychological strategies, behavioural strategies to support adherence to treatments; practical support such as exercise guidance, and social support as appropriate (23). These principles are familiar across the spectrum of conditions managed by physiotherapists and they are critically relevant to supporting patients after ACL reconstruction. In contract to a more didactic clinical approach, supporting self-management by providing the guidance that patients need at every stage of care, can leave patient feeling more in control of their condition (24).

1.4 **Digital health in Physiotherapy**

The use of websites, smartphone apps, decision aids, artificial intelligence and robotics is likely to change the way that physiotherapists do their job, now and in the years to come. Perhaps the most welcome outcome will be the automation that may reduce the amount of administrative work that clinicians do, currently estimated between 15-70% of their workload (25). Other digital innovations will carry a challenge of education and retraining and even psychological adaptation to new models of care (25). Ultimately DHI may have the capacity to deliver effective and personal care and to improve access by reducing variations in care that have been observed across the NHS (26). In musculoskeletal physiotherapy, the management of capacity and demand is a constant challenge for which innovative solutions are needed. The NHS England Digital Framework for Allied Health Professions calls for digitally mature Allied Health Professional (AHP) services to meet the needs of the patients and services alike (27). This strategy includes optimisation of digital health to improve remote access to quality care and improve self-management opportunities.

Both the NHS and the Chartered Society of Physiotherapists have their own App libraries for which they provide approval. The availability of inexpensive smart phones means that patients can access condition specific content through websites and apps. There are still limitations to this. Firstly, although there are general MSK apps with baseline information, there are no apps or websites approved specifically for ACL rehabilitation. Secondly, there are many websites and apps that contain content that may not be evidence based and may expose users to incorrect information or unnecessary risk (28). Further the popularity of some physical activity apps cannot be correlated with their quality (28). Apps and websites that had no medical professional or research involved in their development should be regulated (29). Patients who go on line for information about their ACL rehabilitation and in the absence of approved sources will find thousands of videos on YouTube (30).

The information and exercises videos may be useful however the advice is most often from individuals rather than from an expert group or trusted source. The advice rarely contains the appropriate warnings and guidance (31). Patients prefer to get their information from trusted sources and would certainly value NHS approved information (30). This gives a clear rationale for the development of evidence based and condition specific resources like TRAK ACL (introduced below) which are developed in the NHS and designed to support the self-management components of ACL care.

1.4.1 TRAK ACL

TRAK ACL is a website that was designed to support rehabilitation after ACL reconstruction. It was developed on a background of research and with extensive Patient and Public Involvement (PPI) (30). It contains phase by phase information for recovery which is delivered through animation, infographics, expert videos and texts. Further video and animation content includes the psychological side of recovery, exercise prescription guidance and how to monitor correct exercise technique. The exercise library contains a large number of videos that are categorised into phases and types of exercise. The exercises can be managed independently or prescribed by a physiotherapist. TRAK ACL was designed to be a behaviour change intervention and therefore its functions are characterised in relation to the intended behaviour of exercise. Each function can be mapped through a mechanism of action that is designed to increased engagement with rehabilitation concepts. Details of this intervention and the development work I undertook are provided in Chapter 5.

1.4.2 Behaviour Change theory in digital health

Information from the physiotherapy evidence base and a taxonomy of relevant exercises are only part of the development ideal for a digital intervention such as TRAK ACL. As with many health conditions, human behaviour is a key ingredient to rehabilitation outcomes (32). Successful management of conditions like obesity, heart disease or diabetes have long been tied to behaviours such as adherence to protocols for medication, lifestyle factors or exercise (33). The behaviour to take an effective medication is just as important as the effectiveness of the medication. The same is true for ACL rehabilitation. In order to benefit from strength and neuromuscular control exercises, regular practice and accurate performance is essential and in order to improve confidence and self-efficacy, engagement with key learning materials is essential (34). Attendance at physiotherapy appointments usually facilitates education, learning of exercises and motivation to adhere, amongst other clinical factors. However, patients may struggle to retain the key information or exercise technique and their motivation may depend on multiple factors. A digital intervention for ACL rehabilitation would need to reflect physiotherapy care in the provision of exercises and evidence based information while also interacting with factors that encourage rehabilitation behaviours.

The key framework of behaviour change discussed in this thesis is the Behaviour Change Wheel: a new method for characterising and designing behaviour change interventions (35). The BCW brings together many theories of behaviour change into a single framework and is focused around the COM-B model of behaviour change, where capability (C), opportunity (O) and motivation (M) are known to impact on behaviour (B). In rehabilitation management of ACL patients, physiotherapists often aim to positively influence rehabilitation behaviours through these three domains. Using TRAK ACL physiotherapists can reflect not just the exercise and education content of their practice through the website, but they can use TRAK ACL as a behaviour change intervention to enhance care when their patients are self-managing between appointments. Capability can be either physical or psychological; physiotherapists teach patients to do a number of exercises and provide TRAK ACL so patients can have a model of these exercise to practice technique with confidence. Patients use reflective motivation where the belief is established that exercise adherence will lead to recovery and automatic motivation such as the formation of a daily exercise habit and the knowledge that a physiotherapist can check the exercise log provides extrinsic motivation. The information functions of TRAK and the exercise log facilitate these motivation strategies. Patients are given social opportunities by establishment of social norms around rehabilitation and recovery and physical opportunities by having access to the physiotherapy prescribed exercise video list. The COM-B model, described in more detail in Chapters 5 and 6, was used to design TRAK ACL and optimise its functionality by including behaviour change techniques such as goal setting, weekly logs and a progress dashboard. These interventions inform the complexity of TRAK ACL as a digital health intervention.

1.5 Aim and objectives

The overall aim of this thesis was to explore causes of variability in care after ACL reconstruction and whether a digital health intervention could potentially help overcome these causes and hence lead to improved health outcomes.

Specific objectives were to

1. identify resources used in trials of optimal ACL rehabilitation (as a proxy for resources needed for optimal ACL rehabilitation);

2. explore stakeholder views around criteria for optimal care and reasons for observed variation.

3. explore stakeholder views about the use and potential of digital health interventions in delivery of ACL rehabilitation.

4. further develop and refine an existing digital health intervention designed to support rehabilitation after ACL surgery, with a view to updating it to reflect the current evidence and incorporate behaviour change techniques for exercise adherence.

5. determine the feasibility of undertaking a definitive randomised controlled trial (RCT) to determine effectiveness and cost-effectiveness of this refined DHI to support ACL rehabilitation.

The work packages of this thesis are demonstrated in Figure 1.4 which shows a timeline of key work done throughout my PhD. The first work package was entitled, “A scoping review of the resources needed to deliver Anterior Cruciate Ligament physiotherapy rehabilitation in randomised controlled trials”. This work package was related to objective 1 and is addressed in Chapter 3.

The second work package was related to objectives 1, 2 and 3 and is addressed in Chapter 4. The study was entitled “Toward criteria for optimal management of Anterior Cruciate Ligament rehabilitation programmes. A qualitative study of key stakeholder opinion “.

The third work package was the development of TRAK ACL, a digital tool to support the self-management component of ACL care. This work satisfies objective 4 and was an essential component of objective 5. The development is described in Chapter 5.

The final work package of my PhD was the feasibility trial for TRAK ACL plus usual care compared to usual care described in Chapter 6. This trial satisfies objective 5 to determine the feasibility of a definitive effectiveness and cost effectiveness clinical trial.

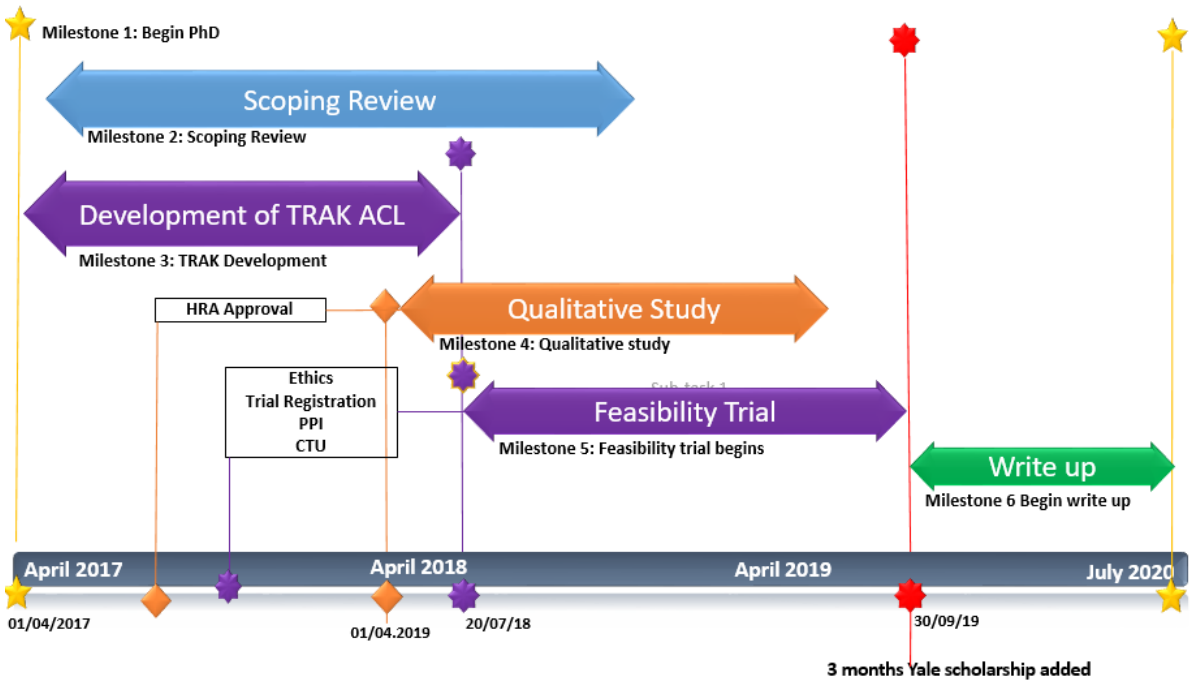

Figure 1.4. Timeline of key work packages of PhD

1.6 **Summary**

The variation in management of anterior cruciate ligament rehabilitation is not well understood. Exploring the nature of ACL rehabilitation variations in care and optimal care will inform a better understanding of current practice and it strengths and limitations. The rationale for the use of digital health interventions in rehabilitation is based on improving access to optimal ACL rehabilitation care in the UK. It is NHS England policy to support the use of DHI to deliver effective and cost effective care (25, 36). Behaviour change techniques embedded in digital interventions have been associated with positive health outcomes (37-41). DHI could improve access to care and reduce known variation in care by providing an evidence based DHI that is available to all (26, 36).

Chapter 2 - A literature review of Anterior Cruciate Ligament Reconstruction: What is it, why does it happen and how is it managed?

2.1 Chapter outline

This chapter includes a summary of anterior cruciate ligament injury and rehabilitation. In the first instance, I have introduced the anatomy, function and epidemiology of injury. I have described the diagnostic process and some key management decisions. The chapter then explores the evidence for rehabilitation interventions through a review of key systematics review in the field, looking at each stage of care as well as the psychological factors that may impact the rehabilitation process. There follows a brief rationale for the potential of digital health intervention to be integrated into ACL rehabilitation care.

2.2 Introduction

Over recent years there have been considerable improvements in surgical techniques for ACL reconstruction. These improvements meant that post-operative rehabilitation is now seen as the main determinant of outcome after ACL surgery (42). Rehabilitation practices were therefore under more scrutiny than ever and it was clear that the proportion of people who achieve full return to sport remained suboptimal (43). It was suggested that improvements in rehabilitation protocols and processes could lead to improvements in health outcomes, as measured by return to sport.

ACL injury resulted in loss of muscle strength and proprioceptive movement control, affecting gait, balance and function. Proprioception is a somatosensory function where afferent nerve input sends information to the brain via the dorsal horns of the spinal cord (44). This information included stress to and position sense of the knee (45), (46), (47)

Research has suggested that loss of proprioception was associated with altered movement strategies which in turn were associated with injury and re-injury to the knee (44). Our ability to measure and modify these losses of muscle strength and proprioceptive ability toward better outcomes has driven both clinical and research practice in rehabilitation.

In order to deliver ACL rehabilitation, we need to understand the clinical evidence base. This chapter reviews the literature on the background of ACL injury and the evidence for rehabilitation, noting its strengths and limitations and introduces the rational for a role for eHealth in ACL rehabilitation.

2.3 **Background**

2.3.1 Anatomy of the ACL

The anterior cruciate ligament is an important stabilising ligament of the knee. It runs between the medial aspects of the lateral femoral condyle to the intercondylar area of the tibia (Figure 2.1). There are two fibre bundles which contribute to stability in different knee positions: the anteromedial and the posterolateral. The ACL is predominantly made up of type I collagen (48). The ACL is innervated by the posterior articular branches of the tibial nerve. It is perfused with mechanoreceptors, especially at the distal end, which inform the role of the ACL in knee proprioception and movement control. The middle geniculate artery provides the blood supply (49).

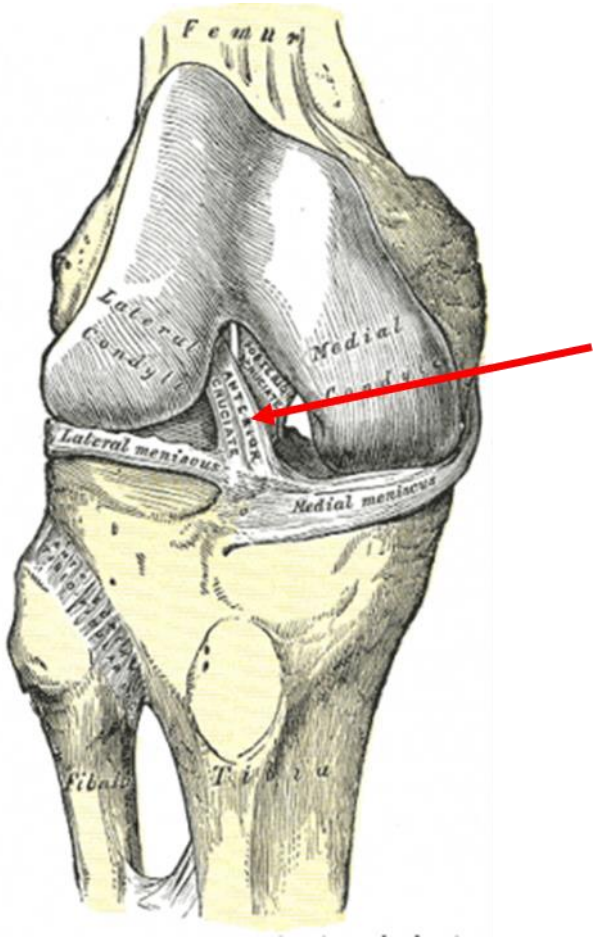

Figure *2.1*. The Anterior Cruciate Ligament (50)

2.3.2 Function of the ACL

The ACL has a primary function to prevent anterior subluxation of the tibia in relation to the femur and to resist the combined forces of internal tibial rotation with anterior tibial translation. It is a primary stabiliser of the knee and plays an important role in knee kinematics (49, 51).

During dynamic movement, the knee can move in all three planes of movement: sagittal, frontal and transverse by translation and rotation of the femur on the tibia. Evidently, most movement occurs in flexion and extension, in the sagittal plane. The purpose of ligaments is to prevent excess movement and any force that moves the knee joint beyond the physiological range can cause a ligament injury. Though excessive range in a single plane of movement can rupture the ACL, combined multi-planar movements that stress the physiological range in more than one direction are a more common mechanism of injury (10).

2.3.3 Epidemiology and Aetiology of ACL rupture

There were 85 cases of ACL injury per 100,000 per year reported by the Scandinavian Ligament Registry in 2009 (52). Bollen et al estimated that in a UK catchment area of 400 000, there were 2 ACL ruptures per week (3). The more recent Scandinavian figure was based on a detailed database and more likely to have been more accurate. The UK operated a similar database, the National Ligament Registry, but data from the last report was still limited by participation (53).

Risk factors for ACL rupture included female sex (4, 54) and playing landing and 'cutting' sports, where quick changes of direction were required (55-58). The ACL commonly tore in a landing injury, where the knee collapsed into a valgus stressed position (Figure 2.2). This could occur in a contact injury when the knee was forced into such a position but more commonly occurred in a non-contact injury. Women were 4-6 times more likely to be ACL injured than men (4). Hewett et al has summarised the multifactorial reasons for this, displayed here in Table 2.1. The female athletes who were more prone to injury often demonstrate dominance of quadriceps over hamstrings, a loading of the ligament tissue known as ligament dominance, a lower limb asymmetry known as leg dominance and a difficulty in controlling the trunk position after rapid perturbations (59-61). Genetics may have been a factor while extrinsic factors include physical and visual perturbations, bracing and shoe to surface interaction as well as intrinsic factors which were anatomical, hormonal, neuromuscular and biomechanical (1, 62, 63). Anatomical factors included having decreased intercondylar notch width on plain radiography (64).

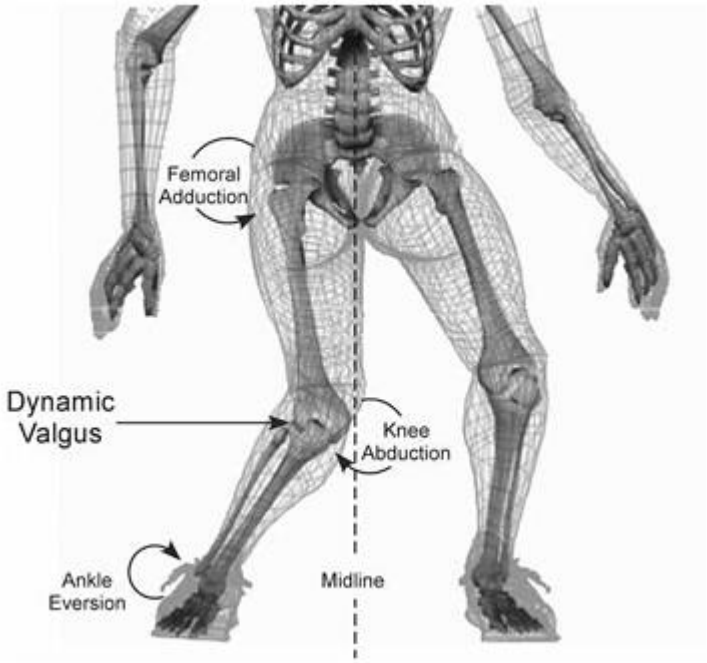

Figure 2.2. Dynamic valgus knee position (65)

Risk factors associated with ACL rupture	
Sex and Hormonal Risk Factors	Females had greater landing forces with reduced mechanisms to control knee position. The muscles of the thigh were quadriceps dominant in females and hamstrings often underperformed. Hips showed greater adduction with less gluteal activation. This lead to increased movement in the frontal plane such as valgus stress at the knee. During the pre-ovulatory stage of the menstrual cycle hormones may have affected the mechanical properties of the ACL. Significant evidence supported this but no hormonal interventions were thus far effective in reducing risk.
Laxity	The association between laxity and hormones may have contributed. Modifying joint laxity was a challenge but overcoming its effects with increased neuromuscular and strength training was a possibility.
Maturation	The rapid anatomic, hormonal, neuromuscular and biomechanical changes that occurred during maturation differed significantly between the sexes. Some females experienced slow development of neuromuscular function while others appeared to regress. Males experienced increased power, strength and coordination (neuromuscular spurt) coincident with the anthropomorphic and hormonal changes. Evidence suggested that a neuromuscular spurt could be induced in females with an appropriate training program.

Biomechanical and Neuromuscular	Deficits such as the ability to control the trunk during external perturbations and single-leg postural control were correlated with injury but were modifiable by training interventions.
Previous Injury	There was a 1 in 60 to 1 in 100 chance of an athlete getting a primary ACL injury. This increases by 15-25 times if they have had a previous ACL injury and is more likely to affect the contralateral limb. This may be due to compensations.
Genetics	There is speculation that genetics may be a risk factor. In the case of inherited collagen disorders such as Ehlers Danlos and Marfans, laxity is demonstrated.
Other	Wearing a brace has been suggested as possibly correlated with injury. Likewise, wearing inappropriate shoes for different surfaces, i.e., football studded shoe for grass, Astroturf appropriate shoes or indoor surface shoes.

Table 2.1. Summary of risk factors associated with ACL rupture identified by Hewett et al (10)

2.4 **History and diagnosis**

The clinical history of an ACL rupture often included a subjective account of a twisting or buckling knee, and an auditory pop accompanied by a shout or scream. Pain, swelling and difficulty with weight bearing were common. The knee could appear misshapen and assistance may have been needed to mobilise (66). The gold standard of diagnosis was an MRI scan, however, the subjective history and clinical tests were strong indicators. A recent systematic review has shown that Lachman's test, involving stabilization of the femur and anterior translation of the tibia, had a sensitivity of 89% for all ruptures and 96% for complete ruptures, with a specificity of 95% (67). The Pivot Shift test was used more by orthopedic surgeons than physiotherapists as it was most often completed under anesthetic. It had a sensitivity of 70% for all ruptures and a 86% for complete ruptures, with a specificity of over 98% (67). Both tests were noted to be less accurate where patients were awake or in the case of partial rupture. An earlier review reported that the Anterior Drawer test had a sensitivity ranging from 22 – 95% and a specificity of over 97% (68). The lack of accuracy of these various clinical tests meant that MRI scans have become a standard part of the assessment of a potentially ruptured ACL. Even MRI could not give a complete visualization of the structures of the knee; for this arthroscopy is required. However, this was not usually needed for diagnosis of ACL (69).

2.5 **Decision on surgical or non-surgical management**

In 2010, Frobell et al published a landmark RCT comparing early surgical management of ACL injury to rehabilitation plus optional delayed surgery in the New England Journal of Medicine (70). They found that there was no difference in outcomes at 2 years and that up to 60% of surgical reconstructions could be avoided (70). They concluded that rehabilitation should be considered as a primary treatment option in patients with acute ACL ruptures. Although this paper was considered to have had a profound impact on treatment options, criticism has included that the follow up was too short and may have failed to identify meniscal problems that develop in 'lax' knees of the non-surgically managed group. Frobell was not the first to suggest that not all ACL patients need surgery, Noyes suggested a 'rule of thirds' where one third of patients needed surgery due to instability, one third managed with modified participation in activities and one third recovered fully (71). This spectrum of the experience of rupture was much discussed and raised the question of why some 'cope' and other don't. (72-74)

Patients with an ACL deficient knee (ACLD) who had better quadriceps strength and improved functional performance, absence of giving way and self-reported knee function became known as 'potential copers' and 'copers' and those who had persistent instability became known as 'non-copers' (75) The majority of athletes who have injured their ACL were 'non-copers' (76). Although the term 'non-copers' sounded pejorative, it referred to the knee function and not the patient and it has emerged as the dominant terminology to discuss and differentiate this patient group in the literature. Identifying patient characteristics in these 'coper', 'non-coper' groups informed decision making for reconstruction or delayed reconstruction and rehabilitation. The characteristics of non-copers, those likely to need surgery, were known to include deficits in quadriceps strength, difficulty/delay activating quadriceps, atrophy of the vastus lateralis, altered movement patterns of the knee, reduced knee flexion moment, and increased quadriceps/hamstring co-contraction (75) Some of these physiological factors were not identifiable in a typical physiotherapy clinic, however, quadriceps strength, atrophy and movement patterns could be identified by experienced clinicians. The rehabilitation needs of non-copers were suggested to be higher than copers and they take longer to return to sport (77-79). Given the demands on the knee of higher level cutting sports, reconstruction was associated with better outcomes in higher level sports participation (80) Often it was the desire to return to sort that became the deciding factor between surgical or non-surgical management (81).

Another factor that was pertinent to decisions on surgical or non-surgical management, was whether or not surgery reduces the risk of developing osteoarthritis. ACL rupture was positively correlated with

development of early osteoarthritis (OA) of the knee and radiographic OA was evident in 50% of ACL injured people regardless of treatment (82). Associated meniscal injury was the biggest predictor of OA knee after ACL injury (83). Meniscectomy surgery further increased the risk (82). One of the strongest arguments for ACL reconstruction was that it reduces the risk for subsequent meniscal tears by up to 4 times (84, 85). This was understood to be related to limiting excessive movement in the knee joint. However, ultimately, there was a lack of evidence as to whether ACL reconstruction reduces the risk of developing knee osteoarthritis (72, 80, 86, 87).

2.6 **Search Strategy**

In view of the large literature in the area of ACL rehabilitation, I deemed a literature review focused on systematic reviews to be the most efficient way to identify and summarise the available evidence on ACL rehabilitation. The literature search was conducted in Medline, EmBase, Cinahl and the Cochrane library.

- Population: Adults post ACL reconstruction surgery in a structured rehabilitation program.
- Intervention: Physiotherapy rehabilitation interventions after ACL reconstruction
- Comparator: Variations of standard multimodal rehabilitation
- Study Type: Systematic Reviews

Studies were included that focused on multimodal ACL rehabilitation and were in English. Studies were excluded that were focused on more complex surgeries or single intervention reviews.

The following search terms were used:

- Anterior Cruciate Ligament OR ACL OR ACLR
- Rehabilitation OR Rehab*
- Physiotherapy OR Physical Therapy OR Physio

Further to this, I followed up on citations within these reviews to explore further the key concepts of ACL rehabilitation and to provide a background of the injury and management strategies most commonly discussed.

2.7 **Results**

2.7.1 Summary of results

The search identified 8 systematic reviews (34, 48, 88-93), including two meta-reviews (48, 89) (Table 2.2). They included a total of 260 primary studies regarding ACL rehabilitation. The total population of participants is unknown as not all studies reported population. The studies identified were reasonably homogenous which is reflected in their similar results (Table 2.3). Variations in inclusion and exclusion criteria account for some differences in scope of results. Van Grinsven included bracing but excluded electrotherapy including neuromuscular electrical stimulation (91). Risberg and Van Melick excluded all passive modalities, such as bracing, cryotherapy, continuous passive motion in order to focus on more active modalities (34, 90). One study includes a wider look at ACL management as well as rehabilitation (48) while most look at rehabilitation alone (34, 88-90, 92, 93). The studies population, intervention, comparator and outcomes (PICO) were described in Table 2.2. It is notable that none of these reviews excluded elite athlete studies so the population may represent a broad spectrum of athletic ability. In this summary, miscellaneous interventions with inconsistent or limited evidence were not reported.

The number of primary studies in each review ranged from 29 to 90, with Anderson et al not reporting the number of primary studies (48). Most only included randomised controlled trials however Van Melick et al also included systematic reviews and prospective cohort studies (34) Lobb and Anderson only included systematic reviews (48, 89). The number of participants was only calculable from Risberg and Kruse (88, 90), other studies did not report it. The majority of studies reported a standardised quality assessment methodology listed in Table 2.2.

Author	Risberg	Wright I	Wright II	Van Grinsven	Kruse	Lobb	Van Melick	Anderson
Year	2004	2008a	2008b	2010	2012	2012	2016	2016
Number and Type of Study (Number of Primary Studies)	33 Randomised Controlled Trials	54 Randomised Controlled Trials	- Randomised Controlled Trials	32 Soundly based rehabilitation programs, Randomised Controlled Trials and reviews	29 Randomised Controlled Trials	5 Systematic Reviews (56 primary studies)	90 Systematic Reviews Randomised Controlled Trials and prospective cohort studies	240 Systematic Reviews. 17 related to rehabilitation (number of primary studies not given)
Number of participants	N=1397	(number of participants not given)	(number of participants not given)	(number of participants not given)	N =1541	(number of participants not given)	(number of participants not given)	(number of participants not given)
Quality Assessment	Criteria established by authors	Method unclear	Method unclear	Cochrane checklist	CONSORT	PRISMA and a best evidence synthesis was performed	AMSTAR, PEDro & adapted Cochrane Library Checklist	Method unclear
Population	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury	Adults post ACL injury
Interventions included	NMES Proprioceptive training, Stair Climbing, OKC Strength, Frequency of exercise	CPM, Early Weight bearing and Motion, Post-Operative Bracing,	OKC v CKC, NMES, Accelerated Rehabilitation, Miscellaneous other inconclusive	Accelerated rehabilitation, Bracing, Cryotherapy, Immediate movement, Immediate	Post-operative bracing, Accelerated rehabilitation, Home based rehabilitation, Neuromuscular	CPM, OKC v CKC, Home based rehabilitation, Bracing, Accelerated rehabilitation,	OKC v CKC, Strength training, Isometric quadriceps, neuromuscular training,	CPM, Bracing, Accelerated rehabilitation, Cryotherapy, Neuromuscular exercise,

	performance, Duration of exercise performance, CKC + OKC, Supervised v non supervised, Perturbation programme, Immediate weight bearing, Isokinetic training, Miscellaneous other inconclusive	Home Based rehabilitation		weight bearing, Early strength exercises, CKC v OKC, Neuromuscular training,	training, Miscellaneous other inconclusive	NMES, Miscellaneous other inconclusive	NMES, Cryotherapy, Accelerated rehabilitation, Early weight bearing, Home based exercise,	Strength exercise, OKC v CKC
Comparator	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.	Standard rehabilitation or variance of time, type, intensity or supervision of exercise.
Outcomes	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry	Functional tests, strength tests, Patient reported outcomes measures, Arthrometry

Table 2.2. Studies included

CONSORT - Consolidated Standards of Reporting Trials , AMSTAR - A MeaSurement Tool to Assess systematic Reviews, PRISMA- Preferred Reporting Items *for Systematic Reviews and Meta-Analyses, PEDro – Physiotherapy Evidence Database CPM –Continuous Passive Movement, NMES - Neuromuscular Electrical Stimulation, OKC/CKC - Open Kinetic Chain/Closed Kinetic Chain,*

2.7.2 Summary of findings

Thirteen physiotherapy interventions were reported amongst the key findings of these reviews (Table 2.3). Some interventions were specifically focused on exercise: isometric quadriceps, open kinetic chain/closed kinetic chain (OKC/CKC), strength and neuromuscular control exercises (34, 82, 88-92). Research on whole body vibration training (WBVT) and neuromuscular electrical stimulation (NMES) explored use of equipment to impact strength (34, 88, 90, 93). Weight bearing, early range of motion, cryotherapy, continuous passive movement (CPM) and bracing were interventions focused on the post-operative recovery phase of care (34, 82, 89-92). Accelerated rehabilitation and home versus supervised rehabilitation examined the context and pace of rehabilitation (34, 82, 88-93). All studies used a variation of standard care as a comparator and the outcomes were heterogeneous including a mix of functional tests, strength tests, patient reported outcomes measures and Arthrometry. Given this, all studies preferred narrative synthesis to meta-analysis. The findings of these reviews were displayed in Table 2.3 and discussed in the context of the phases of rehabilitation.

Author, Year	Risberg, 2004	Wright I, 2008	Wright II, 2008	Van Grinsven, 2010	Kruse, 2012	Lobb, 2012	Van Melick,2016	Anderson, 2016
Isometric Quads exercises	Safe and effective immediately post-operative						1 week post operatively	
Accelerated rehabilitation	Rehabilitation must be monitored by a physical therapist, but continuously monitoring may not be necessary.		Accelerated rehabilitation appears safe at least in the five to six month time frame as	In favour with deference to swelling and pain	Further research needed		Possibly equal results between 19 and 32 week with a selection of outcomes.	May be beneficial
Bracing		No benefit		No benefit	No evidence to support	Strong evidence no benefit		No benefit
Continuous Passive Movement		No benefit				Moderate evidence no benefit		No Benefit
Cryotherapy				Beneficial			Effective on pain for 1 week postop	Safe and effective

Home Based Rehabilitation Or Supervised Rehabilitation	Rehabilitation must be monitored by a physical therapist, but continuous monitoring may not be necessary	Minimally supervised physical therapy in selected motivated patients appears safe			Can be successful	Moderate evidence of equal effectiveness on a range of short term outcomes	Unclear	
Neuromuscular Exercise	Some evidence. Further study needed			Safe and Important	Should not be performed to the exclusion of strengthening and range-of-motion exercises		Neuromuscular training should be added to strength training	Resistance plus proprioceptive training are beneficial
Strength exercises				Safe and Important				Resistance plus proprioceptive training are beneficial
Neuromuscular Electrical Stimulation (NMES)	NMES in addition to volitional exercises significantly improves isometric quadriceps muscle strength compared to volitional exercises alone		NMES deemed necessary for the patient should be instituted early in the postoperative period				Combination with conventional rehabilitation, might be more effective for improving muscle strength for up to 2 months	

Open Kinetic Chain/Closed Kinetic Chain (OKC/CKC)	closed kinetic chain in specific ranges of motion		CKC 0-6weeks			Mod evidence of equal effectiveness on a range of short term outcomes	Both for strength recovery. OKC in restricted range from week 4.	Both may be beneficial
Whole Body Vibration Training (WBVT)					Further evidence needed.			
Early AROM		Beneficial and reduces arthrofibrosis		effective				
Weight Bearing	Immediate weight bearing	Immediate weight bearing beneficial and decreases PFJ pain		Important			Immediate weight bearing	

Table 2.3. Main findings of systematic reviews of multimodal approaches to ACL rehabilitation

CPM –Continuous Passive Movement, NMES - Neuromuscular Electrical Stimulation, OKC/CKC - Open Kinetic Chain/Closed Kinetic Chain, AROM- Active Range of Motion, PFJ- Patella Femoral Joint

2.8 Phases of rehabilitation

There has been widespread agreement that ACL rehabilitation has distinct phases but considerable variation in the literature as to how these phases were defined (20, 34, 48, 94, 95). The Herrington model for task based rehabilitation included 6 stages, which were: preoperative rehabilitation, postoperative recovery, progressive limb loading, unilateral load acceptances, sport specific task training and unrestricted sport specific training (95). Though the model has been widely implemented into practice, it was developed for elite athletes and may need a more cautious implementation for the general population. Myer at al suggested 4 stage model, which, like the Herrington model, requires specific criteria to be met before patients can progress from one stage to another. (42, 95). However, the authors acknowledge that the criteria to progress patients may necessitate use of equipment that is not available in many physiotherapy clinics (42). This topic is explored further in Chapter 4.

More recently van Melick et al undertook a systematic review with a multidisciplinary expert group to provide recommendations based on findings (34). Based on the evidence, they divided rehabilitation into 4 distinct stages of care but unlike the four stages of Myer et al, in this study, the first phase is pre-operative. The content of each phase is clearly outlined.

- Pre-operative
- Impairment based – phase 1
- Sports specific training – phase 2
- Return to play – phase 3

Unless otherwise stated this Van Melick model is used throughout my thesis. I have chosen this model as it is the most recent and develops on the literature already established in the field while taking the newest evidence into account. The contents synthesized in each of the following stages of care are extracted from the review of systematic reviews. In Phases 1 and 2 they are focused on interventions. In Phase 3, there is less evidence for specific interventions and so Phase 3 evidence is also integrated with wider return to sport evidence and guidance that did not come to light in these review of reviews.

2.8.1 Pre-operative management

Evidence suggested that before surgery is performed several factors should be targeted to optimise outcomes, this is often known as prehabilitation (96-99). For example it was known that where a greater than 20% leg symmetry deficit existed in quadriceps strength between the injured leg and the

uninjured leg, self-reported knee outcomes remained lower at 2 years post-surgery (100). Further evidence showed a correlation between extension deficits that exist before surgery and a continuing extension deficit after surgery (101) (34) Patients who engaged in pre-operative physiotherapy aimed at reducing this asymmetry appear to have better outcomes at 2 years (34, 96). This thesis is primarily concerned with post-operative ACL management and will only refer to prehabilitation where directly relevant.

2.8.2 Impairment based – phase 1

After surgery the initial rehabilitation targeted the impairments that were associated with post-operative recovery. This was known as the impairment based phase. Management of swelling was a priority as well as early restoration of range of motion, weight bearing and gait (34, 91-93) Ice, cryotherapy, was known to have a positive impact on post-operative pain, but it was not necessarily equated with drainage (34, 91, 102, 103). Activation of the major muscles groups at this stage was very important. Starting with isometric quadriceps exercises was known to be safe from the first week operatively (34). Strength of quadriceps could be boosted at this stage by use of neuromuscular electrical stimulation (NMES), in combination with conventional rehabilitation, however it is unclear how this impacted long term recovery (90, 93). Early weight bearing and motion of the knee were associated with positive outcomes and should be encouraged (34, 90-92).

Criticisms of this literature included the difficulty of applying it in practical clinical settings. The tailored application of NMES was known to yield improvements in quadriceps strength, however with the effect thought to level off over the rehabilitation process. Decisions to use NMES would have to weigh the benefit against either the cost of a home NMES device or the cost of frequent clinic visits for treatment. Early motion and weight bearing as well as exercise based interventions and cryotherapy were likely the most commonly implemented strategies from this knowledge base due to being practically applicable and inexpensive. In this phase, most of these interventions require daily unsupervised compliance to yield the intended results. This emphasizes the importance of patient education as to when and how to apply the exercises or cryotherapy for best results.

The Van Melick et al review builds on previous protocols with new evidence and offers a set criteria that were appropriate to determine readiness to progress from phase to phase of ACL rehabilitation (42, 95). They were described in Table 2.4, 2.5 and 2.6.

Criteria to Progress from phase 1
Closed wound
No knee pain with phase 1 exercises (VAS)
Minimal effusion,
Patellofemoral joint mobility = to unaffected leg
Knee extension of at least 0° and a 120-130° flexion
Voluntary quadriceps control throughout range
Normalised dynamic gait pattern without crutches
Correct performance of phase 1 exercises

Table 2.4. Criteria to progress from phase 1 (34)

VAS- Visual Analogue Scale

2.8.3 Sports specific training - phase 2

Following the resolution of post-operative impairments the patients can begin the 'sports specific training' phase. The priorities of this phase were about achieving maximum limb symmetry on a range of strength exercises, neuromuscular control exercises and a battery of hop tests. Quality of movement in jumping and landing were measured commonly using either the landing error scoring system, video analysis or observation skills (20, 95, 104). Criticism of limb symmetry includes the argument that the un-operated leg will also be deconditioned during the injury and rehabilitation process and hence should not represent a target. Authors argue that failure to recognise this can lead to overestimating knee function at crucial stages of rehabilitation (105, 106). The ideal limb symmetry is also not known, though targets of 90-100% were common (94, 107). Physiotherapists must use clinical decision making and exercise evidence to set individual targets for patients in this phase.

Within this phase there has been much debate about open (limb not in contact with ground) and closed (limb in contact with ground) kinetic chain exercises (OKC and CKC). There was strong evidence that both were highly effective in the management of post-operative anterior cruciate ligament reconstruction (34). The debate has focused on the concern that open chain exercise, by virtue of the fact that the tibia is not grounded through the foot, could place a traction force or sheering force on the knee and stress the graft causing laxity. Beynnon et al found that ACL shear appeared to be marginally higher during OKC exercises than other routinely performed exercises (108). There was some evidence that suggests that hamstring grafts were more vulnerable than bone patella bone (BPB) grafts to increased laxity if they were loaded in this way too early post-operatively (2, 109). Anderson et al found that OKC was less painful and had less risk for BPB grafts (48). However other

studies found moderate evidence of equal effectiveness over a range of short term outcomes or no difference (89, 110). The relative importance comes back to the role of quadriceps and hamstring exercises in ACL outcomes and the evidence that suggests that open chain exercises can elicit a greater and more targeted effect in strengthening the quadriceps (111). Clinical decision making and models of progressive exposure to OKC exercises that balances caution with the knowledge that OKC exercises have an important role in rehabilitation is the most common approach (34).

Neuromuscular training was defined by Risberg et al as training that enhances unconscious motor responses by stimulating afferent signals and central mechanisms responsible for dynamic joint control (8). In other words, training the control of quality of movement in complex movement patterns such as jumping, landing and changing direction. Rehabilitation aimed to bring these movements strategies into the conscious realm in order to limit compensations and poor movement patterns that may be associated with injury such as valgus knee position in dynamic activities (7, 112). There was little evidence to support one type of exercise over another (113), however, there was strong evidence that adding neuromuscular control exercises to strength optimised long term self-reported function (34). Neuromuscular training was known to decrease the risk of ACL injury in the sporting population (114, 115) The effect of training biomechanical movement patterns was to improve jumping and landing mechanics and trunk control in changes of direction in order to decrease incidence of valgus stress and internal rotation of the hip that is associated with ACL rupture (7, 116, 117).

Exercise prescription guidance was found to be unclear in the literature on ACL rehabilitation by Van Melick et al (34). The American College of Sports Medicine Guidance on exercise prescription is often used to guide practice where it provides a strong evidence base for different levels of exercise dosage that, in regulated training should give very specific results. (118). This illustrates the importance of clinician knowledge to tailor exercise plans to reflect individual patients abilities and goals (118). However, it is known that exercise parameters are poorly reported throughout physiotherapy trials which makes specificity about the exercise ‘effect’ of a multimodal rehabilitation programme difficult (34, 119). Despite the evidence, much is left to clinical knowledge and judgment. The concept of exercise prescription and expertise is discussed at length by participants in Chapter 4.

Criteria to progress from phase 2
Correct performance of phase 2 exercises
LSI >80% for quadriceps and hamstring strength
LSI >80% for a hop test battery Gustavsson hop test battery preferred (120)
IKDC or KOOS patient rated outcome measure
A psychological questionnaire (TSK-11, ACL-RSI, K-SES)

Table 2.5. Criteria to progress from phase 2 (34)

LSI –Limb Symmetry Index, IKDC – International Knee Documentation Committee, KOOS –Knee Osteoarthritis Outcome Score, TSK- Tampa Scale for Kinesophobia, ACL-RSI – ACL Return to Sport after Injury, K-SES – Knee Self-Efficacy Scale

2.8.4 Return to sport – phase 3

In this phase the return to sport information that could be concluded from the ACL review of reviews is contextualised within broader return to sport evidence. Ardern et al found that 81% of ACL reconstructed people returned to some level of sport but only 65% were returning at the preinjury level and only 55% returned to a competitive level. These data came from a sample of over 5000 ACL reconstructed patients including recreational, competitive and elite athletes (43). In medium term follow up of 2-7 years, less than 50% were playing at preinjury level, suggesting that some who returned to sport, do not continue participating (81, 107). Elite athletes returned at a much higher rate of 83% to preinjury level, usually between 6 and 13 months (121)

Return to previous levels of sports (RTS) or recreational activity, sometimes known as return to play (RTP) was a commonly cited goal for patients undergoing ACL reconstruction surgery. However, the process of return to sport was complex and the outcome uncertain. Patients face complex biopsychosocial issues as they recover from orthopaedic surgery (122). For athletes, the impact of an ACL injury could be catastrophic or even career ending, it included loss of opportunity such as scholarship or team place, isolation from lifestyle and work environment or missing a major sports event (123-126). For the general population, the stakes may not have seemed as high, however for active people, there was a loss of identity and isolation that they experience when unable to participate in their usual hobbies as well physical deconditioning and pain (79, 127-132). Many sequelae such as reduced physical activity levels and arthritis can have long terms implications for their health.

A model for understanding return to sport (RTS) was proposed at the First World Congress in Sports Physical Therapy in 2016. This suggests a continuum that begins with ‘return to participation’, before

'return to sport' and finally 'return to performance' (107). The return to sport time frame was variable across different populations and depends on the demands of the sport, the individual and the context for a number of factors (95). It is known that the risk of re-injury was decreased in those who continue rehabilitation beyond 9 months (20)and that only a minority return to the pre injury sport at one year follow up (133). The factors positively correlated with returning to sport were youth, male gender, higher levels of sport i.e. professionalism, absence of a concomitant meniscal tear, psychological readiness and left to right symmetry of knee performance in activities of strength and function (20, 107) Limb symmetry in hop performance was deemed important where it demonstrated both physical and psychological function and confidence, though with the acknowledged limitations. Quadriceps strength was also correlated with improved function in the return to sport phase (134-136) The Bern consensus and the Van Melick review also recommended close follow up of a high quality physiotherapist and evidence based interventions (34, 107).

Criteria to Return to Sport
Absence of pain in the knee during sport and training
Absence of giving way or fear of giving way during sport and training
Symmetry and proper movement control during all sport and training activities
LSI >90% for quadriceps and hamstring strength
LSI >90% for a hop test battery Gustavsson hop test battery preferred (120)
Depth jump test with observation or video-analysis measuring knee flexion, knee valgus and trunk control.
IKDC or KOOS patient rated outcome measure
A psychological questionnaire (TSK-11, ACL-RSI, K-SES).

Table 2.6. Criteria to Return to Sport (34)

LSI –Limb Symmetry Index, IKDC – International Knee Documentation Committee, KOOS –Knee Osteoarthritis Outcome Score, TSK- Tampa Scale for Kinesophobia, ACL-RSI – ACL Return to Sport after Injury, K-SES – Knee Self-Efficacy Scale

2.8.5 Psychological factors

As well as physical rehabilitation there was a growing body of evidence that psychological factors play a significant role in determining who can return to sport. (34) Ardern et al found that only half the ACL injured population returned to sport or to their preinjury recreational activities and that psychological readiness was the factor most strongly associated with this (137). Positive emotional responses such as motivation and confidence and low fear were found to be associated with greater likelihood of

return to play and a speedier return to play (138, 139). Interventions such as guided imagery/relaxation, 'microcounseling', acceptance and commitment therapy were shown to be effective in return to sport care by reducing re-injury anxiety and negative psychological consequences as well as improving psychological coping (140). Measurement of psychological coping could be facilitated by the ACL-RSI outcome or scales of kinesophobia (137, 141). Availability of psychological skills in clinical physiotherapy was not a given. Though some skills may be clinically instinctual, much of the evidence comes from sports psychology. Some clinicians in Chapter 4 referred to feeling ill-equipped to deliver some of the more nuanced psychological interventions. However some of the most effective tools could already be said to be integral to biopsychosocial rehabilitation such as goal setting and positive self-talk, (142) as well as patient education and social support (143).

2.9 **Potential for Digital Health Interventions (DHI) to support ACL rehabilitation**

As illustrated, each phase of rehabilitation had different learning goals and desired outcomes and each phase had different physical and psychological challenges. The final outcome also depended to a great degree on the patient themselves and the extent to which they engaged with this lengthy rehabilitation and they were equipped with the knowledge to do so. Digital interventions such as TRAK, alongside rehabilitation provided the opportunity to reinforce patient education in a variety of ways and gave the patient better opportunities to understand their ACL rehabilitation process (30). Given the complexity and quantity of knowledge involved in ACL rehabilitation, a physio led digital health website could provide a patient friendly source of trustworthy information as well as structured support for positive behaviour change as discussed in Chapter 5.

Ardern et al found that nearly 70% of patients had not tried to return to sport by 12 months post operatively. They concluded that people may need longer than 'typically advocated' for a successful return to competitive sport after ACL reconstruction surgery (133). A recent survey of American physical therapists found that there was a substantial gap between when physical therapists discharged patients and when they returned to sport (144). They suggested that this gap, and all the unknowns contained therein, may contribute to the sub optimal outcomes for return to sport. This was a clinical challenge and it was significant given that the desire to return to sport is given as the most common reason to undergo the surgery in the first instance (81).

The use of digital health interventions to address this gap between end of care and end of recovery could be possible. Rehabilitation appointments that are spread out with added opportunities for support self-management at opportune times, can allow physiotherapists to follow patients up for longer periods of time without increasing resource use. This may provide opportunities to understand

this gap between care completion on or before 6 months (144) and return to sport, after 12 months (20, 145).

As is explored in Chapter 4 of this PhD, there were many different models of care for post-operative ACL rehabilitation in the UK. The use of a digital health tool alongside usual care to support ACL rehabilitation may represent a more versatile approach to care that can be applied regardless of the local service parameters. The TRAK website itself provides a reflection of the care described in this chapter. It has consolidated this information in a way that can be a helpful adjunct for clinicians and an invaluable resource for patients following anterior cruciate ligament reconstruction.

Chapter 3 - A scoping review of the resources needed to deliver Anterior Cruciate Ligament physiotherapy rehabilitation in randomised controlled trials.

3.1 Chapter Outline

This chapter presents the findings of a scoping review of the ACL literature for randomised controlled trials. The purpose of this study was to identify the resources needed for delivering optimal anterior cruciate ligament rehabilitation. Randomised controlled trials were chosen as they represent the highest level of evidence for interventions. The study was intended to satisfy the first objective of this thesis; to identify resources used in trials of optimal ACL rehabilitation.

This chapter, along with Chapter 4, contributes to identifying characteristics of optimal care for ACL rehabilitation. It further helps to unpack the individual components of what usual care means when described in RCT. These components are often not well described which can present challenges to those who would implement research findings. This scoping review has been published in *Physical Therapy Reviews* (146). The abstract is included as Appendix A.

3.2 Introduction

3.2.1 Description of the condition

As previously described in Chapters 2 and 3 and summarised here, the anterior cruciate ligament (ACL) is an important stabilising ligament in the knee. It functions to prevent excessive movement between the tibia and femur during dynamic activity. Injury is common in sport and activities that involve jumping, landing and changing direction (3, 147). Surgery is the most common management strategy and progression through a phased rehabilitation programme is standard (34, 148). Recovery is usually measured in terms of a return to previous levels of activity but evidence suggests that only 55% of affected patients, return to competitive sport (43). There are numerous systematic reviews that demonstrate the most effective physiotherapy interventions (34, 89, 90, 92, 93) and rehabilitation should be continued until the patient achieves a set of criteria relating to functional goals (77). In Hartigan et al 2012, only 5% of patients passed these criteria at three months, 48% passed at six months and 78% passed at 12 months (77). Indeed, 12 months is commonplace for achieving criterion based rehabilitation targets for return to higher level function, while it is known that participation in rehabilitation beyond nine months decreases the risk of re-injury (149). Hence, it is clear that

rehabilitation after ACL surgery may require substantial investment of time and resources and it is not known what the existing literature says about this.

3.2.2 Description of the problem.

An accurate understanding of the resources required for post-operative rehabilitation is needed to enable service providers to deliver evidence based care and for commissioners to understand the costs involved. None of the earlier systematic reviews have discussed the resources that are utilised in the RCTs they included, such as exercise equipment or skilled staff required to deliver physiotherapy rehabilitation. Resources required for post-operative rehabilitation as described in RCTs can be considered in three categories: the time and skill of the lead physiotherapist; and the equipment needed. Just as there is a lack of clarity around the equipment needed for the care described in trials, there is uncertainty around the amount of therapist time required to deliver the interventions described. Recent reviews have highlighted conflicting evidence about optimal supervision time. Van Melick et al noted in a recent systematic review the lack of high quality studies and contradictory results, which made it difficult to determine the benefits of supervised versus home based rehabilitation (34). While some studies reported no significant difference, others reported atrophy and trouble with range of motion leading to 49% of the home based group switching to supervised care (150, 151). Risberg at al concluded that although rehabilitation must be supervised to some degree by a physiotherapist, continuous supervision might not be essential (90), while Wright et al concluded “minimally supervised physical therapy in selected motivated patients appears safe” (92).

In the literature, there is a paucity of cost data on effective models of ACL rehabilitation. The NHS Economic Evaluation Database (EED) includes one American study that looks at cost effectiveness comparing two rehabilitation models (152) and the EED concluded that “the cost data provided in the study are likely to be unreliable and do not provide a true estimate of the implications of introducing a new programme” (153). Non-UK based surgical studies have included cost for surgery and rehabilitation at $17,000-$25,000 per injury but without a break down of cost (1). Neither the cost nor the resources needed for models of physiotherapy rehabilitation for ACL rehabilitation are well described in the literature.

3.2.3 Description of the interventions

In the absence of evidence-based guidelines regarding resources required to deliver rehabilitation after ACL surgery, it is necessary to look at alternative sources of evidence to identify the key resource requirements. In this study, we scoped published randomised controlled trials (RCTs). The basis for

this decision was: RCTs are the “gold standard” for determining effectiveness of treatments. It is not ethical to offer treatment known to be ineffective in a trial. These studies would have examined new or innovative treatments (designed to be an improvement on current effective care) and would have included a comparator arm that reflected current effective care. Moreover, in line with CONSORT reporting guidelines, we anticipated that both the intervention (new practice) and comparator (current practice) would be accurately described, using the TIDieR template (147, 154). The TIDieR (Template for Intervention Description and Replication) template was designed to improve the reporting and replicability of interventions.

3.2.4 Why it is important to do this review

In the light of known variability in outcomes (43), and variability in the content of rehabilitation provided (144), it is important to gain an understanding of the key resources required to deliver evidence based rehabilitation. This is necessary so that service providers can plan appropriately, and commissioners of care can provide appropriate reimbursement. I wanted my work to be relevant to routine health care providers so I decided to exclude studies focused on elite athletes.

Research Question: What does the available RCT literature tell us about the resources needed to deliver anterior cruciate ligament reconstruction rehabilitation?

3.3 Aim and Objectives

The aim of this review was to identify the resources, in terms of equipment and therapist time and skill set, to deliver physiotherapy rehabilitation to adults after ACL reconstruction surgery as described in randomised controlled trials. The purpose of using a scoping reviews methodology for this study was to map the ‘size, range or characteristics’ of the resources used in RCTs of ACL rehabilitation. (155). It aimed to identify data that have not been reviewed comprehensively before (156) and to identify gaps in the literature on this subject (155, 157).

Specific objectives were to:

- Identify RCTs comparing components of, or approaches to, rehabilitation after ACL reconstruction;
- Extract details of resources required to deliver the intervention and comparator in these trials;

- Synthesise these findings to provide an overview of the resources required to deliver rehabilitation in RCTs of multimodal ACL rehabilitation

3.4 Methods

3.4.1 Protocol and registration

This review is registered with the Open Science Framework (https://osf.io/a978k). It was reported with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist (156).

Scoping reviews share the essential characteristics of other review types, namely, 'collecting, evaluating and presenting the available research evidence' (156) The PRSIMA guidance on scoping reviews suggests they can be used to look at the 'size, range or characteristics' of the data on a topic (155). The latter is the focus of this study. This review is reported in line with the Arksey and O'Malley framework which aimed to make scoping reviews 'rigorous and transparent' as well as repeatable, to improve methodological rigor (156, 158) The search was conducted in accordance with Cochrane systematic review methodological guidance in order to ensure a rigorous approach to the gathering of evidence (159).

Scoping reviews often regard the literature with a wide lens however advancements on the original methodology highlight the need to focus on the objectives. The breadth of a scoping review depends on the purpose of the review (160). The purpose of using a scoping review methodology for this study was to map the characteristic resources used in RCTs of ACL rehabilitation. It aimed to identify data that has not been reviewed comprehensively before (156) and to identify gaps in the literature on this subject (155, 157).

3.4.2 Criteria for considering studies for this review

The inclusion and exclusion criteria were defined using the Population, Intervention, Comparator, Outcomes, Study type (PICOS) acronym (Table 3.1).

Population	Adults, (aged 16 or over) who were not professional athletes and had undergone ACL reconstruction without complex concomitant injury.
Intervention	Multimodal ACL rehabilitation programmes, including studies of type and timing of exercise interventions, innovative technologies or home versus supervised rehabilitation. Studies were included if they demonstrated effective care and if the intervention, the comparator or both included a description of standard ('standard ''usual', 'conventional' or 'traditional') multimodal care such that the details of resources needed could be identified.
Comparator	Standard care or standard care plus a variation, including studies of type and timing of exercise interventions, innovative technologies or levels of supervision.
Outcomes	Resources associated with delivering ACL rehabilitation interventions: Number and length of face-to-face appointments; experience of physiotherapist and equipment required.
Study Type	Randomised Controlled Trials (RCTs) where the primary aim of the study was to evaluate effectiveness of a component(s) of multimodal ACL rehabilitation care.

Table 3.1. PICOS: Population, Intervention, Comparator, Outcomes, Study type

3.4.3 Search Methods for identification of studies

The Databases that were used were Medline, EmBase, Cinahl, Pedro, Cochrane and Sports Discuss. Comprehensive electronic searches of these databases were conducted between June and August 2017 with the last search being on the 28th of August 2017. The search strategy consisted of two concepts and an RCT filter was applied (Figure 3.1). The terms 'anterior cruciate ligament', 'anterior cruciate ligament reconstruction' and 'acl' were searched with truncation, exploded in subject headings and searched as a keyword. For the second concept the words 'rehabilitation', 'exercise therapy', 'physical therapy', 'physiotherapy' 'manual therapy' and 'neuromuscular control' were searched with truncation, exploded in subject headings and keyword searched. Within each concept, terms were combined with Boolean search term "or" and then both concepts were combined with 'and'. There was no limitation placed on language. Several pilot searches were run in each database to ensure that key articles were picked up. The search was not limited by year.

Finally the search was limited to randomised controlled trials using the National Institute for Clinical Excellence (NICE) definition, "a study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention" (161). The Cochrane Handbook outlines a highly sensitised search strategy for identifying randomised trials in Medline, which was used to search Medline and the Cochrane library (162). The Handbook also guides that this strategy can be adapted into EmBase by mapping to the local subject headings which was also done.

For Cinahl and Sports Discuss, initially the SIGN filters were used, which are designed specifically for these databases. However this was a more detailed filter and seemed to reduce the numbers very significantly due to its specificity. It was decided in consultation with a specialist librarian that the Cochrane handbook guideline for applying an RCT filter would be used in all databases adapted to local settings in order to create parity. PeDro was the exception to this, which has an inbuilt filter for clinical trials, which was applied. Web of science was also searched by the backward and forward citation of 5 key systematic review articles regarding rehabilitation of anterior cruciate ligaments (88-90, 92, 93, 163) Pilot searches were run to test sensitivity and specificity and no further changes were made (Figure 3.1. Search Strategy).

The basis for the decision to limit evidence to published randomised controlled trials (RCTs) was: RCTs are the "gold standard" for determining effectiveness of treatments since it is not ethical to offer treatment known to be ineffective in a trial. These studies would have examined new or innovative treatments (designed to be an improvement on current effective care) and would have included a comparator arm that reflected current effective care. Moreover, in line with CONSORT reporting guidelines, I anticipated that both the intervention (new practice) and comparator (current practice) would be accurately described, using the TIDieR template (147, 154).

Some challenges that were associated with identifying studies for eligibility were that some of the information needed to include or exclude was not available in the title and abstract and therefore much reading and data mining were required. Further to this, there was ambiguity in the use of terms such as 'ACL deficient'. For example, Beard et al 1994 and Knoll 2004 use the term to describe patients both pre- and post-ACL reconstruction so further reading was required to establish the study eligibility (164, 165).

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 exp Anterior Cruciate Ligament Reconstruction/ or exp Knee Joint/ or exp Anterior Cruciate Ligament/ or anterior cruciate ligament*.mp. (65018)

2 physical therapy modalities/ or exercise therapy/ or muscle stretching exercises/ or plyometric exercise/ or resistance training/ or musculoskeletal manipulations/ or massage/ or rehabilitation/ (93370)

3 physiotherapy.mp. (15504)

4 physiotherap*.mp. (20990)

5 rehabilitation.mp. or exp Rehabilitation/ (365224)

6 manual therapy.mp. or Musculoskeletal Manipulations/ (2711)

7 electrotherapy.mp. (1968)

8 exercise therapy.mp. or exp Exercise Therapy/ (41962)

9 exercise therap*.mp. (34910)

10 neuromuscular control.mp. (1046)

11 acl.mp. (13325)

12 manual therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1965)

13 exercise therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (34910)

14 1 or 11 (68333)

15 5 and 14 (6185)

16 Anterior Cruciate Ligament Injuries/ (8034)

17 1 or 16 (65018)

18 2 or 3 or 4 or 5 or 6 or 8 or 9 or 10 or 12 or 13 (376918)

19 17 and 18 (6491)

20 1 or 11 or 16 (68333)

21 18 and 20 (6576)

22 randomized controlled trial.pt. (462115)

23 controlled clinical trial.pt. (94040)

24 randomized.ab. (403274)

25 placebo.ab. (188761)

26 drug therapy.fs. (1991821)

27 randomly.ab. (280150)

28 trial.ab. (422286)

29 groups.ab. (1725818)

30 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 (4099198)

31 exp animals/ not humans.sh. (4396754)

32 30 not 31 (3544583)

33 21 and 32 (2032)

****

Figure 3.1 Search Strategy

3.4.4 Data Collection and Analysis

3.4.4.1 Selection of Studies

References were combined in Endnote and 4277 articles were identified. A further group of 351 was developed from Web of Science which comprised of the backward and forward citation of 5 key systematic review articles regarding rehabilitation of anterior cruciate ligaments (34, 88-90, 92, 93) and 3194 remained after removal of duplicate references. Of these, 3085 were excluded by title and abstract. The removal of duplicates was done systematically by repeatedly changing the duplicate preferences categories to reveal copies of the same article. Further to this a manual search was performed to ensure duplicates were not missed.

Titles, abstracts, and full text articles were reviewed by the lead reviewer (ED) against the inclusion and exclusion criteria. Translators were used where possible and abstracts in French, Serbian, Italian, Portuguese and Polish were considered with help from multilingual research colleagues at the University College London. The full text of 109 articles was sought on line or through the interlibrary loan system. Full text articles were reviewed by the lead reviewer (ED) and second reviewer (KB). A dialectic process was followed until agreement on inclusion or exclusion was reached.

Where the full text did not included complete descriptions of the interventions, emails were sent to corresponding authors requesting further information (Appendix B Information request letter). The window for reply was set at 6 weeks and a follow up email was sent to non-responders after 3 weeks.

3.4.4.2 Data extraction and management

Data were extracted and collated in Excel for 'sifting, charting and sorting'. (156)

They were organised by

- title,
- author/year/country,
- description of intervention(s),
- description of comparator(s),
- number of participants,
- age,
- gender,
- time since injury,
- type of surgery,
- intervention length (weeks),
- primary outcomes,
- statistical significance,
- consultation time,
- frequency of consultations,
- location,
- equipment available,

- experience level of physiotherapist

Each article and data set were reviewed by the lead researcher independently and data were extracted and collated on a series of spreadsheets. Further data obtained through email contact with corresponding authors were also added to the data extraction spreadsheets while the original email responses or discussions were saved and filed as a record of this data collection method. The data extraction was reviewed separately by a second researcher (KB) and findings were compared and agreed upon (ED & KB).

3.4.4.3 Critical Appraisal of included studies

Critical appraisal of the included studies was done using the Cochrane Collaboration Tool for assessing risk of bias in randomised trials (166). Risk of Bias (ROB) usually pertains to a meta-analysis of effectiveness of interventions which was not relevant here but given the included studies were RCTs, I chose to use the Cochrane ROB tool as a tool of critical appraisal of study quality. Assessing the risk of bias in trials contributes to knowledge of study legitimacy and quality of findings. Since trial evidence is often collated through systematic reviews and used to inform clinical decisions, a record of potential bias that may influence effectiveness would be an important part of this scoping evaluation (167, 168).

Two reviewers separately assessed the studies for each domain (ED & KB). An excel spreadsheet was developed and populated with a note as to how each study met each bias criteria. Higgins and Altman recommend authors must decide which domains are most important in the context of their review (166). Given that the sample size and research teams are often small in these studies, we placed a high importance on Selection Bias and especially on allocation concealment. We also placed a high importance on Attrition Bias and whether statistical adjustments were made to account for dropout rates. With small participant numbers these adjustments could have significant implications on the study results and conclusions.

3.4.4.4 Data analysis

The data from included studies were summarised and synthesised using a narrative synthesis method developed by Popay et al (169). This method of data synthesis is characterised by the use of words and text rather than numbers to explain the findings of the synthesis. The purpose of this was to outline the clear process of synthesis (as described in Figure 3.2) toward transparency and repeatability. Narrative synthesis is commonly utilised for the analysis of systematically collected data

(170-172). Other methods of analysis include Evidence Synthesis or Narrative Review analytical methods which would be less suitable to this review, because the former is less structured and assesses data from a mixture of study types and sources and the latter analyses data that had been gathered neither systematically nor transparently in its review process. This narrative synthesis method aims to ascribe meaning based on the textual content rather than the statistical data. Narrative synthesis is well suited to scoping reviews where both methods focus on the characteristics that shaped the implementation of interventions rather than the interventions themselves (169). The process of narrative synthesis (169) is described in Figure 3.2.

Figure 3.2. The framework of a narrative synthesis proposed by Popay et al (169)

3.5 **Results**

3.5.1 Results of the Search

References were combined in Endnote and 4277 articles were identified (Figure 3.3 PRISMA Flowchart). A further group of 351 was identified from Web of Science and 3194 remained after removal of duplicate references. Of these, 3085 were excluded by title and abstract. The full text of 109 articles was sought. Of these, one study was included and 59 excluded as not meeting inclusion criteria. Of the remaining 49 papers, information about the resources for the intervention or comparator was missing so emails were sent to corresponding authors requesting further information (Appendix B: Information request letter). Information missing included a description of frequency of appointments, care delivered by whom, in what context and for how long per appointment. Of these, 35 studies had to be excluded as authors did not respond, but the authors of 14 papers responded. One paper was then excluded as it did not meet inclusion criteria, 13 were included based on additional information provided, and therefore 14 studies were included for analysis.

Three included studies did not find the intervention to be more effective than the comparator but were included because the care was still effective in both arms (173-175). Christensen et al, Moller et al and Baltaci et al were principally equivalence studies. Christensen et al demonstrated that a group that began rehabilitation earlier had equally good results to the usual care and Moller et al showed that an unbraced group did equally well to a braced group and Baltaci et al indicated that a Wii fit group performed just as well as a conventional rehabilitation group. For Christensen et al and Moller et al, there group outcomes can be corroborated by measuring against known normative values of the Lysholm, Tegner and International Knee Documentation Committee (IKDC) Score (176, 177). Comparisons to normative functional data were not possible with Baltaci et al where outcomes used did not have validated norms (173).

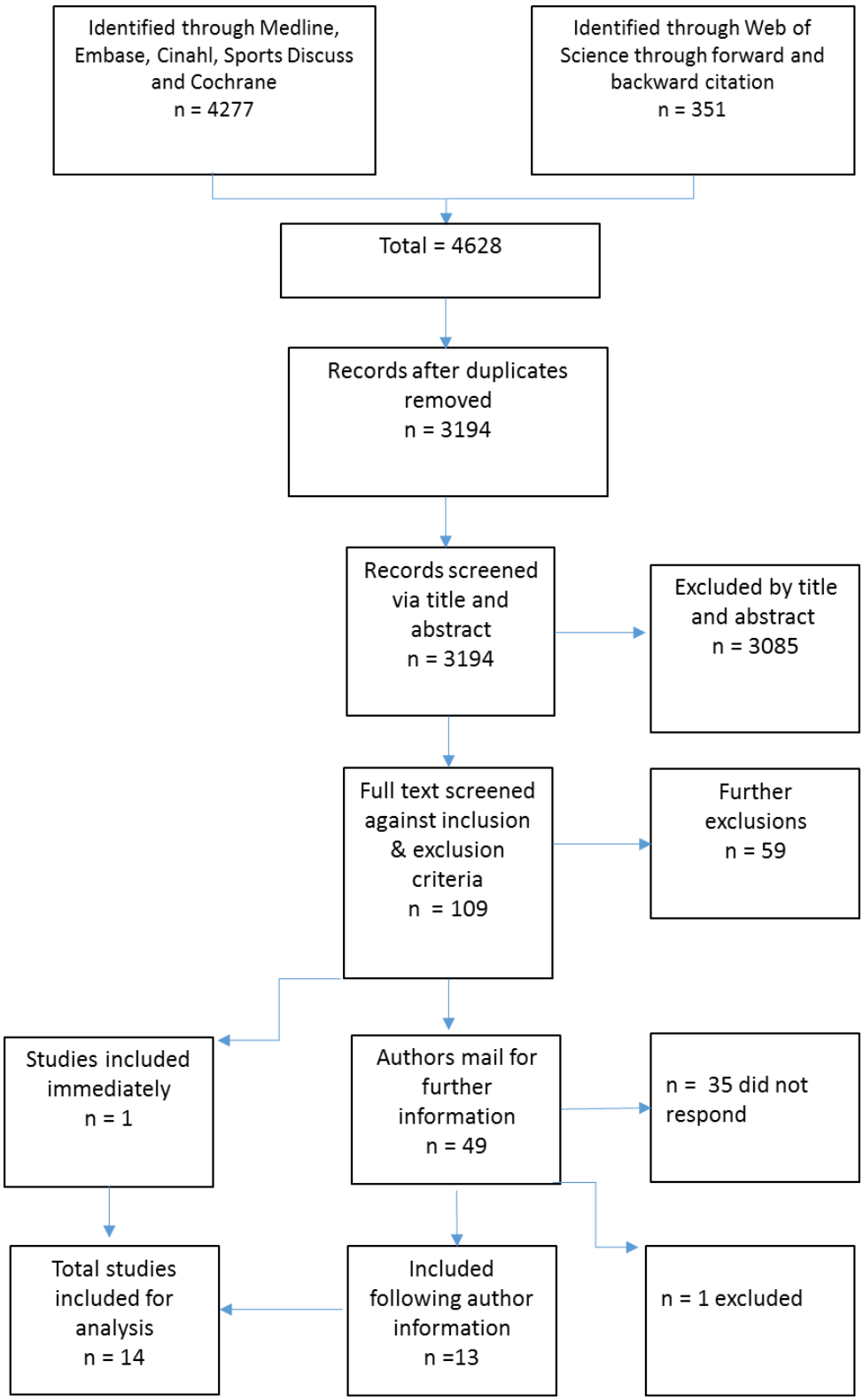

Figure 3.3. PRISMA Included Studies flow chart

3.5.1.1 Included Studies

The primary aim of the study is to look at data that were not reported or emphasised by the authors in the original analysis, such as clinician time taken to deliver the interventions. The secondary outcomes look at the environment and equipment used in delivering these interventions. Also presented are the summary data for the effectiveness of the interventions in the included studies and limitations or harms caused.

A total of 599 patients post Anterior Cruciate Ligament reconstruction were recruited to these 14 studies with a range of 20-80 participants per study. There were 413 males, 152 females and 34 patients with gender not reported. Of the 599 patients, 293 of these had a hamstring graft and 306 had patella tendon graft. The interventions varied from three weeks to 39 weeks. Some evaluated a particular phase of ACL rehabilitation, Chan et al and Ross et al looked at the early stage only, Kinikli et al, Sekir et al, Baltaci et al, Cooper et al and Pistone et al, looked at the early and middle stages together. Bartels et al looked at a higher functioning late stage intervention from 5 months as did Moezy et al. (173, 178-185) where others, Heijne et al, Hohmann et al, Moller et al, Christensen et al and Timm, were interested in the rehabilitation overall (152, 174, 175, 186, 187).

Author, Year, Country, Citation	Gender	Graft type	Age , Control / Intervention (SD)	Intervention/ Comparator	Length of Intervention	Outcomes Measures	Length of follow up	Results
Baltaci, 2013, Turkey (173)	30M	PT	29 ± 7 years / 29 ± 6 years	Wii fit v. standard	12 weeks from immediately post operation	Star excursion balance, Squat test, Muscle testing, Co-ordination, Proprioception, Response time	12 weeks	No significant difference
Bartels, 2016, Germany (180)	14F 36M	HG	31.4 ± 7.48 / 34.4 ± 12.5	Speedcourt system v. standard	4 weeks from week 20 -24	AROM, Finger Ground Distance, Reaction Time, Ground Contact Time, Tapping, Jump Height 2 and 1 leg, Jump Width, Anthropometry	3 weeks	Significant: improvement in jump height P=0.02, reaction time P=0.025 and 3/8 anthropometric measurements.
Chan, 2017, Singapore (181)	46M 14F	HG	27.4 (8.25)/ 26.3 (7.04)	K-tape + standard v. standard care	6 weeks from immediately post operation	Visual Analogue Scale, AROM, Lysolm, Tegner, Patella Circumference	6 weeks	Significant: Visual Analogue Scale P=0.0164 in the tape group.
Christensen, 2013, USA (175)	22M 8F	STG	30.1+/-10.5y 33.1 +/-10.9y	Early aggressive v non aggressive rehabilitation	6 months	AP Laxity, IKDC, AROM, Peak Isometric Force	24 weeks	No significant difference

Cooper, 2005, Australia (182)	20M 9F	26 HG 3PT	31.3(7.8) /24.7(5.1)	Proprioceptive training (PT)v. strength training (ST)	6 weeks from between 4 and 14 weeks onwards	Cincinnati Knee Scale, PSFS, AROM, Hop Tests	6 weeks	Significant for ST: Cincinnati Knee Scale, swelling (p=0.047), walking (p=0.04) and squatting/ kneeling (P=0.01). in activity 2 (p=0.01) and 3 (p=0.01) of the PSFS
Heijne, 2007, Sweden (186)	42M 38F	40PT 40 HG	31 (8) 27 (5) 30 (8) 31 (9)	Early start OKC +standard v. Late start OKC + standard in PT and HG	30 weeks from immediately post-operation	AROM, Laxity, Postural Sway, Thigh Muscle, Torque, Anterior Knee Pain score	7 months	Significant increase of graft laxity in the hamstring graft group (4 weeks) P=0.04 and P=0.02 in two ranges of laxity. significant rotational instability in the pivot shift test in H4 group, P =0.04
Hohmann, 2011, Australia (187)	30M 10F	BPB	28 (20–34) 27 (19–35)	Supervised v. unsupervised rehabilitation	36 weeks	Lysolm Tegner, Single Leg Hop Distance, Timed Hop, Vertical Jump, Strength	1 year	Significant: extensor knee strength at 6 months in the supervised group P =0.004

Kinikli, 2014, Turkey (178)	31M 2F	STG	32.64±8.21 /33.87±8.19	Dedicated eccentric concentric training programme + standard v. standard	15 weeks from immediately post operation	Isokinetic flexors, Isokinetic extensor, Vertical hop, Single Leg Hop for distance, Lysolm Knee scale, ACL-QOL	16 weeks	Significant: vertical hop (P=0.012), hop for distance (P=0.027) the Lysolm (P=0.002) and the ACL-QOL (P=0.00)
Moezy, 2008, Iran (183)	23M	BPB	24.51 (3.38) 22.70 (377)	WBVT v standard care	4 weeks from 13 weeks to 17 weeks	Postural Stability, Joint Position Sense	4 months	Significant: in favour of the WBVT group was given a P=0.05
Moller, 2001, Sweden (174)	30M 32F	BPB	28 (21-53) 31 (19-48)	Bracing + standard v not bracing +standard	28 weeks	Laxity Test, Isokinetic Peak, Single Leg Hop, AROM, Circumference, Lysolm Tegner, VAS	2 years	No significant difference
Pistone, 2016, Italy (184)	34 NR	HG	27 29	WBVT + standard v standard	12 from week 4-16	Isometric strength flexion, Isometric strength extension, Balance, Lysolm	3 months	Significant WBVT: isometric flexion (P=0.05), balance (P=0.001 and P=0.005) and Lysolm score (P=0.001)
Ross, 2000, USA (185)	13M 7F	HG	27.1+/-4.89 28.4+/-5.91	CKC +NMES V CKC	5 weeks, week 1-6	AP Laxity, Unilateral Squat, Lateral	6 weeks	Significant for intervention group:

						step up, Anterior reach		unilateral squat and lateral step P=0.05
Sekir, 2010, Turkey (179)	48M	PT	24.8 +/- 7.2 /25.1 +/- 5.3	Isokinetic hamstrings at 3 weeks +standard v. isokinetic hamstrings at 9 weeks +standard	16 weeks from immediately post operation	Hamstring strength, Quadriceps strength, Cincinnati knee rating scale, IKDC	12 months	Significant: isometric hamstring strength P =0.007 isokinetic hamstring strength of P=0.036. The Cincinnati scale of P= 0.024 at 12 months

Table 3.2. Study Characteristics

Abbreviations: OKC open kinetic chain, CKC closed kinetic chain, NMES neuromuscular electrical stimulation, WBVT whole body vibration training, PT patella tendon, HG hamstring graft, AROM active range of movement, M Male F Female NR Not Reported

3.5.1.2 A guide to graphs

I am going to present the primary data from each study, the length of the intervention, the number of sessions per week and the number of minutes per session, in graphs. The X axis is black and is the 'weeks of the intervention' and the Y axes in orange on the left are the 'sessions per week' and in blue on the right are the 'minutes per session'.

Kinikli et al 2014 demonstrated that adding progressive eccentric and concentric training to a traditional protocol 'may' improve functional results after ACLR with hamstring graft (Table 3.2) (178). Analysis of the temporal data associated with providing the interventions, found that this study was delivered over 15 weeks, post operatively from the date of surgery. All patients had 3 weeks of early rehabilitation, 3 sessions per week of 20 minutes. For the remaining 12 weeks all patients are described as having 45-60 minutes of rehabilitation, twice a week (Figure 3.4). Description of the intervention included rehabilitation in a gym environment and the use of specialist rehabilitation equipment provided by skilled clinicians. They found no significant improvement in strength for their eccentric/concentric exercise programme however, a significant improvement in vertical hop (P=.012), hop for distance (P=.027) and patient rated outcome measures, the Lysolm Knee Scale (P=.002) and the ACL-QOL (P=0.00). The limitations of this study are a small population, a moderate drop-out rate. The authors also acknowledge that their power to detect differences in strength may have been insufficient due to the small population and higher standard deviation (178).

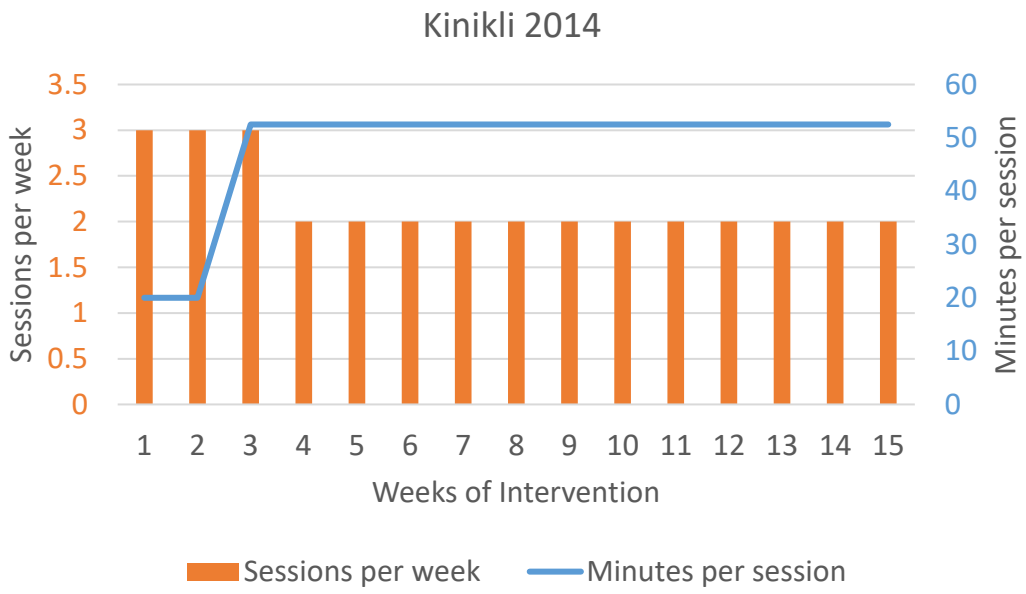

Figure 3.4. Primary outcome results; Kinikli et al (2014)

Sekir et al compared the outcomes for beginning an isokinetic hamstring exercise programme at 3 weeks post op (Table 3.2) (179). The analysis of time associated with delivering the intervention and control showed that Sekir et al had 5 sessions per week for 16 weeks. The sessions were between 40 and 53 minutes long (Figure 3.5). The exercise sessions were supervised in a gym environment and required specialist equipment. Initially supervised by physiotherapists exclusively, from week 7 onwards, the general rehabilitation was supervised by an 'athletic trainer' and the intervention was supervised by the physiotherapist. These occurred in the same space at the same time. They concluded that hamstring isometric strength was improved significantly at 30 degrees knee flexion after 2 months (P value of .007) and isokinetic hamstring strength at an angular velocity of 60 degrees per second showed a significant difference of P=.036. The Cincinnati Knee rating scale showed a significant improvement of P= .024 at 12 months. Much of the debate around early strengthening techniques revolves around the effect of any open chain exercises on graft laxity, this study used manual testing rather than using an arthrometer device so the laxity risk is not established. They further acknowledge the significant difference in groups at baseline for time between injury and surgery. Group I was 16.3 months and group 2 was 25.4 months. This study also had a loss to follow up at 12 months of follow-up (group I, down to n 5 12; group II, n 5 14) and lack of Cincinnati Knee Rating System and IKDC preoperative scores (179).

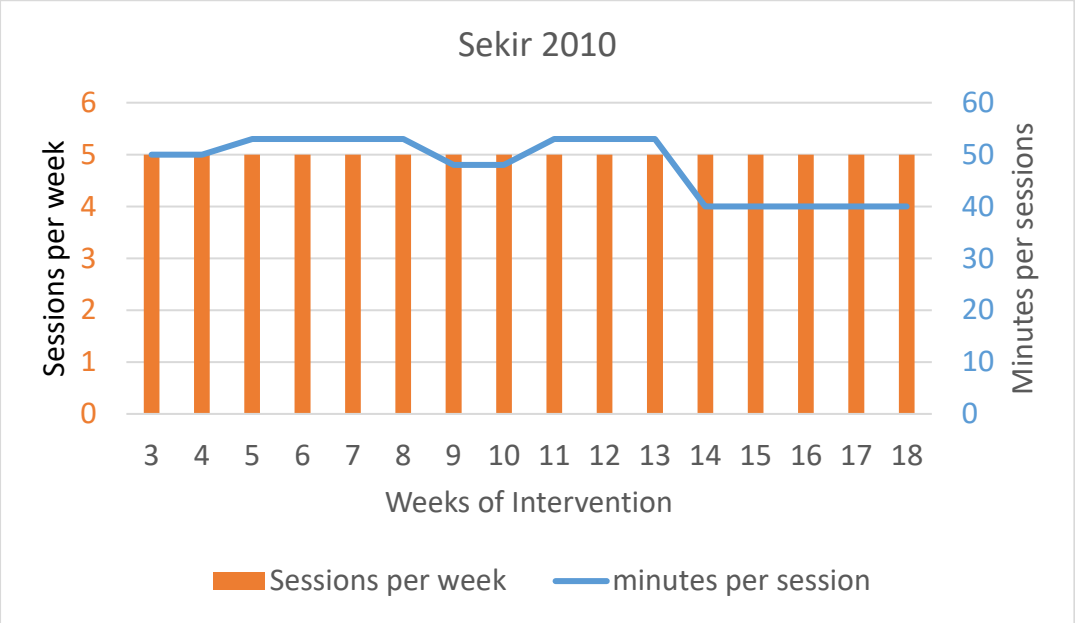

Figure 3.5. Primary outcome results; Sekir et al (2010)

Baltaci et al 2013 started the Wii fit study one week post operatively (Table 3.2). Both intervention group and control were given 3 supervised sessions per week over 12 weeks and each session was 60 minutes long (Figure 3.6) (173). The environment of the conventional rehabilitation is not clear, nor is it clear if the Wii fit sessions were at home or in clinic. They concluded that exercise performed using a Wii Fit did not lead to any significant outcome differences within the given outcome measures over a 12 week period when compared with conventional rehabilitation in this patient group. This study was limited by its small sample size and single clinical site. They also acknowledged that they were working with a highly motivated group and so their results may have depended on levels of exercise compliance which were not measured and could therefore not be repeated. The study was not powered to detect equivalence but does claim "Wii Fit Balance programme might be recommended since it is safe, feasible and cheap" (173).

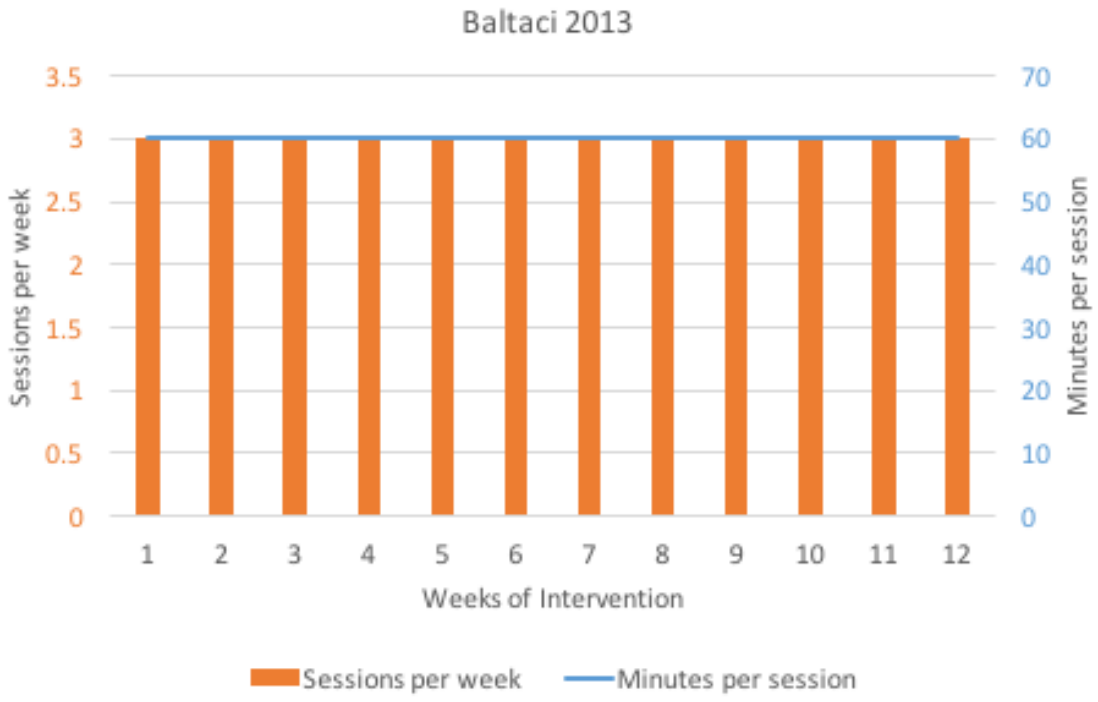

Figure 3.6. Primary outcome results; Baltaci et al (2013)

In the Bartels et al study, looking at later stage rehabilitation starting 20 weeks post operatively, the authors assessed the effectiveness of a novel intervention called SpeedCourt against conventional rehabilitation (Table 3.2) (180). The intervention took place from week 20-24 post operatively. It was delivered over 45 minute sessions, twice weekly for 4 weeks (Figure 3.7). It was delivered by skilled physiotherapists and in a gym environment and required the use of specialist equipment. There were 22 outcome parameters. The significant findings were improvement in jump height 0.02, reaction time .025 and 3/8 anthropometric measurements. This study had a small participation number and was limited by a lack of comparable studies for data analysis.

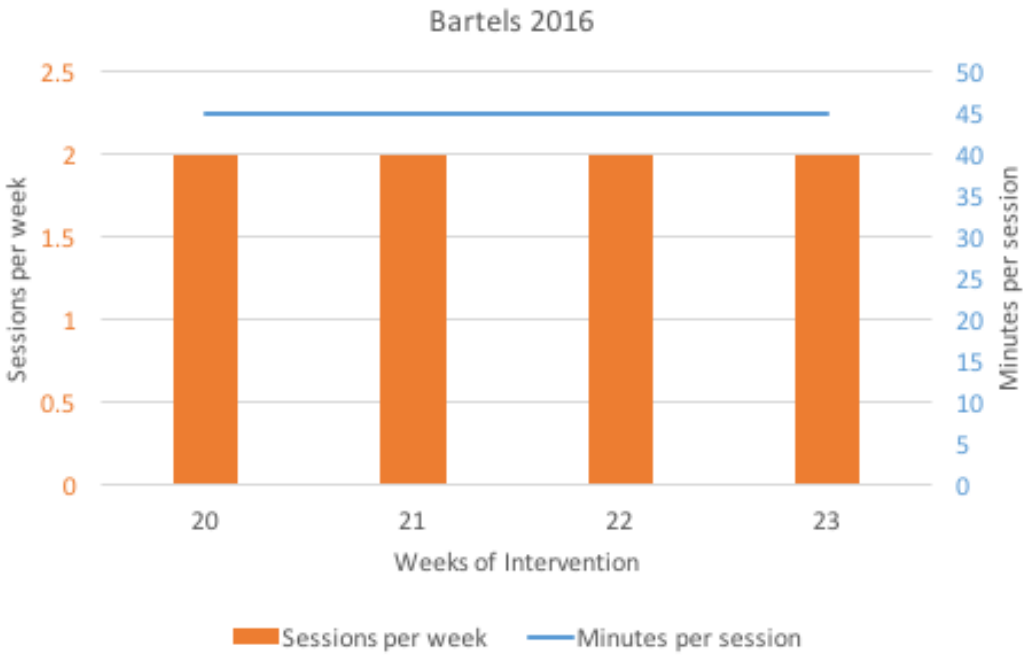

Figure 3.7. Primary outcome results; Bartels et al (2016)

Chan et al investigated 'RockTape' kinesiology tape (KT) in the first week post-operatively as part of a multimodal early phase over 6 weeks (Table 3.2) (181). Patients had 1 session per week at an average of 37.5 minutes per session in both groups (Figure 3.8)). The conventional exercise component took place in a rehabilitation facility and was delivered by 3 specialist physiotherapists. They compared pain scales, function, swelling, range of motion and the Tegner Lysolm and found that only the Visual Analogue Scale, a subjective measure of pain was statistically improved P=.0164 in the tape group. This was done in the context of a multimodal rehabilitation programme of exercise therapy, manual therapy, electrotherapy and gait retraining. The use of a sham tape may have helped to determine the effectiveness of this particular tape brand as opposed to taping in general (181).

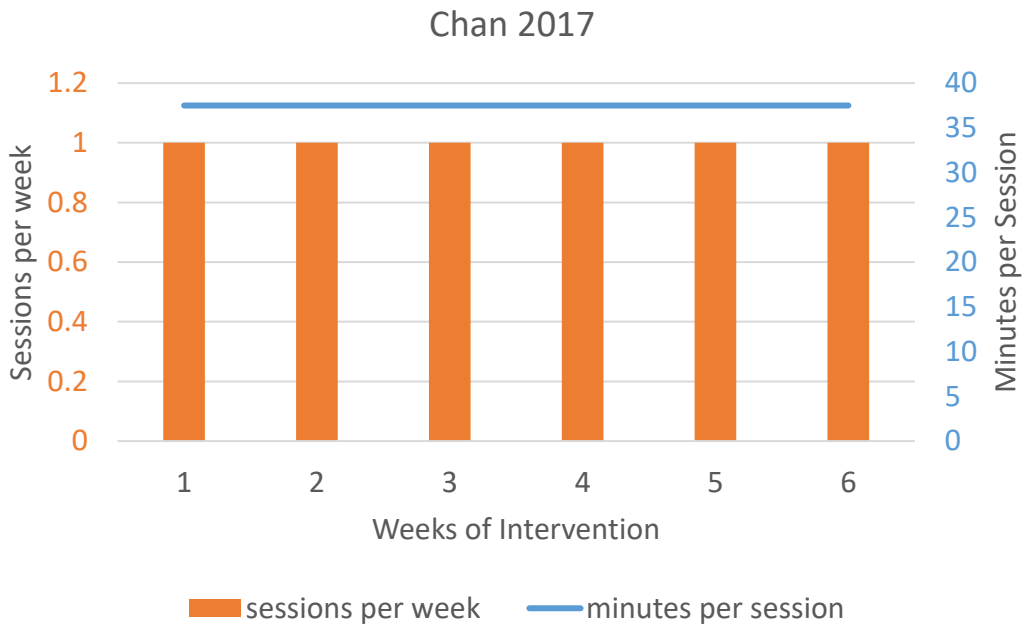

Figure 3.8. Primary outcome results; Chan et al (2017)

Cooper et al looked at the effects of training with proprioceptive and balance exercises compared with strength exercises beginning between 4 and 14 weeks (when phase criteria are met) and continuing for 6 weeks (Table 3.2) (182). The time taken to deliver the intervention and control was 50 minute sessions of rehabilitation, twice weekly over 6 weeks to compare proprioception and balance to strength training in early rehabilitation (Figure 3.9). They also recommended one hour per day of home exercise on non-physiotherapy days and asked patients to complete a compliance diary. They used the Cincinnati knee scale and found significant difference in favour of the strength group across three parameters, swelling (p=0.047), walking (p=0.04) and squatting/ kneeling (P=0.01). They also found significant improvement for the Strength Group in activity 2 (p=0.01) and 3 (p=0.01) of the Patient Rated Functional Scale (nominated activities were running, squatting, kneeling, stairs, and in and out of car). The limitations included baseline differences in the groups which may have affected statistical comparisons. This study focused on functional outcomes rather than strength outcomes therefore there was no data to correlate functional improvements with strength (182).

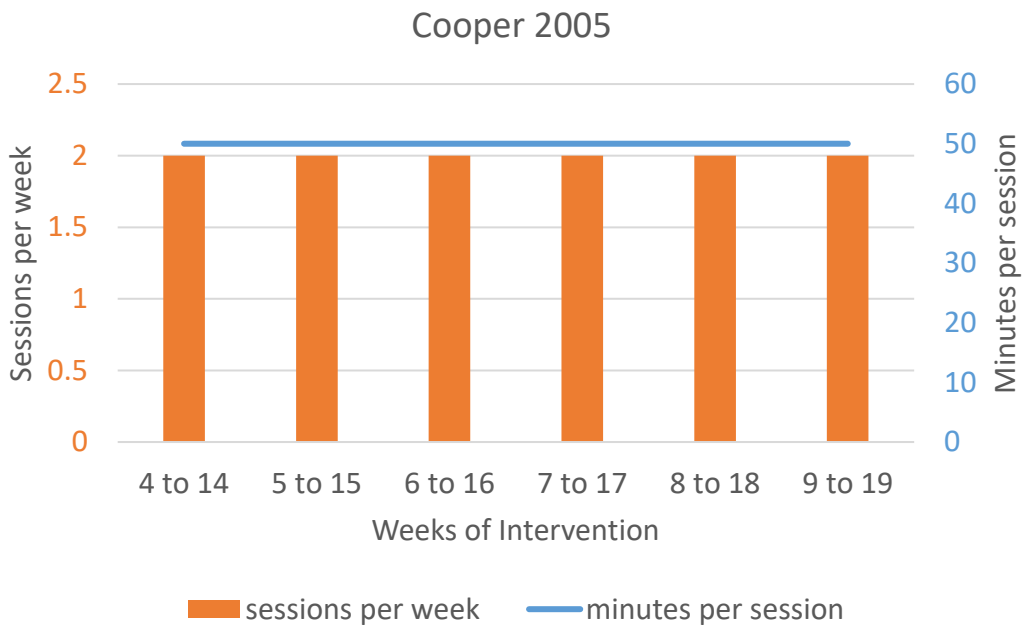

Figure 3.9. Primary outcome results; Cooper et al (2005)

Heijne et al investigated the early (4 weeks) or late (12 weeks) introduction of open kinetic chain quadriceps exercises for both hamstring graft and patella tendon graft patients (Table 3.2) (186). The analysis of time spent delivering the intervention and control showed that Heijne 2007 treated patients on an 'as needed' basis. Their data showed an average of 37.7 sessions over 30 weeks with a spread of 13-109 appointments across the population for the duration of the study. They had an average of 1.25 sessions per week. The first 12 weeks were one hour per session and after that 20-30 minutes per session (Figure 3.10). The treatment was provided by expert physiotherapists in a rehabilitation environment. It can be estimated that management of some patients went on for up to a year based on the clinical decision of need made by the physiotherapist. Heijne et al measured joint laxity with an arthometric KT100 device, they measured muscle torque, postural sway, pain, range and pivot shift (186). Results showed a significant increase of graft laxity in the hamstring graft group that started open kinetic chain exercises 4 weeks post op. P=.04 and P-.02 in two ranges of laxity. They also found a P value of .04 indicating significant rotational instability in the pivot shift test in H4 group. A limitation of these findings is that although they determine the risk associated with early OKC, it does not determine when the time to start OKC exercises is best.

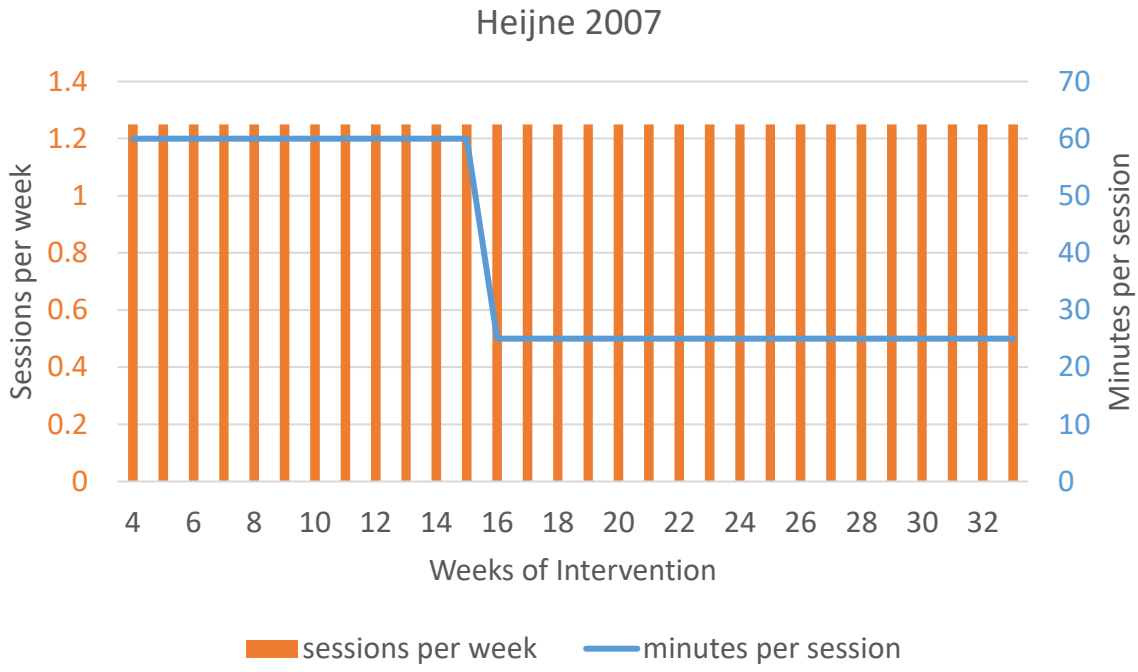

Figure 3.10. Primary outcome results; Heijne et al (2007)

Hohmann et al compared home based and supervised rehabilitation after ACL reconstruction (Table 3.2) (187). The analysis of time taken to deliver the intervention showed that rehabilitation was delivered over 36 weeks, 60 minutes per session. Once a week for 6 weeks, then every other week and then at 24 weeks this was decreased to once a month until 9 months (Figure 3.11). The number of contacts for home-supervised patients is unclear. Descriptions include use of equipment such as exercise bikes which may imply the use of a gym facility but do not otherwise state the environment of supervised rehabilitation or home rehabilitation. The skill level of the treating physiotherapist is not discussed. The prescription of amount of exercise or training load or compliance is not discussed. They used repeated measures over time to look at a collection of strength, hop, jump and patient rated outcome measurements. The only measure of significance was a noted improvement in extensor knee strength at 6 months in the supervised group P =.004. The authors acknowledge that both groups had lower strengths scores than subjects at the same level in other studies (187). The small sample size may have contributed to the difficulty in seeing differences between the two groups.

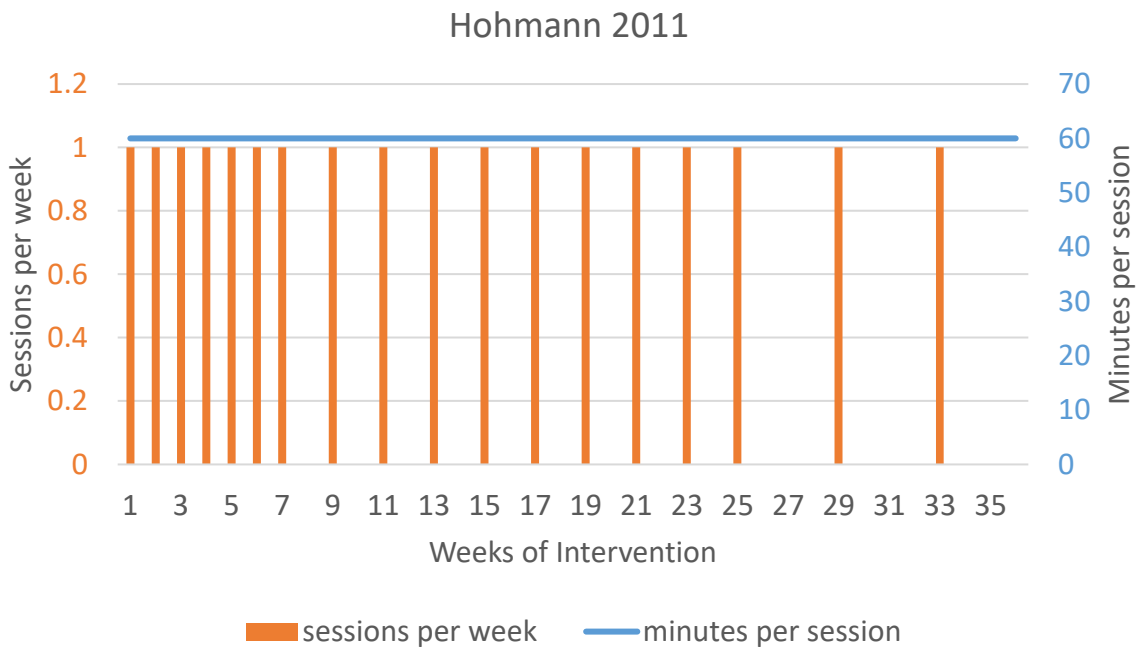

Figure 3.11. Primary outcome results; Hohmann et al (2011)

Moezy et al compared the effect of Whole Body Vibration training (WBVT) to conventional physiotherapy on postural stability measured across several parameters using a Biodex stability system (Table 3.2) (183). The analysis of time taken to deliver the intervention and control shows 3 sessions per week for 4 weeks starting in week 13 post operatively. The sessions are one hour long (Figure 3.12). This study is a brief concentrated programme looking at the effects of whole body vibration training on postural stability in mid stage rehabilitation. It was delivered by experienced physiotherapists and required specialist equipment. They found significant differences in favour of the WBVT group in all but one of the Biodex measurement. The overall improvement was given a P value of .05. "The p values of the changing scores of open overall, open anteroposterior, open mediolateral, closed overall, closed anteroposterior and closed mediolateral stability indices were 0.002, 0.010, 0.0001, 0.001, 0.0001 and 0.046, respectively" (183). They note the small sample size in their limitations but importantly a lack of follow up data due to a loss of calibration of the Biodex system.

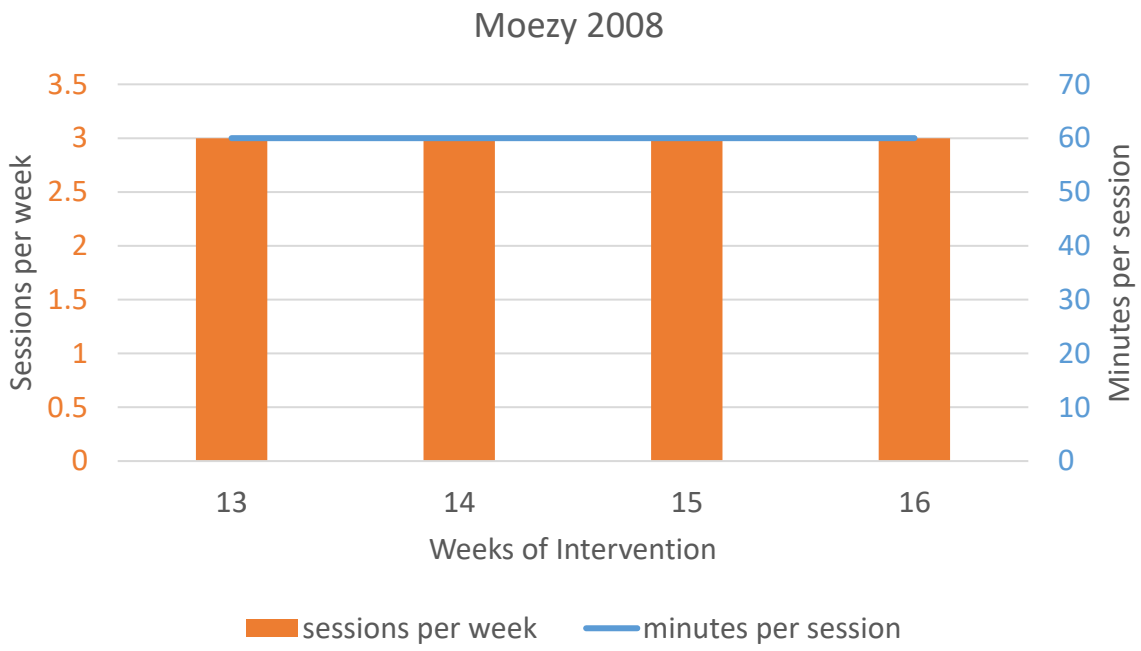

Figure 3.12. Primary outcome results; Moezy et al (2008)

Christensen et al compared the effect of an 'early aggressive' rehabilitation strategy on outcomes after ACL reconstruction (Table 3.2) (175). The analysis of time spent delivering the intervention and control showed that Christensen et al treated patients for 75 minutes per session on average in both groups. They had a gradually reducing level of supervision over weeks, which is reflected in the graph spikes where (blue line) minutes per session are at 0 on the weeks where there was no rehabilitation session (orange bar). They saw patients weekly for 2 weeks, then after a fortnight and then monthly over a period of 6 months (Figure 3.13). The programme is delivered in a gym by specialist physiotherapists. The authors found no significant differences in range, laxity, peak isometric force or IKDC which guides clinicians in the safe application of this strategy for rehabilitation services. However they did not demonstrate a clear benefit. They acknowledge their data were only to 24 weeks so long term implications are unknown (175).

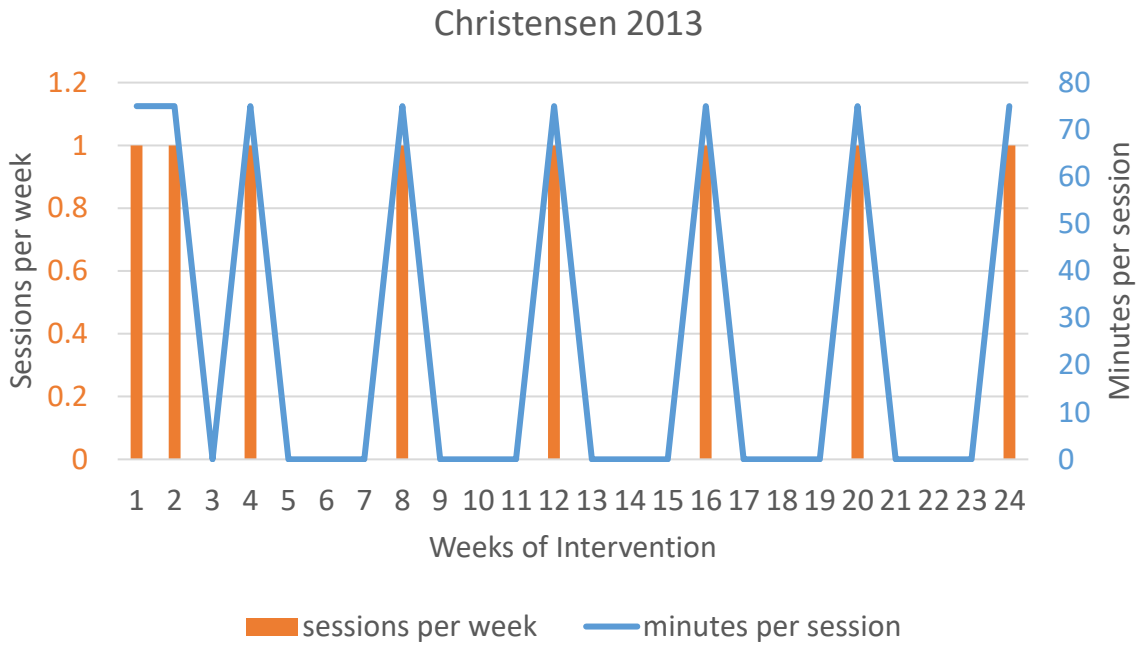

Figure 3.13. Primary outcome results; Christensen et al (2013)

Moller et al were investigating the effectiveness of post-operative bracing with traditional rehabilitation versus not bracing with traditional rehabilitation (Table 3.2) (174). They saw their patients twice weekly for 2 weeks and then 3 x weekly for a further 26 weeks (Figure 3.14). All sessions were approximately 45 minutes in length and happened in a gym based rehabilitation environment with specialist equipment. They measured laxity, peak forces, hopping, and range of motion, VAS pain scale and Lysolm Tegner and found no significant differences between subjects who had been braced as well as part of a post-operative rehabilitation programme and those who had not been braced. Trends toward less swelling in the non-braced group at 2 weeks and increased activity levels in the non-braced group at 6 months were also observed which may indicate faster rehabilitation in non-braced subjects (174).

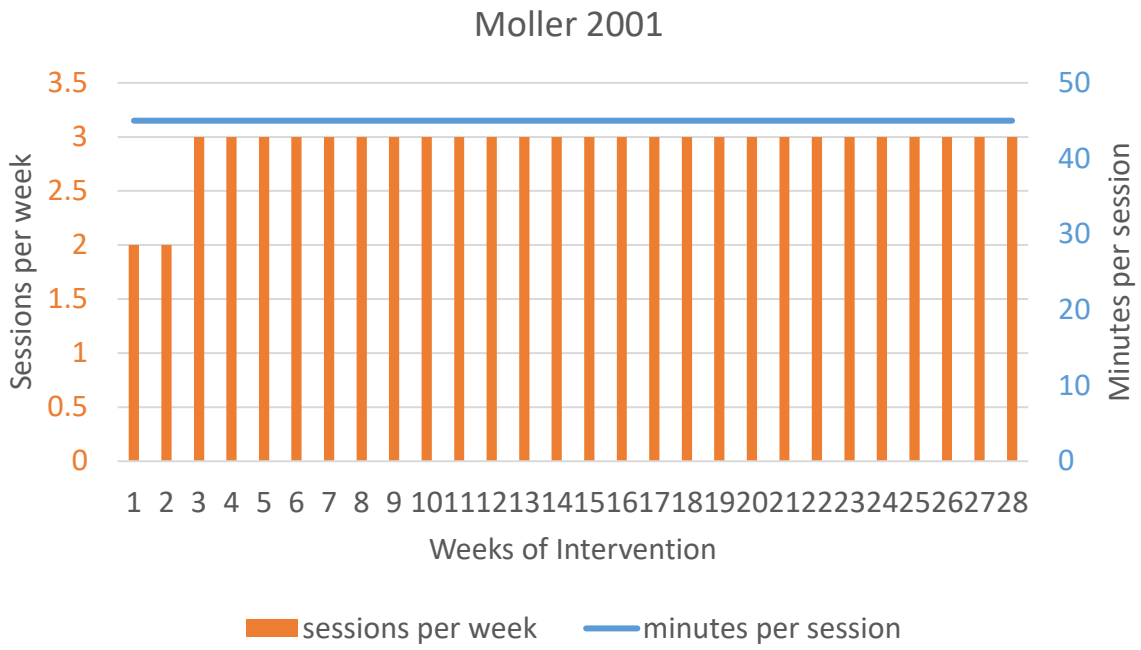

Figure 3.14. Primary outcome results; Moller et al (2001)

Timm compared traditional rehabilitation to traditional rehabilitation with a novel Protonics exercise system (Table 3.2) (152). The secondary analysis of time spent delivering the intervention and control arms of the study showed that Timm used 60 minute sessions 3 times per week to rehabilitate over 24 weeks for the control and 20 weeks for the intervention group in order to pass the criteria for return to sport (Figure 3.15). The rehabilitation used specialist equipment in a gym environment. He used a criterion based progression system and found that the Protonics plus traditional rehabilitation group completed rehabilitation faster than the traditional group. Rehabilitation outcomes were not reported. They used time and cost as outcomes and found that both were significantly .001 in favour of the Protonics group (152).

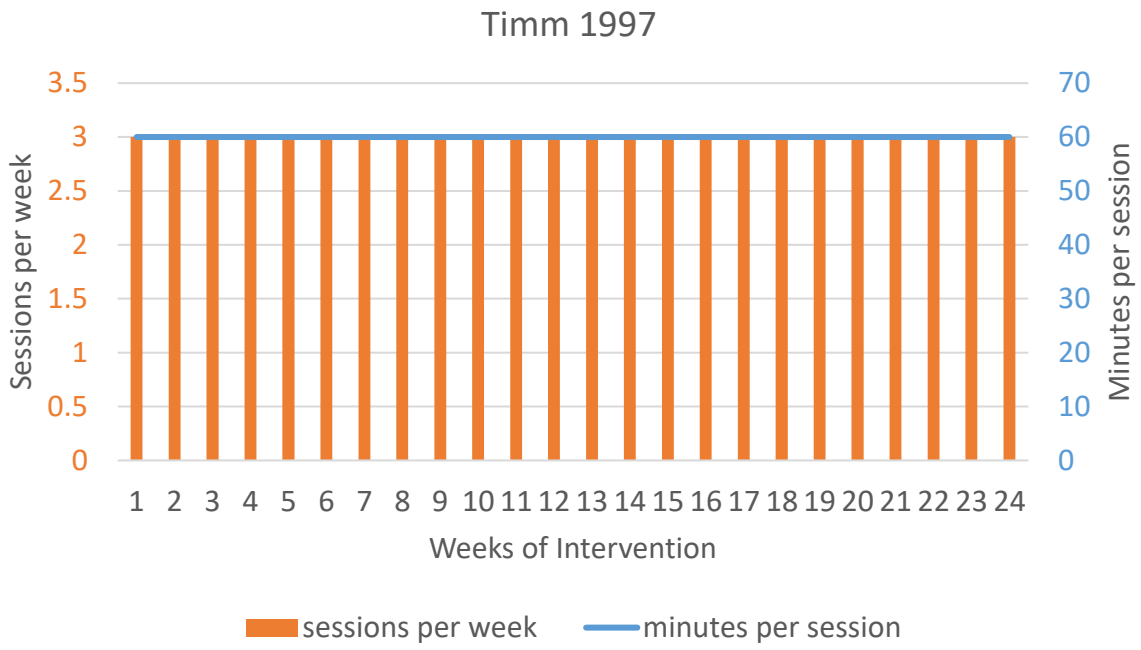

Figure 3.15. Primary outcome results; Timm (1997)

Pistone et al looked at the effects of 4 weeks of early WBVT when added to a traditional programme of rehabilitation against traditional rehabilitation alone (Table 3.2) (184). The analysis of consultation time to deliver the intervention showed 5 sessions per week from week 4 to week 16 in both groups in order to deliver the intervention programme. Sessions averaged 90 minutes in the control group with the intervention group having the same and an additional average of 10 minutes for 4 of the sessions (Figure 3.16.). This rehabilitation programme also required specialist equipment and gym environment to deliver. They found a significant improvement in maximal voluntary isometric flexion (.05), balance eyes open and eyes closed (.001 and .005) and Lysolm score (.001). Their study was limited by small sample size, lack of placebo intervention, a need for longer follow up (184).

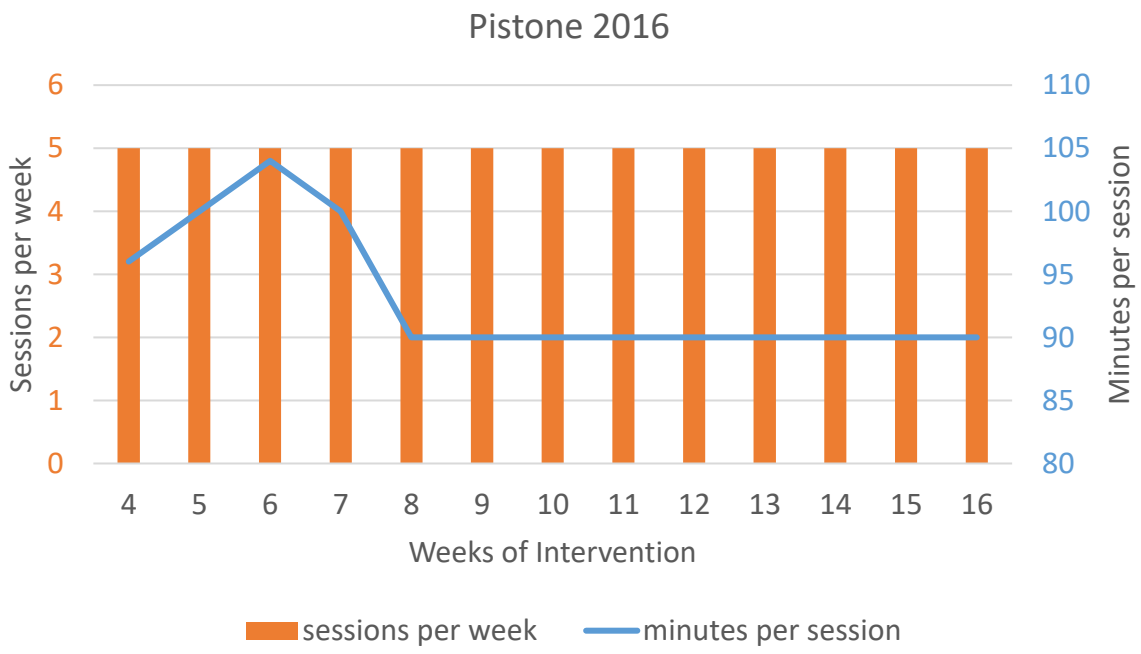

Figure 3.16. Primary outcome results; Pistone et al (2016)

Ross et al described an early intervention of the effects of neuromuscular electrical stimulation during closed kinetic chain exercises as compared with just closed kinetic chain exercises (Table 3.2) (185). The results of the analysis of time taken to deliver the intervention showed that this study took place over 5 weeks immediately post operatively. The intervention was delivered over 5 days per week for 3 weeks and then 3 days per week for 2 weeks. Each session was 30 minutes in length (Figure 3.17). The outcomes for unilateral squat and lateral step up were significantly improved in the intervention group with a P value of .05 for both (185).

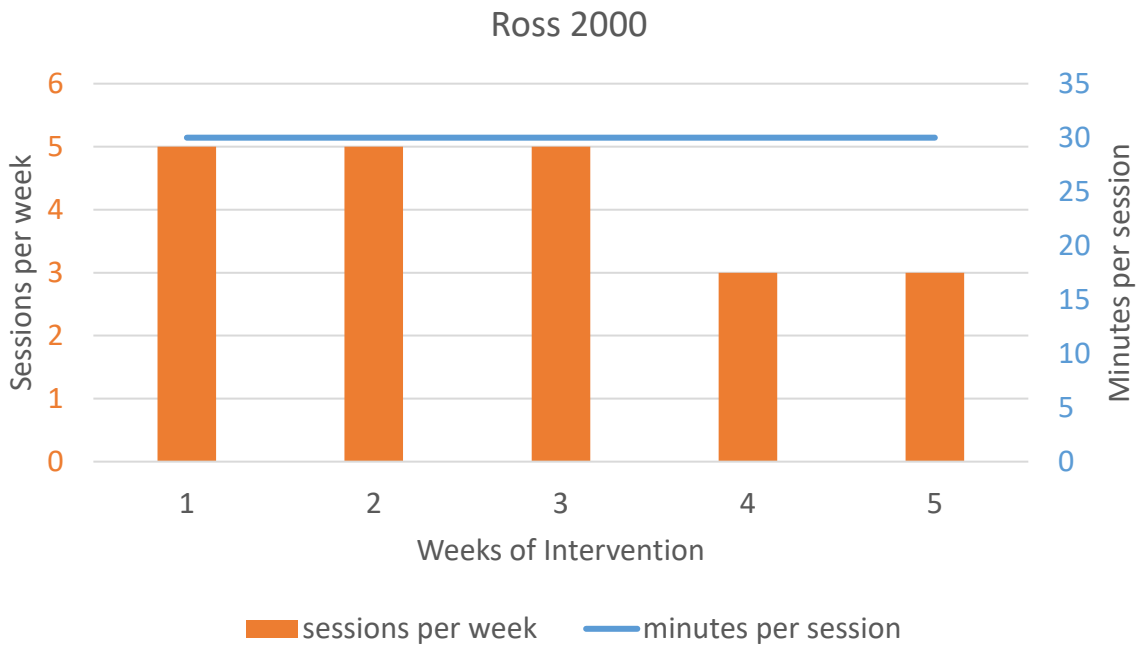

Figure 3.17. Primary outcome results; Ross et al (2000)

3.5.2 Synthesis of results - Resources described

3.5.2.1 Number of sessions per week

The median number of sessions per week was 3, with a range of 1-5 sessions (IQR 1.25 to 3). The first 6 weeks post-operatively showed the highest number of patient contacts (Table 3.3). Where the number of sessions varied within studies (i.e. individual patient attendance varied), a mean number of sessions per week was calculated. Studies that ran over a longer period showed a drop off in the number of contacts where weekly physiotherapy reduced to fortnightly and then to monthly. A comparison of the total sessions per complete rehabilitation was not possible due to the varying scope of the included studies.

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Baltaci 2013	3	3	3	3	3	3	3	3	3	3	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Bartels 2016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Chan 2017	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Christensen 2013	1	1	0	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cooper 2005	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heijne 2007	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	0	0	0	0	0	0	0
Hohmann 2011	1	1	1	1	1	1	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	0	0	1	0	0	0	1	0	0	0
Kinikli 2014	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Moezy 2008	0	0	0	0	0	0	0	0	0	0	0	0	3	3	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Moller 2001	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0	0	0	0	0	0	0	0
Pistone 2016	0	0	0	5	5	5	5	5	5	5	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ross 2000	5	5	5	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sekir 2010	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Timm 1997	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0	0	0	0	0	0	0	0	0	0	0	0

Table 3.3. Results of individual studies - Number of sessions per week. Number in each cell represents the number of sessions that week. (Deeper shade of green associated with more session's per week).

3.5.2.2 Number of weeks of intervention

The length of Intervention ranged from 3 weeks to 36 weeks (Table 3.2) as some studies were of complete rehabilitation programmes (152, 174, 175, 186, 187) whereas others were focused in a phase of rehabilitation (173, 178-185). In only one study were individuals still receiving treatment beyond 29 weeks (187).

3.5.2.3 Number of minutes per session

Table 3.4 shows the number of minutes per session over weeks. It varies between 25 and 104 minutes with a median length of 60 minutes (IQR 45:75). Most studies maintained a standard number of minutes throughout the intervention (173-175, 180, 182, 183, 185, 187, 188). Two studies reduced minutes per session over time (186) (179) and two notably gave more time to their intervention group which has implications related to increased use of clinical time (179, 184).

Minutes p/session																																				
Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Baltaci 2013	60	60	60	60	60	60	60	60	60	60	60	60	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Bartels 2016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	45	45	45	45	0	0	0	0	0	0	0	0	0	0	0	0	0
Chan 2017	37.5	37.5	37.5	37.5	37.5	37.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Christensen 2013	75	75	0	75	0	0	0	75	0	0	0	75	0	0	0	75	0	0	0	75	0	0	0	75	0	0	0	0	0	0	0	0	0	0	0	0
Cooper 2005	50	50	50	50	50	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heijne 2007	60	60	60	60	60	60	60	60	60	60	60	60	25	25	25	25	25	25	25	25	25	25	25	25	0	0	0	0	0	0	0	0	0	0	0	0
Hohmann 2011	60	60	60	60	60	60	60	0	60	0	60	0	60	0	60	0	60	0	60	0	60	0	60	0	60	0	0	0	60	0	0	0	60	0	0	0
Kinikli 2014	20	20	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Moezy 2008	0	0	0	0	0	0	0	0	0	0	0	0	60	60	60	60	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Moller 2001	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	0	0	0	0	0	0	0	0
Pistone 2016	0	0	0	96	100	104	100	90	90	90	90	90	90	90	90	90	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ross 2000	30	30	30	30	30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sekir 2010	50	50	53	53	53	53	48	48	53	53	53	40	40	40	40	40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Timm 1997	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	0	0	0	0	0	0	0	0	0	0	0	0

Table 3.4. Results of individual studies – Number of minutes per session over weeks. Number in each cell represents the number of minutes per sessions that week (Deeper shade of blue associated with longer sessions)

3.5.2.4 The use of specialist equipment and environment

Table 3.5 shows that 13 of 14 included studies described the use of specialist equipment for strength exercise as part of standard care. Eight studies used resistance machines such as leg press, leg extensions or leg curls and 10 studies used free weights to add load. Three studies also mentioned Theraband and resistance bands for strengthening while one study used a Slashpipe, for strength and control. Cardiovascular exercise equipment was also standard in 12 of 14 studies. Exercise Bicycles were most common (11/14) with steppers, Nordic tracks and treadmills also mentioned.

Neuromuscular control exercise equipment, for balance, proprioception, agility and plyometrics, was mentioned in 11 out of 14 studies. Trampolines, foam mats, Bosu balls, gym balls, wobble boards, tilt boards are mentioned, while other studies affirm neuromuscular exercises but do not provide details. One study mentioned use of tape, 5 used neuromuscular electrical stimulation, and 4 used continuous passive movement (CPM). 4 studies included swimming pool exercises.

Author, Year, Country, Citation	Clinician Type	Strength: Resistance Machines	Cardio	Neuromuscular Control	Other
Baltaci, 2013, Turkey	Physical therapists	Resistance Machine Knee Exercises	Bicycle	Balance boards	
Bartels, 2016, Germany	Surgeons only mentioned	Slashpipe	Stepper	Posturomed, Gym ball, BOSU, Foam Mat, Wobble Board	
Chan, 2017, Singapore	Sports physiotherapists with advanced qualifications	Strength no detail	Cardio No detail	Neuromuscular Control' no detail	Neuromuscular Electrical Stimulation
Christensen, 2013, USA	Experienced physiotherapists	Free Weights	Bicycle	Neuromuscular Control and plyometric, staged. assorted (unclear)	Pool Continuous Passive Movement
Cooper, 2005, Australia	Experienced physiotherapists	Free Weights, Theraband, Resistance Band	Bicycle	Wobble boards, mini-trampolines, air cushions, gym balls, Step	
Heijne, 2007, Sweden	Experienced physiotherapists	Leg Press, Leg Curl, Free Weights	Bicycle, Stair Machine, Treadmill	Step, trampoline, slide board, balance boards	
Hohmann, 2011, Australia	Not specified	Free Weights	Bicycle that Measures Watts		Pool
Kinikli, 2014, Turkey	Experienced Physiotherapist	Leg Press, Free Weights, Theraband, Resistance Band	Bicycle	Balance boards, cushions, Step, Ball	
Moezy, 2008, Iran	Not specified	Leg Press, Leg Curl, Free Weights		Tilt Board	
Moller, 2001, Sweden	Surgeons only mentioned	Leg press, Leg Extension, Free Weights	Bicycle	Proprioceptive training (unclear), plyometric (unclear) step	
Pistone, 2016, Italy	Experienced physiotherapists	Leg Press, Leg Curl, Leg Extension, Free Weights	Bicycle	Step, trampoline, 'balance and proprioception' details unclear	Pool, Neuromuscular Electrical Stimulation, Continuous Passive Movement

Ross, 2000, USA	Not specified	Free Weights	Bicycle, Treadmill, stairclimber		
Sekir, 2010, Turkey	Experienced physiotherapists & Athletic Trainer	Leg Press	Bicycle, Stair machine, Treadmill	Foam Mat, Wobble Board, Step, Cones	Neuromuscular Electrical Stimulation, Continuous Passive Movement
Timm, 1997, USA	Experienced physiotherapist	Leg Press, Free Weights	Bicycle, Stair Master, Nordic Track	Proprioception (unclear), step	Pool

Table 3.5. Results of individual studies – Resources used in descriptions of standard care in either intervention or comparator arms of included studies.

3.5.2.5 Physiotherapist skill level

Table 3.5 shows 8 out of 14 studies specified that care was delivered by 'experienced physiotherapists', 2 studies only mentioned orthopaedic experience and 3 did not specify. One study also used an athletic trainer alongside the physiotherapist (179). The term 'experienced' is subjective and no study defined what they meant by experienced. Some research delineates between novice and experienced clinicians but in practice, experience may be qualified in many ways (189).

3.5.3 Critical appraisal of the included studies

The Cochrane Collaboration Tool was used as a tool of critical appraisal for the included studies because the included studies were RCTs (166). It was not used as a tool of meta-analysis which would be irrelevant here but as a tool of critical appraisal of study quality. The results are displayed in Figure 3.18.

Author, Year	Random Sequence Generation: Selection Bias	Allocation Concealment	Blinding participants and personnel: Performance Bias	Blinding of outcome assessment: Detection Bias	Incomplete outcome data: Attrition Bias	Selective reporting: Reporting Bias	Other Bias
Baltaci, 2013	☺	?	?	?	?	☺	?
Bartels, 2016	☹	?	?	?	☹	☺	☹
Chan, 2017	☺	☹	?	☹	☹	☺	-
Christensen, 2013	☺	☹	☹	☹	☺	☺	?
Cooper, 2005	☺	☺	?	☺	☺	☺	?
Heijne, 2007	☹	?	?	☺	☹	☺	-
Hohmann, 2011	☺	☺	☹	☺	☹	☺	?
Kinikli, 2014	☺	☹	☹	☹	☹	☺	-
Moezy, 2008	?	?	?	?	☹	☺	?
Moller, 2001	?	?	☹	?	☹	☺	-
Pistone, 2016	?	?	?	?	☺	☺	-
Ross, 2000	?	☹	?	?	?	☺	?
Sekir, 2010	☹	☹	☹	?	☹	☺	☹
Timm, 1997	?	?	☹	?	?	☺	☹

Figure 3.18. Risk of Bias – Results of individual studies

Low Risk	High Risk	Unclear Risk	N/A
☺	☹	?	-

3.5.3.1 Synthesis of risk of bias as a tool of critical appraisal of RCTs

3.5.3.1.1 Random Sequence Generation: Selection Bias

The Consort statement 2010 stated that, "participants should be assigned to comparison groups in the trial on the basis of a chance (random) process characterised by unpredictability" (154) In this review 8/14 studies either were categorised as either unclear or high risk of bias when it came to random sequence generation. Studies often described processes involving opaque envelopes being selected by team members but without enough measures taken to assure the 'random sequence generation' was robust. This method is easily corrupted either intentionally or unintentionally by clinicians or researchers. Older studies such as Timm 1997 that did not have the benefit of reporting guidelines do not report bias controls and are therefore subject to unclear or high risk of bias throughout.

3.5.3.1.2 Allocation Concealment: Selection Bias

Further to this many studies increased the risk of bias through methods of allocation concealment. Ten out of fourteen fell short of the standard, where for example, a study investigator selected envelopes to distribute to patients (181). Further, it was often unclear at which point allocation took place so we could not know if participants were aware of the group they were in before the baseline measures were taken, this may introduce bias from either clinician or participant (154). There is an acceptable standard of using opaque envelopes that ensures unpredictability of allocation and limits

potential participant bias but it was not compiled in the CONSORT statement until 2010 which may account for some older studies falling short in reporting their methods (154). Cooper et al and Hohmann et al were close to the standard for both categories and therefore categorised as low risk on both counts of selection bias (allocation concealment and random sequence generation).

3.5.3.1.3 Blinding: Performance bias and Detection bias

Blinding of participants and personnel is fundamental to reducing risk of performance bias and detection bias. "Participants may respond differently if they are aware of their treatment assignment" or it "may also influence compliance with the intervention, use of co-interventions, and risk of dropping out of the trial" (154). In this review no study satisfactorily explained the blinding process from a participant and a personnel point of view. Seven studies had a high risk and seven were unclear in their explanations. Blinding of outcomes was particularly important given that many of these studies have subjectively reported outcome measures which could be influenced where personnel and participants are not blind. It has been highlighted as a limitation of these studies that they often did not have a primary outcome but more often a battery of outcomes. This however is in keeping with the COMET initiative that identified a cluster of outcomes that are important for defining success in rehabilitation in ACL rehabilitation rather than just one measure. These are guided by World Health Organisation standards and they are: effusion, giving way, muscle strength (body structure and function), PRO (activity and participation) and return to sport (participation) (148, 190) (191). In surgical and rehabilitation studies it is often difficult to blind patients and personnel and it is of limited value to subject them to the same risk of bias criticism. In this review despite having a risk of performance bias, 7 studies reported, in line with the guidelines, their inability to blind as an open bias. In this instance and given the nature of the studies, though the categorical risk is high, we deemed not to emphasise performance bias as a key domain of bias in this review. Blinding the outcomes assessor (detection bias), which could have mitigated the influence of performance bias if well managed, was unfortunately also high risk or unclear in all but 3 studies. This has significant implications for the handling of outcome data.

3.5.3.1.4 Attrition Bias

Commonly RCTs are faced with incomplete data, where participants in a study are either lost to follow up or noncompliant. This gives rise to attrition bias. There are several methods of limiting the risk of this and of dealing with incomplete data if it arises (192, 193). We placed a high importance on Attrition Bias in this review which occurs when there is no acknowledgment or explanation of data that is missing and when the missing data is not accounted for statistically. For example, in Christensen et al, they identified the missing data and hypothesised the reason for this attrition and then used a

multiple imputation statistical method to account for this to limit the effect on their results. Moller and Moezy both acknowledged and explained their drop-out rates and discussed the implications as a limitation but they did not discuss making any statistical corrections such as an Intention to Treat analysis, sensitivity analysis or imputations (192-194). In 8 out of 14 studies there was a high risk where dropouts were reported but not accounted for statistically with a further 3 studies giving unclear reporting of dropout. There was little or no assessment of the characteristics of the missing data or the implications based on the sample sizes. This failure introduces a high risk of attrition bias that given the generally smaller sample sizes may have a significant effect on results.

3.5.3.1.5 Reporting Bias

We can determine that there is a low risk in the Reporting Bias category which indicates that all studies reported complete outcomes whether or not the results were significant. In some studies however a confounding level of reporting may cause the reader to interpret the results incorrectly, for example outcomes related to improvement over time or improvement relative to the non-operated limb were reported as significant at several time points. This wealth of data is largely irrelevant to the investigation of the effectiveness of the intervention on the operated legs of a test group and a control group but P values and significance are none the less reported.

3.6 **Discussion**

3.6.1 Summary of main results

The aim of this review was to provide an analysis of the resources used to deliver effective physiotherapy rehabilitation as reported in RCTs. Fourteen RCTs of ACL rehabilitation that included or made available a description of the resources of the intervention were included. Overall, reporting of exercise interventions or resources used was scanty. This makes it hard for other researchers to replicate findings or for health care professionals to implement them. The key findings of this review are that ACL rehabilitation in RCTs is most often delivered by an experienced physiotherapist, requires access to a gym and use of specialist equipment, including resistance machines, free weight and neuromuscular control equipment. This physiotherapy equipment is not routinely found in homes and suggests the need for gym access in the clinical environment or community; that includes guidance with specialist rehabilitation equipment. Clinical audits of evidence based ACL rehabilitation services should include an analysis of availability of these resources based on the findings of this review.

It was also clear that substantial therapist time was required for many interventions. The median time per contact was 60 minutes with a median number of 3 sessions per week. Some studies that lasted for longer periods showing a progressive reduction in the number of contacts, perhaps reflecting a

greater emphasis on patient independence as the RCT treatment progressed in keeping with principles of supported self-management (195).

The synthesis of resource use also highlighted that the majority of studies associated with 3 or more rehabilitation sessions per week were also the studies investigating use of high-cost, specialised equipment such as the whole body vibration training (WBVT), isokinetic machines, NMES, Protonics and Nintendo Wii (152, 173, 174, 178-180, 183-185). These studies notably consumed higher levels of resource compared with studies reporting 2 or fewer appointments per week, which investigated exercise interventions or tape and may be considered more low cost interventions (175, 180-182, 186, 187).

The implications of this study for designing future ACL rehabilitation research are that where complex interactions of exercise and other modalities are tested, reporting of resources as part of scientific method would be beneficial. This could aid health managers to make decisions that weigh resource use and effectiveness.

3.6.1.1 Within the context of existing literature

Previous systematic reviews have looked at the effectiveness of interventions such as open and closed chain exercises on strength (34, 89, 90), the relationship of strength and neuromuscular control exercises on function (34, 90), the effectiveness of neuromuscular electrical stimulation in the early post-operative phase (34, 90, 93), bracing post operatively and CPM (88, 89, 92) and comparing supervised rehabilitation compared and unsupervised rehabilitation (34, 90, 93). This review has identified a similar group of studies while also capturing more novel approaches to rehabilitation including the Wii fit, WBVT, Protonics and Speedcourt systems which represented investigations of technological innovations for use in rehabilitation (152, 173, 180, 183).

This scoping review adds to the available literature on ACL rehabilitation. It contributes new findings that key factors such as physiotherapist time, skill level and resources should be reported clearly in RCTs in order to facilitate cost planning and reproducibility of findings. We also contribute the new findings that specialist equipment and the oversight of an experienced physiotherapist are commonly used in RCTs to contribute to effective ACL rehabilitation.

3.6.1.2 Strengths and Limitations

This review was conducted rigorously following Cochrane guidance. The PRISMA-ScR checklist is included to demonstrate exhaustive reporting of process. Our searches identified a similar body of work to previous reviews in this area, providing reassurance that they were adequately sensitive, and

no key studies were missed. The narrative synthesis was appropriately applied to explore factors beyond effectiveness and highlight the resources characteristics of some RCTs that show effective rehabilitation have higher resource use implications than others. However, of the 49 studies meeting the inclusion criteria, only 14 could be included in the review due to incomplete reporting of the intervention in line with TIDier principles (147). It was unfortunate that more authors of primary studies did not respond to our request for further information. Limiting our inclusion criteria to randomised controlled trials may have excluded some studies that provided more information about the intervention content.

3.6.2 Implications

3.6.2.1 Implication for clinical practice and policy

Implications for clinical practice include the knowledge that ACL rehabilitation RCTs describe rehabilitation that requires a gym environment with specialist rehabilitation equipment and oversight of an experienced physiotherapist, however 'experience' cannot be defined from these studies. Clinical audits should include a review of these factors to establish ability to implement the research. Services that are unable to provide this should consider advising patients on how to access these resources elsewhere. Although no conclusions can be drawn about therapist time as a resource, the average of 3 supervised sessions per week seems high and carries a cost burden.

3.6.2.2 Implications for research

Implications for future studies include the need for a more detailed report of the resources used in clinic. Reporting of these details would help healthcare decision makers to effectively manage resources when delivering evidence based care.

3.6.3 Reflections of methodological learning.

3.6.3.1 When is a systematic review not a systematic review?

In this chapter, I set out to conduct a systematic review to look at the resources that were associated with delivering physiotherapy in RCTs. I was very keen to do a systematic review and I considered it an automatic first step in the PhD process so I did not ask myself at that time if another type of review could be more appropriate. As with all my PhD colleagues, I was starting with a systematic review and that was that. I understood from the PRISMA guidance that, "A systematic review is a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research" (196). This first part of the systematic review definition made absolute sense to me and this is still a good description of the process I followed.

The second part of that PRISMA description was "to collect and analyse data from the studies that are included in the review (196)." I interpreted 'data from the studies' to include the descriptive characteristic of the intervention and control groups in the RCTs and this is where I went wrong. 'Data from the studies' must be interpreted as results of the included studies. It is the analysis and synthesis of the results of included studies that is a fundamental characteristic of systematic reviews. The characteristics of the included studies, though very interesting, were not the appropriate data for synthesising in a review of this kind. I understand that now but at the time I was aware of a wide scope of systematic review types and I thought that mine, though less conventional in its objective, was legitimate. One example of a review type that I thought was similar in methodology to mine, was a framework analysis systematic review used by Oliver et al (197) and described by Hough et al in their summary of types of systematic reviews (198). They too looked at the characteristics of their included studies and created a narrative synthesis of this. However they analysed social policy documents and not clinical trials so the concept of 'results' once again varied from the data I was trying to analyse.

So, despite a thoroughly systematic approach and feedback that the paper was well written, it was rejected for publication, twice! I had fulfilled every criteria of the PRISMA guideline other than those pertaining to statistical analysis. There was no opportunity to discuss and the feedback was that the failing was a methodological one. This was the first paper of my PhD and its failure was demoralising. However, where the first rejection was difficult to interpret, feedback from the second reviewer was clear and what finally put me on the right track. They suggested that I had in fact, conducted a scoping review and that I should redraft my work to say so.

I began to explore scoping review methodology and discovered that the feedback was correct. Peters et al explained that scoping reviews are commonly used "…to clarify working definitions and conceptual boundaries of a topic or field". This was exactly what I had been trying to do; to clarify what was constituted by usual care and to identify its' boundaries, all be they very broad. This fit tightly with the purpose of my PhD which was to identify the scope of usual care and explore the role of digital health alongside this care.

Scoping reviews were further described as a tool to explore the extent, range or characteristics of a body of research (156, 157). In this case the characteristics that were explored were the resources associated with delivering the intervention and control arms of the study. The scoping review guidelines outlined by PRISMA (155) were closely aligned to those of the systematic review in its overview, in that it is a type of knowledge synthesis conducted systematically (155). However a scoping review does not contain a meta-analysis or risk of bias analysis. Somewhat unusually for

scoping reviews, I have included the ROB in this chapter where it doubles as a quality assessment tool. The Cochrane risk of bias is amongst the most details tools of quality assessment and I had already done this work, so I decided to include it.

Based on the realisation that I had produced a systematically constructed scoping review, I edited the chapter to reflect this. The learning process was humbling. In my defence, Munn et al recently argued that the diachronic nature of the evolution of systematic reviews continues to cause problems for even experienced researchers who are seeking, as I was, to synthesize evidence (199) In my case my wish to conduct a systematic review blinded me from the first stage of the review process that I should have conducted; which type of review methodology is appropriate for my research question?

Chapter 4 - Toward criteria for optimal management of Anterior Cruciate Ligament rehabilitation programmes. A qualitative study of key stakeholders' opinion.

4.1 Chapter Outline

This chapter presents the findings from a of a semi-structured interview study that was conducted with Physiotherapists and Orthopaedic surgeons who work with ACL reconstruction patients. The purpose of the study was to gather expert perspectives on the management of Anterior Cruciate Ligament rehabilitation in order to explore current practice, variations in care and optimal management strategies in the UK.

In Chapter 2, I discussed the ACL evidence base and the fundamental arguments for rehabilitation after anterior cruciate ligament reconstruction. This knowledge, and the synthesis of debate on key topics in the ACL rehabilitation field, provides the context in which these semi-structured interviews took place. In this phase of research I wanted to explore the real world experiences of delivering care to this patient group. In Chapter 3, the scoping review also explored the resources associated with delivering anterior cruciate ligament rehabilitation. Characteristics of usual care were mined from RCTs and the analysis showed that specialist equipment, space and 'experienced' physiotherapists were needed to deliver ACL rehabilitation. This knowledge further informed the interviews and I asked participants to specifically discuss their resources so that I could explore the relationship between trial standards and real world care.

One aim of this PhD was to identify operational standards in ACL care in order to inform the feasibility of a digital tool to support delivery of this care. This qualitative study provided the opportunity to explore the context of standard care and to investigate participants' experiences of technology in care, and the barriers to and facilitators of use of digital tools in routine clinical care. The inclusion of a qualitative study within the wider PhD constitutes the mixed method approach and lends depth and substance to the findings of the feasibility study. Finally, my own experience as a physiotherapist working with anterior cruciate ligament patients and as a researcher in this field informed the design of this study. I had experienced vastly different approaches to managing these patients across several roles that I held. This had piqued my interest in the variety of care that was available for this condition. Most notably, the availability of expertise, equipment and resources presented a number of

challenges. Further there were polarising opinions on where the care pathway ended and whether physiotherapists saw return to sport rehabilitation as part of their role. I wanted to understand what was driving this phenomenon and what my colleagues' experiences and opinions were.

4.2 **Background**

As described in Chapter 2, there are conflicts in the ACL evidence base that may lead to a variety of management strategies for this patient group. It is also clear from the scoping review of the evidence, discussed in Chapter 3, that specialist equipment, skilled staff and a gym space are most often used in research conditions to deliver effective ACL rehabilitation. It is not known if these resources are readily available and used in the NHS or what current models of care look like across the UK. The National Ligament registry collects details on the types of surgery and patient rated outcomes, which is hugely important; however, the models of rehabilitation care or the resources associated with delivering care are not recorded (53).

Kapoor 2004, concluded that there was a 'wide variation' in how ACL patients are managed in the UK (200). Beard et al stated that evidence suggests a 'highly varied' approach to managing ACL injury in the NHS (201). Others have discussed variation in decision making, timing and graft choice as factors affecting outcomes (202, 203). Recent American studies demonstrated significant variation in practice for both adults and adolescents (144, 204). Greenberg et al wondered if "variability in practice may contribute to suboptimal outcomes" (144). These studies paint a picture of disparate practice in both orthopaedic decision-making and physiotherapy practice.

87% of those who participated in the UK National Ligament Registry data collection, injured their ACL while participating in sport, 47.4% in football alone (53). Given the aetiology of ACL injury is strongly associated with sport, much of the clinical research for this group is also focused on return to sport outcomes (205). Evidence and experience demonstrate clearly that this patient group identify as recreational or competitive athletes (109). Success of their surgery is most often determined by their return to previous levels of sport (43, 81, 145) despite this return to sport outcomes are largely unknown in the UK and return to sport rehabilitation practice in the NHS is unclear. Previous studies have identified that a gap often exists between when patients were discharged from care and their return to sport (144, 204). It was not clear if these discharges are because care was complete or because care had ended for other reasons. Certainly, it suggested patients were discharged long before it was possible to know if their goals were achieved. This suggests an evidence to practice gap which is at odds with the importance of return to sport as an outcome for the ACL population. How

return to sport care is managed in ACL rehabilitation and how return to sport evidence is applied was therefore critical for exploration of variations in management approach.

As there was a lack of published evidence to understand how rehabilitation is delivered in the NHS, experts and experienced clinical staff who hold manager/team leader roles were best placed to provide insights into current practice. The methodology of a semi-structured interview allows exploration of the underlying phenomena that contribute to variations in decision-making and pathways of rehabilitation. By discussing their experiences and offering opinions as to the barriers to and facilitators of ACL rehabilitation the participants can outline the parameters of their practice experience as well as the barriers they face.

4.3 **Aim and objectives**

The aim was to explore the opinions and experiences of Orthopaedic surgeons and Physiotherapists in leadership roles who provide services for ACL reconstruction patients with emphasis on their opinions of best practice care and the barriers and facilitators to delivering it.

The objectives were to

- explore current practice in ACL rehabilitation
- understand participants' views on the contextual factors that influence care, including barriers to and facilitators of optimal, evidence based care
- explore the use of technology in ACL care and opinions on the role of digital tools in evolving care models.

Research Question: What are the experiences and opinions of clinical stakeholder's on the criteria for optimal management in ACL rehabilitation?

4.4 Methods

4.4.1 Study Design

This was a qualitative semi-structured interview study. It was based on the ontology of critical realism, whereby known realities like service structure and their interpretations and unseen causal factors, are given equal value and synthesized to give the deepest level of understanding (206, 207). The participants' experiences and opinions were considered in terms of their many roles and competing realities such as employees, managers, clinicians and gatekeepers of professional ideals. The methodology was dialectic and analytical, aiming to explore the concept of 'standard care' in the post-operative rehabilitation management of ACL patients in different contexts.

4.4.2 Theoretical Approach

The biopsychosocial model of healthcare was preferred to the biomedical model as it aligns with the WHO framework for classifying health and disability (208). This model was also used to underpin discussions of standard care (190, 208-210). It asserted that the subjective experience of the patient through personal psychological and social interpreters are an important part of the clinical presentation and key to managing the condition (211). Recent interpretations of this model have highlighted the need for reflective awareness amongst clinicians, cultivation of trust with patients, and a style of 'empathetic curiosity'. The model encouraged dialogue and placed personal patient education at the heart of care (11). Much ACL evidence suggested that patients' psychosocial experiences have a causal relationship with their outcomes (34, 109, 212, 213) so person centred biopsychosocial care was indicated where clinicians sought to understand the experience of illness as well as the diagnosis (214). The model claimed overall to guide the "parsimonious application of medical knowledge to the needs of each patient" (11). This model informed the construction of research questions in this study as well as underpinning the thesis overall as a backbone of physiotherapy practice.

4.4.3 Theory of critical realism

Ontology is concerned with the nature of reality. It considers that there is a social reality that exists beyond the interpretation of humans but that there are many subjective views of the same reality (215, 216). Even within individuals, there is the possibility of holding differing views of reality in different contexts. Epistemology seeks to understand the nature of knowledge of the world. It is concerned with how knowledge of reality is informed and constructed (215, 217). This is an important paradigm in qualitative research where the researcher is not absent from the research and must

account for how her presence and beliefs affect the production of knowledge. Though some believe objectivity is possible, it is more common to acknowledge assumptions and aim to negotiate that position throughout the research (217) .

The theoretical model that informed this research was critical realism (CR). Archer argued that critical realism is 'a meta-theoretical position'. She described it as a reflexive philosophical stance which can in turn inform our empirical investigations (218). Critical realism can be understood as a blend of realism and constructivism. Realism had at its foundation the idea of a reality that exists regardless of beliefs and interpretation (219). Realists posit a direct relationship between what is observed and reality (217). The approach is rigorous and the researcher aims to generate knowledge by uncovering truths without interpretation or examining the subjective (207). This model has limitations and fails to acknowledge the experiences and beliefs that may influence how reality is interpreted. As an overt example, Gunter Grass illustrated the limits of realism when he described having grown up in house where the lies of Nazism were an accepted reality, only later to discover that not only were they lies, but that they were appalling (220). His point illustrates that knowledge of reality is subjective and often to an extent constructed by those with power. The most dominant narratives develop into systems of belief that can appear to be 'real'. This therefore limits the usefulness of realism as a tool of social inquiry without an analysis of interpretation and belief.

Constructivism on the other hand seeks to deconstruct, to understand how knowledge that seems real can appear indistinguishable from beliefs and experiences. Conditions of politics, gender, sexuality, ethnic or social, psychology or economy can lead to different views that form a known version of reality. Constructivists view these experiences as multiple real views of the social world but none are a 'true' representations of reality (207, 217). However, a constructivist approach raises the potential to create knowledge by enhanced understanding, by observing social reality through a multitude of subjective experiences in order to develop a deeper epistemology.

Critiques of both realism and constructivism centre on their limited way of reducing ontology to epistemological findings (206) In the case of realism, ontology is reduced to facts that can be measured and in the case of the constructivist approach, knowledge of reality is created solely by human views of reality.

Critical Realism brings together the idea that data relating to the more static structures and processes of reality can inform ontology, with the idea that we shape the world by our theoretical influences

and constructs (221). It is interested in what reality is and in how reality is experienced. The latter is given as a means of understanding and interpreting the former (222), though a complete understanding is limited by our theoretical standpoint and our own research interests (207, 221). There are three levels of CR ontology. The Empirical level is most evident and verifiable through measurement while the other levels 'actual' and 'real' are submerged and require in depth analysis to uncover. These three levels can be understood as follows:

The 'empirical' level; where those aspects of reality can be experienced either directly or indirectly. This level includes the most evident of data but also includes the interpretation of theory and experience.

The 'actual'; where reality can occur without necessarily being experienced. The theories that we draw upon to explain our empirical data (218).

The 'real' or deep structures; where causal structures and mechanism are active (221, 223). This level allows exploration of mechanisms that lead to empirical level experiences.

The critical realist approach combining understanding of the empirical structures of the healthcare systems with the importance of the subjective experience, makes it an ideal tool to investigate experiences of delivering care which are at their heart subjective and multiple. The 'real' causal mechanisms may be explored through the interpretation of data. The goal is not to "identify generalizable laws (positivism) or to identify the lived experience or beliefs of social actors (interpretivism); it is to develop deeper levels of explanation and understanding" and form a post positivist conclusion (206, 221).

The critical realist (CR) understanding of the experiences and opinion of clinical stakeholders on delivering ACL rehabilitation aims to identify causal mechanisms that underpin social phenomena toward a deeper understanding. CR as a theoretical structure supports the framework analysis technique where codes are developed a priori from what is already known and a posteriori as they emerge from the participant interviews. The process of applying CR theory to the data involves firstly identifying patterns of codes known as 'demi-regularities' (207). This occurs simultaneously to and is complementary to the framework analysis steps 3 to 6 where codes are organised into concepts and stratified into coherent themes within the framework (see section 1.4.8.1). The second step is known as 'theoretical re-describing' where the data is re-described using known theory in the field, in this case theories of ACL rehabilitation and the biopsychosocial model of care. The final stage is known as

'retroduction'; it moves from observing the phenomena of social life through the participants experiences to proposing causal mechanisms that drive them (223).

4.4.4 Ethics

HRA approval was obtained on 10th of October 2017. IRAS project ID: 227964

4.4.5 PPI

This research was designed under the advisement of the NIHR CLAHRC PPI group. They heard a presentation of the concept and gave verbal and written feedback. This feedback led to study documentation language changes. It was also informed by the NIHR CDRF panel PPI representative who questioned the exclusion of patients in this study and accepted the response that patient interviews would be conducted as part of a process analysis of the feasibility study to be excluded from the PhD but published separately at a later date. The TRAK feasibility study PPI representatives agreed to participate in a data clinic and analysed samples of two interviews. Their conclusions were compared with the existing analysis of results and any new codes or categories were synthesized.

4.4.6 Sample and recruitment

Purposive sampling was used to recruit participants with clinical and research expertise in the field of Physiotherapy and Orthopaedic surgery as well as those in managerial roles. Purposive sampling is used when 'units' have features or characteristics that enable exploration of a central theme (217). In this case the sample can be referred to as stratified purposive, where subcategories of physiotherapist, surgeon or team leader/manager are evident under a broader category of stakeholders to a central theme. Some participants were identified by their reputation in the field, other were identified through contacting hospitals that were mentioned on the National Ligament Registry (NLR) as reporting high numbers of ACL surgeries and by extension a high throughput for rehabilitation. I initially sent an email to the individual or department I wished to contact and then followed up with phone calls. Combining sampling strategies is often resorted to for pragmatic reasons in qualitative research (224). In this case, surgeons often did not respond to emails and follow up phone calls so after months of not being able to recruit, I changed to snowball sampling which was more effective with this group in the time frame, though the limitations are acknowledged in the discussion (225).

Finally, in order to represent areas with different demographics, emails and phone calls were placed to Trusts not mentioned on the ligament registry. This was done by selecting from a map of NHS Trust

areas and choosing areas that were not represented on the NLR. I purposefully targeted areas with differing populations. I developed a spreadsheet of hospital and contact information for physiotherapy departments. Phone calls were made to obtain contact details for the relevant person in each area and then an email was sent. Follow up phone calls were then placed over several weeks. In total 45 individuals were contacted.

Emphasis was placed on confidentiality and the inclusion of participants as individuals based on their career experience and opinions rather than as representatives of their trust.

4.4.6.1 Eligibility criteria

4.4.6.1.1 Inclusion

Participants were included if they had a proven record in clinical management of ACL patients or research involving ACL patients evidenced by publications or experience of managing a department that delivers an ACL pathway. They needed the ability to take time for an interview and be willing to comply with anonymity and confidentiality during the course of the study.

4.4.6.1.2 Exclusion

Persons were excluded if they were unable to speak and read English, unable to provide informed consent or if they were working outside the UK.

4.4.7 Data Collection

4.4.7.1 Semi structured interview topic guide

Interview questions were informed by results from the scoping review described in Chapter 3 and my clinical experience. An initial draft was discussed with research supervisors, key collaborators and Qualitative Research Methods MSc tutors with revisions made following these discussions. (Appendix C: Topic Guide)

4.4.7.2 Pilot Interviews

The topic guide was pilot tested twice. It was apparent in the first interview that the participant felt they were being 'tested' on the evidence. Changes were made to reduce the potential for this risk, in particular an introduction was provided that reminded the participants of the research aims and of my role as a researcher rather than colleague. Further, more open questions were moved to the beginning of the interview and references to the 'evidence base' were moved further into the interview. The revised topic guide was re-piloted. Further changes were made after the second interview when it became clearer that some questions were essentially asking the same thing. A

further question was added directly related to resources as I wanted to be sure it would be addressed. The second pilot interview was included in the dataset as the changes made after those were more about style than content. There was a slight variation in the questions to accommodate the different professions however all participants were equally regarded as 'stakeholders' in post-operative ACL care (Appendix C. Topic Guides). No repeat interviews were carried out.

4.4.7.3 Consent

Written informed consent was obtained in the form of the signed HRA consent document from each participant.

4.4.7.4 Safety of researcher

In the 5 face to face interviews, arrangements were made to meet participants in a public space of their choosing, most often their work environment. Consideration was given to time of day and access in order to ensure participant and interviewer safety.

4.4.7.5 Interview setting and practicalities

Interviews were conducted in person, via skype or over the phone at a time convenient to the participant. Although the phone and skype mediums had limitations, they were useful in overcoming geographical boundaries. Participants were encouraged to take up the interview in their free time at home or in a space provided by the lead researcher, rather than during their workday. No one else was present during the interviews so that confidentiality could be maintained.

4.4.7.6 Interviews

The interviews were audio recorded on an encrypted Dictaphone. No video recordings were made from video calls. Brief notes were kept during the interviews and a reflexive diary was written after interviews.

4.4.8 Data Analysis

4.4.8.1 Framework Analysis

Data were analysed using a framework analysis method as described by Gale et al (226) This method is versatile to different theoretical models and is not anchored to particular ontological or epistemological approaches. It is commonly thought to be more deductive but in fact it lends itself to a mixture of deductive and inductive process depending on the research questions. This made it the appropriate method for this study, where themes had already been identified from the evidence base discussed in Chapter 2 and from the scoping review in Chapter 3. Thematic analysis is still a significant part of the Framework process but the research is flexible along an inductive deductive continuum (226, 227).

The signature feature of framework analysis is the matrix of data that is created by the analysis process. This allows the researchers to systematically sort data into cases, codes and categories towards final themes. The data can be viewed as a connection between a participant and the various themes they discussed or within a theme comparing various participants. This way each theme can be synthesized but without losing the individuals overall viewpoint (226). Analytical memos were kept to reflect on problems or disconfirming data which serves to capture the analytical process and interpretation. The analytical process ends with a group of themes that have come together from the 'interrogation' of the data into categories and codes (226).

4.4.8.1.1 The stages of Framework Analysis and how I applied them.

1. Transcription

I transcribed 5 interviews myself in order to become familiar with the data and to reflect on how variations in process such as location or medium of interview might affect the data. I also noted the effect that my professional role had on participants who I interviewed. I made reflective notes on this. The remainder of the interviews were transcribed by a UCL approved professional transcription service. This was done because of the significant time burden of transcription. The files were transferred via an encrypted process and the anonymised text interviews were made available for me to download directly to the UCL closed network.

2. Familiarisation

I made field notes on the day of interviews that provided memory cues for contextual factors that may have a bearing on data analysis. I listened to the audio files of interviews within one week of

conducting them and made further reflective notes and created memos that would be relevant to interpretation and analysis. I read the interview once the text transcripts were returned to me and used a coloured highlighting system to identify preliminary codes and concepts.

3. Coding

I indexed the data using the NVIVO software package to organise and analyse data. The lead researcher and one supervisor independently coded the manuscripts to identify themes and synthesize data. The software facilitates charts that represent the relationships between participants and themes (Appendix D).

4. Developing an analytical framework

The framework was developed based on the ACL evidence from Chapter 2 and an associated systematic review from Chapter 3. Deductive reasoning was used to code data to the appropriate theme and give depth to the framework. The framework was further developed through the use of colour coded mind maps and insights from data familiarisation.

5. Applying the analytical framework

Transcripts were then indexed, where the identified codes are mapped into the framework. The process is still thematic and also allows for the inclusion of a more inductive process where ideas that emerge from the data can be added to the framework if not already included. I used NVIVO to code the transcripts into the framework. This process was cyclical and led to numerous incarnations of the framework as new categories emerged and were reorganised into subthemes and themes. At this stage the number of categories was at its largest before I began refining them.

6. Charting data into the analytical framework.

Charting the data from broader codes into narrower categories requires a delicate attention to the balance of retaining the meaning and mood of the data, while condensing and reducing it to more salient features. As I refined the data categories within the framework, I often returned to original transcripts to explore intent or meaning of a quote. The list of categories and sub themes began to condense into 6 themes, which were then further reduced to 4 themes with input from PhD supervisors.

7. Interpreting the data

The research team discussed each theme with reference to the data and quotations. We questioned the key concepts and looked to understand relationships in the data and potential causality. We identified patterns in care provision as well as phenomena that may contribute to failures in care, as noted by Gale et al (226). The process was time consuming and required several iterations.

8. Data clinic

This step (step 8) is not a part of the Gale Framework model, however, two data clinics were conducted. The first was with 3 qualitative researchers unrelated to the project and the second with two patient and public involvement participants who have had ACL reconstruction. They independently coded 3 pages of 2 manuscripts. The process was inductive as they were not initially shown the framework. They identified themes of variety in care, pathways of care, resources and staffing, and a sense of care changing over time. Following their coding, they were shown the data and they mapped data into the framework as in step 6. Finally, step 7 was repeated in a group discussion with the data clinic participants to explore their unique impression of relationships and causality in the data. The data clinic was a useful step to ensure rigour and discuss the confirmatory and disconfirmatory data that emerged from this process.

4.4.9 ACL Rehabilitation Model

ACL rehabilitation is commonly discussed in terms of phases. Unless otherwise described, I will refer to the Van Melick et al model of rehabilitation which describes 4 distinct phases: prehab; impairment based rehabilitation; sports specific training; and return to play. This model was described in detail in Chapter 2.

4.5 **Findings**

4.5.1 Interviews

Interviews ran to approximately 40 minutes on average. Data saturation was discussed at 21 interviews. I wanted to reach the point at which I could replicate the interviews and get the same results and where there was no further coding that could be added. I decided to include 3 more interviews. Data saturation was reached at 24 interviews. Despite being encouraged to participate in interviews outside of work hours, most participants were interviewed at work and most were interviewed over the phone (Table 4.1).

Interview	
Home	11
Work	12
Neutral Space	1
Medium	
Video	3
Phone	16
Face to Face	5

Table 4.1. Setting and interview methods

4.5.1.1 Participant Characteristics

There were 24 interviews included in analysis of these results. The sample's characteristics are presented in Table 4.2. There were 19 physiotherapist and 5 surgeons, 11 of this group also had managerial/team lead roles. 20 were male and 4 were female. Participants also described their employment experience. All were clinically experienced within the NHS and/or private practice and some also worked in research, sport and the military. They also worked within different patient populations. This is shown in Table 4.2. Given that the community of professionals in the UK who specialise in this field is small, I have prioritised anonymity and have elected not to include further identifiable data such as age and ethnicity. Twenty-five participants were included. One interview was not usable and the participant was too busy to reschedule.

Participant ID	Job Role	Employer(s)	Experience	Gender	Location
1PM	P & MTL	NHS + Private	Research + Clinical	M	Large Metro Area
2PM	P & MTL	NHS	Clinical	M	Small Metro Area
3P	P	NHS	Clinical	M	Large Metro Area
4P	P	NHS + Private + Sport	Clinical	M	Town/Rural
5P	P	NHS + Private	Clinical	F	Small Metro Area
6PM	P & MTL	Private + Sport	Clinical	F	Small Metro Area
7S	S	NHS + Private + Sport	Research + Clinical	M	Large Metro Area
8P	P	NHS + Private + Sport + Military	Clinical	F	Town/Rural
9P	P	NHS	Research + Clinical	M	Small Metro Area
10P	P	Private Provider + Sport	Clinical	M	Town/Rural
11SM	S & MTL	NHS + Private	Research + Clinical	M	Large Metro Area
12PM	P & MTL	NHS AQP	Clinical	M	Town/Rural
13S	S	NHS + Private	Research + Clinical	M	Large Metro Area
14S	S	NHS + Private	Research + Clinical	M	Large Metro Area
15PM	P & MTL	Private + Sport	Clinical	M	Large Metro Area
16S	S	NHS + Private + Sport	Research + Clinical	M	Large Metro Area
17PM	P & MTL	Private	Clinical	M	Large Metro Area
18P	P	NHS	Clinical	F	Town/Rural
19PM	P & MTL	NHS AQP	Clinical	M	Small Metro Area
20PM	P & MTL	NHS + Private + Sport	Research + Clinical	M	Small Metro Area
21P	P	NHS	Research + Clinical	M	Small Metro Area
22PM	P & MTL	NHS + Private	Research + Clinical	M	Town/Rural
23P	P	NHS + Sport	Clinical	M	Large Metro Area
24PM	P & MTL	NHS	Research + Clinical	M	Small Metro Area

Table 4.2. Participant characteristics

P for physiotherapist and S for surgeon, MTL for manager/team lead
>750,000 = large metro, >100,000 = small metro, <200,000 = town/rural

4.5.1.2 Themes

The data were clustered into 4 key themes with subthemes, described in Figure 4.1.

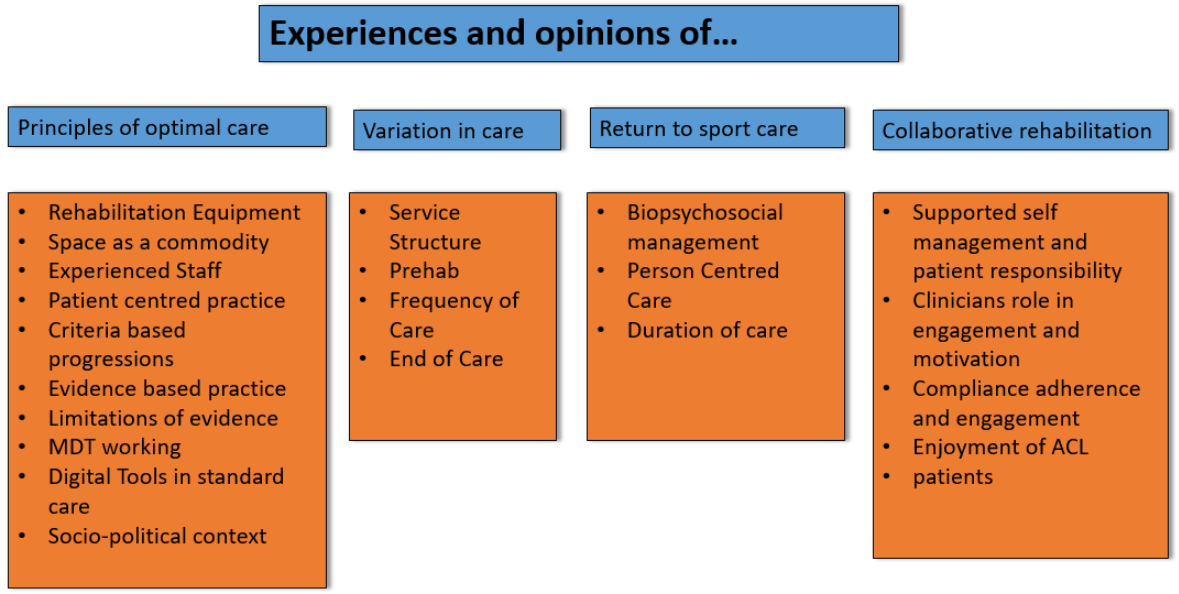

Figure 4.1. Key themes

4.5.2 Principles of optimal care

In discussing their practice, participants went to great lengths to underpin their choices with evidence based and pragmatic rationales. Some of the principles that were emphasized related to known pillars of clinical governance such as patient centred practice and evidence based medicine or the function and importance of the multidisciplinary team. There was also an emphasis on pragmatic considerations such as resource management and the availability of space, equipment and skilled staff. The participants explored the challenges they faced to implementing optimal care and the contextual factors that may have relevance (Figure 4.1).

4.5.2.1 Rehabilitation Equipment

It was notable throughout the interviews that surgeons and physiotherapists were frustrated when they felt that lack of resources rendered them unable to deliver evidence based care to their patients. The participants had an impressive knowledge of the evidence for best practice care with regard to treatment modalities and key outcome measures.

> *If the physiotherapist is not able to provide what they think is ideal, for rehab for that patient, then that rehab is going to suffer. 13S*

Resources for rehabilitation were vastly different within some trusts. A recurring theme in discussions of standard care, was the idea that the quality of care you received could depend on where you lived.

> *In ******* we've got four or five physiotherapy sites and it can be quite varied. It just depends on the facilities, on the space that's available. The type of hospital that the staffs are working within. It's across lots of sites. It could be a bit of a lottery between- we've got one which, they haven't got the space, they haven't got the facilities or the equipment. So, they are trying to make the best of a bad job with the facilities they've got really. It can be quite varied …and be interesting sometimes the conditions working within those clinics or those classes…whether they're just generic fits with no kind of specialism for those people, treating those conditions. In my mind, if something like that is bit more centralised then you would make it less of a lottery between the varieties of how different patients are treated across the trust. 24PM*

All participants believed that because most patients had active/sports goals, there was a need for a gym environment. They discussed a wide selection of equipment that they used, as illustrated in Figure 4.2.

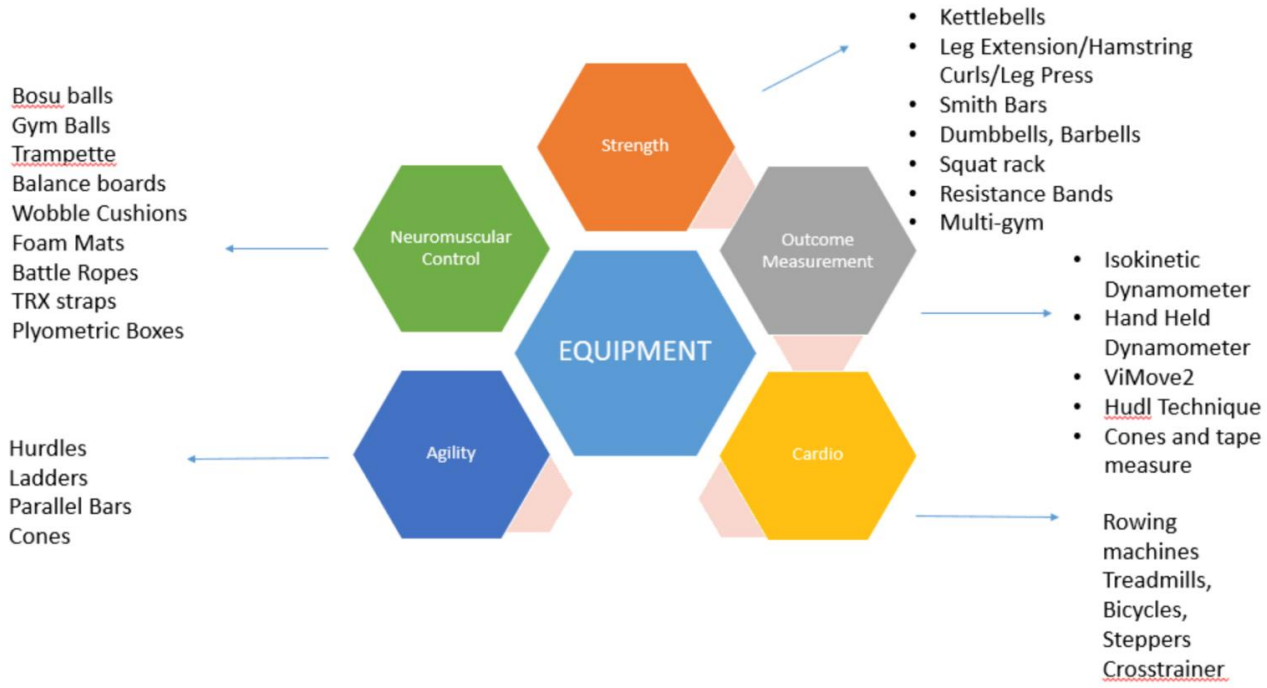

Figure 4.2. Participant's use of equipment

I would say the majority of people would probably need to be within a gym environment. Just because of the access to equipment, and I don't think that body weight exercise in itself… it depends whether people have access to other equipment at home that could help." 3P

In terms of rehab, I would think physio environment would be the next (after patient selection) big thing. 13S

I think it's (gym based care) massively advantageous, yes, for this patient group, particularly. I do think it is, yes 9P

When probed about evidence behind this belief, physiotherapists' and surgeons referred to principles of strengthening and the rehabilitation practice of breaking down sports specific tasks into gym based drills to practice.

If you don't have so much as a leg extension machine or a leg press, how are you really going to test the strength of a top athlete? How are you going to know? If somebody can squat, let's say they can leg press 100 kilos on one leg and 85 on the other, they're huge numbers. You're not going to pick that up if you're just testing them in single leg squats. 4P

Like I said, linking in with a lot of the research, we try and get people utilising loading principles. So, you would obviously need weight to be able to do that effectively really. 19PM

You can take them through a movement pattern retraining programme to make sure that they navigate everyday life obstacles, initially, safely, and, later in the process, that they deal with high-risk movements safely. You're going to need some heavy-load strength training at some point. I'm stressing the heavy load because often we talk about strength, whereas what we mean is neuromuscular activation, really, or endurance exercise. An awful lot of rehab doesn't go heavy enough. That's changed a lot I think. 1PM

It's whether body weight exercise would allow the recuperation of muscle size and strength capacity that traditional S&C (strength and conditioning) teaching would make you think, that it would be required for plyometric-based activity, or sprinting, or change of direction. It's an interesting thought… My gut reaction is the gym environment and resistance exercises, with the addition of weight, are a fundamental part of the rehabilitation, in my view. But it's plausible that you could manipulate other variables, such as repetitions, rest times, time under tension, and the speed at which the exercises are conducted. 3P

Interestingly, some participants described that they were picking up patients from out of area because they were rumoured to be the only clinic in the area with the resources for return to sport physiotherapy. This participant was concerned that this could stress their resources even further.

We certainly don't want the health boards either side to think that we think we're better ... it's a pain for the patient to travel that extra distance and we haven't got the extra capacity. If we're doing well, it's others that need to come into line. 2PM

One clinician was torn between his managerial responsibility to management of resources, capacity and demand, and his acknowledgment of responsibility to the patients for rehabilitation.

Have we got the strength equipment that's required to load those patients who are getting physio? Should we be providing the strength equipment and the weights in order to progress those patients within that clinical setting? Is that our role as a physiotherapist? I think it is to a degree, but you can't have full weights gyms set up in every physio department. The cost. The running of it and isokinetic machines, you need staff trained up for that. 24PM

One clinician stated that the resources she wanted to have were highly unlikely to be made available.

I think, ultimately, yes, what we'd like is a little bit more sophisticated equipment. So from that perspective, we're in a gym that looks like it's from the 1970s … obviously, you just haven't got a cat in hell's chance of getting anything like that here. 18P

Another clinician acknowledged the expense of some equipment but was frustrated by spending prioritising that he had encountered.

So, again, even though in the isokinetic machine, most departments should seriously be thinking about buying handheld dynamometers now. You know, when we're talking people who are willing to address £3,000, £4,000 in an electrotherapy modality, which probably is ineffective. I'm not arguing whether they are effective or not, but they are ineffective using them once a fortnight. 20PM

One participant argued that if the facilities are not available, clinicians still have a responsibility to educate patients as to what they should be doing. This topic intersects with section 1.5.7 where participants explored how they supported self-management.

And again, because we don't have the facilities, again there is the commitment to, Okay, if you're going to do some strength work, you're going to need to find a gym to do it in. I can teach you, but I can't supervise you. 4P

4.5.2.2 Space as a commodity

A phenomenon that occurred in several areas of the country was that within one trust, several sites could pick up patients after surgery from the same hospital. Some of these were spacious and well-resourced while others were cubicles or small rooms in primary care sites. Patients were sent according to address rather than suitability.

*We've got one which is a very small cottage hospital and they could probably fit 4 patients in an advanced lower limb class. They're unable to get patients running or changing direction because they'd have to take them into corridors and there are issues around safety and fire. Lots of red tape which stops people or patients running up and down the corridors, those sorts of things. They haven't got the space, they haven't got the facilities or the equipment. So, they are trying to make the best of a bad job with the facilities they've got really. On the flip side, in *********, you've got two very big gyms, very well equipped. A lot of space where you can get patients doing more running, pivoting, twisting, turning. More dynamic exercises. 24PM*

*It varies across sites. We've got 26 sites across ******** that we work from, ranging from individual rooms in GP practices to big centres that we run. 12PM*

When pressed on why space was important, participants referred to the important of movement analysis in functional rehabilitation. Participants discussed the evidence based requirement to assess dynamic function and performance as a measure of successful rehabilitation.

> *I think a gym is massively advantageous, having floor space is massively advantageous. You know, some of the jump tests that are advocated later on in that timescale, the cross over hops and all that sort of thing, you know, they've advocated outcome measurements, so they should be implemented. If there's no space for that then that's tricky. So, I think space and gym resources are barriers for us. Yes, I think it's a huge advantage for people to- And I think it motivates them, as well, to be honest, as well, yes .9P*

4.5.2.3 Experienced Staff

> *In my experience, in the past week, I've being seeing some patients where they are probably being let down because they're not being pushed as hard as they could be. I question is that the fault of the patient, the fault of the physiotherapist, the fault of the service that we're not directly treating those patients? 24PM*

This physiotherapist when confronted with patients who have been 'let down', looked to service structure and staff for a point of understanding. The skill level of the physiotherapists who managed patients or ran exercise classes was much discussed amongst participants.

> *Get those patients in under the supervision of a physiotherapist who is interested in those types of conditions. With the skillset and the interest in order to challenge and progress those patients, and to prevent them failing really. It's an expensive surgery but you need the rehab to back that up, and to optimise their outcomes. 1PM*
>
> *So we've got a band 7, a 6, and a 3. When I went through all the tendering and compared ourselves to other services where they only have band 4s covering it, I think we see quite a lot of patients that, at the time they come in here, there can be things that have been missed, like cyclops lesions or stuff, which makes a real difference to how quickly the patient can move on. I think there's some things, when they are bog standard, straightforward, then it doesn't need to be someone with my skill. But within that, you will get ones that do need more analysis. 5P*

One physiotherapist identifies that advanced rehabilitation was a specialist skill, not taught as part of the physiotherapy qualification and not covered on many junior rotations.

> *Are we expecting band five and sixes to just know? I know I was as a band five, expected to just rehabilitate someone back to sports, which is not really… is that acceptable really? Is that fair to the patients? 10P*

Other ACL and lower limb classes were run with junior physiotherapists, rehabilitation assistants and in one case, sport therapists. It was not yet common to see sports therapists in the NHS. The participant was asked if this was because they were cheaper. He also clarified that they are trained in advanced rehabilitation concepts and suggested that physiotherapists had not typically considered this part of their role.

They are, yes. I think also, there are not many trained strength and conditioning physios around. It's a bit more of a new movement to consider strength and conditioning within physio. 12PM

Others echo that understanding and argued that in a time when evidence for effectiveness of other modalities has changed practice, exercise therapy and rehabilitation are once again cornerstones of the physiotherapy profession.

It was always important, movement and things, but now…your ability to assess and prescribe exercise is, potentially, more important than your ability to do manual therapies, or other complementary side of things, I'm not sure that that's always been there. 3P

In fact, I've been, anecdotally, with my colleagues now, saying for years that if we paid as much attention into how we assess and prescribed exercise, as to how many forces and angles and neurophysiological effects and that, that we pay to manual therapy in such a way, I think that our profession would be in a better state. 19PM

Clinicians expressed empathy for junior colleagues, recalling their own experience of starting to learn about advanced rehabilitation.

I have experienced the ACL class as a six, as- I guess from a physio point of view, actually, lack of experience in terms of advanced rehab, initially 1PM

Again, that goes back to whatever physio you've got. If you've got a physio that hasn't had that knowledge, which would have been me however many years ago, we've all been there. 8P

One participant discussed a fundamental cultural shift, where he noted some junior physiotherapists saw their role as facilitating earlier discharge and not responsible for advanced rehabilitation regardless of patient goals.

It's that sort of end stage stuff, isn't it? And I think there is a bit of controversy about where the NHS starts and stops with that. Certainly our juniors, it's really interesting when they come in as newbies and they say, "I think I should stop now," and you say, "But the patient hasn't achieved what they came here to do. Why are you stopping?" And then they're like, "That's not my role." 24PM

Training and education on ACL rehabilitation was offered usually once per rotation or less often than that for senior clinicians. Most education took place informally through the supervisory chains. Some clinics used technology like websites and webinars to educate their staff. One senior clinician expressed that after many years of teaching ACL rehabilitation, it was simply those who enjoy it more who tend to develop the expertise.

*So to bring us up to speed, I produced these guidelines and shared them with colleagues at ******** webinar I did, to split it into two: early and late stage. 10P*

So I've run some training on an 18 month basis about rehab and trying to keep people up-to-date with all the stuff that's available out there. I don't know how much of that goes back into practice. I think we have staff who are very keen on the rehab side of things and do it themselves, and therefore are probably giving out some pretty good advice and instruction. I think others are probably much less aware. 21P

4.5.2.4 Patient centred practice in rehabilitation

Individualised assessment and rehabilitation plans as part of patient centred care were emphasized by many as central to optimal practice. Participants suggested that exercise classes were generally ideal for this patient group, however the environment was vulnerable to generalised exercise prescription which was described as contrary to individualised care and unprofessional by many participants.

Nothing bugs me more. I know I give patients protocols as a broad outline, but if they're then given a very standard, printed-out sheet that is not in any way criteria based, that bugs me a bit because patients can be enormously different 16S

I feel all too often in this country with any of our rehabilitations for lower limb, the main patient complaint that I hear is that, 'We're just simply given a sheet of paper and told to go away'. 21P

Class exercise environments were clinically and cost effective and are commonly used. However participant felt staff within them should have the ability to review and progress patients for individual patient centred care. Clinicians who worked in private and NHS settings, commented that it was not as easy to be patient centred in the NHS and that this can present a risk to patients.

I think the important thing, alongside that, is to try to individualise it to the patient. Again, I think I've got far more scope to do that in a private practice model than we might have in the NHS setting. 22PM

They haven't seen a physio for six months, they've been drifting in classes. That to me is a failure of those patients. If those patients went through more of a structured service, more of a streamlined service that would target a lot of those issues. Potentially that is a cost saving and a success for the surgery. A success for the patient getting back to what they want to be doing therefore outcomes and expectations are probably better. 24PM

4.5.2.5 Criteria Based Progressions

Within orthopaedics and rehabilitation there was an ongoing debate about time versus criteria based progression. The resolution of pain and impairment had used to be underpinned by a philosophy of '6 weeks early care, running at 12 weeks and sport at 6 months' as the stages of recovery. However research demonstrated a significant variety in functional performance of patients at these timeframes and now the dominant model was one of individual criteria based progression

Very few patients, if you really look at their glute control, can really control a good single-leg squat at 12 weeks, so I encourage them not to be too obsessed with getting back to running quickly. 16S

There's less protocols, more milestones; range of movement, quality of control. 17PM

Over the last 10 years, criteria based progressions had come to be preferred to time based progressions which was thought to be more patient centred, safer and encourages engagement with rehabilitation at each stage. Individual ability, control, response to load and stress, indicated readiness. Clinicians and managers described that criteria based progression can present challenges for service planning. Some clinics appeared to blend the two strategies while others undoubtedly retain the time based approach to care.

"You've had your six classes in the intermediate class. You're moved on to the advanced." Sometimes they will struggle, have problems. Maybe not have achieved their goals. They've got to get the basics or the fundamentals so they're achieving full extension or a good range of movement in flexion, improving muscle control. Whereas they're just moved on very quickly. 24PM

Meeting markers for strength and function allowed safe progression through phases of rehabilitation. In cases where patients are progressed according to time, this may mask deficits and affect pain, function and satisfaction with the knee.

The problem of not measuring … clinics will invest in electrotherapy but not have any way to measure strength. Leg extension etc. There was some person come in and she was doing loads of stuff … because she was at six months. She was doing all this stuff because that was the marker where she should have been at. There was a 40% deficit in her quads! She was doing loads of jumping and running and turning and stuff and she wasn't able to cope with it. She had lots of anterior knee pain. 1PM

Some clinicians used criteria based progression throughout rehabilitation and then stopped short of fully incorporating the criteria based model for return to sport. They encouraged patients to continue to abstain from a full return to sport even if they could pass functional tests. The reasons for this seemed to be based on the evidence that delaying return until 9 months and every month thereafter reduces risk of re-injury (20). One physiotherapist describes;

I'm quite an advocate of the 12-month period, really. I'm not a massive fan of return to sport prior to that. I am a big fan of function-based rehab, but I am still a believer in biology and tissue healing and the kind of evidence that shows us that there's more risk of re-injury with that accelerated protocol. 10P

4.5.2.6 Evidence Based Practice

Many participants felt their service was adhering to the evidence base and that outcomes and clinical audit were driving practice. They expressed intention to work towards the evidence base but then admitted being confounded by problems such as inconsistency of available evidence or lack of resources.

> *Obviously, one is looking at it from an evidence-based perspective, what kind of input leads to better outcomes. 22PM*

Participants often referred to well-known research studies, systematic reviews of rehabilitation or guidelines that informed practice.

> *Something like the COMET guidelines will define success in quite a specific way. We've got the patient reported, we've got function, we've got strength, we've got instability etc. I think we do have guidelines to help guide us as to what criteria we might want to put together in test battery in order to determine success. 22PM*

They noted the challenges of keeping up with evidence controversies such as the open and closed chain debate, as discussed in Chapter 2.

> *We allowed them to do some more open change stuff in line with some of the more recent evidence that shows that it doesn't massively potentially increase strain on the graft. They've got a big study by Fukuda; I think it was in 2013 maybe, something like that. So, we started doing more open chain. 19PM*

Participants discussed challenges of implementing evidence in practice due to resources. This participant described how he would not undermine the patient's confidence in the service but he would like to do more if he were not so resource limited.

> *I do feel we're somewhat limited. If I was to go from using function-based rehabilitation again, you know using literature and good evidence-based practice, there's certainly a stage I'm going to get to in my rehab and say, "Right," I wouldn't tell the patient but ideally, I'd be doing x, y and z right now but I just physically can't because I've just not got the facilities to do that. 10P*

Efforts to collect outcome measures were also mentioned by many participants. Surgeons discussed the relevance of the National Ligament Registry for building the possibility of long term outcome data. Most but not all were using it. Some were using it for private practice but not in the NHS.

> *I do use the National Ligament Registry. I think it's a great tool for collecting data set in one place, and you can do it across NHS, and private, and your physios can help a lot with collecting outcomes. 11SM*

4.5.2.7 Limitations of the available evidence.

Physiotherapists in particular referenced the size of the ACL evidence base across the different phases of rehabilitation, as a challenge that is hard to reconcile with the learning needs of rotational staff. Further to this, physiotherapists discussed their impression that some evidence has been found to be of moderate to low quality.

> *I'm not sure if you find this but it's quite difficult to keep up with all the ACL research. 2PM*
>
> *Actually, the studies are so poor methodologically, when you do your risk of bias tool, you're like Oh My God. Even with all this information, you think "Oh, Jesus, I really can't take anything from these types of clinical studies". 9P*
>
> *Was it Anderson in 2016 had over 200 systematic reviews forming their systematic review, and the amount of concrete answers that that elicited is minimal? 3P*

Another impression that was mentioned often by physiotherapists was that the results of research conducted on professional athletes or in the military were often extrapolated to general population patients.

> *The data there is, is in professional sport and its sport specific so it's difficult then to extract like that for the normal population. 17PM*
>
> *The literature doesn't delineate between elite sport, where there's absolute access, even though there are some failings within those systems, and just NHS provision, private hospital provision, and how that works. You very rarely see any data in the paper on how many times the patient attended, for instance, and what their compliance was with the home programme. 21P*

4.5.2.8 MDT working

A dominant theme in interviews was the importance of the relationship between the Orthopaedic surgeons and the Physiotherapists who manage ACL patients. Surgeons highlighted the need to know and trust their physiotherapy team. Physiotherapists reflected that roles where they collaborated closely with their orthopaedic colleagues led to better patient care. Frustrations of poor communication as well as the challenges of reconciling different belief systems were also discussed.

> *I think it's impossible to actually do a good job if you're not able to collaborate with the physio. It's simple, I mean I just don't think, without a joined up pathway is, I think people get lost. 7S*
>
> *I have quite a good relationship with the physios, and they will email me about patients who they think are struggling, and then I'll see them sooner .I would say, it's not just nice for the physio, it's nice for the surgeon, because you build that relationship with your physio, and then you have confidence in that physio. 11SM*

Combined clinics were a notable phenomenon in the NHS and were seen by participants as key to improved communication and respect.

> *I think we seem to be getting on better with orthopaedics than we ever have. I think our stock is at the highest it's been for a long time and with ortho. 2PM*
>
> *So what I've done in my NHS practice, so I actually have now an ESP who works with me in clinic who basically sees patients in clinic as a normal member of staff, but is a sort of link into the physio department. So I have a very close relationship with the NHS, with the physio department, and that works very, very well. 7S*
>
> *Yes. That's probably improved a lot more over the past couple of years. We now have a physio that works in clinic for a short period of time. We've got some new, keen consultants that we've built some good links with… So we do have that clear pathway back to them, if we're having any problems. 18P*

One physio who developed a collaborative role with orthopaedics and began to work alongside the surgical team in knee clinics, described how the MDT environment changed her understanding of how surgeons communicated with their patients.

> *I always used to think that the consultant never told them anything, and then when you actually go into a clinic, you realise people are told a lot. But they only take away a small proportion of what they're being told. 5P*

Clinicians who have worked in both good and poorly communicating teams, observe that difference and the effect on culture and patient management. Both clinical groups described the frustration and vulnerability of trying to manage patients without good relationships within the medical team. In some cases there was evidence of significant mistrust and impact on care.

> *So I operate on lots of patients, so privately lots of people come in from a long, long way away to have surgery with us, but we always touch base with our physios and the protocols and the op notes, have conversations with them over the phone. And if I'm not happy with their physio then I will, brutal as it may sound, I'll move the patient on. So if I don't think that physio's up to it then I'll move them on to someone else. 7S*
>
> *The physio hasn't contacted me, you know, there wasn't that sort of relationship to sort of say, "Well, I said to her, listen, you should have phoned me straight away before it got this bad". You know, it was quite clear once we got into it, that actually she didn't the knowledge, the depth of knowledge to recognise that actually we do expect the knee to be fully mobile by… You know what I mean, he was just sort of sitting on the knee, letting it get stiff. 7S*
>
> *Often I get the impression that physios – some physios – can just ignore the effusion and increase the amount of cycling or strength training they're doing. Yet you can just see this effusion just getting worse, and worse, and worse. 16S*
>
> *I think that's important for both parties, you don't want to work with someone who hasn't got the same thought process really. 7S*

Physiotherapists who had worked in areas where communication was poor discussed feeling their autonomy was threatened. Protocols that were restrictive beyond what some physios saw as 'evidence based', caused frustration. One physiotherapist described that communication is marred by hierarchical power dynamics and called for his team to assert themselves.

> *We are really protocol-driven by the consultants. What was previously set up by the physios at ********* I've got the protocol in front of me now. It was first written in 2005, so it's 13 years old now, with the last update being three and a half years ago. We're governed really by what they say we have to do. 9P*

> *I think we need to be more confident telling the consultants what needs to be done. I think the consultants don't always give us leeway in terms of what we can and can't do. They tell us, "Don't do this." For example, open chain exercise, up to six weeks – I think people don't do that because the consultants say. And they're worried that if they do compromise the graft, the consultant and the patient are going to come back to the therapist. 15PM*

Some clinicians spoke of cases where both surgeons and physiotherapists do not understand the others' role and decision making. Notwithstanding the evidence for improved communication and relationships, the risk of poor communication leading to tribalism was evident.

> *Consultants always think differently as well. They don't always follow the gold standard research. You've got some doing one thing, another doing different approaches, different grafts, all sorts of different things; which makes rehab a little bit difficult to design 12PM*

> *I feel like, perhaps, our consultants push operations, because there are financial implications if they're not operating. Does that make sense? 18P*

> *So there's that whole ability to educate piece, and that also includes our orthopaedic colleagues, who are incredibly well educated about the surgical bit. Their anatomical knowledge is excellent, but they confuse anatomy with biomechanics, and they definitely don't understand exercise, and especially the interface between biomechanical loading within exercise and the needs of the patient to develop a strong system. 20PM*

4.5.3 Socio-political context

Discussions of 'usual care' were replete with talk of resources and austerity. Participants from some areas described being affected by socio-political changes. They described how changes of policy and lack of resources have negatively impacted on the care they give.

> *The focus in ******** has very much been looking at triage roles and diagnostics, and I think the sort of therapies and the rehab side of things has been left behind a little bit. And so all of the sorts of developments are based on trying to ease pressures on primary care and orthopaedics, as opposed to achieving better outcomes. 21P*

> *Or, for reasons of cost, they might be discharged at three months post-op and then never, ever get their lower-limb strength back, which is always a shame when you see an ACL two years*

down the line for whatever reason and they've still got significant wasting, which they never regained afterwards. I think that can be a challenge. 16S

I think services are amazingly stretched and therefore protecting services in terms of having some stability is difficult, in terms of freeing up clinician time so that they interact properly and they do the extra quality things, which ultimately can save time but take an initial investment to do, like setting up care pathways. I think these things are incredibly stretched. We've got commissioning targets which typically restrict numbers of contacts, for example. It's never been the case that, (at least here), rehab fitted with what the commissioning target would ideally require. That's particularly the case now. 1PM

One experienced clinician who recently changed role reflected on the impact of defunding and how it gradually altered physiotherapy practice in his trust. He poignantly questioned how his profession was valued.

It probably makes sense but when you're the clinician who's working with those patients for many years and then you come out of that service and you're looking at it from a different perspective then you can see the gaps and 'is it a failure' of it. I'm not sure what to tie it down to, maybe it's sort of hesitation and I guess lack of decisiveness about value in the physio service, physiotherapy for health, our place in the NHS. 24PN

Surgeons also discussed frustrations with the limitations of AQP private contracts. This consultant worried about quality of care, unnecessary referrals and the false economy of some commissioning choices.

Yes, I mean basically what they've done, all that commissioning work's gone out to the people who tend for it. In my mind it's a disgrace basically, and I think that, as we talked about at the start, it's false economy because people doing a physio assessment over the phone, I mean, how does that work? Now, the problem is with all these sort of physios in the community working for Connect and places like that, is that one of two things happen, is either a patient gets a poor service or a patient gets referred in to see me, when actually sometimes, say… We get loads and loads and loads of referrals that actually if they'd seen our physio team initially they probably wouldn't need to be seen by us. 7S

4.5.4 Variation in care

This theme addressed structural variations on how services managed ACL patients. It explored the pathways through care that participants described and the variables that might otherwise influence those pathway. It further summarised participant's experiences of the frequency with which patients were seen and the factors that influenced this as well as whether or not prehabilitation was part of the management pathway. Finally, the participants explored the end of ACL rehabilitation care and described the factors that led to various routes to discharge.

4.5.4.1 Service Structure

The data elicited multiple descriptions of care models for ACL patients after reconstruction. Participants described variations in management including: ACL rehabilitation in staged classes with criteria based progression; rehabilitation in generalised lower limb classes (once the post-operative impairment phase was complete); ongoing one to one physiotherapy the parameters of which were largely unknown and dependent on the physiotherapist; private practice rehabilitation where insurance appointments or patient financial resources may be limiting factors; out of area physiotherapy where the care is unknown; and "any qualified provider" services where a budget for number of appointments is agreed in advance and was mentioned in the data as being 4-6 appointments. Figure 4.3 illustrates the pathways that participants described. Each participant discussed the balance between the resources, the local service structure and the needs of the patients.

> *Rehabilitation takes that long, a year or more. What we require is a model by which, over that time frame, we are responsive to resource-effective care, especially within the NHS model, resource-effective care, both from our perspective and also from the perspective of the patient. 22PM*

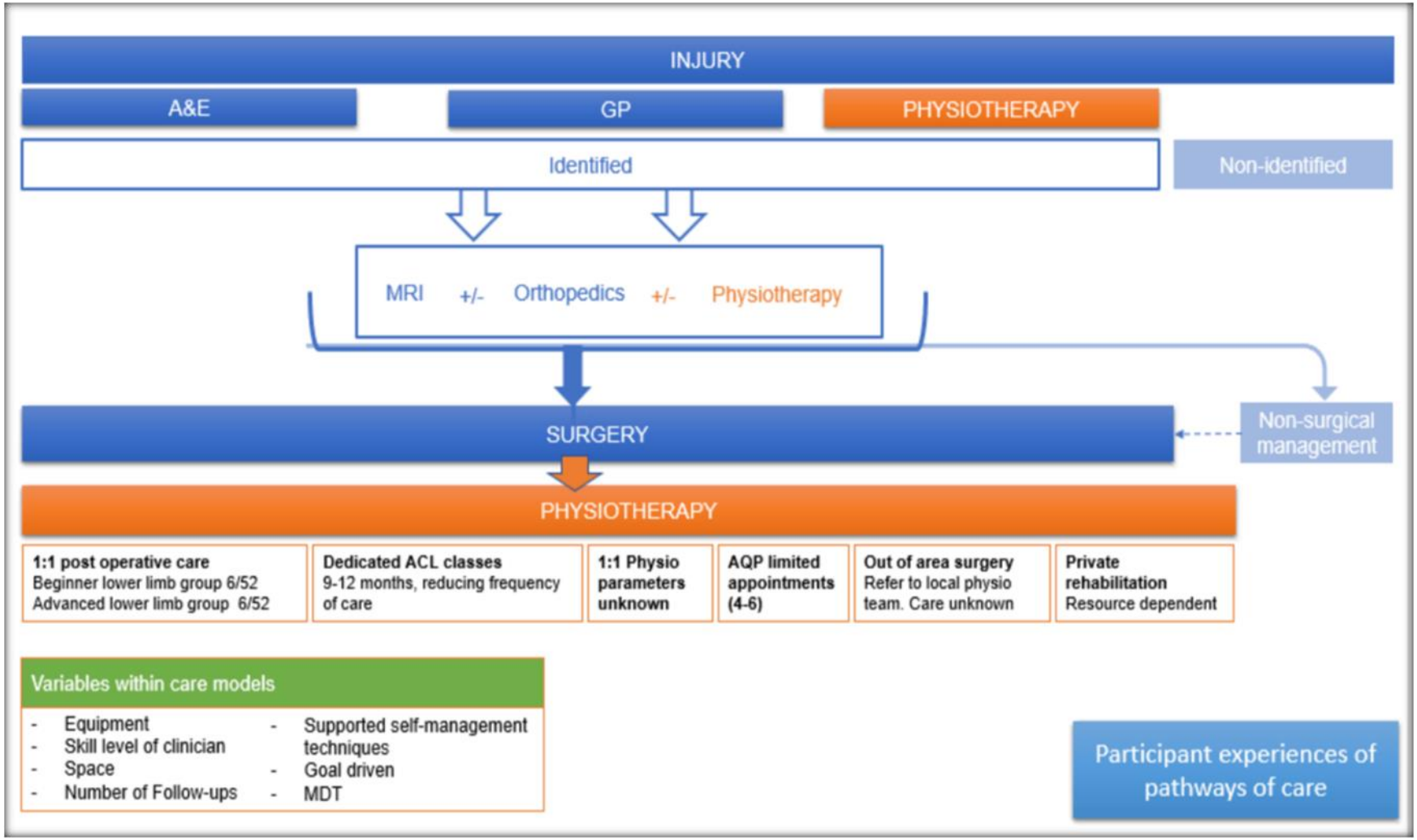

Figure 4.3. Summary of participant experiences of pathways of care

4.5.4.2 Prehab

The importance of early referral to physiotherapy after injury as a part of the timeline of care was emphasized by most participants. Physiotherapy treatment before surgery was known as 'prehab' and there was evidence that it improves outcomes.

> *I think the first most important thing is early contact with the physio. 11SM*

Participants discussed the overall benefits of taking time before operating. One surgeon described how it is an effective process to screen patients for non-operative management. He explained that NHS waiting times actually facilitated incidental benefits of 'prehab'. Another surgeon echoed this and stressed the importance of beginning the relationship with physiotherapy preoperatively.

> *A con of the private sector is that because things happen too quickly, we perhaps are too quick to operate. We're perhaps too quick to go down one route, particularly the surgical route and not necessarily explore the non-operative. There is a natural waiting time in the NHS which allows you to explore prehabilitation and non-operative means. And we know that from research there are a small proportion of patients that can cope for their daily needs and their sporting needs without ACL reconstructive surgery. And that can be overlooked in the private sector, although you would expect a balanced surgeon to present that argument regardless in equipoise in both sectors. 14S*

> *Because of the NHS waiting list situation, most patients can get in to see the physio for a bit of prehab, meet their physio and then it should carry on seamlessly thereafter. 14S*

One physiotherapist also jovially indicated that prehab was useful for more than just the evidenced exercise plans but to get to know the patient and their baseline activity levels. He seemingly refers to fun', as a proxy for the excitement of new challenges for someone who is new to gym based rehabilitation.

> *My first question pre-op is always "Can you go to the gym and see how much weight you can lift?" There are two points to that question pre-op. One is, if they go "Gym, what? What do you mean?", then immediately you know you're probably going to have some fun. 20PM*

4.5.4.3 Frequency of Care

In early post-operative care weekly contact was offered in many of the services that participants discussed. The logic for this related to the importance of managing impairment based limitations such as range of motion, swelling and gait as well as early psychological challenges associated with pain and fear avoidance behaviours.

> *We would be seeing people weekly for probably the first three months 21P*

> *We see them the whole way through. We rehab them for two one hour sessions every week and just push them and push them and see how they get on really. 2PM*

Surgeons discussed the risk to patients who were not achieving early phase goals.

> *I think a range of motion early on is absolutely crucial, because that's something that's so difficult to get back at a later stage. I think, in the first few weeks, if you're struggling to get a range of motion, I've taken patients back to theatre occasionally, and they improve, but often, they just struggle to get that back. 11SM*

Some services chose to see patients less frequently at this stage and 'save' the more concentrated input for later. Clinicians in these type of services often saw the patient once in the interim and then brought patients into a class at 6 weeks post-op, noting that they have not been assessed for criteria based suitability but progressed in line with a time point post-surgery.

> *"You've had your six classes in the intermediate class. You're moved on to the advanced." Sometimes they will struggle, have problems. Maybe not have achieved their goals. They've got to get the basics or the fundamentals so they're achieving full extension or a good range of movement in flexion, improving muscle control. Whereas they're just moved on very quickly. 24PM*

A number of physiotherapists suggested that although they didn't routinely see patients weekly, they had the freedom to respond to emerging problems.

> *If we need to, we can see them weekly. 12PM*

The strengths of this model are in its affordability. The vulnerability of this model was that patients who were not meeting criteria may not have been identified for weeks and may have been progressed inappropriately.

During later stages of rehabilitation greater emphasis was placed on patient individuality and patient responsibility depending on their progress and their goals. Physiotherapists once again described needing the freedom to manage individuals differently.

> *If you've got someone that's highly motivated and you put them in the gym in the clinic and they're really going for it and they're really getting stuck into it and stuff. They're able to replicate and do what you want. Then you probably don't need to see them as often. 4P*

4.5.4.4 End of Care

The interviews revealed that patients were discharged from care for a number of reasons. Participants described that some care ended due to collaborative decision making with the patient while some care ended inappropriately and may have been due to inadequate resources. (Table 4.4)

4.5.4.4.1 Reasons for discharge

Patient goal achievement	*Okay, they've got to be at least back to training within their sport, but not necessarily competitive or games yet. So that I can still suss out any issues that they may have come across in training, and see, "Oh, they're still struggling with this, still struggling with this," and then just make it a bit more training, sport specific, with whatever their issues are. 6PM*
Service goal achievement	*So yes, that is a concern of mine, is that I think people- there's an interesting thing in NHS services we have with our managers all the time, is at what point do you stop? My interpretation has always been that if somebody's had an operation to achieve a goal, then we stop when they've achieved their goal or they can't achieve their goal. Whereas there seems to be a perception from some levels that actually, that latter end of the goal is higher than "normal" that we stop at normal. I've never understood that point. But we do see that, certainly from some of the staff. Once they are walking normally and back at work, then they get discharged. 21P*
DNA/Lost to follow up	*I think patients can sometimes lose interest. I especially saw that on the NHS. … I think that can be a challenge. 16S*
Early discharge to continue independent rehabilitation	*In terms of what happens now, I'm certainly seeing a lot of people coming back to other clinics who have been discharged a lot sooner. So they make minor functional goals and then get discharged to do the later bit of the rehab independently, which often is why they end up coming back to see us, because they haven't succeeded with that. 21P*
Maximum sessions reached	*We've got an NHS contract but it's, sort of, funded through our- You know, they fund our private company to do it, if that makes sense. So, we have four sessions, and there are a couple of (ACL) people I've got in mine. 9P*
No equipment or staff skill level to challenge patient	*There's an odd coming together of the fact that band 5s are encouraged to do early discharge, and at the same time, they don't have the advanced knowledge. I'm not sure whether that's a lack of awareness or education of the physiotherapist or is that pressure on the service to get these patients through the system and off the list? I'm not sure but it has crossed my mind. 24PM*

Table 4.3. Reasons for discharge

4.5.4.4.2 DNA policies

Participants discussed how the traditional, discharge policy was not always appropriate. Many participants described variations on an open door policy or a 'stay in touch' approach and they discussed the challenges of this.

> *There is a responsibility that we do try to have a flexible arrangement but, at the same time, we need to know what our demand and capacity is. 22PM*

Some services maintained 'open' arrangements for the longer term as a first point of access for knee related reviews.

> *Then we had almost an open access for a couple of years after that because a lot of them would have the odd tweak that normally they wouldn't have a problem with but because of their surgery history, they have a bit of a panic. It's just easier if they just pop in and see us. 2PM*

4.5.5 Return to sport care

Another much discussed topic in the interviews was the 'return to sport' phase of care. Most participants described models of care focused on helping patients achieve their goals, however, within that, they had encountered a number of controversies. These included, responding to the physical and psychological needs of athletes of all levels in the NHS, having the resources to offer end stage rehabilitation, having official policies around return to sport strategy, as well as clinical debates around time to discharge and needs of different sports. One surgeon outlined his strategy for ensuring that patients get return to sport care in the hospitals he has worked in over his career. He refers to RTP (return to play) rather than RTS (return to sport), however the meaning is the same.

> *I try to encourage the department to include an RTP strategy for most patients, because people are driven that way now. You know, there's not just bide my time and then I'll just go back to whatever. They need to know upfront what the goals are: skiing, football, netball, and then hopefully build that in to some of the later stages of rehab. 14S*

4.5.5.1 Biopsychosocial management

When asked to characterise how they managed patients in this phase of care. Participants suggested a mix of physical and psychological preparation for returning to their sport.

> *For me that's a 2 to 3 month phase, often whereby they have to go through that conditioning side of return, irrespective of limb symmetry and functional capacity. They have to put them through the neuromuscular and the cognitive side of football. And the return to football and return to other people around you. Whether it's rugby or football, to be fair. Any sort of team related sport needs that final phase done very, very well. 17PM*

Okay, they've got to be at least back to training within their sport, but not necessarily competitive or games yet. So that I can still suss out any issues that they may have come across in training, and see, "Oh, they're still struggling with this, still struggling with this," and then just make it a bit more training, sport specific, with whatever their issues are. 6PM

I guess my bias is very much towards motor learning, which has been very evident in everything that I've written about. But I think that sort of neurological adaption, the idea that we're trying to compensate and adapt at an early stage and using everything we can to get the nervous system on board early is where I would go, which you have to be very individually focused. 21P

Well we want you fatigued. We want you to be able to perform all this stuff fatigued so when you go to the gym and you do your exercises and your weights and you're under the barbell. I want you to go on a run of 2,000 metres first or I want you to run 5k to the gym and then I want you to hit it hard because if we know that the biggest injury risks are the more tired you are. 2PM

Others wondered if we did enough and if we have the facilities to challenge active/sports people.

I think that's probably an area where we, as a physio collective, I think we tick our boxes in to return to play criteria. I don't think we guide people, especially along that final phase. It's because of resources and facilities. 17PM

The psychological challenges for ACL patients in this phase were evident and understood to be part of the rehabilitation process.

Nonetheless, they can have a lot of fear avoidance, potentially. They're going to have a fear of movement, particularly any change of direction off that side. They may have fears about returning to physical activity, which is a healthcare concern more generally. Returning to sport, which is a lifestyle concern, will also give them fears, potentially. 10P

One physio considers failure to rehabilitate confidence as a bigger factor than returning to sport at the same level.

They have psychological issues around trusting that knee and they actually can't tolerate high degrees of repetitive load or regular load without having flare-ups. I think that's a failure. I don't think a failure is not being able to go back to the same level of sport. 20PM

4.5.5.2 Person Centred Care

When participants discussed the importance of patient centred practice, they reflected that different sports have very different demands so rehabilitation at the sports stage very much depends on patient goals. One physio broke down his decision making.

What type and what level of sport they are trying to get back to, if that's what they're getting back to at all, their level of physical functioning prior to injury and their exercise history, as it were, or experience, and the extent of concurrent injuries and things like that, could, potentially, influence that. 3P

The spectrum of patient ability and goals was much discussed. At one end of the spectrum, a surgeon highlighted the very high quality athletes that often use NHS care, he mentions female athletes in particular due to the often poor funding of their sports.

> *That was a big challenge I had on the NHS, was when you did get underfunded elite-level sportsmen, actually giving them the service they deserved. One club that I'm very closely affiliated to is *******, and they have a strong ladies team, but this season alone I've seen three ACL ruptures. Although ****** is a Premiership club with good funding and all the rest of it, the team – ladies team – doesn't have good funding. They've all had to get it on the NHS. 16S*

Another physiotherapist reminded that for patients from less technically complicated sports, rehabilitation will be more straightforward.

> *If you're just sticking to everyday running, then do you need that high level of rehab? You probably don't. You just need to make sure that you've got the strength and you've got the function to do that. 4P*

4.5.5.3 Duration of Care

The evidence for both tissue healing and rehabilitation suggested that the patient's rehabilitation journey can go on for over a year. Participants felt conflicted by the pressure to return people to sport and the evidence that risk of re-injury appears to drop after 9 months and drop significantly after 2 years.

> *I am a believer in the fact that I think, although you might use criteria to move from one stage to the next, I am still a great believer in the fact that patients should not return to a high-torque sport until nine months post-op at the earliest, because I think there's a lot of biology involved. There's a lot of evidence out there to suggest that, if you get them back any sooner than nine months, their risk of re-rupture is higher. 16S*

> *But certainly if we look at the research it would seem that the failure rate sort of plateaus off at around sort of two years. And I think that is because between 12 and 24 months they are improving their proprioception control. And if you speak to enough patients that they will say that it's about two years down the line that they really forgot about the knee and just got on with life. 7S*

One participant stressed that patient expectations can be high and need to be managed in line with their functional performance.

> *When people get fixated on 9 months or 6 to 9 months because they've seen a professional footballer do this, that and the other. There are then the honest discussions which go, "(A) You're not a professional footballer and (B) you can't put in the time and effort required to achieve that." The emphasis really is on them. 17PM*

4.5.6 Collaborative rehabilitation – Whose role is it anyway?

This section focused on the participant's opinions of the level of responsibility that sits with patients during rehabilitation and in how patients were supported to engage with their rehabilitation. It explored clinicians approach to supporting self-management and how digital interventions may play a role. It also explored the psychological side of rehabilitation and clinicians' knowledge of psychological determinants and the challenges of managing these.

4.5.6.1 Supported self-management and patient responsibility

Study participants discussed the varying degrees of responsibility that were placed on the patient in differing models of care. Most participants described a gradually increasing independence throughout care but with assessment reviews, education interventions and management as needed. Clinicians believed that patient engagement, motivation and locus of control are keys to success.

> *I'll definitely put a lot of emphasis on, "I'll help you with this but you've got a lot of work to put in."10P*

> *We can organise patients to an extent, but they can organise themselves a great deal more… Rehabilitation works better for people who have either an internal locus of control or are able to increasingly adopt an internal locus of control. I think a lot of what we're doing is motor relearning or motor learning. A lot of what we're doing absolutely requires active patient involvement and it can't be done for them. Patients being not only involved in goal setting, but driving it and not only involved in a treatment, but driving it, I think is absolutely core to what we're doing. 1PM*

Perhaps one of the most controversial topics in ACL rehabilitation was whether or not patients needed access to a gym in their own time. This had a cost implication and for those who had never attended a gym, could be socially intimidating. Despite the challenges participants agreed that for patients with return to sport goals, use of a gym was essential.

> *Actually, as we've touched upon, we're, as ever with physio, explaining that they need to be highly motivated and attend or join gyms two or three times a week in addition. 23P*

> *If they're not putting in that work and they're just relying on coming to see you once every three or four weeks or attending weekly in a class and they feel that's their physiotherapy, then it's not enough. 17PM*

> *So if they are not doing their exercises, we'll basically lay it on the line and say, "Well, we can't get you better, it's up to you," and they have to make that decision themselves. 5P*

> *If we're seeing them once so we can push them on a little bit and they're working once or twice, preferably twice a week, somewhere else and doing some daily bits and self-monitoring, then that's all important. 1PM*

4.5.6.2 Digital tools in standard care

Surgeons and physiotherapists discussed the use of technology as part of standard care. They highlighted the benefit of using software to collect outcome measures, to educate patients, to encourage exercise performance, to use as a monitoring tool for clinicians, or to engage and motivate patients. While some physiotherapists mentioned a preference for drawing exercises or taking photos of the patients doing their exercises, there were a significant number of exercise websites mentioned in the course of the interviews (Table 4.3). Some felt that digital tools were an essential part of meeting patient expectations.

> *You know, people giving out paper to paper; in this modern day and age, I think people prefer it when they get an e-mail with a planner and videos. 15PM*

Technology mentioned by Participant	Function
Physiotec	Exercise Prescription Software
Technogym	Exercise Prescription Software
Simpleset	Exercise Prescription Software
Physiotools	Exercise Prescription Software
TRAK	Education. Exercise Prescription Software, BCTs
Hudl/Ubersense	Video analysis software
My Recovery	General advice and general exercise
YouTube Pages	General advice and exercises
Gurus on FB or YouTube	Advice and general exercise
Rehab My Patient	Exercise Prescription Software
National Ligament Registry	Database

Table 4.4. Digital resources mentioned

4.5.6.3 Benefits of digital tools in ACL care

As part of his rationale for digital tools this therapist challenged the assumption that patient education and exercise teaching was firmly understood when taught in the clinical environment.

> *In review clinics patients will report that they don't know generally which exercises to do. Or which exercise to focus on at this point in time 24PM*

Another physiotherapist also emphasized education and he identified the role of digital to reinforce his practice of educating and empowering patients. He discussed supporting patients to improve their self-management in between appointments.

> *I personally believe the more I can educate the patients as to how they change variables, the more they can be empowered to face the progression of their rehab without me being there. 15PM*

There was a further emphasis on education and communication by this participant. He argued for specific learning tools with distilled clinical information to support the learning. He reinforced that this overlays a model of person specific care in a condition specific environment.

> *I think the way that we interact with them is possibly the most important. If that's then supported with infographics, with videos, with interaction with other patients at later stages, if it's supported by people reading around the problem. I think groups, with an individual programme, but a group of people with a similar background and story and rehab process is probably very valuable. 1PM*

Monitoring patient outcomes and criteria for progression was discussed. Digital tools for monitoring were seen as useful for patients self-managing and for physiotherapists as a record of patients' progress.

> *Simple as. If the research suggests you've got to be achieving these functional landmarks before you move on to the next ones. Without that information in front of you… I suppose you could have it all in your head and try and memorise it, but that's not very realistic in my opinion 10P*

Some participants who didn't use digital monitoring demonstrated an appetite for it and saw the potential to positively reflect patients progress to them and to unburden clinical contact time by allowing patients to complete outcomes and compliance diaries using technology.

> *I don't know, because I've never used software like that. I massively see the value in it. We've got training diaries that are written training diaries that are typically an 18-week booklet. I'm looking at a big pile of them now, right at the side of my desk. But also, if patients are able to fill in on the app exactly when they're doing their exercises, how much of them they're doing, which ones they're doing, then I think that's very beneficial for them to see their progress. 10P*

The economy of digital tools was also discussed. One participant highlighted how a website can take the patients rehabilitation forward even when the physiotherapy environment had reached its limit.

> *Websites and apps can go beyond what the clinic and the clinician can offer in person. For example if the clinician doesn't have a gym or much rehabilitation equipment, but the patient has athletic goals, then the website can facilitate the advanced learning. Okay, if you're going to do some strength work, you're going to need to find a gym to do it in. I can teach you, but I can't supervise you. 21P*

Automated emails to patients that collated and stored outcomes were increasingly popular. Data can then be used to demonstrate effectiveness of care to commissioners.

> *We collect outcomes on everyone. We've got a very state-of-the-art data collection system that gets them immediately post-injury and then collects data at two weeks, six weeks, twelve weeks, six months, one year post-op. Like all data collection systems, there is an issue with*

patients actually responding. I suppose our overall response rate is around 50%, but we're getting reasonable data for that now. 16S

Others highlighted that using digital allowed patients' access to their exercise plans and the key points of learning which means that they were still getting evidence based care but patients may choose to attend less often and work more independently.

From three months, we have the choice of them going to a class every week, every two weeks, or we ask if they want to come back for monthly testing. Because if they can't commit to the class, but they're happy to do their own rehab, we ask that they come back every month, so we can just make sure that they're getting on okay. 2PM

99% of the time they're on their own, right? .Yes, healthcare across the board cannot afford that much physio, so we have to balance where, you know, patients are getting good service but it's cost effective. So I think there's a lot to say for an ACL rehab programme where patients can be going to the gym and doing the work, and that's where these apps come in brilliantly, because you can set their programmes up. 7S

4.5.6.4 Challenges of digital tools in ACL care

Not all services were using technology and some had taken a position against using it, often as a reaction to the perceived unreliability of many on-line resources. Some had faced challenges using or implementing technology in the NHS or described that their departments had not begun to work this way.

Yes. I know there are apps out there, and things, aren't there, as well? But I have to admit, we're perhaps a little behind on that, which is something to think about, really. We ought to mention that that might be something, if there's something out there, appropriate. 18P

No, I tend to tell people to avoid using stuff, personally. 5P

One surgeon describes his concern in cases where digital is proposed as an alternative to care.

It's an insult to the people doing it, and that's why I've resisted and there's still massive pressure at the moment in doing virtual fracture clinics. And as I said, it's an insult to the person who's referred that patient into clinic to then just telephone the patient. I think there are a lot of people who sort of buckle to the pressure, but I think it's important to maintain appropriate clinical standards. 7S

Other areas of concern were also noted. YouTube came in for much debate as it is not a 'closed' site. A common concern was that on YouTube the patients are led to different content without the oversight of a physiotherapist.

The problem with YouTube, the videos are so end stage, niche and exciting, but they negate the drudgery and control work and slow hours of strengthening and building motor control patterns. Patients can be tempted to engage with advanced movement patterns before they can control basic movements. Some of the fancy sexed-up videos you see on YouTube, they're

great, but they're incredibly end-stage niche. To get to those points there are a lot of building blocks which are about just rock solid repetition of movements in more and more challenging environments. 20PM

Surgeons discussed trying to make digital tools that are popular with private patients, available on the NHS. While physiotherapists discussed the challenges of implementing digital in a clinical environment. This led to frustrations with NHS processes. They discussed time pressures, cultural barriers and data security barriers as key factors.

At an organisational level:

So that's the main barrier is that the NHS is slow to adopt and we're way behind other countries in terms of healthcare systems in adopting digital applications and digital modalities. We know that. 14S

"So there are lots of apps and stuff, patient information that they can access. The NHS are trying to do that, again it's a lot more difficult in the NHS because you've got to get people to authorise content and stuff. …So we're working on that". 7S

At a clinical team level, this respondent talks about a failed attempt to introduce a digital intervention:

I don't know. We tried to unpick it a little bit afterwards, and we couldn't really get to the nub of it, but essentially I think people were generally perceiving most things as something they had to do as well as what they traditionally do, as opposed to thinking of it in entirely different ways. 21P

4.5.6.5 On the clinicians role in motivation and engagement

Physiotherapists commonly mentioned the need to understand goals for different sports and activities as a key component of personalised care. One physio described committing time to understanding the functional patterns of dance, which he was not previously familiar with, but which was his patients' primary goal.

We spent about 40 minutes with her looking at dance moves that she does or she wants to do which she feels are just at the edge of her capabilities just now. 1PM

One clinician directly links his efforts to engage and stimulate ACL patients, to outcomes.

If you can break that boredom, the uptake and the buy-in from the patient will be better …and in my opinion if you can get them to buy-in, to get them to do more, they'll get a better outcome. 15PM

Some clinicians described exhaustive efforts to gamify the rehabilitation process to limit 'boredom' over the lengthy rehabilitation. There was much evidence for balance exercise in ACL rehabilitation

(7). This physiotherapist described a balance and control drill moving from one piece of unstable balance equipment to another without settling on the floor.

> *So if you can imagine from being at school, it'd be like playing pirates, but a lot lower level. You played pirates or you played lava floors, you know, where you couldn't go down on the floor. 20PM*

4.5.6.6 Compliance /Adherence/ Engagement

Clinicians described the barriers that patients face in engaging with their rehabilitation. These barriers could be categorised as Physical, Lifestyle, Social and Psychological.

4.5.6.6.1 Physical

Physical symptoms like pain or lack of range of motion could inhibit progress, especially in the initial post-operative phase which could create stress for the patient. One surgeon discussed some typical presentations and why they may occur.

> *I think one challenge is certainly getting full extension back. I think there's a group of patients that you can usually pick out straightaway who have a tendency to develop fixed flexion, and they're often the ones that develop fixed flexion after the initial injury. 16S*
>
> *I think donor-site pain can be a real obstacle. It's rare, but sometimes you get the patient with a lot of hamstring pain. If they do, that will tend to promote a fixed flexion deformity because they don't want to stretch their hamstrings. 16S*

4.5.6.6.2 Lifestyle

Some clinicians describe particular frustration with patients who were not active or particularly healthy before the surgery.

> *There are a few that just, you know, aren't sporty, obviously, and rupture their ACLs and then aren't particularly interested in rehab and they are difficult ones, because you know that they're potentially more at risk of a re-rupturing if they've not got good strength of control and they do something off the cuff, like, perhaps play a bit of football and they haven't really rehabbed that well. So, I think they're the difficult ones. 9P*
>
> *And we have certain areas where people have never been to a gym, wouldn't know what one looked like, certainly don't have access to it. 21P*

4.5.6.6.3 Social

Clinicians observed that social factors such as job type or family responsibilities impact how well people could care for their knee post operatively. Pressure from bosses and sports managers is often cited as a confounding factor in return to activity/sport planning.

The majority of people that we're going to be seeing are going to be weekend warriors or kind of, I guess, manual labourers. And the sort of socioeconomic side of things I think, again, is huge. We have people who pointedly just can't take time off work in the post-op period to allow things to settle. 21P

Often the people I work with it's a sedentary desk-based job, which for a knee isn't great for knee extension and management of swelling. And they can't leave the desk given the high-pressured nature of their jobs at times. 17PM

And in the military, pressure to return to duty.

Listen, it takes a long time to return to peak performance, and try and speak to the medical team about that because there are some of the managers have an unrealistic expectation. 8P

4.5.6.6.4 Psychological, motivation, self-efficacy

The psychological recovery from ACL injury and the particular association between psychological recovery and return to sport were much discussed in the literature. Participants clearly felt this was important. Managing these symptoms was a challenge and while some clinicians felt that success with these symptoms was fundamental to their practice others felt that they were underequipped to manage these symptoms even when they recognised them.

We've got to have the facility to deal with their concerns and their fears because every patient presents with the psychosocial components, the presentation. These patients are perhaps less likely to have lots of long-term conditions. Not that they won't, but less likely to be in a chronic-pain situation before injury. Nonetheless, they can have a lot of fear avoidance, potentially. They're going to have a fear of movement, particularly any change of direction off that side. They may have fears about returning to physical activity, which is a healthcare concern more generally. Returning to sport, which is a lifestyle concern, will also give them fears, potentially. 1PM

But I wouldn't be 100% sure what sort of intervention is most applicable, or most appropriate, for those people. Whether it would even come from our profession, other than reassurance and supervised exercise… I wouldn't even say that we have an appropriate way of, actually, identifying it. So, even then, it's more either experienced…mean, not that we routinely use here to identify that. I wouldn't know what score, or anything that would stratify people into what intervention would then be appropriate, based on that information. 3P

When they're transferred into the gym, we ask them about any worries or concerns, and make sure that they have a really good understanding of the healing process, and the time scale. I think part of it is actually reassuring them that it is really common for people to be concerned. We'll address it as in talking to them about it, but then just through gradual exposure, because they all have their own individual exercise programmes. 5P

Some physiotherapists also discussed the iatrogenic effect of old ACL myths that were still being whispered in some treatment corridors. The use of braces without due cause, anxiety about open chain exercise and using fear of re-rupture to motivate patients can have a negative impact on

psychology and healing. Another clinician observed that physiotherapists too were affected by the fear of re-injury.

> *People are perhaps overcautious and that comes across to the patient, who then becomes overcautious. 21P*
>
> *The fear is on both sides. It has a large impact, I believe. 3P*

Many surgeon and physiotherapist participants saw reassuring, engaging and motivating patients as part of their role. These 'soft skills' were commonly referred to as part of the job and in some sense the patients' self-efficacy was also something that can be positively influenced or changed by the physiotherapist or surgeon.

> *If they're not particularly motivated, then that's sometimes difficult to get them on board….. I find their motivation wanes in the middle. Like, that they're good at the beginning, good at the end, but it's really up to me to keep them engaged when they're going through the hard strengthening in the middle which is going to make, hopefully, a long-term difference. 6PM*

Emphasis was again placed on relationships and patient education when supporting ACL patients with the psychological sequelae of ACL injury. The much documented psychological vulnerabilities of this patient group referred in particular to the psychological distress suffered by active women and men, when they felt isolated from the sports they love and their primary peer groups. One therapist described the balance of his practice in relation to psychological versus physiological education and care.

> *Actually, I probably spend 99% of the time talking to the athlete, talking to the patient and trying to build confidence and understanding. 20PM*

4.5.6.7 On the enjoyment of ACL patients

Participants were asked to describe their experiences of working with ACL reconstruction patients. Many highlighted that this was a preferred patient group. Both surgeons and physiotherapists felt that many ACL patients were young and active, and therefore had good rehabilitation potential and that this improved their job satisfaction. Physiotherapists found that for some patients the predisposition to sport and activity meant they would engage well in rehabilitation.

> *Well, they're young, and fun. 5P*
>
> *If you get too many arthritic backs it's nice to have an ACL. 2PM*

'Relationships' and 'bonds' with patients were frequently emphasized by surgeons and physiotherapists. The psychological and social needs of the group presented welcome complexities to care providers. One surgeon referred to the importance of the patient-doctor relationship with this

patient group. He described his belief that this patient group requires surgeons to go 'the extra mile' as an essential component of care.

> *… everyone likes the idea of being a soft tissue knee surgeon and, oh yeah, the sports knee and all this sort of stuff, but you can't just dabble in it, if you're going to do it you'll do it, and that involves going that extra mile to have those relationships. And if you're not willing to have those relationships you just shouldn't do the work. 7S*

A physiotherapist with many years' experience referred to the evolution of his clinical practice into being focused on relationships.

> *The length of time it takes to recover but also the personal bonds you get with patients. That's kind of where I've naturally migrated to, with my rehab side of things. 17PM*

One participant expressed the satisfaction of his work as 'pride' in the achievements of his patients. This implied a significant investment of the clinician in the patients' outcomes. Significantly, he also reports communicating this feeling to his patients, implying an established familiar relationship.

> *I'm always quite proud of them and tell them a good duration of the time. 15PM*

4.6 **Discussion**

4.6.1 Summary of principal findings

The principal finding of this study was the wide variation in care that stakeholder participants reported across different settings for ACL reconstruction rehabilitation. Exploration of the varied pathways exposed variations in resources available, such as equipment, space, the time and availability of skilled staff, as well as variations in values and aims of treatment. Participants in this study perceived that reasons for this included local health policy, availability of funding, lack of cohesive multidisciplinary teams to lead care, geographical spread of services across many sites, changes of attitudes within physiotherapy and changes of attitudes toward physiotherapy. Underlying causal mechanisms such as the impact of health policy on resources and changes to professional identity owing to long term lack of resources were proposed. However, despite the reported variation in care delivered, there was broad agreement about what rehabilitation should include for optimal care and that the evidence base provides a template for optimal care. Some participants depicted highly resourced and outcome driven care. Others identified that their intersectional lack of resources such as rehabilitation facilities and trained staff, may be 'failing' their patients. Some models were conducive to evidence based care, while others create impediments to it.

The availability of gym space and equipment was noted to be essential for optimal rehabilitation. The bare necessities were detailed as weights and resistance machines, balance challenging equipment, cones and ladders, and cardio equipment. Importantly, all participants discussed the importance of these resources but not all participants were in a position to provide these things for their patients. Clinician time as a resource was also discussed in relation to frequency and duration of care. Some clinicians experienced conditions where early discharge from care was encouraged irrespective of criteria based progression or patients goals. For many it was the goals of the service, rather than the goals of the patient that brought about end of care.

The relationships between orthopaedic and physiotherapy teams was elevated as a matter of most importance as a facilitator of good care. Hospitals where physiotherapists were present in orthopaedic clinics seemed to encourage optimal communication. Whereas in some trusts, the barriers both geographical and organisational between physiotherapists and orthopaedics, meant that they were unfamiliar with each other's practices and beliefs which led to poor communication and lack of mutual understanding.

Knowledge and expertise of the physiotherapy team were also discussed as important facilitators of good care. This study found that evidence based care drives the practice of most participants and was central to the 'knowledge' that was passed through clinical teams. Often senior clinicians with a special interest led ACL rehabilitation programmes, however participants identified the depth of knowledge across the team also varied, especially where care was provided across many sites with limited supervision. The emphasis on providing specialist training and support within clinical teams was highlighted as a key criterion for delivering good care. Participants identified that knowledge on sports rehabilitation in particular was important for a population of patients whose goals were often focused on returning to sport. However participants also identified that these skills were not universally valued or seen as a learning priority within conflicting demands of NHS.

Finally, many participants described their enjoyment of this patient group and at various stages, identified that 'a particular interest' or 'special interest' was beneficial in those who lead care with this group. The physiotherapists and surgeons appeared to empathise with the physical and psychological effort that ACL rehabilitation takes as well as the social implications of such a process.

4.6.1.1 How this research fits with and builds on previous literature

The evidence based approach to ACL care is individualised, criteria based progression through phases of care that align with biological and functional recovery (20, 34, 42, 88, 228). This study is the first to show that the significant variation in UK ACL care pathways means that some services are not in a position to meet these standards. Services that offered appointments in only one phase of care, in inappropriate settings or have automatic progression rather than individualised care, appeared to be in contravention of evidence based principles.

The finding of this study show that in some services the aim of treatment is no longer related to achieving the patient's goals. This is a significant finding where in the past, patient centred practice has been a guiding principle of physiotherapy (229-232). It aligns with the biopsychosocial model and the WHO International Classification of function, disability and health, in putting the patient and their goals at the heart of care (214). This study demonstrated a deviation from this value. ACL patients were known to be an active group. The National Ligament Registry reported 87% of their registered patients as having been injured while participating in sports (53) and return to sport has been identified in the seminal Lynch paper, as one of the 6 COMET criteria for defining a successful outcome after anterior cruciate ligament reconstruction (148). The return to sport stage of rehabilitation was characteristically different from other phases of care with set goals and criteria of relevance crucial for those who intend to participate in sport after ACLR (20, 107). It included complex problems and decision making that presents challenges for patients without a supervising physical therapist (233). Returning to sport too soon was correlated with risk of re-injury and the return to sport tests were implemented to recreate the physical challenges of sport in a controlled way and measure the individual's ability to perform the necessary physical tasks of their sport (20, 234) When individuals fail to pass the return to sport test criteria, delaying their return to sport, is thought to protect them from re-injury (235). Without this testing and shared decision making about return to sport, risk was increased. Myers et al suggested the need for functional screening to manage the difference between the athletes perceived readiness and actual readiness to return to sport (42). The findings of this study suggested that a new paradigm has emerged where some services see advanced rehabilitation and return to sport goals as beyond what they are obliged to offer in post-operative rehabilitation. In these cases, there is no suggestion that rehabilitation was complete but that independent work should continue. Supported self-management was an important part of the NHS long term plan but it was not clear what measures are taken, if any to 'support' or guide patients to continue rehabilitation

independently. This phenomenon leads to a 'rehabilitation gap' where much was unknown about rehabilitation or risk management of further injury.

This research finds that participants' who did offer return to sport services, relied on the evidence base and outcome measures to guide their practice. Some felt that they had more capacity for return to sport in their private practice roles. It was known that those who pass return to sport criteria significantly reduce the risk of re-injury to the graft (20, 236-238) Batteries of functional tests are still best practice to determine the resilience of the knee to sporting function (34, 107) but testing return to sport criteria requires strength equipment and other modalities for physical outcomes. Clinicians described effective and resourceful efforts to measure performance and function with whatever equipment they had available, evidencing in particular the need to accurately measure strength of quadriceps and hamstrings, and single leg jump and landing control as factors associated with limiting injury risk (107, 148). This illustrates the importance of availability of resources as a tool of assessment and monitoring against known criteria for progression in ACL care.

Clinicians identified and robustly defended the need for adequate gym equipment to deliver ACL rehabilitation. Resistance equipment to provide external loading during rehabilitation as well as combinations of equipment for cardiovascular exercise and to challenge neuromuscular control that were deemed as basic essentials. The correlation between strength motor control and positive outcomes were cited by participants (20, 34) as well as the challenges of monitoring and measuring progress toward known criteria (148). This study demonstrated that the provision of this type of rehabilitation equipment was not standard, as participant accounts described how some pathways lead to cubical based rehabilitation without access to gym facilities. The implications of ACL injury on long term strength and performance of the lower limb are known (47, 239, 240) and strength and motor control exercise rehabilitation programmes are evidence based interventions. This study demonstrated that many clinicians appeared frustrated with the gap between the best practice they know to be optimal and the need for appropriate resources to facilitate it.

In line with previous research (241, 242) , participants clearly valued a multidisciplinary approach to rehabilitation. The participants also noted that hospitals where physiotherapists work collaboratively in orthopaedic clinics were not only cost effective but had improved inter-professional understanding (243, 244). The participant's experiences of both good and bad care highlighted the importance of teamwork and communication in providing safe care. Leonard et al discussed that effective communication was fundamental to high quality care and to patient safety. They added that failures of communication commonly cause inadvertent harm to patients (245). This is in keeping with

participant experiences and this research also identifies that failures of communication appear to run the risk of a culture of mistrust and blame.

There was certainly an argument in the literature that unsupervised rehabilitation could be safe with highly motivated patients and it is economical (92). However, without appropriate patient selection and pathways that ensure patients have access to the advice and information appropriate for each stage of care, this model is not grounded in evidence. Participants discussed supporting patient self-management by using technology in their practice. It was used for patient education and advice, for exercise technique, sets and repetitions as well as for recording outcome measures. Although much of the technology discussed was used in ad hoc way rather than integrated fully into the care plan as has been achieved in other rehabilitation models, where digital has been used as an equally effective alternative to access 'hard to reach' populations or offer an alternative to face to face follow ups (246-248). In trusts where face to face or personalised care was significantly limited due to resources, integrated use of digital health tools could go some way to supporting the patients to access the best evidence and information and to self-manage. This combined model of digital plus usual care can aim to fill the gaps where currently there is no care at all. It is a concern that the boundaries between unsupervised rehabilitation and inadequate care may be overwhelmed in a financially strapped health care system. Though resources may have been a notable factor in participant experience and opinion, ambiguity in the evidence for supervised rehabilitation leaves rehabilitation practice open to deconstruction.

Empathy in the clinician patient relationship is a central principal of biopsychosocial care (11). Many surgeon and physiotherapist participants identified themselves as sportsmen and women, referring often to their own experiences of injury and rehabilitation. Some physiotherapists appeared to construct rehabilitation as a proxy for sports based games in order to appeal to patient interests. It is suggested that empathy may be a factor in patient engagement and patient experience of care (249, 250) and has been linked to positive outcomes (251, 252). For the participant group empathy seems be an important contextual factor in 'going the extra mile' with this group and appears to be related to a shared 'sports' interest.

4.6.1.2 What new findings does this research contribute?

There is a significant variety in pathways and practice for patient accessing rehabilitation after anterior cruciate ligament reconstruction. Though it may have been anecdotally suspected, this study confirms a significant variation in patient's access to physiotherapy time and resources. Further, it confirms that

in some cases clinics have no return to sport pathway and patients are being discharged at the point of return to function regardless of having any sport based goal and with no guidance pathway in place to review or to support self-management. Participants agreed that access to adequate rehabilitation equipment is a key ingredient for providing ACL care. The essential rehabilitation equipment discussed pertained to evidence based management strategies for positive outcomes and the prevention of long term sequelae and further injury risk.

Lack of resources was one element of a mosaic of care limiting factors. An uncomfortable relationship was suggested between pressure to discharge patients from care and a lack of knowledge of advanced rehabilitation. The latter is not confronted where care is ended prematurely. Where facilities, resources and knowledge are lacking, participants have identified a culture of early discharge with no consideration for return to sport goal. Although the management of capacity and demand is delicate, the relationship between these three contextual factors may be key in identifying services with barriers to evidence based care.

Surgeons and physiotherapists from all models of care placed significant importance on the educational component of care and on engaging and motivating patients to self-manage in addition to clinical appointments. The patients' responsibility in their rehabilitation was strongly emphasized, however given the significantly different face to face input that patients receive, the balance between patient responsibility and clinical responsibility are very different in different models of care. It is also not clear that patients who are given less face to face care are then supported or monitored in other ways, such as virtual rehabilitation, phone or email follow up. The use of technology in care appears to be widespread if somewhat varied in its application. The principles of supported self-management and patient education can go some way to plugging the resource gaps that are evident in some pathways. Empirical evidence for the importance of return to sport to ACL outcomes exists, however a lack of evidence to support one care model over another or models of reduced care with technology supported self-management leave clinicians unarmed for decisions about resources.

A previously unidentified contextual factor is the challenge and frustration that clinicians express when reconciling their roles as professional gatekeepers of orthopaedic and physiotherapy specialities with their role as leaders in a cost conscious health care environment. Participants' experiences depict that some are troubled by the schism from the long held principle of patient centred goals and the obligation to deliver evidence based practice. Local health policy and clinical resources were discussed and are implicated as a causal mechanism for services that are not delivering evidence based practice.

One participant summarised that the progressive defunding of local services caused him to question how physiotherapy care is now valued in his Trust. Though this experience is not individual to ACL rehabilitation, this is a noteworthy account of the experience of progressive defunding was having on an experienced physiotherapy team.

The relationships between orthopaedics and physiotherapy might be at an all-time high, due to extended scope roles and physiotherapists often working in orthopaedics clinics. Participants highlighted this as a critical factor in the provision of good care and sited the combined clinics as the ideal environment to foster teamwork. In cases where communication was poor and the hierarchy was maintained at the expense of open communication, participants felt there was a negative impact on care. Both clinician groups indicated empathy with one another and with the ACL patient group. Several participants referred to their own sports injuries during the interviews. The cultural importance of sport and a common 'sports' identity may be contextual factors in explaining the overwhelmingly positive relationships that participants have with this patient group. Although many clinicians develop clinical interests, it is suggested that special interest in this patient group may be related to a common identity with sport culture.

4.6.1.3 Strengths and Limitations

The strength of this study is that qualitative interview methodology allowed the exploration of critical issues affecting physiotherapy care in order to explore the phenomena that may be causal. By purposively targeting clinical leads, experts and researchers around the country, the interview methodology facilitated a wide ranging exploration of the factors influencing the variations in care.

The use of snowball sampling methodology as part of this study methodology, with regard to recruiting orthopaedic surgeons has potentially biased the sample. The surgeons that recommended one another may hold similar professional values and attitudes. A further limitation of the sampling method was that I often contacted people through their work place. Although I stressed individuality, anonymity, personal career experience and opinion, I am aware that some participants may have felt they were representing their employer. I had attempted to organise interviews outside of work time in order to mitigate this challenge, however, often, this was not what suited the participant.

4.6.2 Implications for clinical practice, policy and research

4.6.2.1 Implications for clinical practice and policy

This group of expert stakeholders has identified the important of adequate equipment and specific training to deliver evidence based ACL practice. Local strategies to ensure appropriate training and adequately rehabilitation equipment are needed in services that manage patients after ACL surgery. Clinics that are treating patients without this, may be apt to advise patients of the limits of their care environment and suggest alternatives.

Participants also highlighted the need for clinics who manage ACL rehabilitation patients to have a return to sport strategy that reflects the evidence base and the needs of the patient group. In some cases, participants highlighted models of reducing care, with longer breaks between follow ups and infrequent but effective review appointments to stretch resources and engage patients over the lengthy rehabilitation cycle. Where clinical pathways present impediments to evidence based, patient centred care, further strategies are needed at a local level to address this.

A functional multidisciplinary team was strongly emphasized. Physiotherapist roles in orthopaedic clinics are noted to be particularly favoured by participants in fostering team work and communication, toward higher quality care. Education and promotion of patient self-efficacy and self-management were much discussed in models of care where patients were seen less frequently. The use of various exercise based digital tools that monitor exercises, educate technique and gather outcome measures was suggested by some as a means to manage patients in a resource effective way.

4.6.2.2 Implications for research

Availability of resources such as clinician time, equipment and staff training are presenting critical challenges to the management of ACL patients in some Trust areas. Research is needed to explore cost effective models of rehabilitation that include return to sport strategies.

4.6.3 Reflexive notes

Having worked in qualitative research over a number of studies, I was aware that using the phone and skype for interviews might affect the communications with participants. This participant group was spread out across the country and so I was limited in the number of face to face interviews I could do. Initially I did not notice any particular differences, but as I became more familiar with my interviews, through listening to the recordings and reading the scripts, I did notice inconsistencies. When face to

face, I was better at probing for detail and delving deeper into topics. I picked up cues from participant remarks and asked pertinent follow up questions that improved the data. In phone and skype interviews, I was frustrated to notice that I had missed cues sometimes and opportunities to excavate a concept further. This may have been due to missing out on the various non-verbal communications and interactions. Another reason may be that in using the phone, I felt freer to make notes. This was helpful for a number of reason but may have contributed to a loss of focus. Given the choice, I would prefer to always interview in person.

My role as a physiotherapist created a notable impact on some of the physiotherapists that I interviewed. I noted that some participants felt that their knowledge and their adherence to the evidence base were being tested. I have considered the impact that this may have had on the data and I noted that there were varying degrees of pride in practice and regret about the conditions of practice. As interviews progressed, when I was interviewing physiotherapist colleagues I represented myself clearly as a junior researcher and very 'typical' clinician. Interestingly there was an opposite effect when I interviewed very established experts in physiotherapy or orthopaedics, where I felt somewhat tested and unsettled. I referred to the Kvale et al research that looks at how power and dominance are constructed in interviews, and I was mindful of this as the research progressed (253).

Chapter 5 – The development of TRAK ACL, a digital intervention to support the self-management components of ACL rehabilitation

5.1 Chapter Outline

TRAK is a digital health intervention (DHI) for knee rehabilitation. This chapter will describe the optimisation of the TRAK website with a view to maximising its acceptability to patients and physiotherapists, its readiness for trial and its potential efficacy for anterior cruciate ligament reconstructed patients. Previous iterations of this website were known as "TRAK" or "TRAK for ACL" whereas the iteration that was developed and tested as part of this PhD was known as TRAK ACL. In the Background I will introduce the models that were used to inform the research and design process at various stages of development. I will describe how each model was used and why each model was important to the development process. The Medical Research Council Framework for Designing Complex Interventions and the Interaction Design Lifecycle Model are described as models of development, establishing user requirements and feasibility. The Behaviour Change Wheel for designing interventions was the principal framework of development informing the behavioural components of TRAK ACL and the Normalisation Process Theory was utilised to understand and predict potential usage problems. The Person Based Approach is used a posteriori to reflect on the process I undertook.

Many of these theories assume that the researcher is starting at the very beginning of a development process. In contrast, TRAK was developed under pragmatic conditions and through several cycles of funded research, some, but not all, of which I was involved in. The Background also includes an account of how TRAK ACL was developed through multiple iterations. I will describe the TRAK research and development work that occurred prior to my PhD in two parts; work that was conducted by others and work conducted by me.

The Methods section will describe the process of the development undertaken as part of my PhD, which focused on the Behaviour Change Wheel intervention design process. The Results section shows the completed logic model for TRAK ACL and a detailed visual tour of TRAK ACL. Finally, I will discuss the development process in relation to the theories and reflect on the strength and limitations of the intervention.

5.2 Background

5.2.1 Frameworks for developing digital health interventions

5.2.1.1 The Medical Research Council Guidance on the development of complex interventions

A 'complex intervention' is one that has a number of interacting components, behaviours required, more than one acceptable outcome and flexibility permitted in its use (254). The MRC guidance for developing and evaluating complex interventions describes 4 phases: Phase 1 focuses on development, and includes theory, literature reviews and modelling; Phase 2 focuses on optimisation of both the intervention and the evaluation methods; Phase 3 concentrates on evaluation, usually in the form of a randomised controlled trial to determine clinical- and cost-effectiveness; and Phase 4 is about implementation (Figure 5.1) (255). While these were originally thought to be linear, it is now recognised that these phases should be iterative and context sensitive (254). This thesis is concerned with the Development and Optimisation phases of the MRC model.

Phase 1 has 3 components. The first is identifying existing evidence. This will frequently require either incorporating the knowledge from existing systematic reviews in the field or conducting new systematic reviews. The second is identifying and developing theory, including developing a "logic model" or "pathway of change" that predicts how and why the intervention will function, while the third is modelling process and outcomes. Modelling can help identify rate limiting or other key factors which may need exploring through a series of studies (254). The authors of the MRC framework suggest that not all components are needed in all cases.

Phase 2, or optimisation, focuses on optimising both the evaluation methods and the intervention design. Key to this phase is ensuring that the evaluation parameters match the intended proximal and distal outcomes of the intervention (255) and that both the intervention and the evaluation methods can feasibly be delivered in practice (256)

Feasibility and pilot trials are a key step in demonstrating whether a Phase 3 trial to determine clinical- or cost- effectiveness can be undertaken and will answer the questions posed, and are important in preventing wasteful use of scarce research resource. (257) By identifying problems of acceptability and feasibility in phase 2, researchers can decide whether to proceed without wasting money and effort on a pointless trial. Whereas the development stage allows you to consider reasons the intervention itself might fail, the feasibility stage invites you to consider how the clinical trial may fail

(254). Such detailed planning aims to help avoid the chasms and pitfalls that seem especially large for early career researchers.

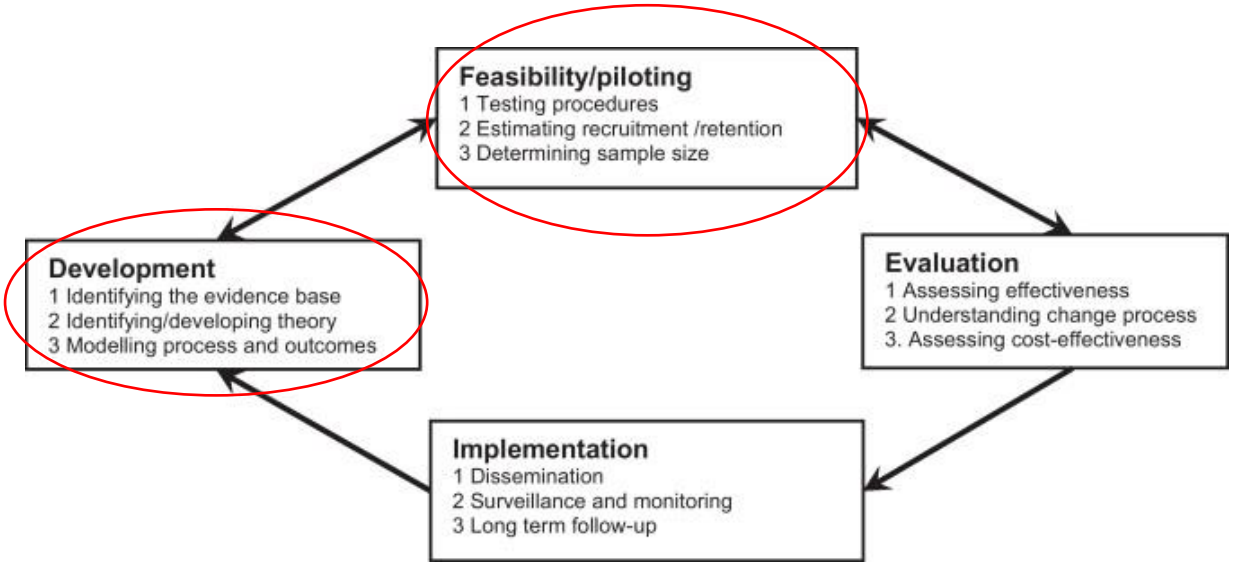

Figure 5.1. The Medical Research Council guidance for developing and evaluating complex interventions. Focus of TRAK research

5.2.1.2 The Interaction Design Lifecycle Model

The Interaction Design Lifecycle Model (IDLM) comes from the human computer interaction field of research (Figure 5.2) (258, 259). It provides a useful model for understanding the creative and collaborative design process and informs much Digital Health Intervention (DHI) development. The term lifecycle model captures a series of purposeful activities and their relationships to one another. In the HCI field it was intended to place a formal structure on the creative design process (259) The iterative stages are non-linear and include establishing requirements, designing alternatives, evaluating and prototyping (259).

Establishing requirements can be a complementary process to the MRC development stages 1 and 2. Theory and logical deductions inform a knowledge of the content, the user groups and the active components of an intervention. Designing alternatives to optimise user experience or functionality can be cyclical and require multiple iterations with a spectrum of relevant users. Prototyping involves giving users a physical DHI with which to interact. This is a vital step in usability and acceptability testing. When interventions appear ineffective it may be that they are in fact ineffective, but it may also be that they are being used in the way intended, or by the target population.

In the development of DHI by clinicians, no effort is spared in the reviewing of clinical evidence. This knowledge is then used to dictate the content of DHI. However, understanding the importance of design to user experience is equally critical to meeting the needs of intervention users.

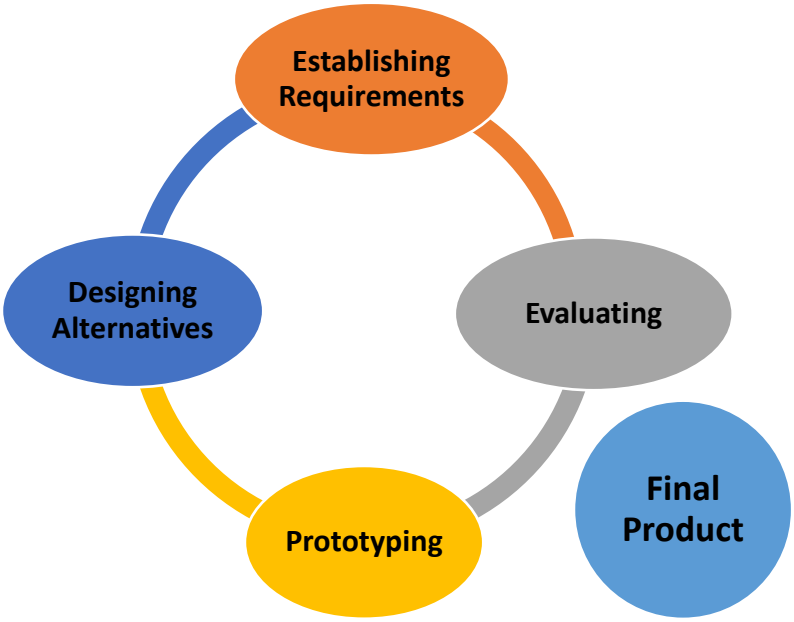

Figure 5.2. Interaction Design Lifecycle Model (259)

5.2.1.3 The Normalisation Process Theory (NPT)

It has been observed that many digital health interventions fail to become integrated into routine clinical practice ((36, 260, 261). Normalisation Process Theory is a mid-range sociological theory that focuses on the work of implementing, integrating and embedding (normalising) new practices or ways of working into routine health care (262). It can be applied both to developing interventions and to developing trial or other evaluation studies (256). Many researchers have used it to help design and optimise interventions which can be easily implemented into healthcare systems (262). It provides a structure to identify factors that may contribute to why interventions ultimately fail to be implemented and encourages thorough examination of these factors early in the development process (256). If overall the NPT finds that an intervention has little chance of implementation then it is considered that it may not be wise to take this intervention to trial (256).

There are 4 main components to NPT: coherence (sense making); cognitive participation (engagement); collective action (work done to enable the intervention to happen); and reflexive

monitoring (formal and informal appraisal of the benefits and costs of the intervention) (256). In the development stage, key questions are suggested about the DHI; does it have 'clear purpose' and 'benefits'; the level of engagement with the target user groups, the effort required by clinical collaborators, and how will the impact of the DHI be monitored. Consideration of these issues at the development stage can strengthen the intervention and increase the specificity of a later evaluation.

5.2.1.4 The Behaviour Change Wheel (BCW)

The use of behaviour change principles in physiotherapy is common practice (30, 41, 209, 230, 263, 264). Without necessarily identifying the 'behaviour change' elements of care, many physiotherapy interventions focus on changing patient behaviour in order to improve outcomes. For example, in common conditions such as osteoarthritis of the knee or ACL rehabilitation, relevant knee exercises and education are taught in a class environment where the emphasis is on behaviours that lead to positive outcomes. This OA knee intervention is acting on giving people the capability, opportunity and motivation to change their behaviour (34, 40, 41, 91). At the centre of the BCW is the COM-B model, where C-capability, O-opportunity and M-motivation are suggested as an interactive system leading to B-behaviour (Figure 5.3) (265). Michie et al argue that a thorough analysis of the target behaviour is the first step and it is critical to the success of an intervention (265). In many rehabilitation interventions, the key behaviour that we want to change is exercise.

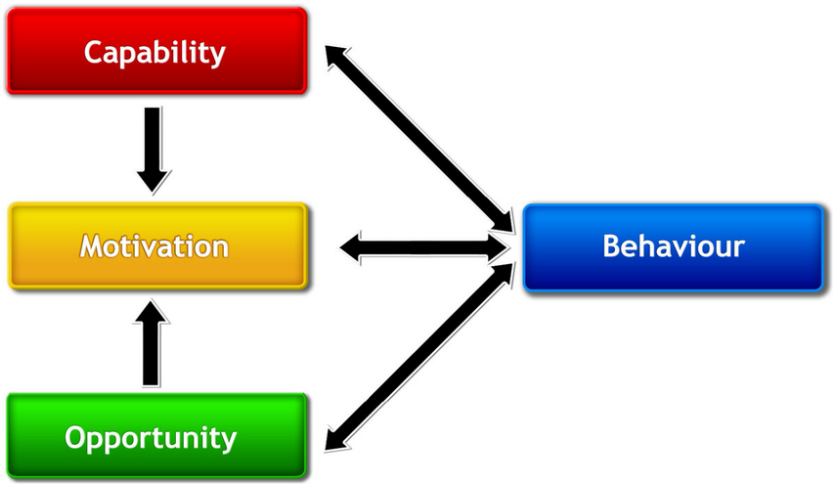

Figure 5.3. COM-B model, from the Michie et al 2011 (with permission) (35)

Evidence shows that exercises are fundamental to recovery from ACL surgery as discussed in Chapter 2. Indeed many MSK conditions are known to benefit from targeted exercise. Conversely, poor outcomes are often associated with lack of exercise or deconditioning. However exercise adherence

is not static and can fluctuate over time (266, 267). This suggests that exercise, as a behaviour requires exploration.

Research in the management of osteoarthritis, a common MSK condition, shows that exercise adherence is best when patients are supervised by a physiotherapist but is known to reduce as physiotherapy is withdrawn and over time (268). Exercise adherence is associated with better outcomes but the adherence must be maintained (40). Marks et al found that poor adherence is the most compelling explanation for the declining impact of the benefits of exercise over time. They concluded that interventions should focus on supporting 'self-efficacy, social support, and skills in long-term monitoring' to improve adherence (269). DHI provide an opportunity to explore evolving care models that can potentially meet this need at a manageable cost.

The knowledge that we should exercise may not be enough to motivate many people, even after injury. Beinhart et al found that positive determinants for increased adherence include "greater health locus of control, supervision, participation in an exercise program, and participation in a general behaviour change program incorporating motivational strategies" (270). Jack et al identified multiple patient barriers to exercise adherence in MSK conditions, including "low levels of physical activity at baseline or in recent weeks, low in-treatment adherence with exercise, low self-efficacy, depression, anxiety, helplessness, poor social support/activity, greater perceived number of barriers to exercise and increased pain levels during exercise" (271).

Research tends to focus on patient barriers and neglects to explore barriers introduced by health care providers and the health service (266, 271). This underscores the importance of identifying variations in care, like those identified in Chapter 4, which may have an impact on factors relating to exercise adherence. The causes of non-adherence are likely to be multi-dimensional and therefore strategies to improve adherence with physiotherapy treatment cover a wide range. Combined interventions may be effective at promoting adherence with exercise (272). As skilled physiotherapists are a limited resource, we need to explore other options for supporting positive adherence behaviours in the community and with self-management strategies.

5.2.1.5 The Person Based Approach (PBA)

The PBA was designed by Yardley et al to be a complementary tool of process when applying behaviour change theories such as the BCW (273). It was produced to help develop health-related behaviour change interventions, often digital. It focuses on the users experience with an in depth look at users

relationship to the behaviour and to the behaviour change technique. There are two key elements to the person-based approach. The first involves extensive "qualitative research with a wide range of people from the target user populations, carried out at every stage of intervention development, from planning to feasibility testing" (274). The aim of this was to enable a deep knowledge of the psychosocial context of users and their opinions and experiences of behavioural aspects of the DHI. The second was to identify "guiding principles" that would "inspire and inform" the intervention development by highlighting the distinctive ways that the intervention will address key context-specific behavioural issues.

In this study the PBA is referred to as a model with which to reflect and consider opportunities missed.

5.2.2 History of the iterative development of TRAK

Many of the described theories assume that development begins at a fixed point and that all theoretical knowledge of the development process is held a priori. TRAK ACL was developed over time by committed clinicians, often working with very limited time and resources.

5.2.2.1 Studies by Dr Kate Button and Professor Irena Spasic

The initial TRAK website was designed at Cardiff University as a collaboration between the physiotherapy and computer science departments. The aim was to explore the potential of on-line interventions to support improved self-care in the management of knee conditions (275). Its functions were based on the knowledge that exercise interventions in the management of knee conditions are effective (276) but that research was needed to explore the potential benefits of digital tools to improve self-management (277). The website was developed with 4 key functions; "information provision, a three-step exercise program based on a standard care for the rehabilitation of knee conditions, self-monitoring with visual feedback and virtual support" (275).

The authors set out to identify the treatment modalities and concepts used in rehabilitation studies on knee conditions and thereby define 'standard care' for knee conditions (277). The concepts and categories that were identified formed the 'domain' of knee rehabilitation and they were mapped in terms of their properties and the relationships between them. This relational map was known as the TRAK ontology. It was developed in line with the Open Biological and Biomedical Ontology (OBO) Foundry that exists to provide ontological templates for biomedical data to allow subsequent epidemiological analysis (278). The intention was to map these classifications of treatment concepts onto the TRAK interface. TRAK would not only provide clinical content to patients but provide an

opportunity to quantify uptake and usage of different modalities such as exercise types or advice and information (277).

This work informed the first incarnation of TRAK as the TRAK App suite which was hosted on Facebook (275). It was usability tested with patients and physiotherapists using the Systems Usability Scale, a self-described 'quick and dirty' measure of usability (279) but with over ten years of credibility as a 'robust and versatile' tool (258). TRAK was shown to have 'unanimous acceptability' by physiotherapists and patients. Qualitative work also showed the intervention was thought to 'facilitate communication, provide information, help recall information, improve understanding, enable exercise progression, and support self-management in general' (275).

For the subsequent iteration, TRAK was transferred to its own website rather than hosted through Facebook. Exercise videos were added instead of pictures and patient exercise plans were personalised, so that exercise videos could be selected by clinicians for individual patient users. New educational content was added to support self-management concepts. Feedback from clinicians led to the decision to remove the contact portal from future iterations as it increased work burden and presented a risk if patient contacts were not responded to. Patients exercise progress logs continued. This iteration of TRAK was investigated using mixed methods research with physiotherapists and patients (280). This work provided further evidence that a digital tool to support self-management for knee conditions was acceptable to patients, while also identifying substantial barriers to usage by clinicians, including concerns about safety and added workload.

Part of this evaluation of TRAK included proposing a logic model of potential mechanisms of action, for measurement in future work. The mechanisms of action were mapped in relation to the Behaviour Change Wheel (265). This retrofit exercise mapped 7 mechanisms of behaviour change, Education, Enablement, Modelling, Persuasion, Training, Environmental restructure and Restriction that related directly to the core concepts of capability, motivation and opportunity as they pertain to behaviour (280). It was identified that future iterations of TRAK would need to be able to measure user interactions with these mechanisms of behaviour change that underpin the functionality of TRAK.

5.2.2.2 TRAK for ACL patients, an Acceptability study: my work before PhD

Using the same interface (275), a third iteration of TRAK was developed where the content was created by me in line with evidence based physiotherapy principles. It was evaluated in an Acceptability study in a London NHS hospital where I was the principal investigator (30). The

population of new users were patients following reconstruction of the anterior cruciate ligament. We called the intervention TRAK for ACL. This new user group required a cycle of design alternatives; creating condition specific content, meeting expectations of technology and meeting demographics expectations within video content (259). This group are typically younger and have higher functional goals than other knee cohorts (281). Identifying the need to diversify content to reflect the intended user population was an important part of 'establishing requirements and designing alternatives'.

The clinical content was developed by conducting a review of the relevant literature. I put together a lengthy educational document focusing on the key characteristics of each phase of rehabilitation. The content was a 'plain English summary' of the chapter 2 ACL evidence. The main sub headings of each phase were; what to expect from phase 1, what are the criteria for progression from phase 1 and what are the common challenges of phase 1. It was sent to four experts in the field of ACL rehabilitation for comments and improvements. Three were physiotherapists who had published on ACL rehabilitation and who had national reputations in the field and the fourth was an orthopaedic 'soft tissue of the knee' surgeon who was also took a close interest in rehabilitation. Edits were made based on their feedback and a further round of consultation took place where a consensus was reached on the content.

The TRAK Acceptability study was methodologically qualitative. Twenty-four patients and 5 physiotherapists used the intervention for 16 weeks. Physiotherapists were broadly positive about TRAK however they identified that ergonomic factors like the provision of tablets and information systems limitations, such as access to good Wi-Fi, cost them clinical time and frustrated them, which affected their user experience (30). They also highlighted a number of technical shortcomings where the TRAK interface could be improved for a more efficient clinician user experience. Patients reported that "TRAK, specifically the videos, increased their confidence and motivation with their rehabilitation" (30).

Importantly, patients also found TRAK "clunky" and identified a need to meet the design expectations they were familiar with from other commercial digital health tools. This design ideal would underpin the upcoming new prototype of TRAK. Interaction design is about designing products that are easy and enjoyable to use (259). These products have purposeful functionality but have at their heart a user centred experience, or in the case of TRAK, a patient centred experience. As a low cost digital tool, TRAK development was focused on functionality and evidence based content. Further iterations would need to address design limitations.

In the rest of this chapter I detail the work undertaken as part of my PhD to further develop and optimise the existing "TRAK for ACL" intervention. To distinguish the final intervention from the pre-existing one, I refer to the one used in my PhD as TRAK ACL.

5.2.3 Aim and objectives

The aim was to optimise TRAK ACL with a view to user acceptability, feasibility and potential effectiveness.

The objectives were to:

- synthesize previous TRAK research and map it onto the MRC framework and the Interaction Design Lifecycle Model
- utilise the Normalisation Process Theory to optimise patient uptake and use by exploring potential implementation challenges for TRAK ACL.
- apply the steps of the Behaviour Change Wheel Intervention Design Process in order to optimise the behavioural components of TRAK ACL

5.3 **Methods**

5.3.1 Design

Using the theories described above, this section aims to identify evidence from previous research and use it to optimise TRAK ACL in preparation for feasibility testing. The guiding principles of TRAK ACL were to deliver evidence based physiotherapy knowledge, on an acceptable and usable interface, populated with behaviour change techniques that target the desired behaviour.

5.3.2 Objective 1. Mapping the TRAK design history onto the Medical Research Council Framework

The Medical Research Council has described the process of development and evaluation of complex interventions in the 4 stages (254). TRAK ACL was developed through iterative cycles of Development and Optimisation, though its effectiveness and cost effectiveness and implementation have not yet been tested.

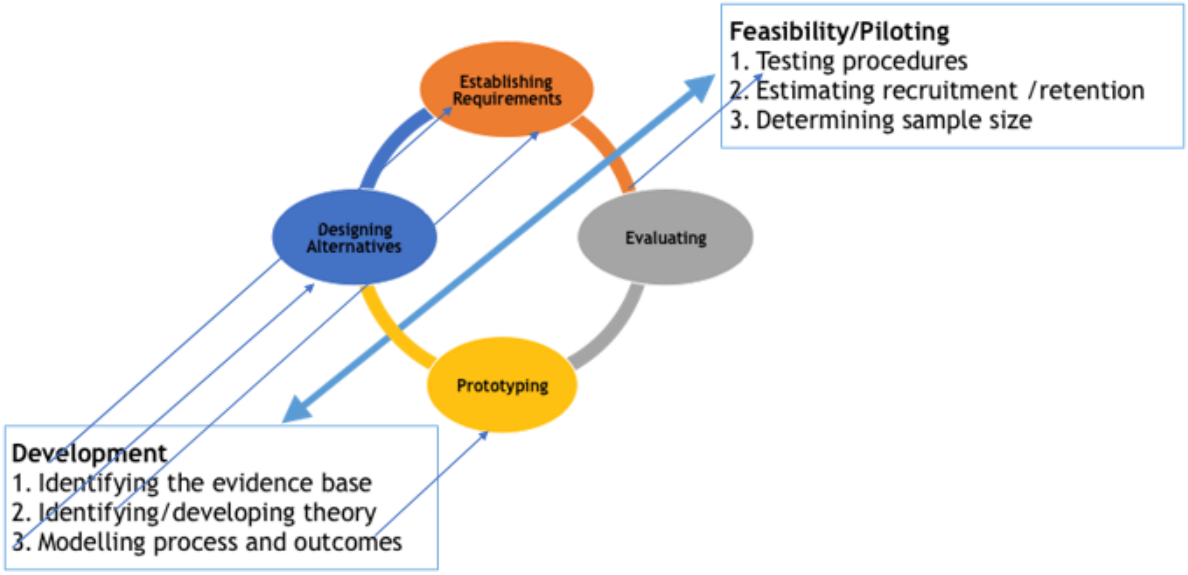

Figure 5.4. Map Interaction Design Lifecycle Model (IDLM) onto the Medical Research Council (MRC) framework

The MRC guidelines stress that development and evaluation can be non-linear. This low-cost intervention has benefited from multiple smaller funded projects resulting in a step-by-step and iterative approach to its development. Cycles of work have focused on identifying not just the appropriate evidence based health content, but identifying user needs that arise through the human-computer interactions. The iterative stages include establishing requirements, designing alternatives, evaluating and prototyping (259). These stages describe the process through which iterations of TRAK have been developed. Figure 5.4 shows how the IDLM and MRC framework for complex interventions interact throughout the development process. The activities undertaken in the development of TRAK are mapped using these two frameworks in Table 5.1 before being described in further detail. Only the work highlighted in yellow was conducted as part of this PhD.

Research	MRC Phase	Interaction Design Phase
2013 – Button et al. TRAK ontology: defining standard care for the rehabilitation of knee conditions.	Identifying the evidence base through a review process 1.3 Modelling processes and outcomes through design of a classification system	Establishing Requirements by reviewing the evidence Prototyping by manifesting a design that stakeholders can interact with
2015 – Spasic et al. TRAK app suite: a web-based intervention for delivering standard care for the rehabilitation of knee conditions	2.1 Testing procedures with a usability, acceptability study	Establishing Requirements through qualitative data Evaluating usability
Unpublished development work - E Dunphy	1.1 Identifying the evidence base for ACL rehabilitation and behaviour change science	Designing alternatives: Adding and removing functions in response to previous results. Designing alternatives: Specific content for an ACL evidence base Designing alternatives: Creating content in more acceptable formats such as infographs and animations.
2016 – Dunphy et al. Taxonomy for the rehabilitation of knee conditions (TRAK), a digital intervention to support the self-care components of anterior cruciate ligament rehabilitation: protocol of a feasibility study.	1.1 Identifying the evidence base 1.2 Identifying appropriate theory 1.3 Modelling Processes and outcomes	Establishing requirements for integration with current care Prototyping Evaluating
2017 – Dunphy et al Acceptability of a digital health intervention alongside physiotherapy to support patients following anterior cruciate ligament reconstruction.	1.1 Identifying the evidence base Identifying appropriate theory 1.3 Modelling Processes and outcomes 2.1 Testing procedures with an acceptability study	Prototype Evaluating Establishing requirements Designing alternatives
Unpublished development work. E Dunphy	1.1 Identifying the behaviour change evidence base	Designing alternatives for a new TRAK ACL based on acceptability results. Establishing requirements through an analysis of systems around the target behaviour – exercise
2018 - Integrating self-management support for knee injuries into routine clinical practice: TRAK intervention design and delivery.	2.1 Testing procedures through mixed methods research	Evaluation of TRAK through mixed methods continues to inform acceptability and feasibility with different populations.

Table 5.1. TRAK iterative development research mapped to phases of MRC framework and Interaction Design Lifecycle Model.

5.3.3 Objective 2 Normalisation Process Theory

In this study anticipating future user experience and potential recruitment challenges was an important part of the design process that was informed by NPT (256). NPT posits that the intervention should be coherent to users, i.e. that it should have a clear purpose, with clearly identifiable benefits to users. NPT predicted that it was important that users could readily see the point of TRAK ACL, and quickly understand how to use it. The design of TRAK ACL was influenced by the knowledge that trial participants would be younger and many would be from diverse backgrounds (282).

Different social informatics, related to location and population demographics needed to be considered, as they are known to affect user engagement (283, 284). All the videos on TRAK at this stage featured members of the clinical team in Wales who were all from a White ethnic background. Cultural, activity based and age related signifiers and iconography are known to frustrate users for whom they were not developed (281). Demographic differences in the two cities where TRAK was being evaluated called for 'designing alternatives' (259). The Office for National Statistics (ONS) puts the white British population in London at 59% and in Cardiff at 84%. "London was found to be the most ethnically diverse area, while Wales was the least diverse" (285). Identifying the need to diversify content to reflect the TRAK ACL user population was an important step in identifying potential barriers to recruitment. This NPT step is complementary to the IDLM, 'designing alternatives' and to the MRC 'modelling process and outcomes' (254, 256). The interaction design model facilitated the integration of potential requirements of a new cohort of patients that were more diverse than the previous users. In order to optimise TRAK usage within this group, content was developed to reflect the greater ethnic diversity of the London ACL knee population (256). Patients from the London cohort were invited to participate in an award winning Patient and Public Involvement (PPI) group. This led to the creation of over 150 new exercise videos featuring patients from diverse backgrounds as models, as well as contributing to meeting the design expectations of a younger than average knee cohort. This co-design with patients also informed the protocol of the TRAK ACL Feasibility study discussed in Chapter 6 (286).

A further expectation of patient users was that the technology of TRAK be updated and less 'clunky'. Following the development of new patient information content as discussed in Objective 3, design improvements were made using recommendations from a digital design expert with knowledge of healthcare user interfaces and user-friendly products.

In parallel with thinking about the experience of NHS patients using TRAK, consideration was given to the physiotherapist users who would facilitate the management of patient profiles in TRAK. I

hypothesised that physiotherapists' collaboration would be essential for engaging patients with TRAK ACL. The NPT encourages consideration of how TRAK ACL would affect the current care model and how physiotherapist/patient consultations may change. It was known from previous studies that physiotherapists in one to one consultations and in groups had generally positive experiences of TRAK; however, there was some evidence that although physiotherapists used TRAK in initial patient consultations, they tended to stop using it as treatment continued (30, 275, 280). Results from physiotherapist interviews in the TRAK Acceptability study highlighted some particular concerns (30). Using the NPT we can read these as potential barriers to implementation which a newer version of TRAK ACL needed to overcome. Physiotherapists wanted tablets to use in the consultation/ACL class, so that they did not have to break away to use a computer. They felt a wider selection of exercises was needed to be able to reflect the choices they make for individual cases in clinical practice. They wanted to see a greater emphasis on 'Red Flag' education (screening for serious problems after surgery) in the educational sections so patients using TRAK would get more information on when to seek support. They wanted to have a tick box section to monitor criteria for progression. Finally, they asked for increased technical efficiency, such as quicker exercise selection, playlists of exercises and collated 'dashboards of progress' that could be printed or saved with medical notes. It was clear from this feedback that "real world" effectiveness would depend on designing an intervention that met the requirements of the two user groups, clinicians and patients (256).

The content of TRAK ACL was upgraded to meet both sets of user requirements. A series of expert videos were made with a leading orthopaedic surgeon and a clinical specialist physiotherapist that addressed the educational needs. The content from these videos was replicated in animations and infographs to explore different modes of knowledge translation to patients. More videos were produced to meet exercise library expectations, which now totalled over 200 exercises. TRAK ACL was migrated to a new design interface, which was more contemporary and had more efficient processes such as minimal clicks/taps per action, and no typing needed other than when first setting up a patient.

NPT encourages developers to understand the context in which the intervention would be delivered. Time is precious in physiotherapy consultations as for many healthcare consultations. TRAK ACL would need to be delivered efficiently. In this case, physiotherapists would be delivering the intervention in either ACL exercises classes where fast effective care happens with a number of patients in a shared space or in a 1:1 consultation, which could take place in a busy and pressured environment. In anticipation of time as a barrier and of upsetting the patient/physiotherapist interaction, iPads were made available for clinicians at Site 1 and 3 for the duration of the trial. This intervention aimed to

reduce the impact on current models of care so that physiotherapist might facilitate greater integration of TRAK ACL into their consultation behaviours.

5.3.4 Objective 3 -The development of TRAK ACL with the Behaviour Change Wheel intervention design process

A key principle of the development of TRAK ACL was to move beyond theories of ACL rehabilitation and to incorporate the personalised behaviour change functions that were requested as part of the output of the qualitative data and aligned with known theoretical links between behaviour change and outcomes. The TRAK acceptability study established a new set of user requirements that would inform subsequent iterations of TRAK (30). Study participants asked for more personalised functions, self-monitoring functions, a prompt system, a reward system 'to tell you well done', several measures of progress and a 'dashboard' that collates progress (30). Many of the changes that they requested were based on their experiences of other health apps such as 'Nike Run' and 'My Fitness Pal'. Many of the functions they described mapped onto theories of behaviour change (265) This section explores the process of designing TRAK ACL and understanding the minutia of exercise as a behaviour in order to optimise the specificity of TRAK ACL as a behaviour change DHI.

5.3.4.1 Stage 1. Understanding the behaviour

5.3.4.1.1 Stage 1.1 - Defining the problem.

Rehabilitation is standard post ACLR and is associated with good outcomes (7, 20, 34, 90, 91). Improved access to care, uptake and performance of physiotherapy could lead to improved outcomes. The health service encounters barriers such as the cost and skill level of physios. Patients encounter barriers such as having time to commit for face-to-face physio appointments over the course of rehabilitation as well as the motivation, skill and confidence to self-care. Improved exercise behaviours could be achieved by a DHI that was evidence based, widely available and incorporated behaviour change techniques.

5.3.4.1.2 Stage 1.2 - Select the target behaviour

The main behaviour of ACL rehabilitation is exercise, however behaviours interact as a system. The behaviours involved in rehabilitation include accessing an exercise environment, attending physiotherapy, obtaining gym clothes, allocating time for exercise, educating oneself on personal exercise rehabilitation plans and the exercise itself. An intervention may be improved if it focused on one behaviour while acknowledging that it is the centre of a system of behaviour (38). When these behaviours were prioritised in terms of the desired rehabilitation outcome, then 'exercise' itself

emerges as the central behaviour. Other behaviours can be seen in terms of their relationship to the central behaviour as identified in Figure 5.5, a conceptual map of rehabilitation behaviours.

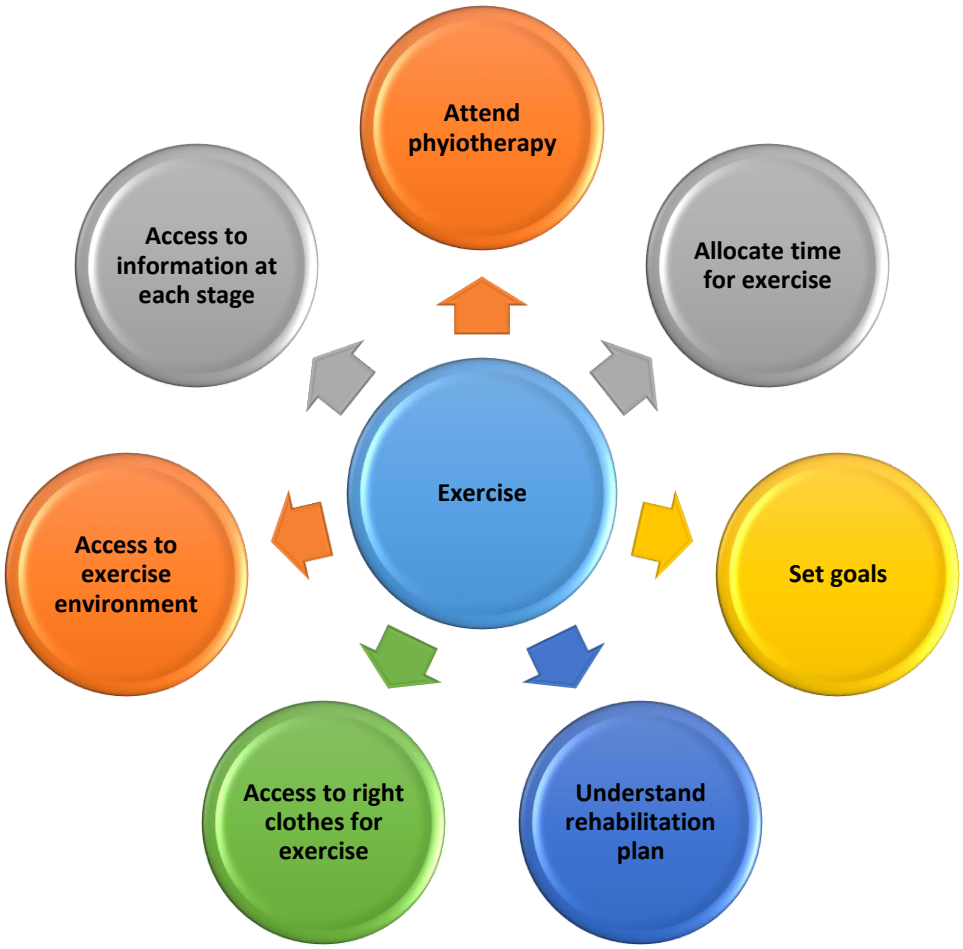

Figure 5.5. Conceptual map of the core behaviour and the behaviour system

5.3.4.1.3 Stage 1.3 - Specify the target behaviour

A specified breakdown of the desired behaviour is presented in Table 5.2. Behavioural recommendations that are too vague may lack the detail necessary to implement. The BCW intervention design guidance emphasised the need for specificity. This concept is not alien in physiotherapy where SMART goals are an embedded part of clinical practice. The more clearly defined the parameters were, the less ambiguity in its achievement (287). Exercise as a behaviour is broken down to show the multitude of factors that patients will need to engage with in order to properly plan their exercise.

Who	What	When	Where	How often	With whom
•ACLR patients	•Comply with personal exercise plan •Make time for exercise •Obtain skill •Access equipment •Access clothing • Access space	•stage approriate •access evidenced based guidance	•Gym •Home •Physiotherapy clinic •Work •Public space	•access evidence base guidance for stage •goal dependent	•physiotherapist •fellow patients •friends •family •teammates

Table 5.2. The specificities of the behaviour

5.3.4.1.4 Stage 1.4 - Identify what needs to change

Understanding the target behaviour was key to the success of the intervention. This stage of the process involved a COM-B analysis of exercise as the core behaviour in rehabilitation interventions (265) Table 5.3 introduces and defined the categories within capability, opportunity and motivation, and looks at how patient experience of exercise can be effected by these categories. The BCW authors guide that these identified components can then be targeted as potential 'levers for change' (265).

COM-B Component Definition (265)	Exercise at an individual level
Physical Capability Physical skill, strength, stamina,	Stage appropriate exercise Muscle strength and control Increase physical stamina Skill to do the exercise correctly Manage physical limitations and pain
Psychological Capability Knowledge or psychological skills, strength or stamina, to engage in the necessary mental processes	Knows what exercise is important and why Know the relationship between exercise and recovery Understands graded frequency and intensity Increased capacity for mental effort Reduce/manage psychological fears
Physical Opportunity Opportunity afforded by the environment involving time, resources, locations, cues, physical 'affordance'	Have protected time for exercise Access to rehabilitation equipment Access to exercise space Money to access gym or exercise kit Strategy to remind or prompt exercise
Social Opportunity Opportunity afforded by the interpersonal influences, social cues, cultural norms, that influence the way we think about things, e.g. the words and concepts that make up our language	Shared experience such as 'ACL rehab class" Attending physiotherapy for social support Support from family, friends or teammates who may have experienced similar Access to encouraging accounts of successful rehabilitation
Reflective Motivation Reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and what is bad)	Believe that rehabilitation will achieve desired outcome Intend to exercise to achieve goals Believe that exercise yields wellbeing generally Believe that failure to exercise will result in poor outcome Believe that the advice they are given is evidence based and reliable
Automatic Motivation Automatic processes involving emotional reactions, desires, (wants and needs), impulses, inhibitions, drive states and reflex responses	Have a habit of exercise for wellbeing Harness the 'want' to achieve physical goals Be able to overcome avoidant reflexes

Table 5.3. The COM-B analysis of Exercise behaviour

5.3.4.2 Stage 2. Identify intervention options

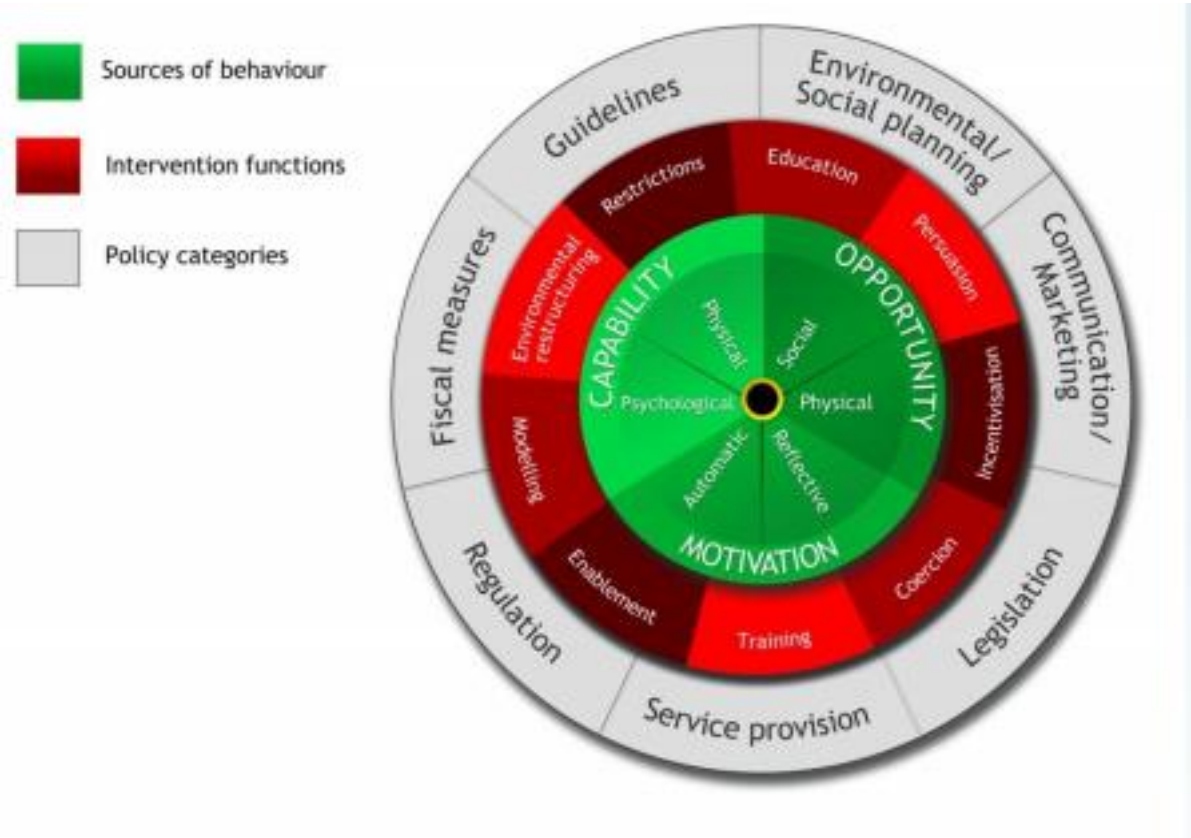

Figure 5.6. The Behaviour Change Wheel taken from Michie et al 2011 with permission (35)

5.3.4.2.1 Stage 2.1 - Intervention functions

At this stage of development, the identified capabilities, opportunities and motivations that impacted on individual exercise behaviours were mapped to the interventions functions that make up the red ring of the behaviour change wheel (Figure 5.6). Table 5.4 demonstrates the connection between the changeable components or 'levers' of the COM-B analysis, the intervention function category and the intervention functions created in TRAK ACL. The intervention functions should aim to maximise an individual's capability to perform the desired behaviour by helping to develop the physical and psychological skill, stamina and know how to complete the behaviour. Likewise the intervention functions should aim to maximise the opportunity and increase motivation. However practical considerations were paramount where there TRAK ACL was a low cost intervention with extremely limited resources. The functions that we mapped were selected based on the expectation that they could be delivered in time for the feasibility trial, with the resources available within my PhD.

COM-B Component Definition (265)	'Levers' of exercise at an individual level	Intervention functions	Intervention function examples
Physical Capability Physical skill, strength, stamina,	Stage appropriate exercise Muscle strength and control Increase physical stamina Skill to do the exercise correctly Manage physical limitations and pain	Education Training Modelling	Staged and categorised exercise library featuring ACL patients Personalised exercise plans Videos to show technique Guidance on how much and how often to exercise
Psychological Capability Knowledge or psychological skills, strength or stamina, to engage in the necessary mental processes	Knows what exercise is important and why Know the relationship between exercise and recovery Understands graded frequency and intensity Increased capacity for mental effort Reduce/manage psychological fears	Persuasion Education Training Restriction Coercion	Videos, infographs, animations, text education on positive and negative outcomes. Guidance video on how much and how often to exercise. Progression only when criteria met Criteria based progression checklist Psychological coping video including strategies
Physical Opportunity Opportunity afforded by the environment involving time, resources, locations, cues, physical 'affordance'	Have protected time for exercise Access to rehabilitation equipment Access to exercise space Money to access gym or exercise kit Strategy to remind or prompt exercise	Environmental restructuring Persuasion	Prompts to remind Exercise videos with and without equipment Guidance on how to use equipment for exercise
Social Opportunity Opportunity afforded by the interpersonal influences, social cues, cultural norms, that influence the way we think about things, e.g. the words and concepts that make up our language	Shared experience such as 'ACL rehab class" Attending physiotherapy for social support Support from family, friends or teammates who may have experienced similar Access to encouraging accounts of successful rehabilitation	Persuasion Training Modelling	Shared monitoring with physiotherapist Videos of ACL patients performing desired behaviour
Reflective Motivation Reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and what is bad)	Belief that rehabilitation will achieve desired outcome Intend to exercise to achieve goals Belief that exercise yields wellbeing generally	Incentivisation Education Persuasion	Goal setting Exercise Log Weekly progress log Reward system Information videos, animations, infographs, text

	Belief that failure to exercise will result in poor outcome Belief that the advice they are given is evidence based and reliable		
Automatic Motivation Automatic processes involving emotional reactions, desires, (wants and needs), impulses, inhibitions, drive states and reflex responses	Have a habit of exercise for wellbeing Harness the 'want' to achieve physical goals Be able to overcome avoidant reflexes	Education Persuasion Incentivisation Modelling	Goal setting Educational materials ACL patient exercise videos

Table 5.4. Mapping COM-B 'levers' to intervention function categories and to intervention functions of TRAK ACL.

5.3.4.2.2 Stage 2.2 - Policy categories

The policy categories of the BCW refer primarily to the higher policy decisions. However, consideration was given to department level policy changes that could support the intended behaviour of exercise. These changes were implemented at a local level to positively influence the use of the DHI in clinical care (Table 5.5). Policy changes affected the exercise behaviour indirectly by facilitating changes within the physiotherapy team and changes to the model of care.

Policy categories	Examples
Guidelines	Creation of a DHI guidance document that guides or mandates practice in relation to the intervention
Regulation	Establishing top down principles of behaviour in the clinical team to support implementation of the DHI
Environmental /Social planning	Providing tablet devices in consultations and altering the model of care
Service provision	Delivering ACL care through the DHI as well as in face to face care

Table 5.5. Policy categories utilised to change exercise behaviours

5.3.4.3 Stage 3. Identifying content and implementation option

5.3.4.3.1 Stage 3.1. - Behaviour Change techniques

Behaviour change techniques (BCT) can be considered to be the smallest active components within an intervention (265) The BCT can be effective alone or in groups. The functions of TRAK ACL identified in step 2.1 have multiple BCTs at the heart of their functionality. Michie et al created a standardised taxonomy of 93 BCT that was used to map the smallest active components developed to target the exercise behaviour in this study and to describe the content that already existed (39). Table 5.6 shows the BCTs that underpin the functions of TRAK ACL. The multiple identified BCTs within each TRAK ACL

function were understood to map back onto the intervention functions, Persuasion, Education, Training, Incentivisation, Coercion and Restriction.

Intervention functions of TRAK ACL	Description	Behaviour change technique (BCT)
Information	Animations, infographs, expert video and text to accompany each phase of rehabilitation. Relevant education topics such as psychological strategies for rehabilitation. Education on positive and negative outcomes. Guidance video on how much and how often to exercise	1.2 Problem Solving 11.2 Reduce negative emotions 3.2 Social support practical 3.3 Social support emotional 4.2 Information and antecedents 5.1 Information about health consequences 15.1 Verbal persuasion about capability
Exercise Videos	Stage by stage, categorised exercise library featuring ACL patients Personalised exercise plans Videos to show technique Guidance on how much and how often to exercise Exercise videos with and without equipment	4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour 8.7 Graded Tasks 12.6 Body changes 2.3 Self-Monitoring behaviour
Prompt email	4 different prompt emails sent out one per week in a 4 week cycle to draw attention to the benefits if exercise and features of the TRAK ACL website	7.1 Prompt/cues 12.6 Body changes
Personalised log in	Facilitates personal exercise plan and monitoring of progress by physiotherapist	2.1 Monitoring of behaviour by others without feedback
Weekly Log	A once weekly 3 click summary log of adherence to the types of rehabilitation	1.4 Action Planning 2.3 Self-Monitoring behaviour
Exercise Log	A record of each exercise done or exercises that are being targeted	2.3 Self-Monitoring behaviour
Achievements	A physiotherapy record of achievements against evidence based criteria	2.1 Monitoring of behaviour by others 2.7 Feedback on outcomes of behaviour 10.10 Reward (outcome)
Dashboard of Progress	A collection of Goals and Achievements and Progress Logs	2.1 Monitoring of behaviour by others 2.7 Feedback on outcomes of behaviour 2.3 Self-Monitoring behaviour
Goal setting	A patient only area to record and achieve personal goals	1.1 Goal Setting behaviour i.e. exercise weekly 1.3 Goal setting outcome i.e. lose 5lbs 1.4 Action Planning if frequency, duration, intensity are recorded 1.5 Review Goals 2.2 Feedback on behaviour: trophy
Award System	Award Trophy for goals achieved and positive reinforcement	10.3 Non Specific reward
Playlists	A variety of pre-grouped exercises targeting evidence based outcomes, organised to engage and limit boredom.	6.1 Demonstration of the behaviour 12.6 Body changes
The TRAK website	The use of a DHI as part of the care model for ACL rehabilitation	12.5 Adding objects to the environment 12.1 Restructuring the physical environment

Table 5.6. The Functions of TRAK table

5.4 **Results**

The Logic model for TRAK ACL following the Behaviour Change Wheel design process is presented in Figure 5.7.

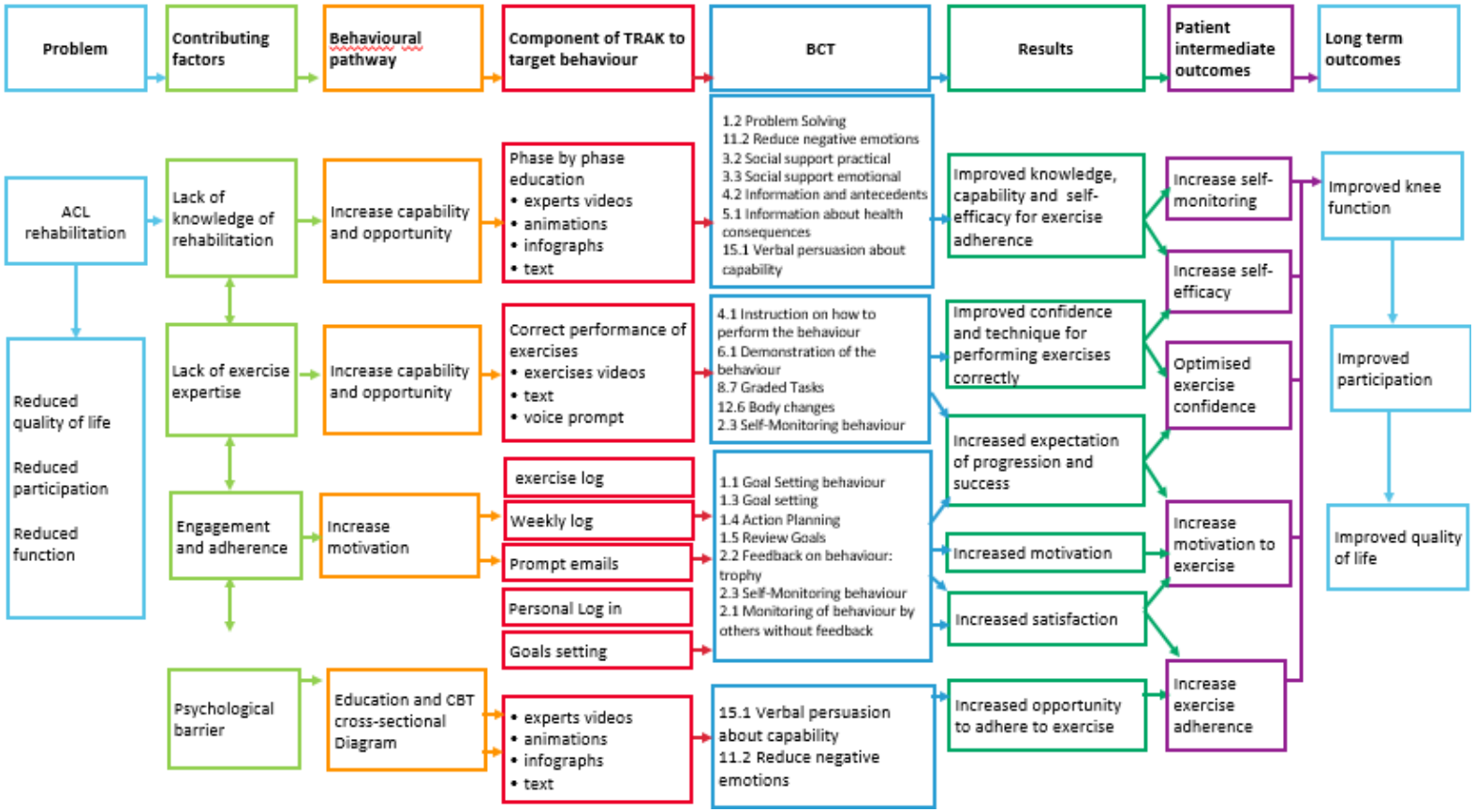

Figure 5.7. Logic Model TRAK ACL

5.5 **A visual tour of TRAK ACL**

The new TRAK ACL website was a high fidelity prototype that users could interact with to establish its strengths and limitations 'through testing and tinkering' (259, 288). It had a more sophisticated design template than previous iterations to optimise acceptability, feasibility and potential effectiveness. The content was updated to implement findings of the NPT analysis. It focused on salient clinical information and delivery of the behaviour change functions directly linked to the target behaviour. Figures 5.8 to 5.13 provide a visual tour of TRAK and its functions.

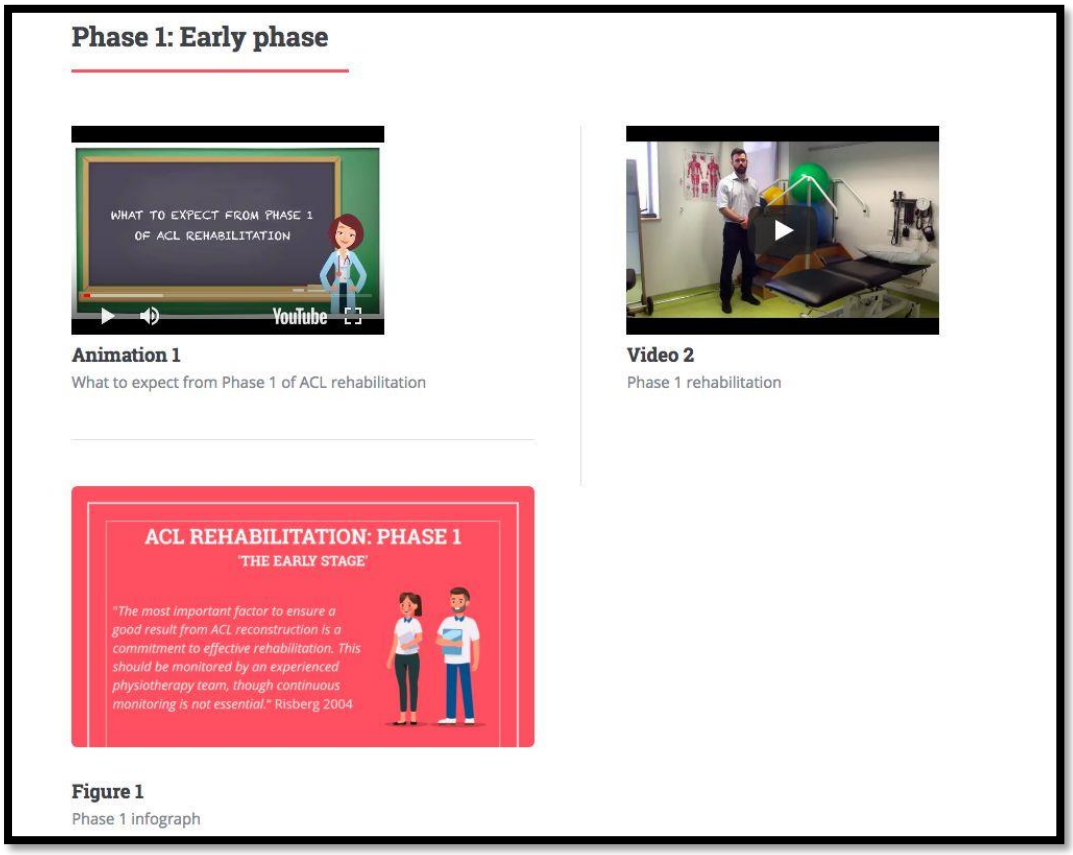

Figure 5.8. A variety of information resources for phase 1 of rehabilitation

Figure 5.8 and 5.9, shows a patient education section where are variety of information resources are available with the same content, guidance for the 'early phase'. Education is fundamental to physiotherapy practice and to the value of TRAK. In order to best develop patient information content for new TRAK, the Interaction Design theory provided an awareness of 'cognitive ergonomics interaction' with digital design (259). This refers to the complex variety of mental processes that affect interaction amongst humans and systems. These are the psychological, linguistic, perceptive and reasoning skills of a variety of users (259). The implications of this are that individual users may prefer

to engage with learning material in different formats. In line with this knowledge, I have developed TRAK information content to be available in a variety of formats to support the psychological, linguistic, perceptive and reasoning skills of a variety of users to improve access by proving choices. The same information content is provided in text format, infographic format, video format and animation format. The user experience is central to the process of interactive design and attention to cognitive ergonomics aims to accommodate as many patient users in the provision of information as possible.

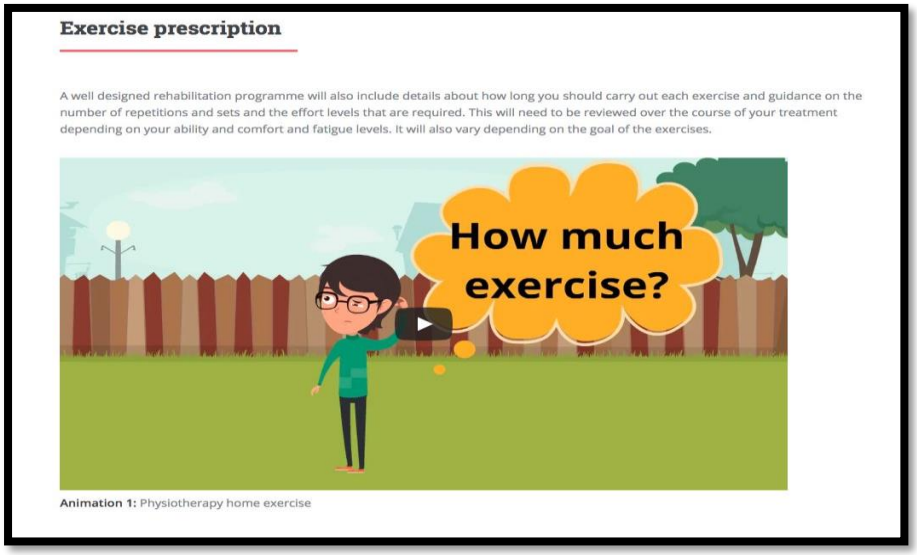

Figure 5.9. Topic specific information resource

Figure 5.10. Evidence based resource on psychological challenges of ACL rehabilitation

Figure 5.10 shows a still of the animation for the psychosocial challenges of ACL rehabilitation. This video aims to normalise the challenges that patients face in each stage of rehabilitation and offers guidance based on a cognitive behavioural concepts used in physiotherapy rehabilitation (289). The information is also available in text, infographs and expert video. The video is included alongside a cognitive behavioural therapy learning diagram known as a cross sectional formulation which is often used in physiotherapy and encourages patients to consider impact of kinesophobia on movement and exercise (290-292).

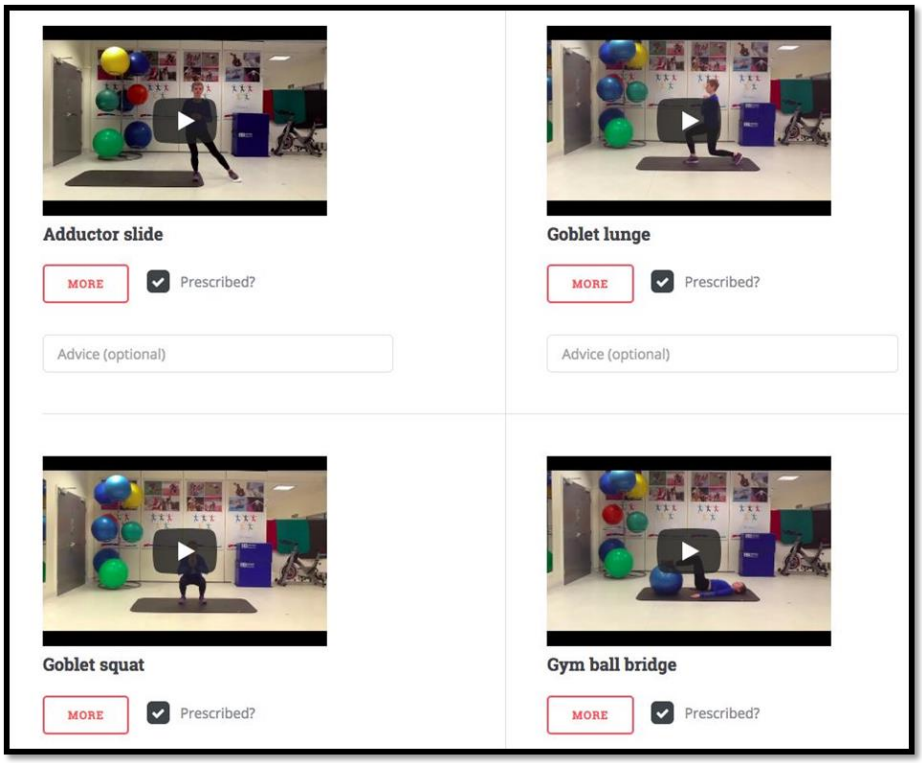

Figure 5.11. Personalised exercise plan

The exercise library includes access to approximately 200 exercise videos. They are categorised into phases of care and within each phase they are broken down alphabetically within categories of Strength, Flexibility, Cardiovascular, Balance, Agility etc. The exercise library can be viewed in its entirety by patients or, they can click at the top of the page to just show their prescribed exercises. Figure 5.11 shows a group of phase 3 strength exercises that have been selected for a patient. The ticked box can only be ticked or unticked through a physiotherapists log in.

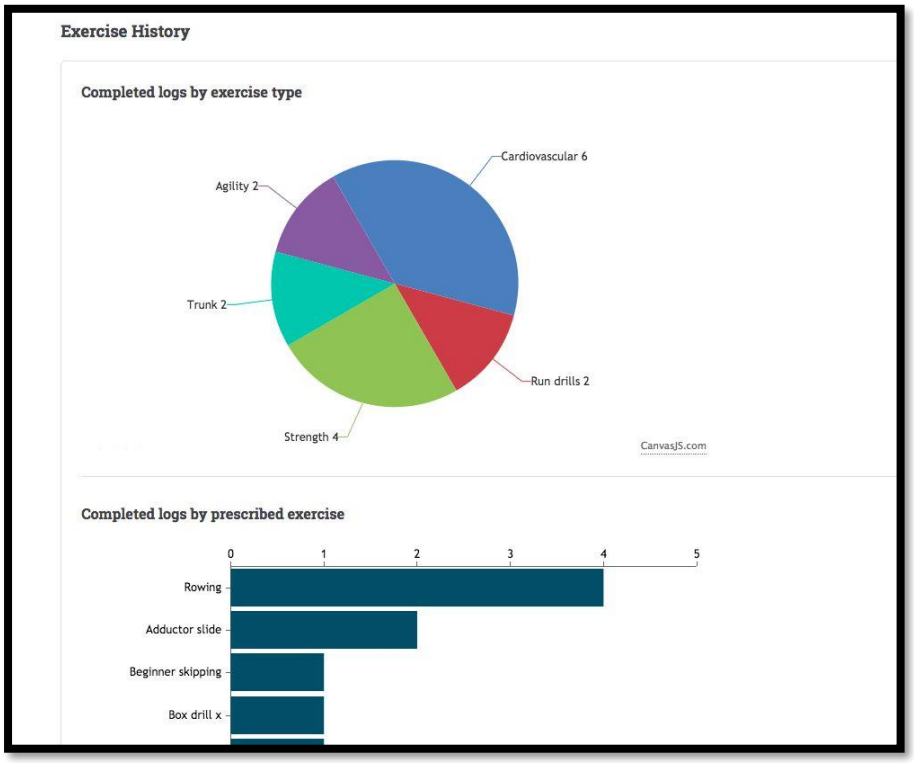

Figure 5.12. Dashboard

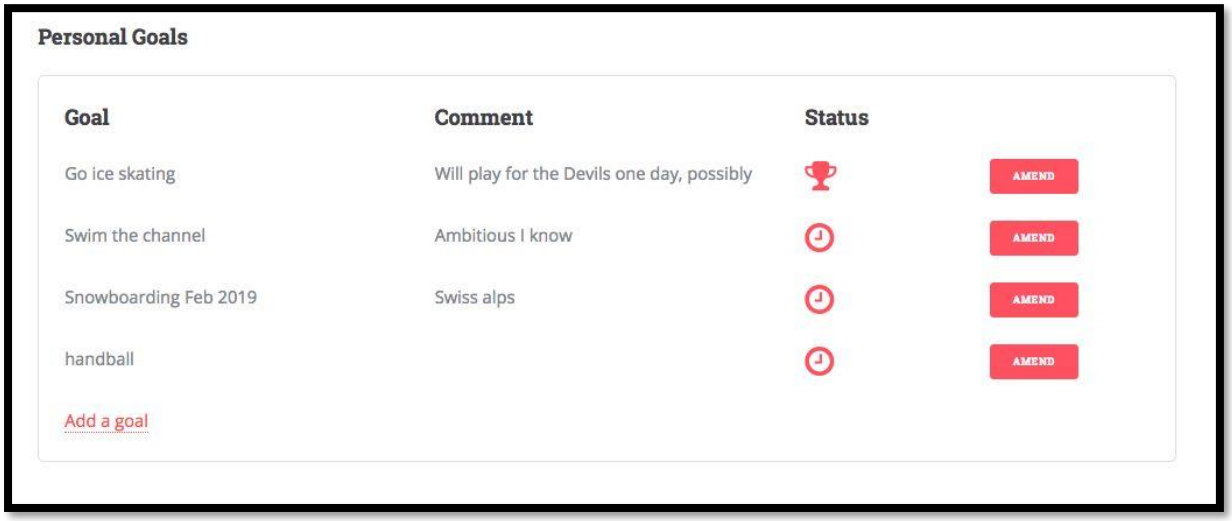

Figure 5.13. The Personal Goals area in dashboard

The dashboard is shown in figure 12 and 13. It was intended to show a collation of the patient's goals, achievements and their exercise adherence. It included a pie chart of the type of exercise they most often focused on which was output of their weekly log. It also showed the frequency, intensity, time and type (FITT) of completed exercise (293) from the exercise log (the bar chart). The last part of the

dashboard was the achievement section, which was where physiotherapists recorded a patient's progress through ACL rehabilitation against the evidence based criteria for passing each phase as described in Chapter 2. The achievements section was unfortunately not completed in time for the feasibility trial.

The weekly prompt email was sent out on Sunday afternoons (Figure 5.14). There were 4 different emails that reminded patients to exercise and engaged them to key functions of TRAK ACL. The emails include a link that would take patients directly to their log in page.

Dear TRAK User,

We hope your recovery is progressing well.

This weeks' prompt email reminds you to Focus on Information!

It's common knowledge that we only remember some of what we hear, so when your surgeon or physiotherapist tells you important information regarding your recovery it is difficult to remember it all. Further to that, people learn and absorb information in different ways. To help you learn the most about your ACL reconstruction and rehabilitation TRAK provides the information you need, phase by phase, in a variety of formats.

This content is found under the Learn More About heading.

- Simple text
- Expert Video
- Animation
- Infographic

Experts in ACL Surgery and Rehabilitation have contributed to the content of the Learn More About section of TRAK. The advice and information is based on the most up to date clinical information. Of course there are still variations in individuals experience and you can discuss these with your physiotherapist.

Go to TRAK now and learn all you can about your rehabilitation!

http://bit.ly/trakacl

Good luck! Speak to your physiotherapist if you need guidance.

Written by Emma Dunphy for TRAK

Figure 5.14. An example of a prompt email

5.6 **Discussion**

5.6.1 Summary of main results

This chapter has described the refinement of TRAK ACL with a view to optimising user acceptability, feasibility for trial and potential effectiveness. I combined the MRC framework and the human computer interaction IDLM and then used the Behaviour Change Wheel framework and Normalisation Process Theory to provide theoretical insights. The engagement with design theory and behaviour change a priori evolved from the findings of previous studies (30). Evidence from the NPT process stimulated a conversation about designing for our planned user group, which led to the more PPI consultations and further video development to reflect the diversity of user group (256). Animations were also created with diverse characters to reflect our users.

A multimedia approach was taken for the educational content. Knowledge translation multimedia has been well received in other patient facing research (294). Infographics are concise, visually stimulating and associated with good recall of information in health education (295, 296). Animations, when broken into 'chunks' as with the phase by phase ACL education, are known to enhance effective communication (297) Expert videos have provided new ways of engaging patients that they have respond positively to (298, 299). As was learnt from earlier qualitative findings, patients wanted TRAK ACL to meet their expectations of digital tools in terms of the available commercial apps.

Application of the behaviour change wheel facilitated an integral understanding of exercise and allowed me to systematically consider the COM-B components, intervention functions, and the BCTs used to deliver the intervention. The results showed that a number of BCT could be incorporated into the design of the website to increase its validity as a behaviour change DHI.

5.6.2 Post hoc comparison of the development process with the Person Based Approach

The Person Based Approach is suggested by Yardley et al as a systematic method of qualitative research to gain an in depth knowledge of the user group and therefore limit the problems of engagement (274). This approach was not used in the development of TRAK ACL but provides a useful benchmark to compare the development process.

The Person Based Approach (PBA) is described in 4 phases: Planning (0-6months), Design (3-9 months), Development and Evaluation of acceptability and feasibility (6-18 months) are the first three stages. The final stage Implementation and trial (12-18months) is not relevant to this study. The planning stage calls for identification of key behavioural issues using; primary qualitative research, synthesis of

already existing qualitative research, consultation with experts, a review of clinical evidence and observation of the context of the intervention. TRAK ACL was very much in line with these steps however the timeline and order was not as suggested. A group of clinical ACL experts were consulted on the content of TRAK ACL and the context of delivery from an ACL rehabilitation point of view however their views on behavioural elements of the intervention which had yet to take shape

The second stage of the PBA was concerned with 'Guiding Principles". This phase is concerned with a common language for researchers and developers to be able to summarize and work on key features of the intervention from both a clinical and deign perspective. In this study the behaviour change wheel provided a framework for the mechanisms of action logic model, defining target behaviours, the intervention components that act on these behaviours and the associated behaviour change techniques (35, 39). This made mapping the intended functions of TRAK ACL and its mechanisms of action into a list of key design tasks a more relatable two way process.

The third phase includes the development and evaluation of acceptability and feasibility. The model calls for a mixed methods approach to this phase. The feasibility goals include establishing procedures, teaching and training requirements and trial parameter. TRAK ACL had been through acceptability testing prior to this PhD. A further qualitative study based on the participant's experiences of TRAK ACL feasibility trial is being conducted but is beyond the scope of this PhD. The TRAK ACL feasibility study is described in Chapter 6.

The PBA does acknowledge that budgets, time constraints and availability of other resources may create practical conditions in which the model cannot be fully applied. In the development of TRAK ACL the majority of steps of the PBA were applied though the time frames and the depth of application reflect the scale and resources available to this project.

5.6.3 Strengths

TRAK ACL is a reflection of the best clinical research evidence for the management of ACL rehabilitation (34, 88, 90, 92, 93). The content was strengthened by extensive PPI and qualitative research. The Person Based Approach to intervention design was not used a priori for this study and certainly the time lines are very different however this approach calls for deep and thoughtful exploration of user needs and user experiences through qualitative work in relation to the key functions of the website and TRAK ACL was indeed developed in this manner. A synthesis of previous relevant qualitative work (275, 280) was utilized alongside targeted primary research for ACL patients

(30) and with further user input from the PPI group who contributed to video content, performed in the videos, attended training and meetings to keep up to speed about TRAK ACL. Some also continued to attend meetings throughout the clinical trial as PPI reps. The second stage of the PBA was concerned with identifying 'guiding principles' to focus the design process. This chapter maps the logic model that underpins the functions of TRAK ACL. This clearly outlines the mechanisms of action and the behavioral determinates needed for change (274).

Yardley et al argued that the development of interventions based in behaviour change mechanisms requires a deep understanding of the user perspective and the psychosocial context. This is necessary because engagement and uptake can be complex and many studies report poor engagement from patient users for reasons such as too busy, feeling incapable or disliking digital tools (284). The Topol review stated 4 reasons why clinician users may not engage; not enough time, not enough training, not satisfied with the intervention or not keen on digital health (25). Since the user experience is at the heart of the success of any DHI, incorporating the views and preferences of the user group is a fundamental (274, 300). A synthesis of previous relevant qualitative informed knowledge of the user experiences (275, 280). Further primary research for ACL patients with an earlier iteration of TRAK ACL was also included to explore needs, challenges and context of the users experience of TRAK ACL (30). Patient and public involvement was a significant part of the user centered design process. Patients informed the prototype and the content, they took part in modeling behaviors for video content and mediums of communication. They reviewed language for accessibility and where complex 'medical' terms are used, explanations are offered for what they mean.

5.6.4 Limitations

The MRC framework notes that "ideas for complex interventions emerge from various sources, which may greatly affect how much leeway the researcher has to modify the intervention, to influence the way it is implemented, or to adopt an ideal evaluation design". This was certainly true of TRAK ACL where for much of its development it was subject to the shifting priorities of a number of research projects. It has been argued that an intervention should be stable and no longer going through cycles of change when it is taken to trial (301). Although TRAK ACL was conceptually stable, the resources to deliver the website were limited and so difficult choices meant that some of the intervention functions did not work and others did not work as intended.

5.7 **Reflections on the challenges of development**

There were a number of challenges that the TRAK ACL development process faced some of which were ably dealt with by the team and others, which were more challenging. Initially, it was thought that TRAK ACL could exist within the already available TRAK digital infrastructure. However, the concept of TRAK ACL as a behaviour change DHI could not be supported within the original TRAK infrastructure. My knowledge of the demands of website development and human computer interactions was limited by lack of experience. There were many steps in migrating TRAK ACL to a new site and new content had to be added and multiple parts of the planned BCT functionality still needed to be created. I was undoubtedly naïve about how much of this could realistically be competed. Blandford et al highlight the methodological variations between the Human Computer Interaction approach and the Health care approach which can leave 'an adequately sized chasm' for early career researchers to fall into (302).

Another challenge of working with a low cost intervention was that priorities for TRAK were not fixed and stable until later stages of its development. It is known that interventions design is iterative and evidence suggests that because if this, it is important to wait until the interventions is stable before proceeding to trial (301). In the build up to the feasibility trial, the TRAK website was linked to other projects at Cardiff University. TRAK needed to remain agile to the needs of other users at Cardiff University however, this presented multiple challenges of specificity of content and how to separate usage from different user groups. The fear was that the agility of the website might have diluted the specificity of the intervention. There was much debate about how to organise content and this could have delayed the intervention's readiness for a feasibility trial (256). However a solution was reached by creating a copy of the TRAK website, which could be then specified for ACL content, this became TRAK ACL.

With the creation of TRAK ACL, the purpose of the website was specifically as a prototype for the TRAK ACL feasibility trial. The clinical content was ready but the functionality of TRAK ACL was still being developed with finite resources. We used a shared Google Drive 'Snag list' to monitor and prioritise development work that was needed before the start of the trial. Ultimately, the trial started without the completion of a number of functions and as clinicians began to feedback glitches in the website, the snag list grew. Smaller tasks like adding or editing content were attended to quickly by the developer however some key functions were not delivered. Soon the main developer was lost to the project and no more direct support was available for TRAK ACL. The IT team Professor attempted to

shore the gap by making herself available for essential work and we explored options like, exporting the website to UCL if we could find a developer to work on it here. This option was extremely complex and involved interesting learning about intellectual property and UCL IT systems. It was ultimately ruled out.

At this stage, TRACK ACL was indeed usable and we decided to proceed with what we had. The achievements section and usage feedback were never created and the dashboard, prompt emails and clinician view did not work as planned. The consequences of this were difficult to measure but are discussed further in the feasibility chapter. Finally, this meant there was no usage information for me to monitor throughout the trial so I did not know if physiotherapists and patients were using TRAK in the way I expected.

Agile software development refers to the principles of cooperation in self-organising, multidisciplinary teams who respond to change in challenging environments to design and develop DHI (288, 303). The development of TRAK ACL as a collaboration between Cardiff University Information Technology, physiotherapy team and I, aimed to respond to the need for greater access to physiotherapy across the UK. The strength of the collaboration were in its MDT learning and the successful creation of a TRAK ACL prototype. Future research might explore the benefits of improved costing plans for adequate funding for IT or exploring the private sector for a digital partner.

Chapter 6 – A study to determine the feasibility of an effectiveness and cost-effectiveness randomised controlled trial comparing TRAK ACL plus treatment as usual to treatment as usual.

6.1 Chapter Outline

In Chapter 2 it was established, based on a review of the literature, that ACL rehabilitation programmes follow evidence-based guidance to progress through a range of physical challenges in order to gradually restore function to the knee. Most people who undergo ACL reconstruction are active, so, for many, rehabilitation continues through from the early, intermediate and advanced phases, on to a final phase known as the return to sport phase (53, 109, 304). In Chapters 3 and 4 it was shown that there are many variables that can impact on how care is delivered to patients. In Chapter 3, the scoping review of RCTs of ACL rehabilitation showed that resources such as equipment, space and skilled physiotherapists are important elements of the care delivered in published physiotherapy trials. Further in Chapter 4, healthcare professionals discussed their varied practice and the different challenges they face in providing care for this patient group. Specifically, challenges were identified in providing the very things that were commonly present in RCT conditions, namely, skilled staff, space and equipment.

The variation in approaches to care as well as access to resources indicated that patients' experience of care could be very different across the UK. The NHS Long Term Plan underscores the importance of identifying inappropriate variations in care and targeting them for change (36). It appears that not all patients have access to the physiotherapy care, information, education, exercise and physical activity knowledge needed at each stage of rehabilitation. Digital health tools such as the TRAK website, introduced in Chapter 5, may provide an opportunity to teach and reinforce the key lessons and exercises of each stage of care, as well as engaging patients through behaviour change functions. Physiotherapists who face challenges in providing care due to lack of time, experience or resources could use TRAK as a tool to supplement the care they give.

In Chapter 4, supporting patients to self-manage their ACL rehabilitation was also discussed. Physiotherapists reported guiding patients to exercise regularly and in many cases, to access a gym to help them meet the evidence based targets for recovery. Supporting patients to work through the

phases involved educating them in face to face contacts and providing tools for them to self-educate at each stage of care. These tools ranged from drawings or paper-based exercise handouts to digital tools. The rationale for investigating the potential of a specifically designed digital tool such as the TRAK website is clear. TRAK could support the learning that patients get from their physiotherapist at each stage and re-emphasize the key outcomes and education of each stage of recovery. As discussed in Chapter 5, TRAK uses behaviour change techniques such as prompts, rewards, goal setting and progress logs to help patients engage in the rehabilitation behaviours. TRAK can be used to improve access to care in areas where ACL rehabilitation is not common or a priority and therefore may be inadequately resourced. NHS Digital has argued the need for website and apps to supplement care and support improved self-management (305).

This chapter details a randomised feasibility trial of TRAK for ACL patients to determine the feasibility of recruiting and retaining patients to a future RCT and collecting their outcome measures over several time points. The Medical Research Council framework for Developing and Evaluating Complex Interventions, highlights the importance of feasibility work for testing procedures, estimating recruitment and retention and determining the sample size of a future RCT (254). Failure to do enough feasibility work is noted as a key factor in undermining the outcomes at trial (254) The process gives an opportunity to test the acceptability of recruitment pathways, outcome measures and uptake of the intervention to ultimately determined if a full scale trial can be done (306).

6.2 Aim and objectives

The aim was to determine the feasibility of an RCT comparing TRAK ACL plus treatment as usual to treatment as usual (TAU).

The study objectives were to:

- assess the feasibility of recruiting and retaining participants to the RCT
- assess the feasibility of gathering costings data and patient reported outcomes
- assess implementation issues such as participants' and physiotherapists' engagement with the website
- assess engagement with the mechanisms of behaviour change

- inform the protocol for a fully powered RCT which could determine the clinical and cost-effectiveness of TRAK ACL compared to TAU.

Research Question: Can we recruit and retain ACL patients, engage them to use TRAK and collect outcomes and demographic data needed for a definitive Phase 3 trial to determine effectiveness and cost-effectiveness of TRAK?

6.3 **Methods**

6.3.1 Design – A randomised controlled feasibility trial

This study was a parallel arm individually-randomised feasibility RCT comparing post-operative ACL rehabilitation treatment as usual with treatment as usual plus TRAK ACL. It is reported in line with the CONSORT reporting standards extension for pilot and feasibility trials (307).

The development of a protocol for this feasibility study was supported by the PRIMENT clinical trial unit (CTU) at University College London. The CTU is a fully registered UKCRC (UK Clinical Trials Collaboration) trials unit. Detailed input was provided from a CTU statistician and a health economist. The TRAK ACL trial process was mapped against the standard operating procedures (SOP) of the CTU and the development of the Access database was informed by the trials unit team. The CTU team provided both formal and informal training in health economics and statistics. A trial steering committee (TSC) was established with the CTU members and PhD supervisors. A PPI representative was also appointed and kept informed in one to one updates. Throughout the trial the TSC discussed and advised me on trial process.

6.3.2 Ethics

Ethical Approval was obtained from the Research Ethics Committee, Bloomsbury on the 19th of March 2018. The REC reference is 18/LO/0403. An initial amendment was approved on the 9th of May 2018 in order to add the health economic outcomes which were not included in the initial application. A subsequent amendment was approved on the 12th of June 2018 in order to add Site 3.

The trial was registered with the ISRCTN (International Standard Randomised Controlled Trial Number) on the ID ISRCTN55635910. It was also registered with the NIHR Clinical Research Network Portfolio: CPMS ID 37879

6.3.3 Setting

The study took place at 3 sites. The first site was in a central London teaching hospital. The second site was a south of England community NHS Trust associated with a secondary care hospital serving over 1,000,000 patients. The third site was in a University Health Board hospital in Wales. The third site was added after a problem with recruitment in the South of England NHS Trust that led to that site being closed (described below). Both site 1 and 3 are notably challenged in some areas with social determinants of health. The London hospital is in one of the city's most deprived boroughs with a population approaching 300,000 (308) while the Welsh hospital serves over 470,000 with a third of area households in poverty (309).

6.3.4 Participants

Eligible participants were adults who had undergone ACL reconstruction within the last 12 weeks and been referred to participating physiotherapy units for rehabilitation. They could be newly referred or already participating in a structured NHS rehabilitation programme. Participants had to have sufficient command of spoken and written English to be able to use TRAK, and had to have access to the internet at home or on their phone. All participants had to provide written informed consent. Participants were excluded if they had complex co-morbidities or surgeries such as multi-ligament reconstruction or fracture.

6.3.5 Recruitment

The study recruited participants from the ACL rehabilitation pathway at participating NHS hospitals. Recruitment opened in July 2018 and was scheduled to continue until the end of January 2019. Clinical physiotherapists informed patients about the study when they attended for their regular physiotherapy appointments. Due to recruitment challenges (discussed in detail hereafter) the recruitment period was extended until the end of March 2019. Figure 6.1 showcases the different recruitment periods.

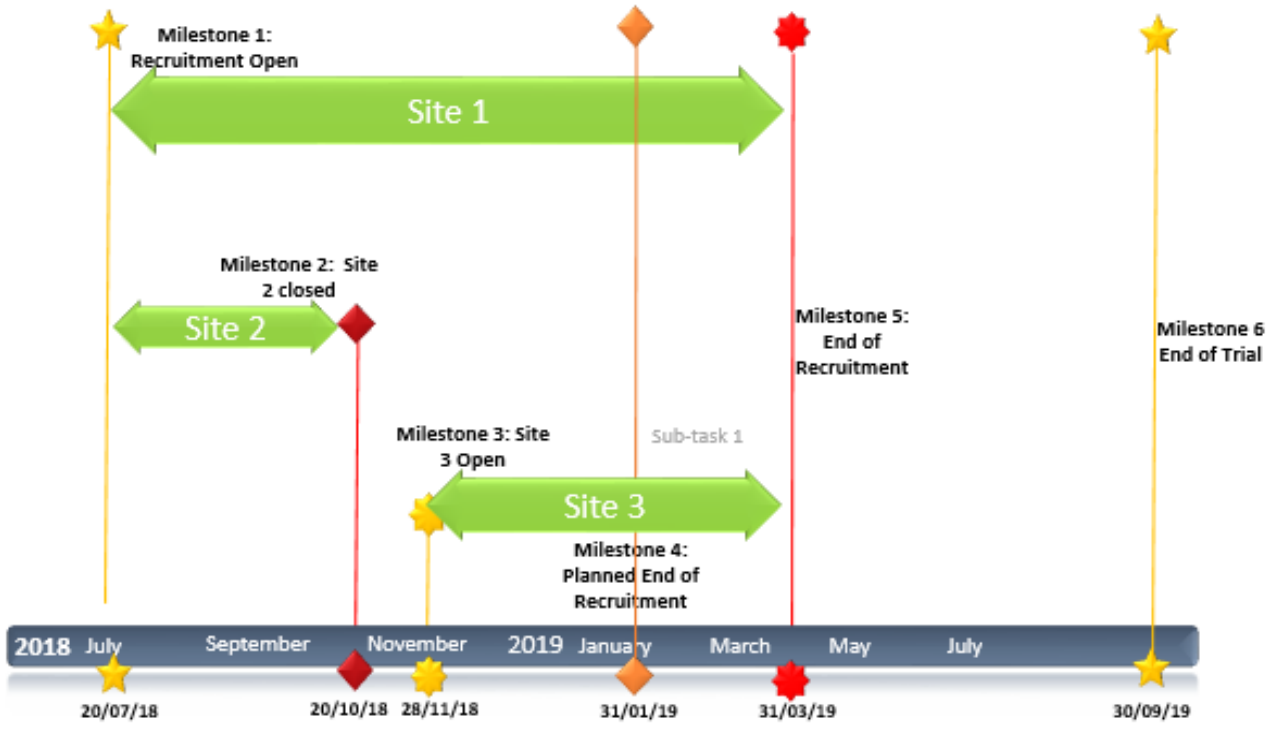

Figure 6.1. GANNT chart of recruitment

6.3.6 Randomisation

The trial statistician used computer generated random number sequences to draw up a spread sheet where trial participant numbers could be added sequentially, with allocation to the intervention or control arm. Randomisation was performed after informed consent and baseline data were collected by the blinded assessor. Participants were also allocated a trial participant number by the blinded assessors. The trial participant number was then passed to the treating clinician, who added the participant to the spreadsheet in the same order the consent and outcomes were taken. When the clinical physiotherapists added the participant's trial number to the spreadsheet, they were randomly allocated to the TRAK ACL plus TAU arm or TAU. There was a small risk of allocation bias since the treating physiotherapists could see the spreadsheet in full. However this risk was offset by the fact that the blinded outcome assessor was issuing sequential trial ID numbers that could then be checked to confirm that they were added to the randomisation spreadsheet in the order of recruitment. After the trial was closed and data analysis underway, all patients were confirmed to have been added to the randomisation spreadsheet in the order that they were recruited and their baseline outcomes were taken.

6.3.7 Intervention

Participants randomised to the intervention arm received Treatment as Usual (TAU) plus training in, and access to, the TRAK ACL website. TRAK ACL has 3 views, one for participants, one for physiotherapists and a third administrator view.

6.3.7.1 TRAK ACL website

TRAK ACL is an evidence based website specifically designed to support patients after ACL reconstruction. TRAK ACL reinforces the teaching and exercise prescription that is given by a physiotherapist in face to face care. The website includes an extensive phase by phase (early, middle, advanced and return to sport) exercise library. Physiotherapists can prescribe groups of exercises for their patients or guide them to work independently in a particular phase. The website also includes a library of evidence based information that is provided as animations, infographs, text and expert videos. This is organised into the same phases (early, middle, advanced and return to sport) as the exercise library, to facilitate focused learning at each stage of care. The expert videos featured one video of an orthopaedic surgeon who collaborated with the study and others were of a senior physiotherapist colleague. The surgeon was educating patients as to what to expect from the ACL surgery and recovery. Website features such as personal goal setting, progress logs and dashboards of progress are associated with theories of behaviour change and are known to promote engagement with rehabilitation behaviours. The TRAK ACL intervention is described in detail in Chapter 5.

6.3.7.2 TRAK training for staff

Each hospital site was provided with a two hour training event that covered the functionality of the TRAK website, the research process and the integration with current care. The contents of the TRAK training were decided based on previous TRAK studies that have been run and feedback from previous TRAK users (30, 280).

The purpose of the training was to educate the physiotherapist participants as to the purpose of the project and its potential learning. They were introduced to the concepts of supported self-management and behaviour change that underpin the functions of TRAK. Technical training included enabling each physiotherapist to set up and manage a TRAK user and, in turn, teaching the patient how to access and utilise the key functions of TRAK (Figure 6.2). Moller et al highlight the need for "strategies to maintain provider skills" with the intervention so follow up training sessions were offered and the training guidance was provided to each participant by email (38).

Clinicians were taught to induct patients to the key functions of TRAK. Laminated guidance sheets were on hand in the rehabilitation area to remind clinicians of the key points. A summary manual of instructions was emailed to participants (38) TRAK had quick start functions that automatically selected the groups of exercises traditionally given to patients at the beginning of ACL rehabilitation. These groups of exercises were called playlists and were editable for individual patient needs. They provided necessary shortcuts for physiotherapists working with patients in a time pressured situation.

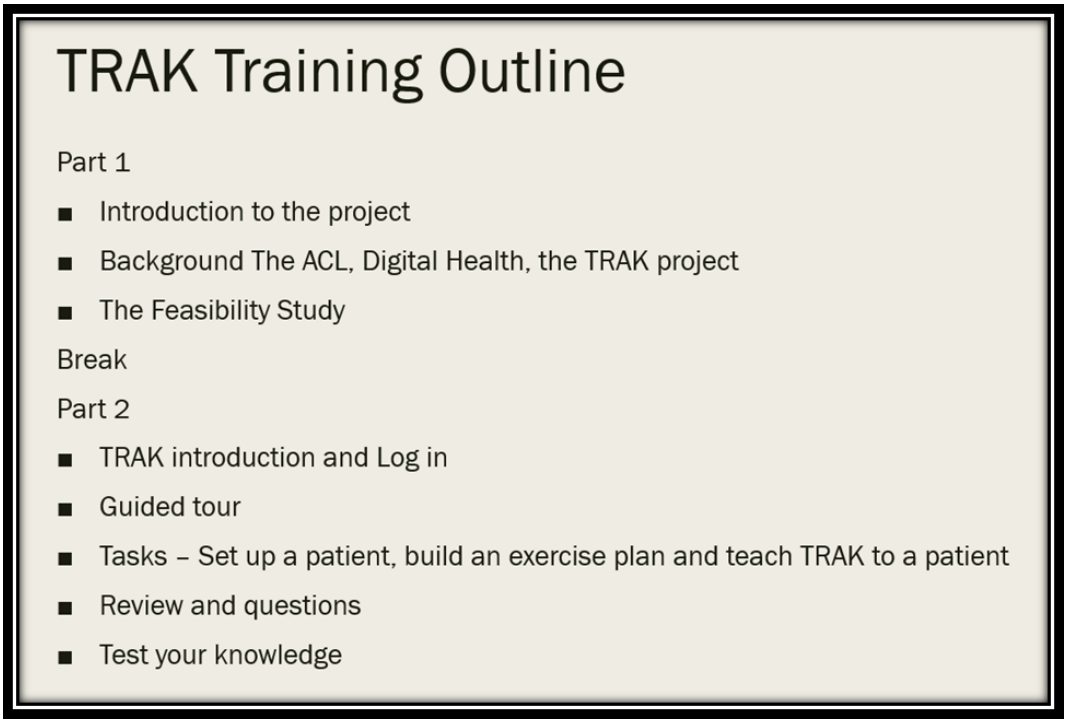

Figure 6.2. Contents of TRAK training

As was discussed in Chapter 5, the results of a previous TRAK Acceptability study showed that physiotherapists had highlighted ways to make TRAK easier for them to use such as the inclusion of grouped exercise 'playlists' and shortcuts (30). These functions, seen in Figure 6.3, were also included as part of the training so that use of TRAK might be more smoothly integrated into clinical practice. Figure 6.3 shows the functions where exercises could be selected as a group to save time, which we referred to as playlists, but the developer referred to as 'prescribe default exercises'.

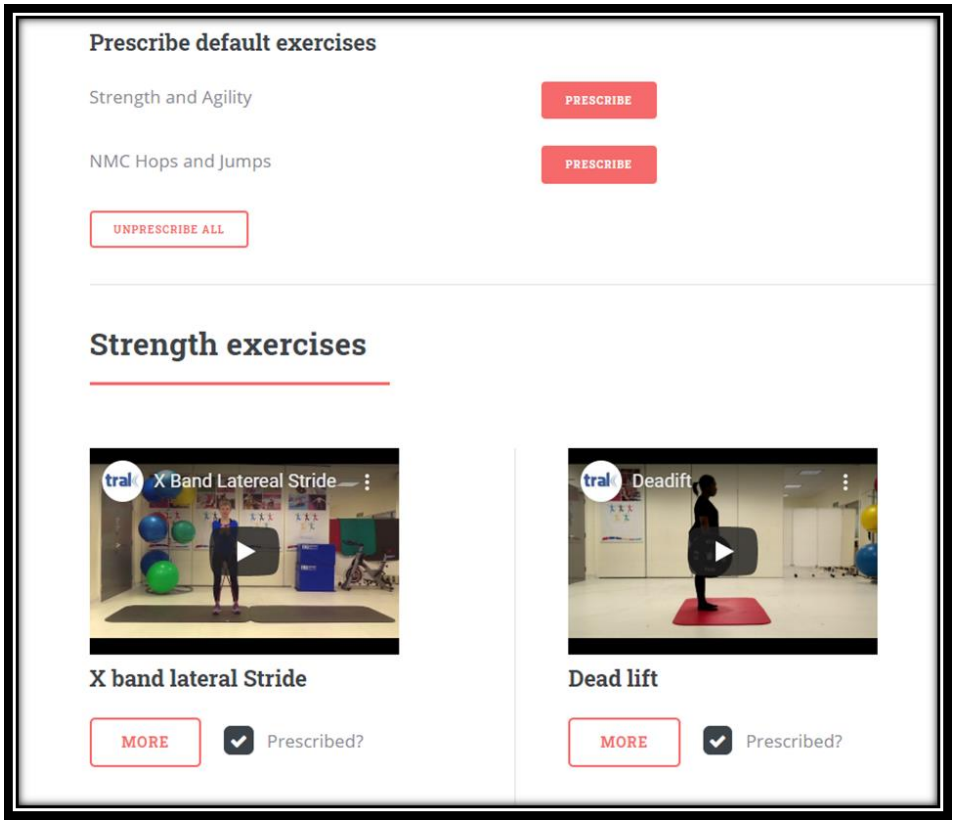

Figure 6.3. Playlists / 'Prescribe default exercises'

The initial 2 hour training session was completed at each site. Further training was offered at all sites. In Site 1, further individual training was needed as 3 new staff joined over the study period. In Site 2 the group session was repeated for staff who missed the initial session. No further training was required at Site 3 where one staff member was an expert user and provided informal support to other staff.

6.3.7.3 Patient Participant Intervention Training

A TRAK induction was provided for patients in the intervention arm. TRAK induction was facilitated by the treating physiotherapist. Each patient was given a TRAK alphanumeric log in, which was a combination of their site location and the first four numbers of their numeric birthdate. In two cases, patient birthdays were the same, so all six birthdate numbers were used. The password for all patients was set as 'patient', since it was discovered on a previous TRAK study that forgetting and resetting passwords was a barrier to usage and took up considerable clinical time to manage. Patients were guided to set goals, record progress and follow exercise plans as directed by their physiotherapist. They were invited to request extra TRAK ACL support if they felt it was needed. All those allocated to the intervention also received treatment as usual.

6.3.7.4 Tablets and Wi-Fi

One of the key findings of previous TRAK studies was that tablets were an essential part of delivering TRAK efficiently within clinical time. Use of tablets was in turn dependent on the quality of hospital Wi-Fi. Each site was assessed for quality of Wi-Fi within physiotherapy spaces. Where the hospital Wi-Fi was good enough to support the use of the internet on a tablet, no further action was taken. At Site 1, several meetings with IT facilitated access to a stronger Wi-Fi network than was available publically in the gym. In one location at Site 2, the gym was not able to access the local trust Wi-Fi and so I obtained a 'MiFi', personal modem from communications company EE to ensure that the team in this facility could use TRAK.

Two iPads were provided to each of Sites 1 and 2. These had been borrowed from another study at UCL where they were no longer needed. Site 3 was already in possession of several smaller tablets that it could use. Once Site 2 was closed the MiFi device and the two iPads were taken to Site 3. Security locks were purchased for the iPads and insurance was taken out in the event of theft or damage. Data collection forms were provided already printed for each site as well as a lockable metal file box.

6.3.8 Control Group

Treatment as usual for ACL rehabilitation varied across the included sites. At all sites patients were referred to the physiotherapy team by the orthopaedic department following ACL reconstruction.

6.3.8.1.1 Treatment as usual at Site 1

Patients were seen in a group environment dedicated to ACL patients. Care continued until rehabilitation goals were met and this could vary between individuals depending on their goals but was usually from 6-12 months. The first three months of care were weekly one hour appointments and then, as patients progressed, fortnightly. This continued until patients progressed (if they chose) to the return to sport stage, where attendance could be fortnightly or monthly depending on needs. Patients were seen in the first week after surgery. Between 1 and 4 new patients could arrive at the induction timeslot on the nearest Wednesday after their surgery. They were given an induction by a clinical physiotherapist to the ACL rehabilitation pathway, which included reassurance, education, setting expectations, wound check, baseline outcomes and exercise education. The session was informal with questions encouraged throughout. Following the induction of 30 minutes, the rehabilitation early stage group class began. This class was populated by people who had had surgery recently. The objectives of this phase of care were to manage swelling and pain, restore range of

motion, heal the wound, normalise gait and balance. Patients typically took about 6 weeks to meet the objectives of this phase and progress to the next phase however they do not progress until the objectives are met. The phase by phase objectives were discussed fully in Chapter 2. Patients progressed through the classes and phases in line with their recovery and ability to meet criteria. Different time slots and classes accommodated the different stages of care and in each class the objectives of that phase were reinforced to the patients. Classes were well staffed so that individual assessment, problem solving, exercise prescription and management could occur.

6.3.8.1.2 Treatment as usual at Site 2

Treatment as usual at Site 2 had the same structure as Site 1. There were weekly dedicated ACL rehabilitation classes where patients progressed through phases of care. Unlike Site 1, Site 2 care was split across several sites.

6.3.8.1.3 Treatment as usual at Site 3.

At Site 3, treatment as usual for ACL patients involved referral to one-to-one physiotherapy in the first instance. Patients were given an urgent post-operative priority and then allocated to an individual physiotherapist at one of several sites across the catchment area. Induction was personalised but aimed to include reassurance, education, setting expectations, wound check, baseline outcomes and exercise education. Patients were managed on a one-to-one basis until they had reached the competency to join a generalised lower limb rehabilitation class for 6 weeks. They were reviewed in one-to-one care after this. Those who were unable to attend the exercise class continued to be managed on a one to one basis.

6.3.9 Outcome Measures

As this was a feasibility study, the primary outcomes were those pertaining to the feasibility of undertaking a definitive randomised controlled trial of TRAK ACL. The rationale for trial feasibility measures such as recruitment, retention and ability to collect outcomes is to inform the parameters of a future trial and answer the question “Can this study be done?”, i.e. can we recruit patients, retain them to the study and collect outcomes and usage data that would inform the parameters of a future RCT (310) The Medical Research Council guidance on developing complex interventions suggests that feasibility is ‘vital preparatory work’ and it is often skipped which can lead to unpredicted problems (254).

A secondary objective was assessing the feasibility of collecting outcome measures that might be used in the definitive trial. These included secondary outcomes related to assessing the clinical and cost-effectiveness, as well as mediator outcomes which aim to explain the relationship between other variables (311). These outcomes were selected to reflect the proposed pathways of action of the intervention. Hence they included a measure of knee function (clinical), self-efficacy (mediator) and three outcomes pertaining to health resource use, work related impairment and health related quality of life (cost-effectiveness). The latter facilitates a calculation of an Incremental Cost Effectiveness Ratio (ICER), following NICE guidance.

The measures used for these outcomes were selected following a review of the literature, using the following criteria:

- Psychometric properties of validity and reliability.
- Sensitivity to change
- Validation for use in the target population
- A need to keep response burden down so as not to impact the behaviour of participants through the trial processes (312)

Study outcomes were taken at baseline and 3 and 6 months.

6.3.9.1 Primary study outcomes

- Feasibility of recruitment, measured by the number of people recruited to the trial at 2 sites.
- Feasibility of retention, measured by the number of people still in the trial at the end of the study.
- Feasibility of collecting outcome measures, measured by the number of complete outcomes that can be taken for each time point.
- Feasibility of collecting participants' intervention usage data. Usage data provided a broad spectrum of information from the TRAK ACL website that informed understanding of how the website was used.

These data were key to understanding how patients and physiotherapists engaged with the website. Figure 6.4 shows a logic model connecting the research questions to the data measurements and how those relate to current evidence.

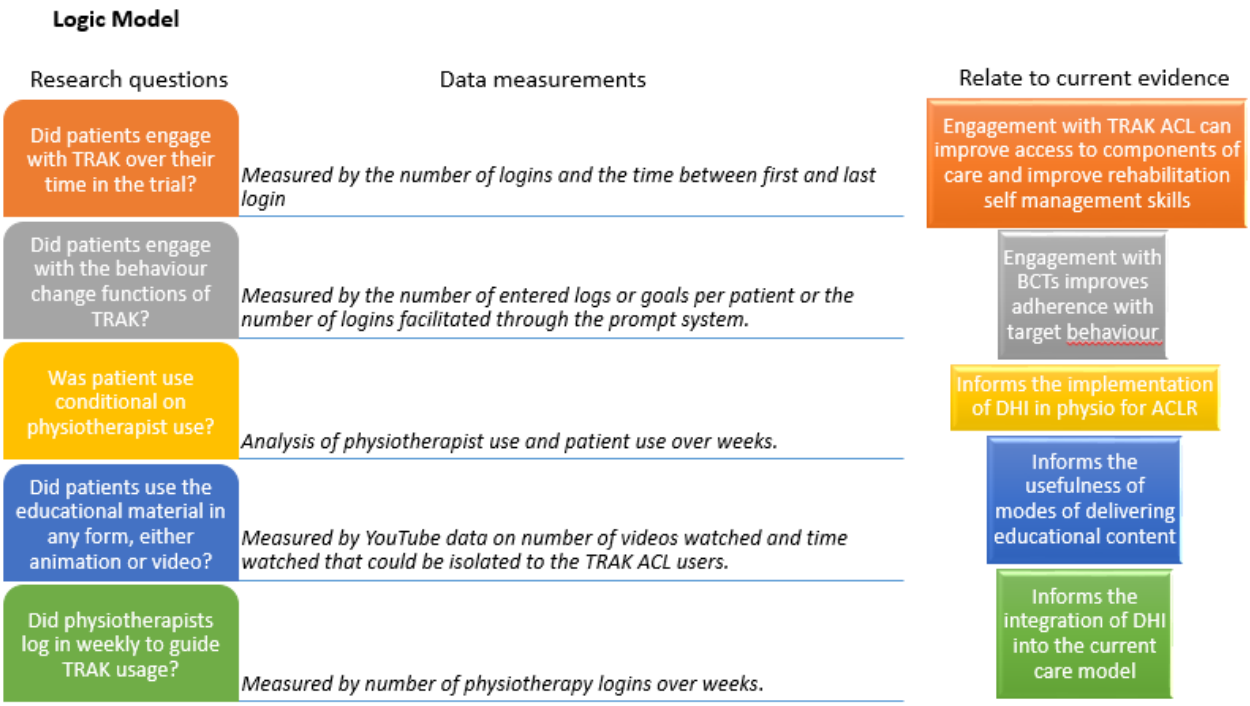

Figure 6.4. Logic Model for usage data collection.

6.3.9.2 Secondary study outcomes

6.3.9.2.1 Knee Injury & Osteoarthritis Outcome Score (313)

The KOOS is a patient rated outcome measure that assesses five outcomes: pain, symptoms, activities of daily living, sport and recreation function, and knee-related quality of life. The KOOS has been shown to be valid and reliable for the both clinical and research use. It measures knee function and knee related quality of life and it has been validated for use with anterior cruciate ligament reconstruction patients measuring both the sensitivity to surgery and sensitivity to physiotherapy. (313, 314). The selection of the KOOS and its suitability as a primary outcome for a future trial are discussed at length in the next section.

6.3.9.2.2 Stanford Self-Efficacy Questionnaire (22)

Self-efficacy in healthcare refers to a person's belief in their ability to influence their health and related to their confidence and control (315). Self-efficacy scores are commonly used in evaluations of self-management interventions. This outcome was developed with osteoarthritis patients. It is commonly

used in research of musculoskeletal interventions though it has not been validated specifically for anterior cruciate ligament reconstruction patients. This questionnaire was created by Lorig et al who tested it for construct validity, (the degree to which a test measures what it purports to be measuring) (p = .01). They also tested for concurrent validity by comparing to known outcomes in the field (p = .01). They found that it met reasonable standards for both and had good test, retest reliability (p = .01). (316)

6.3.9.2.3 EQ-5D-5L (317)

This outcome measures health related quality of life and is an essential tool in measuring QALYs, (quality of life years) that are needed for a health economic evaluation. It has 5 domains, mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain can be measured on 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. It is widely validated for use with knee conditions (318, 319). Authors demonstrated reliability through analysis of consistency of measures and established construct validity with convergent (the degree to which two measures of constructs that theoretically should be related, are in fact related) and divergent validity (constructs that should be different in fact are) testing against the subscales of the WOMAC (Western Ontario and McMaster Universities Index) knee outcome. The EQ5D5L was deemed to have corrected the earlier ceiling effect that was noted in OA knee patients with the EQ3D3L (318).

6.3.9.2.4 Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI).

This is an important tool for measuring impairments of paid work and unpaid work caused by a persons' health. This information is important to a health economic analysis of the impact of anterior cruciate ligament reconstruction and rehabilitation on work, in a future trial. It has been extensively validated with long term conditions and arthritis (320). The construct validity was tested by the correlations between the WPAI and a number of health outcomes and other measures of productivity (321) The test retest reliability was established previously (322)

6.3.9.2.5 The Client Services Receipt Inventory

This is a versatile tool of heath economic analysis that was validated for its different components with over 500 studies since its development in the 1980s (323, 324). It has been used in musculoskeletal topics such as arthritis though not directly in anterior cruciate ligament studies (325). This tool has been modified for physiotherapy studies in line with the guidance (324) and it measures health resource use for ACL patients at each stage of the trial. It aims to reflect the total costs incurred by patients, their employers, families and local healthcare services during a period of illness.

6.3.9.2.6 Strength

The feasibility of taking strength outcomes was also tested. Strength is a key measure of recovery in physiotherapy research and is a key determinate of outcome in ACL rehabilitation studies (7, 20, 186, 326-329). Strength symmetry tests of the knee are known to be key part of functional test batteries that patients should pass after ACL reconstruction (20, 106, 330). They are included as means to demonstrate the feasibility of taking physical outcomes from patients in a trial situation. Strength tests were inappropriate for immediately post-operative patients and were completed at 3 and 6 months only. There are evidenced ways to test strength that require adequate break times, calibrated isokinetic or handheld dynamometers or gym equipment (331, 332). Notwithstanding its limitations, the limb symmetry index is then used to compare strength of the operated and un-operated side (106). In the clinical environment the resistance machines were not calibrated nor could the full time be taken for validated rest and retest. Strength tests were only completed for patients at the Site 1 as equipment was not available to resource this at Site 3.

6.3.9.3 KOOS^4: Primary outcome of a future trial.

The KOOS^4 was chosen as the primary outcome of a future trial on ACL reconstructed patients using a DHI. KOOS was developed to meet the need for a longer term outcome for knee conditions. The Lysolm (333) was known to measure short term impairment and the WOMAC (334) long term impairment, but this did not allow for monitoring patients whose initial short term traumatic injury in many cases led to development of osteoarthritis and long term knee sequelae, as is the case for many ACL injuries. The KOOS was intended to be able to measure injury in the young as well as the long term consequences and clinical outcomes as patients age (335).

The KOOS has 5 subscales; Pain, Symptoms, Activities of Daily Living (ADL), Quality of Life (QOL) and KOOS Sport/Rec. Though it is possible to use a single subscale of KOOS for a primary outcome, such as KOOS Sport/Rec which is recommended for younger cohorts (70, 336), we have elected to use KOOS^4 which is a composite score of 4 out of the 5 KOOS subscales, KOOS Pain, KOOS Symptoms, KOOS Sport/Rec and KOOS QOL. The excluded category was KOOS ADL. It has been established in earlier studies where the cohort of ACL patients often have no issues with activities of daily living (ADL) and the authors eliminated this category so as not to cause 'unwanted noise' in the results (70). Each subscale of KOOS has a different number of items so KOOS^4 is calculated as an average of the four included subscales and not as a total score. This method was originally used by Frobell et al in a landmark study on ACL surgery outcomes (70) and has been popular subsequently as a primary outcome in RCT (337-340).

The Minimum Clinically Important Difference (MCID) is a term used to describe the smallest difference in an outcome that is clinically meaningful, as opposed to statistically significant. Previous studies have established that the minimal clinically important difference for the KOOS[4] is 8-10 points, both for patients with osteoarthritis and those who have had surgical interventions such as anterior cruciate ligament reconstruction (335). Responsiveness of the KOOS to changes of the patients' condition after ACLR was calculated by effect size. For the KOOS ACL cohort, when measured 6 months after surgery the effect sizes were large (>0.8). Pain, symptoms, and activities of daily living ranged from 0.84 to 0.94 and Sport and recreation function and knee-related quality of life ranged from 1.16 to 1.65 (313). The KOOS QOL is known to be the most responsive domain (335).

6.3.9.4 Study support at each site

At Site 1, the study was supported by a research physiotherapist who was funded to work on the study for 4 hours per week. Her primary role was to be a blinded outcome assessor and complete the trial databases. Her secondary roles were to support the treating clinicians, to ensure that any new staffs were confident with the intervention and ensure equipment such as iPads and iPad case locks were ready to use. This role was funded by NIHR as part of the fellowship.

At Site 2 there were two research physiotherapists already in post in the physiotherapy department. Their roles were part funded by the Clinical Research Network (CRN) to support research in physiotherapy. They saw the study on the CRN portfolio and contacted me directly, requesting involvement in the study. We agreed their role would be to remain blinded and collect outcome data.

At Site 3, the blinded outcomes assessor was KB, a supervisor of this PhD, who was also a research lead at the trust. The identification of patients, recruitment and randomisation were performed by a volunteer clinical physiotherapist. The volunteer participated through good will and engaged in a quid pro quo with me where I agreed to deliver teaching to her team on other clinical issues. Further research support for Site 3 came from Site 1 where the funded research physiotherapist was able to chase outcomes by sending postal outcomes and placing phone calls to patients. Following initial training no one was available on site weekly to support physiotherapists at Site 3 with TRAK.

6.3.10 Data Collection

If patients were interested in taking part in the study, the research physiotherapists and blinded outcome assessors provided them with a Patient Information Sheet (Appendix E) and invited them to take time to read it and ask questions before providing informed consent to participation. If they

consented outcomes were taken at time point 1. At Site 1, the blinded assessor took all outcomes. At Site 2, a research physiotherapist took all outcomes. Outcomes were repeated at 3 and 6 months. In this study, both outcome assessors and the lead researcher were blinded but neither patients nor treating physiotherapists could be blinded to the treatment allocation. The time points and outcomes are shown in Table 6.1.

Measures	Baseline	3 months	6 months
Recruitment and Consent	X		
Demographics	X		
Retention		X	X
KOOS	X	X	X
CSRI	X	X	X
WPAI	X	X	X
EQ-5D-5L	X	X	X
Self-Efficacy Questionnaire	X	X	X
Strength Symmetry Data		X	X

Table 6.1. Outcomes and time points

Abbrev: KOOS (knee injury & osteoarthritis outcome score), CSRI (client service receipt inventory), and WPAI (work productivity and activity impairment questionnaire: general health)

6.3.10.1 Health economic data collection

The study evaluated the feasibility of collecting data for a health economic evaluation. The EQ-5D-5L would be used to calculate quality-adjusted life-years (QALYs) in a full trial. Collecting the Client Service Receipt Inventory and the Work Productivity and Impairment scale demonstrate the feasibility of collecting information required for calculating patient-level costs of health care resource use in both arms of the study. All were collected at three time points.

6.3.10.1.1 Demographics & Trial information

Demographics and trial information were collected at time point one to describe baseline characteristics of the study population.

Demographics:

- Date of Birth
- Ethnicity
- Gender
- Education
- Employment

Trial Information:

- Consent
- Mobile Number
- Address
- Date of Entry
- Date of Leaving
- Reason for Leaving
- Site
- Adverse Events

6.3.11 Data Analysis

6.3.11.1 Statistical Analysis

The target was a sample size of between 50 and 70 participants as is indicated for feasibility trials to inform a future RCT protocol (341-343). It was not necessary to fully calculate a sample size for a feasibility trial (342) however I wanted to be able to estimate the rate (proportion) of eligible people who would be willing to participate, would be retained to the study and would comply with the intervention (344). Working with the CTU statistician, I calculated that a sample size of 25 in each arm would give a 95% CI of 0.60 to 0.85, indicating that I could be 95% certain that at least 60% of the target population will remain in the trial for at least 6 months.

All primary outcome measures were summarised separately by study arm. Differences in outcomes between arms were estimated using linear and logistic regression. As described in Table 6.2, quantitative data were analysed as follows: binary and other categorical measures such as recruitment, retention and adverse events, were summarised using frequencies and percentages. Continuous measures were summarised using means and standard deviations (or medians and interquartile ranges for skewed distributions).

Measures	Binary (Frequencies and Percentages)	Categorical (Frequencies and Percentages)	Numerical Measures (Means and SD or Median and IQR)
Recruitment	X		
Retention	X		
KOOS Collected	X		
CSRI Collected	X		
WPAI Collected	X		
EQ-5D-5L Collected	X		
Self-Efficacy Collected	X		
Strength Symmetry Data Collected	X		
Demographics DOB			X continuous
Demographic Ethnicity		X nominal	
Demographic Gender		X nominal	
Demographic Education		X ordinal	
Demographic Employment		X nominal	
Adverse Event	X		
KOOS			X
CSRI			X
WPAI			X
EQ5D5L			X
Self-Efficacy			X
TRAK Number of log ins			X Discrete
TRAK Pages visited			X Discrete
TRAK BCTs used			X Discrete
TRAK videos watched			X Discrete

Table 6.2. Outcomes in TRAK ACL trial. (The cells in yellow are primary outcome measures)

Ideally I would have used a fixed effect model to adjust for potential therapist effect on the usage data. Physiotherapists may have had varying degrees of access to patients or different levels of engagement with the DHI. Unfortunately, the usage data could not isolate individual therapists to the actions they took with which patients. Therapist activity can only be measured as a/ a login and b/ when they added another user or c/ 'updated cloak' which means some action was taken but it is unknown for which patient and what actions were taken. Figure 6.5 Anonymised clinician usage log shows the usage data we have for clinicians.

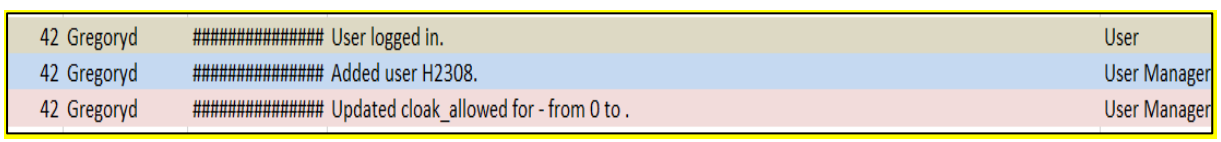

Figure 6.5. Anonymised clinician usage log demonstrating 3 types of measure of clinician function.

The precision of estimates was assessed using 95% confidence intervals. Power analyses were conducted to calculate the sample size necessary to detect an effect of the intervention in a future RCT with the Knee Osteoarthritis outcome score as the primary outcome. Missing data for feasibility analysis were accounted for using a multiple imputation technique. Intention to treat principles were applied to data for all recruited patients (345)

Health economic data generated from the trial included the QOL data (EQ-5D-5L), data from the CSRI and WPAI outcome measures, and cost of the intervention, and was analysed for completeness. The primary objective was to demonstrate the feasibility of collecting the relevant data for a health economic evaluation of a full scale RCT.

6.3.11.2 Summary of recruitment, attrition and follow-up

Participant flow was described using a CONSORT diagram.

- Proportion of screened patients who were eligible for the trial
- Proportion of eligible referrals consenting to the trial
- Proportion of people for whom baseline data were collected
- Proportion of participants in each randomised group who dropped out or were lost to follow-up by 3 months or 6 months. Reasons, if available, were summarised.
- Proportion who continued physiotherapy but not TRAK study
- Proportion of attrition from the intervention compared with attrition from the trial

6.3.11.3 Summary of baseline data

Baseline data (sociodemographic characteristics) were summarised by treatment group using frequencies and percentages as appropriate. This allowed for descriptions of the balance of baseline characteristics between the intervention and control groups.

Feasibility of recruitment was measured by number of eligible patients who consent to participate from 20.07.18 until 31.03.2019, and submitted to baselines measures and randomisation.

6.3.11.4 Summary of 3 month follow-up

Feasibility of retention at 3 and 6 months was measured by the number of participants still in the trial and providing outcome data at these time points. Feasibility of collecting each outcome at 3/12 and 6/12 was recorded as a binary outcome. Descriptive statistics were used to summarise findings for secondary outcome measures. The study was not powered to detect any difference in secondary outcomes however, these were summarised using means (with SDs), medians (IQR), counts (%) as appropriate. Reasons for missing data were summarised.

6.3.11.5 Summary of Health Economic Analysis

Binary outcomes and data completeness for these questionnaires were reported for each time point. Methods, ease and data completeness of collecting number of physiotherapy appointments was a particular focus of the work.

6.3.11.6 Summary of TRAK usage data

In line with the trial statistical analysis plan, usage and acceptability of the TRAK intervention were measured by the number of logins to the TRAK website, educational videos watched and behaviour change functions used i.e. exercise log, goal setting or weekly progress. These data were available from the server at Cardiff University where TRAK ACL is hosted and from the YouTube site where the videos were hosted. They were analysed as numerical data and reported in means and standard deviations (medians and IQR) if skewed (Table 6.2).

6.3.11.7 Analysis of usage data and the AMUsED Framework

The importance of quality data for accurate measurement of usage was much discussed in the literature (283, 346-348) and underscored the importance of determining what TRAK ACL can measure and how it informs the feasibility of a future clinical trial.

The Miller et al 'AMUsED' (Analysing and Measuring Usage and Engagement Data) framework guided systematic in-depth usage analyses and aimed to be transparent and repeatable (347). It included three stages, firstly, familiarization with the intervention and the relationship between the intervention and the data that were captured, secondly identification of the most meaningful measures of usage related to the intended functions of the website and specified research questions to guide a more systematic analyses of usage data, and finally, preparation of relevant datasheets and planned statistical methods to analyse the data.

6.3.11.7.1 Step 1

The relationship between the intervention and the captured data in this instance refer to 2 main functional features of the website; the clinical functions and the behaviour change functions. These are discussed in detail in Chapter 5 as part of the logic model that maps the functions of TRAK ACL.

6.3.11.7.2 Step 2

The second step involved the mapping of the research questions onto the captured data to ensure that measures of usage are meaningful to the key questions of research. A framework of key research questions with regard to the intervention were mapped out in Figure 6.4. A logic model for usage data.

6.3.11.7.3 Step 3

The final step in the AMUsED framework was the preparation of datasheets and consideration of available analytical methods with which to examine the data. The TRAK data were collated into 7 data sheets for analysis. They included patient logins, physiotherapist logins, prescribed exercises, weekly logs, personal goal setting, exercise logs and patient engagement (summary of logs and goals). The analysis was summarised using descriptive statistics and visual plots of usage data.

6.3.11.8 Databases

An access database was developed for data collection. This database was designed to facilitate limited data entry mistakes and cleaner data output. Entries were restricted to 0, 3 and 6 months for each participant under their allocated trial number. The database was maintained by a blinded assessor until the trial was complete.

6.3.11.9 Adverse Events

Frequency (%) of events or accidents in the study were summarised by randomised group.

6.3.11.10 Data exploration

This study was not powered to detect a difference in the TRAK and TAU subgroups for clinical or health economic outcome measures. An analysis of outcomes was nevertheless conducted to compare and to observe and hypothesize for future research questions. The KOOS, EQ5D5L, WPAI and Self-Efficacy Score were described and then analysed using a simple linear regression model. In each case a single predictor, the binary TRAK/TAU variable is related to a single continuous outcome variable.

6.4 **Results**

6.4.1 Recruitment

Patient recruitment and the flow of participants through the trial are shown in Figure 6.6. A CONSORT flow diagram. Recruitment ran from 20th of July 2018 to 31st of March 2019. 59 people were assessed for eligibility across two sites. At Sites 1 and 3, 4 people declined to participate (n=8). Reasons were not recorded. Following baseline outcomes 51 people were randomised to the TRAK and TAU arms of the study. 26 patients were allocated to TRAK and 25 to TAU. At the conclusion of the trial, data showed that 2 people from the TRAK arm were never given the intervention though they continued to provide outcomes. In TAU, 2 people from this group were given the intervention by the treating physiotherapist by mistake. However, this was not known until the end of trial.

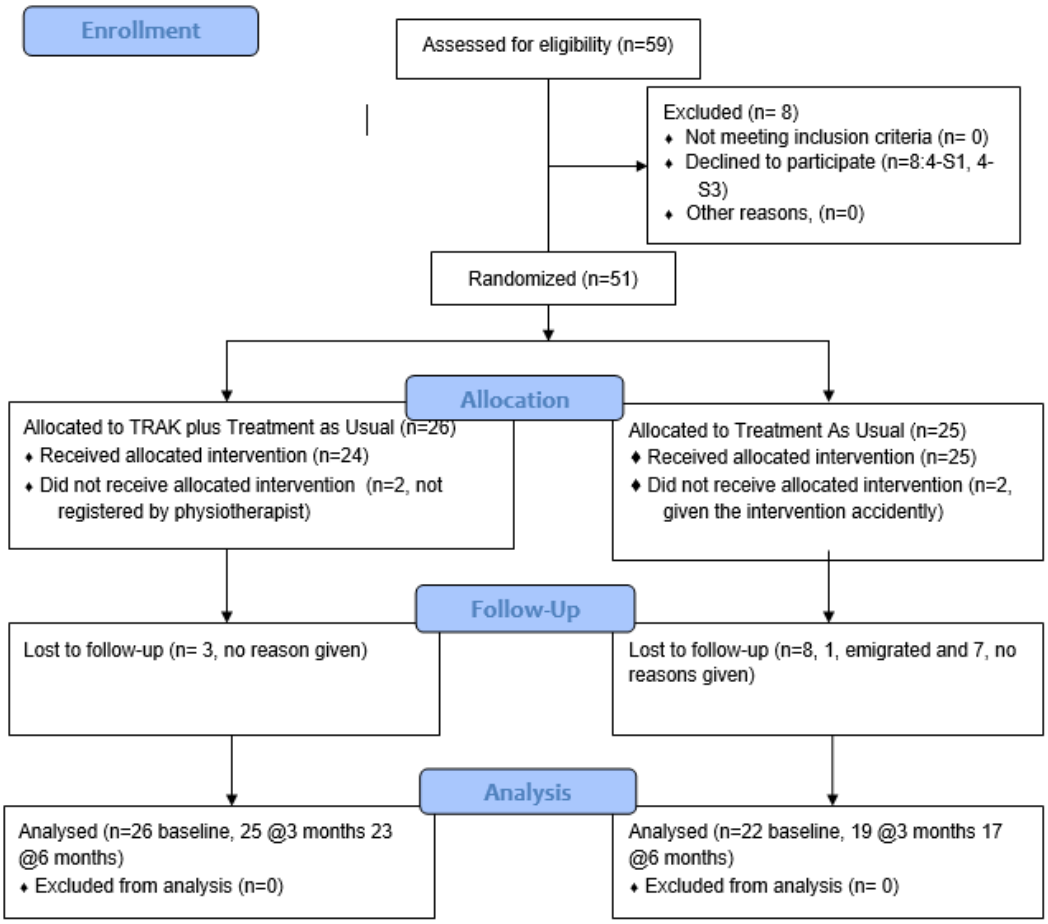

Figure 6.6. CONSORT Flow Diagram

6.4.1.1 Characteristics at baseline

There were 51 study participants overall. The treatment as usual (TAU) arm and the TRAK arm were well matched for baseline characteristics, presented in Table 6.3. The average age in the TRAK group was 30.8 and the average age in the TAU group was 28.4. There were more men than women in the study, thirteen men and 12 women in the TAU group and 15 men and 11 women in the TAU group. The majority of study participants were of white ethnicity, 18 in TAU group and 19 in TRAK group. There were 3 black people, 1 Asian person and 3 people who identified as mixed race in the TAU group. The TRAK group had one person who identified as Asian other, 2 South Asians, 2 black people and 2 who identified as mixed race. Ethnicity broken down by site reflected the demographics differences between the two hospital Trusts, where all participants in Site 3 were white. Eighteen people in TAU and 13 people in the TRAK arm had a degree or higher degree education. There were 3 and 5 people in the TAU and TRAK arms respectively with A Level or equivalent while six people had GCSE level education. 20 people in TAU and 19 people TRAK participants were employed. All others identified as students (5 and 7 respectively).

Patient Characteristics	TAU	TRAK	Site 3	Site 1
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age	28.4 (8.2)	30.8 (11.4)	29.0 (9.0)	29.82 (10.2)
Site	n25	n26	n10	n41
	Freq (%)	**Freq (%)**	**Freq (%)**	**Freq (%)**
Gender -Female -Male	 12 (48.0) 13 (52.0)	 11 (42.3) 15 (57.7)	 3 (30.0) 7 (70.0)	 20 (48.8) 21 (51.2)
Ethnicity -Asian -Asian other -Black -Mixed black and white -Mixed other -Mixed white and Asian -South Asian -White	 1 (4.0) 0 (0.0) 3 (12.0) 2 (8.0) 1 (4.0) 0 (0.0) 0 (0.0) 18 (72.0)	 0 (0.0) 1 (3.9) 2 (7.7) 1 (3.9) 0 (0.0) 1 (3.9) 2 (7.7) 19 (73.1)	 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 10 (100)	 1 (2.4) 1 (2.4) 5 (12.2) 3 (7.3) 1 (2.4) 1 (2.4) 2 (4.9) 27 (65.9)
Education Level -A level or Equivalent -Degree/Higher Degree -Diploma Higher Education -GCSE or equivalent	 3 (12.0) 18 (72.0) 2 (2.0) 2 (2.0)	 5 (19.2) 13 (50.0) 4 (15.4) 4 (15.4)	 1 (10.0) 6 (60.0) 3 (30.0) 0 (0.0)	 7 (17.1) 25 (61.0) 3 (7.3) 6 (14.6)
Employment Status -currently employed -student	 20 (80.0) 5 (20.0)	 19 (73.1) 7 (26.9)	 7 (70.0) 3 (30.0)	 32 (78.0) 9 (22.0)

Table 6.3. Baseline characteristics of participants

6.4.2 The closing of Site 2

The study opened for recruitment at two NHS sites on the 20th of June 2018, Site 1 and Site 2. However, Site 2 NHS Trust had an unexpected dearth of ACL patients that were eligible for the study. This problem was identified quickly and after one month it was decided that it presented a significant challenge to the recruitment target. Two local physiotherapists, experienced in research were acting as research leads for this site. They identified several potential causes for the failure to recruit any patients at all. Firstly, there had been recent changes in the orthopaedics department that may have led to fewer ACL surgeries being done. Secondly, the physiotherapy team was spread across many locations and, despite the goodwill, the research physiotherapists were unable to visit these locations to recruit patients. Therefore physiotherapists at those places were asked to recruit patients which

they had no allocated time for. The team was known to be very busy which may have meant that they were unable to identify or recruit patients. Finally, the research physiotherapists identified an interesting possibility, in that they had recently signed up to a number of musculoskeletal health studies from the Clinical Research Network portfolio as part of a local plan to be more engaged in research. An unexpected outcome of this may have been to introduce an element of research fatigue to the clinical team. They identified a feeling amongst the team that research activities were time consuming and adding to an already difficult workload.

I made several trips to Site 2 to deliver training and resources. I obtained a MiFi device for a location that had reported was limited by poor Wi-Fi I printed all the outcomes questionnaires in London and took them to the sites in Site 2 on public transport, when time and resources for printing were highlighted as a limitation. In discussion with the local team, I offered supplementary training on TRAK to guide people again through the short cuts and basic instruction. The local research physiotherapists found oversight was difficult due to the team being spread over a number of locations and the research physiotherapists being under resourced to visit them all in person. This issue with recruitment extended for 3 months and no patients were recruited.

6.4.3 Retention: Numbers analysed

Retention was measured by the proportion of participants providing outcome data at 3 and 6 months. In total 44 patients were retained to the study at 3 months and 40 when the trial closed. Table 6.4 demonstrates that over the course of the study, three people were lost to follow up in the TRAK arm and 8 were lost to follow up in TAU. Only one reason was given for discontinuation of the trial (emigrating). Others no longer attend physiotherapy and no more is known. The 3 month dropout rate in the TAU arm is higher than the TRAK arm.

A logistic regression analysis was used to compare the odds of staying in the trial according to which arm a participant was allocated to, demonstrated in Table 6.4. The coefficient for the constant was the estimated odds for retaining people to the study from the TAU group and the TRAK coefficient was the estimated odds for retaining people to the study from the TRAK group. When comparing the odds of staying in the trial between groups, there was no evidence that retention was associated with allocation. The regression showed that the odds ratio = 7.89 with 95% confidence interval (.858 - 71.21) and a p value of .066 at three months. Likewise at 6 months where participants in the intervention arm have greater odds than those in the TAU arm of being retained to the study. The odds ratio = 3.60 with 95% confidence interval (.831 - 15.65) and a p value of .087.

Retention	Total	TAU	TRAK
	Freq (%)	Freq (%)	Freq (%)
Retention -Baseline -3 months -6 months	 51 (100) 44 (86) 40 (78)	 25 (100) 19 (76) 17 (68)	 26 (100) 25 (96) 23 (88)
Retention by Site		**Site 3**	**Site 1**
		Freq (%)	Freq (%)
Retention -Baseline -3 -6		 10 (100) 7 (70) 7 (70)	 41 (100) 37 (90) 33 (80)
Retention Odds	**TAU**	**TRAK**	**P value (confidence interval)**
	Freq (%)	Freq (%)	P value (confidence interval)
3 months	19 (76.00)	25 (96.15)	0.066 (.875 -71.21)
6 months	17 (68.00)	23 (88.46)	0.087 (.832 -15.66)

Table 6.4. Retention per treatment group and across sites

6.4.4 Completeness of outcome data

The completeness of outcome data was used to indicate the feasibility of collecting data at a future full scale randomised trial. The completeness indicated the participant's acceptance of the number of outcomes, the complexity, the type of information and the time taken. The Knee Osteoarthritis Outcome Score, the Self-Efficacy Scale, the WPAI and the EQ5D5L were collected at each time point. Of these the KOOS was the most clinically relevant outcome to the ACL reconstructed patient. It had 100% item completion for each taken outcome and all persons who remained in the trial at each time point completed the outcome as shown in Table 6.5. The Self-Efficacy Scale, the WPAI and the EQ5D5L were also complete for each outcome taken, shown in Table 6.5. The trial blinded outcome assessor was key in ensuring the completeness of outcomes. She was able to guide patients in how to complete outcomes correctly and in the case of outcomes that she gathered from Site 3, she sent outcomes by post and placed follow up calls to patients to support outcome completion. The number of physiotherapy appointments was also collected as part of determining the feasibility of a future health economic analysis. The mean appointments were 16.01 with a standard deviation of 5.04 as shown in Table 6.5.

The Client Service Receipt Inventory (CSRI) was exceptional in that it was only completed by 54% of participants at baseline, and then 69% and 89% at 3 and 6 months. Although it appears that the outcome data were more complete at later time points, this is misleading. The CSRI was tabled without the calculated costs in order to demonstrate detail, complexity and scale of this outcome measure. This table was over 10 pages long and so is moved to the appendix (Appendix F). The baseline time

point captured much more health resource use data, however in its complexity, many multipart questions were left incomplete. For example, if patients were asked if they had seen their GP at the surgery, 15 people responded yes, but only 14 people then answered how many times that they had seen their GP. This item is then marked as having missing data. At the 6 month time point, many questions were answered with 'No' so the further parts of the question were correctly blank and therefore no data was missing. Feedback from patients was that the questions were complicated and participants declined to share some personal financial information.

For feasibility of strength testing, we recorded as a binary outcome whether the patient completed knee extension strength tests on a knee extension resistance machine at 3 and 6 months, demonstrated in Table 6.5. At Site 3, clinicians did not have access to resistance equipment so strength tests were not possible. At Site 1, at 3 months, 33 participants were strength tested bilaterally, eight were not, (four had dropped out of the study and four were in pain where strength test was not appropriate). At 6 months there were 33 people in the study at Site 1, 30 of those submitted to strength testing and results were recorded. Three did not attend the test.

Outcome Completeness	Total	TAU	TRAK
	Freq (%)	Freq (%)	Freq (%)
KOOS			
0	51 (37.38)	25 (40.98)	26 (35.14)
3	44 (32.59)	19 (31.15)	25 (33.78)
6	40 (29.63)	17 (27.87)	23 (31.08)
No if items	42	42	42
Complete items	42 (100)	6 (100)	6 (100)
Self-Efficacy			
0	51 (37.38)	25 (40.98)	26 (35.14)
3	44 (32.59)	19 (31.15)	25 (33.78)
6	40 (29.63)	17 (27.87)	23 (31.08)
No if items	6	6	6
Complete items	6 (100)	6 (100)	6 (100)
CSRI			
0	51 (37.38)	25 (40.98)	26 (35.14)
3	44 (32.59)	19 (31.15)	25 (33.78)
6	40 (29.63)	17 (27.87)	23 (31.08)
No if items	114	114	114
Complete items	64 (54.38)	79 (69.29)	102 (89.47)
WPAI			
0	51 (37.38)	25 (40.98)	26 (35.14)
3	44 (32.59)	19 (31.15)	25 (33.78)
6	40 (29.63)	17 (27.87)	23 (31.08)
No if items	6	6	6
Complete items	6 (100)	6 (100)	6 (100)
-EQ5D5L			
0	51 (37.38)	25 (40.98)	26 (35.14)
3	44 (32.59)	19 (31.15)	25 (33.78)
6	40 (29.63)	17 (27.87)	23 (31.08)
No if items	5	5	5
Complete items	5 (100)	5 (100)	5 (100)
Strength Outcome	**3 months**	**6 months**	
Leg Extension			
Total in study at site 1	37	33	
Yes	33 (89.18)	30 (90.90)	
No	4 (10.81)	3 (9.09)	
Reason	Pain or DNA	Pain or DNA	
Physiotherapy appointments	**n=51 Mean (SD)**		
Total Physiotherapy appointments per person	16.01 (5.04)		

Table 6.5. Outcome and Data Completeness

6.4.5 TRAK ACL usage data

6.4.5.1 Allocation

Twenty six people were allocated to use the TRAK intervention in total. Not all patients that were allocated to TRAK received the intervention. At Site 3, n=2 patients were allocated to the intervention but were never signed up to TRAK by the treating physiotherapist, the reason for this is unknown. So only three patients at Site 3 were signed up to TRAK. Of these, only one patient was given personal prescribed exercises on TRAK ACL by the treating physiotherapist (Table 6.6).

At Site 1, two patients were signed up to TRAK but never logged in. One explained this as a technical problem, saying he was never able to login while the reason for the other remains unknown. Hence usage data were only available for 22 participants. All patients at Site 1 received a personalised exercise plan. Two patients at Site 1 were allocated to the treatment as usual group but were then given the TRAK intervention. This occurred by accident and on the same day, through clinician error. Their outcome data was still collected and analysed in the TAU group and usage data was not included in usage analysis in line with intention to treat principles.

TRAK Usage	Total	Site 1	Site 3
	Freq (%)	Freq (%)	Freq (%)
Allocated to TRAK	26 (100)	21 (81.0)	5 (19.0)
Did not receive the intervention Reason	4 (15.0)	2 (8) Technical problems prevented log in and unknown	2 (7.5) Not signed up by PT
Total for analysis	22(85.0)	19 (73.0)	3 (11.5)
Received the intervention by error Excluded from analysis	n=2	n=2	n=0

Table 6.6. Allocation to TRAK ACL

Usage of the TRAK intervention was measured by the number of log in's to the TRAK website, videos watched and behaviour change functions used e.g. exercise log, goal setting or weekly progress. These findings are displayed in Table 6.7. Logins are a simple measure of TRAK usage and all logins are deemed to be a measure of interaction with TRAK. Analysis was limited such that logins are not timed out automatically by TRAK and therefore patients can remain logged in as long as the window they use was open.

6.4.5.2 Logins

6.4.5.2.1 Patient participants

There were 279 patient logins to TRAK in 63 weeks from the 22 participants for whom we have usage data in the intervention arm. One participant accounted for 113 of these. The median number of logins per patient participant was 5 with interquartile range of 3 to 13. The median (interquartile range) patient logins per week was 4 (2-7). The time between patients first and last log in was mean 18 weeks (12.2SD), which suggests that users engage over time and phases of care (Table 6.7). Limitations of TRAK ACL ability to measure logins are noted in limitations section.

6.4.5.2.2 Physiotherapists

There were 108 logins by 8 physiotherapists over the trial. The median (range) physiotherapist logins per week was 2 (0-5) (Table 6.7). The median (range) logins per physio over the duration of the trial was 11.5 (6-18.5). The mean (SD) number of weeks of use was 28.8 (18.4). The logins of physiotherapists and patients over 60 weeks, shown in Figure 6.7, showed consistency of patient usage as physio usage dwindles and disappears over the last 20 weeks. One physiotherapist user was responsible for much of the login activity. Figure 6.8 shows the login activity with this 'superuser' separated out from other patient logins.

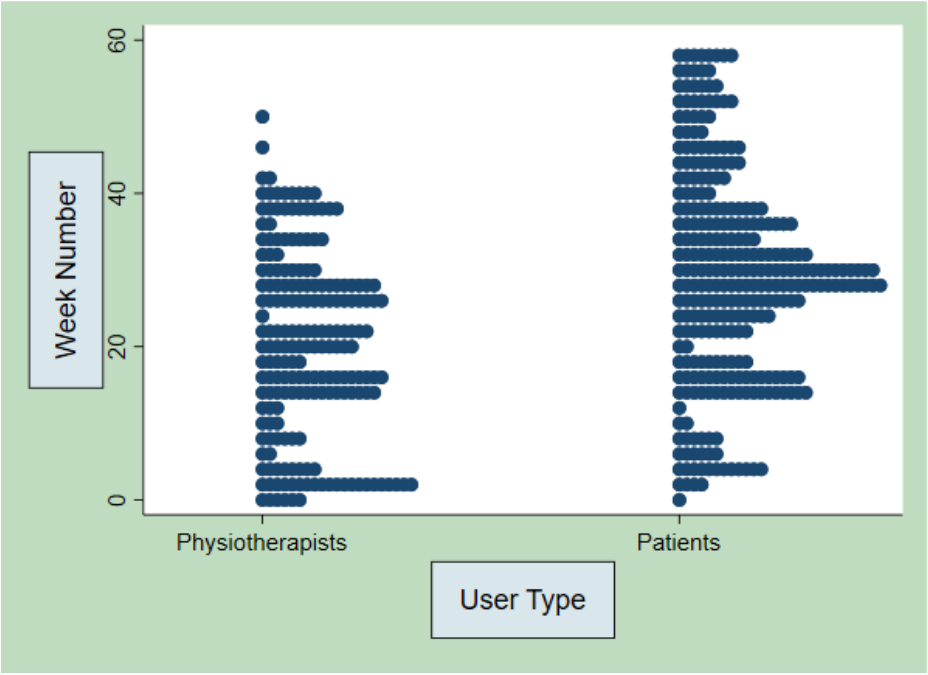

Figure 6.7. Physiotherapist and patient logins over 60 weeks.

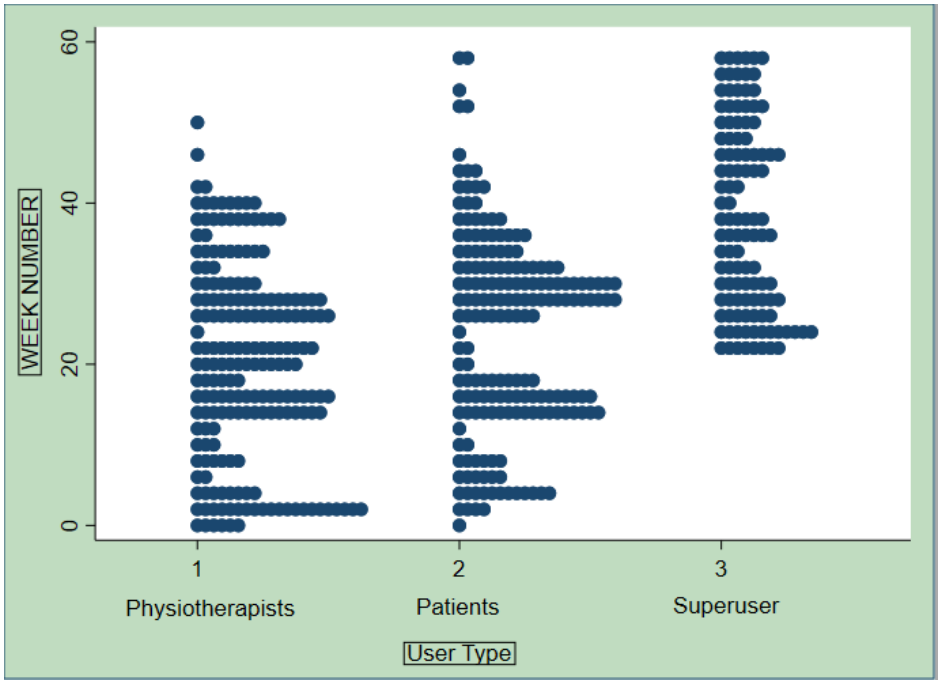

Figure 6.8. Physiotherapist and patient logins with ‘superuser’ separated

TRAK Usage	
Logins	**Freq (%)**
Physiotherapist n=8	108 (27.90)
Patient n=22	279 (72.09)
	Median (IQR)
Logins per patient n=22	5 (2.0-17.0)
Logins per physiotherapist n=8	11.5 (6.0-18.5)
Logins p/week: Patient	4 (2.0-7.0)
Logins p/week : Physiotherapist	2 (0.0-5.0)
	Mean (SD)
Weeks of use (first to last log in) patients	18 (12.2)
Weeks of physiotherapist use	28.8 (18.4)
Prescribed Exercises	Median (IQR)
Prescribed exercises per patient	34 (27.0-51.0)
Prescribed exercises per physiotherapist (n=5)	163 (29.0-195.0)
Prescribed exercises per physio per week (n=5)	23.2 (15.0)
Types of exercise prescribed	**Freq (%)**
Total	776 (100)
Agility	37 (4.77)
Cardiovascular	13 (1.68)
Flexibility	108 (13.92)
Hops and Jumps	70 (9.02)
Neuromuscular Control	122 (15.72)
Run drills	8 (1.03)
Strength	396 (51.03)
Trunk Strength	22 (2.84)
Exercise Phase	**Freq (%)**
Phase 1: Early Physiotherapy	320 (41.24)
Phase 2: Intermediate Physiotherapy	373 (48.07)
Phase 3: Advanced Physiotherapy	83(10.70)
Phase 4: Return to Sport Physiotherapy	0

Table 6.7. Logins and Prescribed exercises

6.4.6 Prescribed exercises

There were 776 prescribed exercises. There was a median (IQR) of 34 (27-51) exercises per patient. Strength exercise was the most commonly prescribed type of exercise, 396 (51.03). Otherwise the exercise types were spread across a range of physical rehabilitation categories outlined in Table 6.7 such as agility n = 37 (4.77%), cardiovascular n= 13 (1.68%), flexibility n=108 (13.92%), hops and jumps n=70 (9.02%), neuromuscular control n=122 (15.72), run drills n=8 (1.03%) and trunk strength n=22

(2.84%). The prescribed exercises were also spread across the various stages of care. Phase 1: Early Physiotherapy had n= 320 (41.24%) Phase 2: Intermediate Physiotherapy had slightly more at n= 373 (48.07%). There were n=83 (10.70%) in the Phase 3: Advanced Physiotherapy. There were no exercises prescribed in the Phase 4: Return to Sport Physiotherapy 16 (1.83).

Only 5 physiotherapists updated exercise plans. There were no exercise plans updated after 10 months. All patients at Site 1 had exercise updated at least once however only one patient at site 3 was prescribed exercises.

Behaviour change techniques	Median (IQR) n=22	Number of individual users	Number of uses	Spread
Goal Setting	1 (0-3)	11 users	43 Goals (n=11)	1-11 (n=11)
Weeks over which goals were used	4(4-8)			
Weekly Log	0 (0-1)	10 users	124 logs	1-71(n=10)
Weeks over which weekly log used	4 (4-12)			
Exercise Log	0 (0-16)	8 users	989 logs	3-713 (n=8)
Weeks over which exercise logs used	14 (8-20)			

Table 6.8. Behaviour Change Functions

6.4.7 Behaviour change functions

The use of behaviour change functions is described in Table 6.8. Of the 22 users, 11 entered personal goals. These 11 entered a total of 43 goals, with a range of 1 – 11 goals per user. For the 22 users overall, the median number of goals was 1 (IQR 0 – 3). There were 10 users who utilized the weekly log function. The weekly log was designed to form a broad summary of the user's rehabilitation behaviour. There were 124 weekly logs in total with a spread of 1-71 logs per patient. The median weekly logs was 0 (0-1) n=22. The exercise log was a detailed record of the exercises a person was focused on; 8 users entered 989 logs with a range of 3-713, and the median was 0 (IQR 0-16) n=22.

Educational Videos	Views	Average View Duration	Total Duration	% of total viewed
Orthopaedic Surgeon Video	7	00:01:04	4:02	26%
Phase 1 Animation	11	00:01:31	2:05	73%
Phase 2 Animation	11	00:02:20	2:50	82%
Phase 3 Animation	7	00:02:14	2:34	87%
Phase 4 Animation	6	00:02:10	2:46	78%
Psychological Factors Animation	6	00:01:59	2:32	78%
Home Exercise – How much and when?	21	00:01:08	1:39	69%
Expert Videos	**Views**	**Average View Duration**	**Total Duration**	**% of total viewed**
Expert video Overview of ACL rehabilitation	4	00:01:02	2:32	41%
Phase 1 Expert Video	4	00:01:26	2:26	59%
Phase 2 Expert Video	2	00:00:24	3:14	12%
Phase 3 Expert Video	0	0	4:15	0%
Phase 4 Expert Video	1	00:00:21	4:20	8%
Psychological Expert Video	0	0	4:14	0%
Good Control Bad Control	2	00:00:38	00:38	100%

Table 6.9. Educational videos and animations

6.4.8 Educational videos and animations

The educational components of TRAK ACL are also behavior change functions but are grouped separately for reporting clarity. The analysis of video usage was limited to YouTube analytics as TRAK itself was unable to measure videos clicked by users. The YouTube analytics allows a breakdown of 'external' view sources which means sources that were not accessed on YouTube's own site. These could isolate the views that came directly from the TRAK website as they were identifiable through the registration of the server. The videos on TRAK ACL are unique to this website so all data could only have come from TRAK ACL. There is one exception, the 'Home Exercise, How Much and When' video can also be accessed by users of another Cardiff project so the user numbers here are not measurable in a meaningful way. They are reported here for completeness but would need to be set up separately in a future trial. Results are shown in Table 6.9.

The educational animations that summarized key learning for each phase were viewed are reported in number of views and mean percentage of total animation watched. The Phase 1 Animation was viewed 11 times (73%). The Phase 2 Animation was viewed 11 times (82%). The Phase 3 Animation was viewed 7 times (87%) and the Phase 4 animation was viewed 6 times (78%). The Psychological factors of ACL rehabilitation animation was viewed 6 times (78%). Finally, the Home Exercise-How Much and when video was viewed 21 times (69%).

The orthopedic surgeon expert video was viewed 7 times the average view was 1 minute and 4 seconds (41%). The physiotherapist expert videos contained identical content to the animations but were offered as an alternative medium. The Phase 1 video was viewed 4 times (59%). The Phase 2 video was viewed 2 times (12% the Phase 3 video was not viewed at all. The Phase 4 video was viewed once for 21 seconds (8%). An expert video alternative to the psychological factors video was not viewed at all. A video demonstrating 'Good and Bad Knee Control' was viewed twice (100%).

6.4.9 Analysis of secondary outcomes

6.4.9.1 KOOS

Each of the subscales of KOOS was analysed separately. The baseline KOOS Pain score was calculated first and showed a mean 8 point difference by which the TAU group was managing better than the TRAK group (59.11 TAU and 51.28 TRAK). This indicated the randomisation was not even and therefore an adjustment for baseline was added to the regression analysis.

KOOS Pain scores are shown in Table 6.10 for time point 0, 3 and 6 months. When comparing the two groups, TRAK and TAU, the intervention effect is measured by the p value and 95% confidence intervals. The difference in the intervention effect from baseline to 3 months and baseline to 6 months for Pain was 3.97, p= 0.172 (-1.803 to 9.756) and 1.09, p=0.775 (-6.609 to 8.799). For KOOS Symptoms (Table 6.10) the intervention effect difference from baseline to 3 months and baseline to 6 months was 1.49, p=0.673 (-5.603 to 8.596) and -6.70 p=0.199 (-17.096 to 3.687). For KOOS activities of daily living (ADL) the intervention effect difference between baseline to 3 months and baseline to 6 months was 2.54, p=0.258 (-1.936 to 7.018) and 2.08, p=.188 (-1.061 to 5.222). For KOOS sport and recreation (SportRec) the intervention effect difference between baseline and 3 months and baseline and 6 months was 7.8, p=0.278 (-6.51 to 22.111) and, 2.27 p=0.71 (-10.007 to 14.560). Finally for KOOS quality of life (QOL) the intervention effect difference between 0 and 3 months and 0 and 6 months was 4.94 p=0.274 (-4.060 to 13.948) and -4.10 , p=0.485 (-15.900 to 7.685). The KOOS scores at each time point for the 4 key KOOS domains are shown in Figure 6.9.

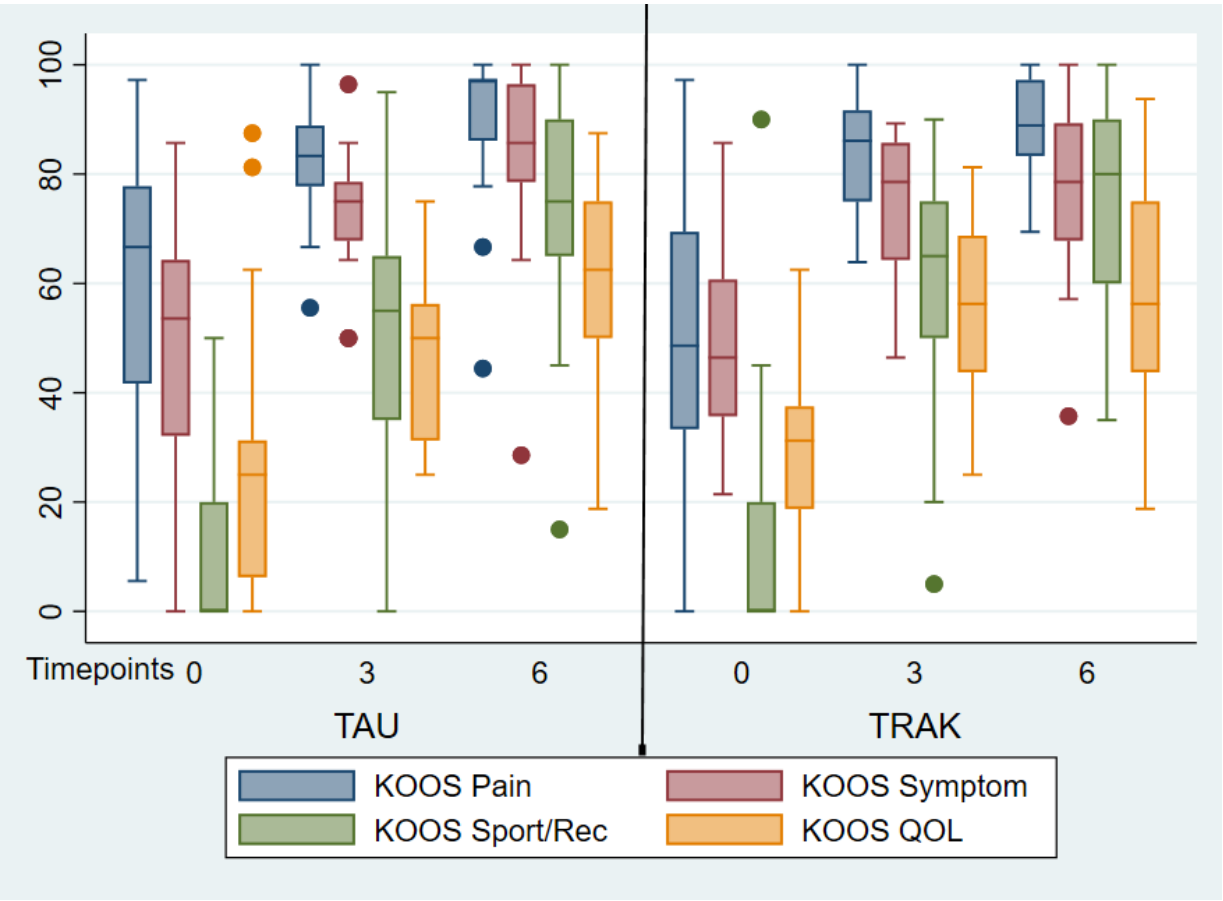

Figure 6.9. Four domains of KOOS at 3 time points for TRAK and TAU.

The scores for each subscale did not differ significantly between groups. This indicates that there was no detectable effect of the intervention on the outcomes. In all cases the 95% confidence interval includes 0 which means that the data were consistent with null hypothesis that there is no difference between TRAK and TAU in the Knee Osteoarthritis Outcome Scores.

Outcome	TAU Summary Statistics N= , Mean (SD)	TRAK Summary Statistics N= , Mean (SD)	Intervention Effect Difference of means (95% CI) and p value
KOOS KOOS Pain 0 3 6	 25, 59.11 (24.00) 19, 82.31(10.68) 17, 89.54(14.71)	 26, 51.28 (24.79) 25, 84.22(10.10) 23, 89.37(09.57)	 3.97 (-1.803, to 9.756) p= 0.172 1.09 (-6.609 to 8.799) p=0.775
KOOS Symptoms 0 3 6	25, 49.71(12.17) 19, 72.93(11.12) 17, 84.03(17.64)	26, 47.12(17.02) 25, 74.43(11.88) 23, 77.33(14.79)	1.49 (-5.603 to 8.596) p=0.673 -6.70 (-17.096 to 3.687) p=0.199
KOOS ADL 0 3 6	25, 64.17(27.00) 19, 91.87(08.06) 17, 95.76(06.13)	26, 57.35(25.29) 25, 94.17(06.40) 23, 97.44(03.61)	2.54 (-1.936 to 7.018) p=0.258 2.08 (-1.061 to 5.222) p=0.188
KOOS SportRec 0 3 6	25, 9.8(14.10) 19, 50 (23.51) 17, 72.94(22.01)	26, 10.58(20.51) 25, 57.8 (23.14) 23, 75.22(16.41)	7.80 (-6.51 to 22.111) p=0.278 2.27 (-10.007 to 14.560) p=0.71
KOOS QOL 0 3 6	25, 25.25(24.70) 19, 47.69(15.48) 17, 61.76(08.99)	26, 28.37(17.87) 25, 54.75(17.23) 23, 59.23(20.10)	4.94 (-4.060 to 13.948) p=0.274 -4.10(-15.900 to 7.685) p=0.485
Self-Efficacy Score 0 3 6	 25, 7.27(1.65) 19, 8.30(1.39) 17, 8.50(1.50)	 26, 7.69(1.84) 25, 8.43(1.00) 23, 8.47(1.32)	 .126 (-0.601 to 0.854) p=0.728 -0.03 (-0.949 to 0.871) p= 0.932

Table 6.10. Exploration of Intervention effect data, KOOS and Self-Efficacy

6.4.9.1.1 KOOS[4]: sample size calculation for a future trial

The developers of the instrument recommend that when using the KOOS, a change of 8-10 is most commonly considered the minimal clinically important difference and the standard deviation is set to 15 (70, 313, 335, 349). They caution that the circumstances of the study may vary this and should be taken into account in the design.

An ideal approach would be to use the SD of the KOOS[4] at baseline from this feasibility study, Table 6.11. The limitation of this was that for the purposes of feasibility we recruited to this study from 0 - 12 weeks post operatively. We did this to boost recruitment and knowing that patient rehabilitation can continue for 9-12 months (18) so we would still be able to follow participants up for 6 months. The unintended result may have been to impact the baseline SD which was 17.2671 for KOOS[4,] the

likely outcome of a future trial. This may be considered high and needs to be compared to other evidence. Table 6.11 shows the Mean and standard deviation at baseline for all domains of the KOOS as well as the overall Mean and SD for KOOS[5] and KOOS[4].

Domain	Mean	SD
KOOS PAIN Baseline	55.11983	24.48464
KOOS Symptom Baseline	48.38936	20.10576
KOOS ADL Baseline	60.69781	26.11042
KOOS Sport/Rec Baseline	10.19608	17.49173
KOOS QOL Baseline	26.83824	21.33418
Mean KOOS5	= 40.24826	
Mean KOOS4	= 35.13588	
SD KOOS5		= 18.4658
SD KOOS4		= 17.2671

Table 6.11. Means and SD for KOOS at baseline

Given the limitations of the feasibility trial mean and standard deviation for KOOS[4], I compared to other published studies. The Frobell study used a standard deviation of 15 points on the KOOS[4] and aimed to detect a 10 point difference. This is in line with the KOOS developer guidance (349) . This gives a standardised effect size of 0.67, which is quite a large effect size to detect. However other studies report similar SD at baseline for KOOS[4]. Paradowski et al , SD18.25 at baseline (350) Bjornsson et al referenced the Frobell paper as did Desai (351) and the Lind study suggested an SD of 15 at baseline (337). This makes the SD of 17.2671 from the feasibility study seem reasonable and therefore suitable.

Therefore the primary outcome of a future substantive RCT would be the KOOS[4] at 6 months follow up. A power calculation assuming a standard deviation (SD) of 17.2671 on the KOOS[4] estimates that a sample size of 172 participants (86 per study arm) is required to detect a 9 point difference on the KOOS[4] between intervention and control groups with 90% power and 5% alpha. After inflation for 20% loss to follow up, this figure increases to 108 participants per arm, 216 in total.

6.4.9.2 Self-Efficacy Score

The baseline mean for the TRAK group was 7.69 (1.84) and for the TAU group 7.27 (1.65) (Table 6.10). When comparing the two groups, TRAK and TAU, the intervention effect is the observed difference between changes from baseline to follow up. The 95% confidence interval gives the range within which

the “true” point estimate of effect will lie in 95% of studies undertaken with this population and intervention. The p-value tells you the likelihood of this effect having occurred by chance. The difference in the intervention effect from baseline to 3 months and baseline to 6 months for the Self Efficacy score was .126, p= value p=0.728 ((-0.601 , 0.854)) and -.03, p= .932 (-0.949 - 0.871). The 95% CI includes 0, which means that the data were consistent with the null hypothesis at the 5% level, and we therefore we accept the null hypothesis of no difference in between TRAK and TAU for Self Efficacy.

6.5 Discussion

6.5.1 Principal findings

The aim of the study was to determine the feasibility of an RCT comparing TRAK ACL plus treatment as usual to treatment as usual in the management of post-operative ACL patients. The finding show that a future RCT would be feasible, by demonstrating that patients can be recruited and retained to a study of TRAK ACL and that outcome collection had 100% completeness in all but the CSRI. The KOOS[4] is a suitable primary outcome for a future trial with a sample size of 216. This indicated that a future study could determine if TRAK ACL with treatment as usual was more clinically effective and cost effective than treatment as usual. The TRAK ACL usage data indicated that patient engagement was skewed by one patient using it extremely frequently and others less frequently. The time between patients first and last log in was mean 18 weeks (12.2SD) which, along with use of educational and behaviour change content, depicts use of TRAK ACL across multiple phases of care.

6.5.1.1 Recruitment and retention

Eighty-six percent of those approached about the study were recruited. It is known that recruitment challenges can be a key reason why randomised trials fail (352) so a robust recruitment outcome was important (353). Recruitment method was highlighted as a key barrier to participation in previous DHI studies where in one example less than half of the physiotherapists allocated to delivering DHI actually recruited patients (354) and in another only 30% of eligible patients were recruited (355). Strategies such as personalising the intervention (personal exercise plans) and dedicated staff support for the study were recommended both of which were implemented in the TRAK ACL study which may have contributed to recruitment success (284). A Cochrane review also found that patients were more likely to be recruited to a study where they knew which care they were being given, i.e. not randomised, in patient preference studies (356). Although patients in the TRAK ACL recruitment process did not know which arm of the study they were being given, they knew that they would be given treatment as usual in each arm of the trial which may have diminished any sense of risk from the randomisation process. As in previous DHI studies, the decision to use TRAK ACL alongside treatment as usual as opposed to instead of treatment as usual was taken strictly with a view to strengthening recruitment (30, 280), as was the role of the dedicated research assistant. These recruitment decisions were informed by the knowledge that ensuring a trial is planned to minimise impact of the trial on both patient and clinician groups could boost recruitment (256).

The challenges that we did face in recruitment occurred at Site 2. The usually predictable flow of ACL patients was affected by changes in the orthopaedic department and the physiotherapy research team may have struggled to implement the study across several sites. A future trial could improve recruitment by engaging the support of the orthopaedic team or physiotherapists managing 'prehabilitation' and introducing the study before surgery, since some patients who have just had an operation may not be as open to the being recruited given potential pain and stress they could be experiencing.

Seventy eight percent of participants were retained at 6 month follow up as was evidenced by their completion of outcomes. This retention rate was achieved thanks to the role of a research physiotherapist who had dedicated time to pursue outcomes including calling participants and mailing outcome measures with stamped addressed envelopes to participants who were unable to attend the department at the time of their follow up. This role seems key to facilitating outcome collection from patients who were still attending physiotherapy or from those who had completed care. Some patient loss can be explained by typical drop out from physiotherapy over the duration of ACL rehabilitation which is known to be long (18). Exercise interventions can struggle with retaining patients over time (357-359). DHI with a focus in behaviour change can equally struggle with attrition (360, 361). Eysenbach et al described two types of attrition; non usage attrition (non-use of the DHI) and drop out attrition (lost to follow up in the trial) (362). Considering the latter, in most cases, reasons for leaving the study were unknown. The biggest single loss to follow up happened in the TAU arm between 0 and 3 months. The reason for this is unknown but we can speculate that this may be because participants hoped to be allocated to the intervention. Overall the difference in dropout rate between the two groups was not significant at a 5% level but was not powered to see a difference. Overall, recruitment and retention targets were reached which indicated a future trial would be feasible but would need to include dedicated research support at each site to optimise retention and outcome collection and prevent any burden on the clinical team. Further the possibility of recruiting pre-operatively through orthopaedics may have merit.

6.5.1.2 Feasibility of collecting outcome data

The gathering of clinical outcomes such as KOOS, and the self-efficacy scores and EQ5D5L and WPAI was also shown to be feasible in this trial. There was 100% completion by all patients who were retained to the trial at 6 months (the primary end point of a future trial) in 4 out of 5 outcomes. Two patients at Site 3 did not get signed up to TRAK ACL despite being allocated to it. Two patients at Site 1 were given TRAK despite not being allocated to the intervention. Such breaches of protocol were

unfortunate but their outcomes were collected at all-time points in 3 cases, and two out of three time points for one patient. They were managed by using an intention to treat analysis.

Adoption of digital tools for the NHS has typically required evidence of not just the effectiveness, but of the cost effectiveness. The collection of EQ5D5L enables the calculation of the incremental cost-effectiveness ratio (ICER) which is the difference in costs between two health care programs divided by the difference in outcomes between the programs. The comparison typically being between a treatment as usual programme and a new approach with the same patient group (363). WPAI data will inform participant's experience of Work Impairment and absenteeism and presenteeism. The number of physiotherapy appointments was also collected so that the cost of physiotherapist's time could be calculated, however, the appointments were a mix of 1 hour and 30 minutes at Site 3 but the duration was not recorded.

The exception to good outcome collection was the client services receipt inventory (CSRI) which was lengthy and unpopular. It was completed to 54%, 69% and 89% at each time point respectively. The increasing completeness reflects that decreasing complexity of health needs as participants are rehabilitated. In a future trial, it may be that we can improve data completeness significantly by providing this questionnaire digitally instead of on paper which would make it quicker and easier for patients to complete. Participants could be prompted to submit the detail that is needed in complex, multipart questions which could significantly improve the completeness. The inclusion of option lists that clarify values such as 'day' 'week' 'month', standard dosage of medicine or frequency, would render the data more comprehensible. The CSRI is considered a valuable tool of health economic analysis and should be included where possible (323, 364). Lessons have been learned about the challenges of using such a complex questionnaire that could be implemented in a future RCT. A digital version that prompts and shows options would help to reduce incorrect entries or invalid content.

Collecting strength outcomes is a critical part of an ACL rehabilitation study. It is an especially meaningful measure for those who would return to sport (107). Strength of the lower limb and especially quadriceps function is highly correlated with recovery after ACL surgery and the measurement of lower limb strength and function will be key to a future clinical trial (20, 34, 42, 90, 148). Strength testing is inappropriate postoperatively, so it was only measured at site 1, at 3 and 6 months. For the purpose of feasibility, leg extension (quadriceps strength) was measured in both the left and right leg of 89% of Site 1 retained patients at 3 months and 90% of retained patients at 6 months. Those not measured were either experiencing a flare up of pain, which renders strength

testing inappropriate, or else they did not attend when they were due to be measured. Importantly, clinical trial standard strength testing is time consuming and requires standardised conditions and calibration of machines which was not the case in this study (365). A future clinical trial would need to cost timing and a staff member to manage physical outcome collection as it is unlikely that clinical physiotherapists could manage this within treatment time. However this study has shown that strength testing is acceptable to participants and it is feasible to collect repeated measures over time.

The encouraging levels of recruitment and retention and outcome collection are in keeping with other physiotherapy digital intervention feasibility studies (280, 366, 367) and may indicate a growing acceptability of digital health interventions.

6.5.1.3 Engagement with TRAK ACL

6.5.1.3.1 Patient Engagement

Usage data from TRAK ACL show there was consistent engagement by some users over time indicating improved access to care. Of the 22 users, there was a median (IQR) 5 (2-17) logins per participant. The mean (SD) weeks of use (first to last login) were 18 (12.2). The usage data shown in this trial are in keeping with reported use of health websites and apps used alongside care in other published studies. In a 12 week smartphone intervention study for chronic pain, 22 (45.8%) reported never visiting the website, six (12.5%) visited it once, eight participants (16.7%) viewed it twice, and 11 (22.9%) viewed it three times or more (368) In an Australian physiotherapy DHI study for postnatal care only 33% had watched the digital health resource (355). In a trial of a DHI for weight loss, Mathews et al had 59 participants who over 3 months logged in a mean of 4 (1-10) for females and 2 (0-3) for males (369). The Help Diabetes intervention ran for 12 months where the mean login per user was 18.7, the mean pages visited were 10.5 and the mean number of days in which the website was accessed was 10 (37). Measurement of the TRAK ACL intervention usage was limited by not having an automatic log out. If a participant opened TRAK ACL on their smart phone, they could remain logged in for weeks and use unlimited exercise videos, infographs and text education without leaving a digital trace. This indicates logins, as a measure of frequency of use, could be higher than was measured. Crucially, patients' mean engagement period of 18 weeks suggests that users were accessing TRAK in different phases of care to meet different learning needs. This is supported by the data from YouTube showing views of animations that summarise evidence for each phase of care with multiple views. Future considerations for a trial of TRAK ACL should include an automatic log out function and a facility to measure the pages visited.

There was one 'super-user' who demonstrated very high engagement throughout their participation in the trial and the data also showed that some users had very low engagement with the intervention despite remaining in the study. This suggests a different experience of TRAK ACL as part of their care. Qualitative work that is beyond the scope of this PhD will be undertaken to explore this. Factors influencing usage engagement are known to be multiple. O'Connor et al described "personal agency and motivation; personal life and values; the engagement and recruitment approach; and the quality of the DHI" as key factors in engagement (284)'. A future study would need to be able to measure interactions between physiotherapist users and patient users so we could account for treatment effect and explore the relationship between patient engagement and physiotherapist engagement.

6.5.1.3.2 An assessment of engagement with the mechanisms of behaviour change

Behaviour change techniques (BCT) are the smallest active components of an intervention (265). They were purposefully built into TRAK ACL to reflect the knowledge that exercise is a behaviour and as such, can be changeable based on the interaction of capability, opportunity and motivation (35). These in turn facilitate the behavioural interventions Persuasion, Education, Training, Incentivisation, Coercion and Restriction (35).

The full list of TRAK behaviour change functions was provided in Chapter 5, however some functions did not work in practice; the achievements function (a physiotherapy led measure of patient progression) and the dashboard (a summary page) were not delivered; the prompt email function was not working. Use of the behaviour change mechanisms such as logs, goal setting and educational and motivational content was measurable and was accessed by up to 50% of TRAK users. Logically these patients may have improved adherence to the target behaviour. However, the participants' use of playlists was not measurable.

11 users set 43 goals, 10 used the weekly log (124 logs) for a median 4 weeks and 8 users used the exercise log over median 14 weeks. Of these the 8 users who used the exercise log for median 14 weeks represent the most user active group in the study, almost one third of the TRAK users overall. The technical set up of these features of TRAK fell short of the sophisticated plan that the TRAK team had intended. The various resource barriers that TRAK development faced, described in Chapter 5 may have contributed to negative user experience of these features for some. It is equally possible that some TRAK users were not aware of these features as they logged in infrequently and did not engage with other features, so their usage is not possible to measure. A future version of this website would need to embed a user training video or site guide as part of improved user experience.

The usage of educational and motivational information videos and animations was only measurable through YouTube, the disadvantage of which is that we cannot match the user to the use. Though we can be sure that all analysed views came from users of TRAK ACL. TRAK was set up to offer rehabilitation education and information in several mediums to provide choice; text, animation, expert video or infographs. These data showed a good uptake and percentage viewed in animations of phase by phase care (11, 11, 7, 6 per phases 1-4). The expert videos of the same phase were less viewed (4, 2, 0, 1), however we do not know if these views were other users or the same users as viewed the animation. The data showed a preference for animation content over expert videos, but both mediums were used by the study participants suggesting that providing information in a number of ways may be useful for engaging participants. The inability to map views to particular users through TRAK is disappointing. It is reasonable to assume that the same subset of patients were engaged with TRAK throughout however it is also possible that other users who were less interested in other BCTs were engaged by the animations and videos. The limitations of TRAK to measure the use of text and infographs as 'pages visited' means that there is no way to know how other forms of information developed for TRAK ACL, were utilised.

In a future trial TRAK ACL will need to be able to monitor individual use of all behaviour change techniques. As guided by the AMUsED framework which would form an evaluation framework for a future trial, individual patient use should be relatable to individual characteristics and then onto outcomes (347) The framework would then facilitate a sophisticated analysis that shows if, for example, people who log more strength exercises have better strength outcomes, if people who use the return to sport exercises are younger in age or if people who engage with more learning have higher self-efficacy. The more accurate measurements of usage would also facilitate a better understanding of the relationship between physiotherapist usage and patient usage which could help to inform implementation strategies for how DHI are used in physiotherapy.

6.5.1.3.3 Physiotherapist Engagement

Physiotherapists had a median of 2 (0-5) logins per week and the mean use of TRAK was 28.8 weeks which suggests that TRAK ACL was integrated into the care model to some degree. 8 physiotherapists were responsible for all logins but only 5 physiotherapists updated patient exercise programmes. No exercise programmes were updated after 10 months of the study and usage dropped significantly when the research assistant was no longer attending the exercise classes at Site 1. 4 patients who were still using TRAK at this stage of the study, continued to use the intervention regularly after physiotherapist logins declined and disappeared. Fewer physiotherapists than expected were active

in the TRAK study. 21 physiotherapists were trained across Sites 1 and 3 and were managing ACL patients but fewer were active on TRAK. In some cases, therapists may have been managing TAU patients or management of TRAK patients in groups may have been delegated to certain clinicians and not others.

At Site 3, two of the three patients who were enrolled in TRAK were never given personal exercise plans. The reason for this is unknown, though in previous TRAK studies clinicians referred to time and difficulty integrating use of a website into patient consultations (30, 280). Despite this, usage data shows that the participants who were not given personal exercise plans in Cardiff, did still access TRAK and use measurable functions such as goal setting and weekly logs. It may be that physiotherapists can guide patients to use TRAK ACL independently without prescribing exercise. This could include guidance to videos and learning content and encouragement of self-management, which would not leave any footprint. It does however, raise questions about the specificity of exercise prescription and individualised, person centred care.

It will be important to identify factors that influence physiotherapists' engagement with TRAK ACL (264). Although the work is beyond the scope of this thesis, it is an important step before applying for funding to a clinical trial. One significant measure of physiotherapist usage was their activity in exercise prescription. 5 physiotherapists prescribed exercises throughout the trial. Some with a measure of consistency and some only at used well at certain time points. The prescribed exercises are spread across the exercise types and phases and the only notable absence is the return to sport phase. Strength exercises are the most common category of exercise followed by neuromuscular control and flexibility exercises. This is in keeping with clinical guidance (7, 90). It is worth noting that categorisation in TRAK ACL does not allow for labelling exercises that may have more than one function. The absence of any logins from physiotherapists who managed the return to sport phase of care at site 1 is not well understood since the qualitative work was not yet undertaken. However, I can surmise that this was because the class was run after usual working hours and there was no research support after hours. It may indicate that a lack of trial support is a barrier to use. Not all patients would have progressed to this class during their 6 months in the trial. Although physiotherapists from this stage of care were trained in delivering TRAK ACL, some months passed before patients recruited to the study arrived in this stage of care.

Kloek et al discussed the multifactorial reasons for physiotherapist lack of engagement with DHI in a study of an osteoarthritis knee intervention. Their participants suggested the barriers included,

whether or not the intervention was appropriate, added value, took too much time and added to workload, challenged professional autonomy as well as environmental factors and financial consequences of embracing digital health (354). The Topol review: preparing the healthcare workforce to deliver the digital future, suggests that in order to embrace digital technologies clinical staff need 4 things; the time and willingness to adopt new technology, to understand the new technology, the technology must be well designed to meet user needs and there must be proper workplace support to maximise the potential of the technology (25)

A future trial would benefit from addressing some of these concerns with participating clinical teams. The TRAK training from this study was two hours and needed to focus on practical use of the intervention. A future trial should include a workshop on the points above to identify and overcome barriers where possible. Future qualitative work beyond the scope of this PhD is also underway to explore this.

6.5.1.4 Secondary outcomes

Although this study was not powered to detect any difference between groups we performed an analysis of the 5 subscales of KOOS and the self-efficacy scale. There were no significant differences found between TRAK and TAU groups at 3 or 6 months. However, the number and completeness of outcomes collected was crucial rather than any difference between groups. This demonstrates that in a future randomised controlled trial that is fully powered we will be able to determine the effectiveness and cost effectiveness based on outcomes.

6.5.2 Primary outcome for future trial

KOOS^4 is a composite score of 4 out of the 5 KOOS subscales, KOOS Pain, KOOS Symptoms, KOOS Sport/Rec and KOOS QOL. Excluding KOOS ADL which was found not to be relevant in the ACL cohort in earlier studies (70). KOOS^4 has been well utilised in ACL rehabilitation studies (70) (337-340)

From the figures of similar studies we decided to base the sample size calculation on an SD of 18 and aim to detect a difference of 9 points on the KOOS with 90% power and 5% alpha. The sample size is inflated to account for the 20% drop out at 6 months follow up (the primary endpoint) as per Table 4 reported loss to follow up from this feasibility study. A sample size of 216 may be considered high for a physiotherapy trial however this would give the data needed to inform the effectiveness and cost-effectiveness of a DHI such as TRAK ACL in the management of ACL patients.

6.5.3 Strengths and Limitations

The strengths of this study were that it was carefully planned. It had a pre-specified published protocol (286). It was very well supported during the planning stage and during the study by the supervisory team and experienced statisticians and health economists from the Clinical Trials Unit. This enabled the successful recruitment and retention of patients to the study and the successful collection of outcomes. The intervention and its various resources were utilised by patients for education, exercise adherence and behaviour change support thereby demonstrating improved access to care.

Hales et al described that, barring technical failures, digital platforms have the advantage of objectively measuring which parts of the intervention were engaged with, and therefore ''received,'' (370). In this case technical failures have limited the measurement of engagement in some important areas that should be improved upon before a future trial. In particular, the intervention needs modification to capture the usage data for education and information content. Physiotherapist activity cannot be matched to particular users and we cannot measure pages visited or videos clicked by each user. The data for logins may also be influenced by the fact that logins do not time out as was planned, meaning that patients can login once and then use the website on multiple occasions until they close the page. The inclusion of this engagement detail at a future trial is achievable and would enable a thorough examination of fidelity and of what constitutes effective engagement with the interventions (347). Application of the AMUsED framework is intended for a full trial situation where the data can be compared to outcomes and experiences that were also recorded. As part of measurement of feasibility our methodology enables the research team to look at the data to establish whether such an analysis would be possible in a future RCT.

6.5.4 Implications

6.5.4.1 Implication for research

The evidence suggests that TRAK is suitable to go forward to a randomised trial investigating whether patients using a DHI as well as treatment as usual have better outcomes than patients with just treatment as usual. Future research should aim to ensure that DHI are stable and capable of measuring all relevant aspects of engagement before going to trial. Implementation and clinical engagement research is needed to further understand the role of physiotherapists in delivering such an intervention.

6.5.4.2 Implications for policy

DHI are becoming more commonplace in NHS physiotherapy yet clinician barriers to participation are still evident. This study suggests ACL patient's acceptance of and engagement with a DHI in addition to treatment as usual. Implementation in clinical care requires the support of the physiotherapy leadership and attention to the experiences of physiotherapists.

6.5.4.3 Implications for clinical practice

DHI in ACL care have the potential to increase exercise adherence and therefore improve outcomes. The recruitment and retention in this study shows that patients were interested in exploring this possibility.

6.5.5 Reflections on the functionality of TRAK ACL

The prompt email was designed to cue patients once a week to engage their rehabilitation plan through TRAK. There were 4 versions of the email and each one reminded patients of different functions of TRAK. During the trial, the trial physiotherapists reported that the patients were not receiving their prompt emails. We requested patients to check their junk email but there was no trace of it. Unfortunately there was no resource to address this issue. Analysis of logins from the prompt email link is not possible.

The Achievements section of TRAK ACL was intended to function as a physiotherapy led checklist of criteria for progression through phases of rehabilitation. The huge advantage of this was that our orthopaedic colleagues could log in a see a patient's achievements progress. It would also have been presented as part of the dashboard function, which was to show, weekly log, goals and achievements together as totem of progress for the patient. As described in Chapter 5, the development of TRAK ACL was not properly costed in advance and the developer who did work on TRAK left the study in the early weeks of the trial. The loss of the achievements sections was a particular disappointment to our 2 collaborating surgeons who had viewed this as a valuable place to briefly check the patient's progress.

Finally, as we aimed to reconcile the needs if this TRAK ACL study with other work of the TRAK website host, we chose to copy the website and create a separate version dedicated to TRAK ACL and add all the ACL content to this. This solution enabled us to isolate many functions to the trial participants, however it meant that the exercise videos were copied across both TRAK ACL and another TRAK

website. The exercise videos therefore cannot be analyzed for views because of this as the views could not be isolated to TRAK ACL.

6.5.6 Reflections on physiotherapist engagement

After 12 week of the TRAK ACL study, I received usage data from the developer who was predominantly working on TRAK ACL. The data showed early engagement was limited and patients were not being given exercise plans when they were recruited. I summarised this account and fed it back to the treating clinicians. I offered training, support with set up and short cut reminders. Clinicians described lack of motivation and opportunity (time due to staff shortage) as main reasons for non-engagement. At the time, I perceived the conversation to be impactful. Based on this and with the support of NIHR, I reallocated some funding from my grant with NIHR and introduced a clinician incentive; a prize of £150 amazon voucher for the top 2 active clinicians on the TRAK study with follow up prizes of £50 each for 2 more physiotherapists.

Unfortunately I had no opportunity to measure the impact of the incentives as shortly after this, the main developer on the TRAK ACL study was no longer in his role and we were unable to secure someone to take his place despite several, attempts as discussed in Chapter 5. No further usage data was available for monitoring throughout the trial. This meant that physiotherapist activity was not known until the end of trial data came through.

Chapter 7 - Discussion

7.1 Chapter outline

This chapter considers my thesis as a whole. In it, I summarise the main results, consider how this adds to the existing literature, discuss the methodological strengths and weaknesses, and consider the implications and conclusions that can be drawn from the work. I then summarise the overall implications of the thesis for policy, clinical practice, teaching and research. Finally I reflect on what I have learnt as a researcher, and what I might do differently if I had my PhD time again.

7.2 Main results

This thesis started by demonstrating that there was significant variation in how ACL rehabilitation is provided across the UK. This implied that some patients may have better access to optimal, phase by phase ACL rehabilitation than others. The reasons for the variation in care included variability in the availability of resources, such as equipment and staff skill sets. A digital health intervention (DHI) may have potential to improve access to care, and my previous research as well as the qualitative interviews with healthcare professionals in this thesis suggested that use of such an intervention could be feasible and acceptable. I optimised and refined a DHI (TRAK) that already existed and renamed it TRAK ACL. I applied behaviour change theory and user-centred design principles to present evidence-based information and physiotherapy exercises. Finally I showed that a definitive trial to establish the clinical- and cost-effectiveness of TRAK ACL was likely to be feasible, as I was able to recruit and retain participants, who showed adequate engagement with the intervention.

7.2.1 Findings on variations in care

7.2.1.1 Equipment

Results of the scoping review showed that ACL rehabilitation in RCTs requires access to a gym and use of specialist equipment, including resistance machines, free weight and neuromuscular control equipment. Although there was some consistency of resources use across studies, the details of equipment and staff needed to deliver usual care interventions were often not well reported which in some way contributes to a wide lens of possibility for what is ‘usual’. In qualitative interviews, physiotherapists added further detail, listing their basic requirements as weights and resistance machines, balance challenging equipment, cones and ladders, and cardio equipment. The importance

of these resources were discussed by all participants, however not all participants were able to provide the equipment they deemed necessary for patients.

Clinicians linked the importance of having the right equipment to delivering optimal, evidence based care. They referred to evidence for different rehabilitation interventions, especially for strength interventions and the negative outcome implications of poor strength. However, clinicians described very different access to resources and equipment, many described well-resourced care while in some cases clinicians had experienced significant shortcomings. Different sites within the same Trust were also known to be more or less optimal. Physiotherapists who did not have access to rehabilitation equipment employed creative solutions which were often adequate, however, in some cases, physiotherapists advised patients to seek proper rehabilitation equipment in the community. The limitation of this advice is that it was informally given, rather than an important part of the rehabilitation pathway.

7.2.1.2 Clinical staff

The scoping review showed that ACL rehabilitation is most often delivered by an 'experienced' physiotherapist, however there is no clear definition of what 'experienced' means. Patients' access to skilled physiotherapists was also acknowledged by qualitative participants as a factor contributing to variations in care. Knowledgeable senior clinicians were often leading teams with varied experience and exposure as is the norm in clinical life. However participants identified that factors such as the amount of teaching time, teaching methods and the size and geographical spread of teams, influenced the cascade of clinical knowledge.

The qualitative interviews further exposed a paradigm shift in physiotherapy services that has been driven by a need to be more cost effective. Many services were placing an increasing emphasis on patient self-management and earlier discharge from care. This finding has two important implications. Firstly, that there may be an unintended variations in values and aims of physiotherapy treatment. The second implication is that where patients are being discharged to meet their goals through self-management, then a pathway and resources to support self-management should be in place. Social prescribing services that link patients in with community services and DHI such as TRAK ACL could form part of such a pathway. Both variations in frequency of appointments and length of time to discharge after the initial stages of care present a clear rationale for the use of digital tools such as TRAK ACL to support self-management.

7.2.1.3 MDT

Lack of a cohesive MDT seemed in all cases to present barriers to optimal care. This most often arose where geographical barriers were a factor, i.e. rehabilitation sites were not at the hospitals where surgeries were done. The importance of the multi-disciplinary team was emphasised by both physiotherapists and surgeons. Clinicians identified that whenever communication was poor this also led to other sub optimal outcomes. For example vulnerable patients may not be flagged in a timely manner, changes in surgical procedure may not be disseminated or well understood which has implications for patient care and patients who do not attend physiotherapy are not identified to their surgeon as being potentially at risk of poor outcomes. Participants in the qualitative study identified that poor communication could lead to misunderstandings and a lack of insight into each other's practice which had a negative effect on this important clinical relationship. Such problems were magnified when patients are referred from out of area via their GP which makes the communication even more difficult. On the other hand physiotherapy departments with strong relationships with orthopaedics benefited from co funding rehabilitation equipment and collective audit and research projects. Both of which have positive implications for patient care.

Causal factors for variation in care can be diverse. Qualitative interviews suggested healthcare policy, local budgets, local leadership and attitudes within and towards physiotherapy as potential underlying factors. The resources allocated in randomised trials can vary as much as those in a clinical context which may influence resources such as how many skilled physiotherapists are available and how much time they spend. Pragmatic trials which take place under more 'real world' conditions' may have more in common with clinical conditions where decisions are regularly made to balance capacity and demand.

7.2.2 Optimal Care

Despite the reported variations in how care is delivered there was a reassuring consensus on what optimal care may be and a sense that evidence base provides the template. Rehabilitation must be delivered across all the phases of care and should be led by a skilled physiotherapist. Cascading clinical knowledge to junior staff is important and robust learning structures should be in place. Especially where sites are spread out and some sites may lack expertise. Rehabilitation includes return to sport rehabilitation which it is acknowledged not all services have the capacity to deliver face to face. However if patients are self-managing, a pathway should be in place to support this. Care must be patient centred and therefore focused on the abilities, limitations and goals of individuals. Care must be outcome driven; qualitative data showed that participants believed outcome measures to be an

essential matter of governance. In many cases, barriers to outcome measures were highlighted and strategies to manage these were important priorities. Patients need access to resources such as gym equipment and the skills to progress themselves correctly. Clinics should aim to be properly resourced to deliver rehabilitation and where limitations are insurmountable, social prescribing and methods of supporting self-management should be explored. No conclusions can be drawn about the amount of optimal face to face time however the self-management components of care are not clearly described and indicate the need for a universal resources for patients during ACL rehabilitation.

7.2.3 The development and feasibility testing of TRAK ACL.

The development of TRAK ACL was successful in its attempt to realise the clinical evidence base for ACL rehabilitation as a digital health intervention. This iteration served to optimise the technical functionality and specificity of this DHI for supporting self-management of ACL rehabilitation patients. The functionality of TRAK ACL and its mechanisms of action can be understood through the logic model presented in Chapter 5. TRAK was developed with extensive patient and public involvement (PPI) in both the content and the functionality which has strengthened its acceptability and legitimacy as a co-produced DHI.

The feasibility study aimed to learn if a future effectiveness and cost effectiveness RCT comparing TRAK ACL plus usual care to usual care in the management of post-operative ACL patients was likely to be deliverable. The results showed that such a study would be feasible, by demonstrating that patients can be recruited to such a trial, and that a sufficient proportion of participants engaged adequately with the intervention and provided follow-up data.

Implementation of TRAK ACL and assessment of patient and physiotherapy engagement through usage data was an important objective of the feasibility study. The results of the logins over time showed that participants engaged with TRAK ACL over different phases of care. The information videos and animations were key mechanisms of actions for the targeted behaviours and they were well utilised. The uptake of other behaviour change tools included goals setting and logging progress was once again skewed but popular with a subset of users. Physiotherapist's usage was less than anticipated. There were a number of factors that may have influenced this which may include not enough time, not enough training, not satisfied with the intervention or not keen on digital health (25).

7.2.4 How these findings fit with the current literature

This thesis is original in its exploration of the nature and context of variations of care both in randomised controlled trial conditions and in clinical practice. The scoping review is the first published attempt that I am aware of to focus on the resources required to deliver optimal care. Previous ACL literature reviews tended to present data on whether specific treatments are effective and should be provided (88, 92, 93, 331), although Van Melick et al also includes recommendations about MDT communication (34) and Risberg et al include the importance of skilled physiotherapists in their analyses (90). Other studies observing resource variations in physiotherapy care are predominantly not within the musculoskeletal discipline (371-373). Two MSK studies that did study variation in care were looking at joint replacements and they did not specifically addressed resources (374, 375). The findings of Scurlock-Evans et al in a review of barriers to evidence based practice were consistent with the Scoping review findings where time and skill level of physiotherapists were important factors in ability to deliver evidence based care (376).

Previous qualitative studies on ACL rehabilitation were mainly focused on patient experience (109), long term consequences (377) and adherence to exercise (378). However, one study focused on clinical practice in New Zealand had similar findings regarding the importance of inter-professional communication to improving care and that pathways could be complex and prevent easy access to care. This study similarly found clinical practice was based on evidence and the biopsychosocial model of care and they identified need for clarity of exercise progressions and return to sport testing (379). None of these studies explored the characteristics of optimal care, variations in care or underlying factors that this PhD focused on.

Numerous feasibility studies for physiotherapy rehabilitation digital health interventions have found that DHI are acceptable to patients and physiotherapists (380-384). Several common challenges were identified. Time constraints were identified by physiotherapists on a number of occasions as a challenge to engagement (30, 383, 385). Patients identified lack of access to technology or less interest in technology as barriers (30, 386) In a large RCT of an online intervention for knee OA, the intervention was found to be effective and patients who were employed and had higher self-efficacy had better engagement with the DHI (386). Another 12 week OA knee study showed efficacy over a range of outcomes including pain, physical function, stiffness, surgery risk, and understanding of the condition, compared to a control group (387). A study for a hip and knee OA on line intervention found that older patients or patients with co morbidities preferred their face to face appointments but also utilised the DHI, therefore a blended approach may be more appropriate for some (388).

One feasibility study looked at the role of a digital intervention in the management of anterior cruciate ligament reconstructed patients (389). This intervention took place from post operatively to 3 months. The intervention was not well described in the publication. They described that information was provided which included exercises and a communication function including reminder texts and emails. The mechanisms of action or development process were not described in the publication. This group reported adherence at 30% average and no difference between control and intervention. They recommended more personalised functionality be utilised in future studies (389). Another ACL digital intervention formative study described the development of a wearable device to provide feedback and record progress on strength and range of motion is an ambitious prospect combining several types of feedback monitoring but as yet the technology is limited by inaccuracies and has not been tested on ACL patients (390) One ACL app digital study showed good results for strength in the early post-operative phase of care. The app is paired with a pressure biofeedback unit and gamifies the activation of quads by using activation strength to control an avatar on the screen (391). This would have great potential in paediatric patients but requires investment in the unit.

The evidence shows that TRAK ACL is unique in its mix of rehabilitation evidence and behaviour change. As displayed in the logic model in Chapter 5, much of the impact TRAK ACL was designed to make was behavioural. TRAK ACL was also the only intervention that maps the entire ACL rehabilitation pathway and is personalised between patient and physiotherapist. The TRAK ACL feasibility study was the only digital ACL feasibility study that included a health economic analysis making it the most suitable to determine effectiveness and cost effectiveness in a future RCT.

7.3 What are the methodological strengths and weaknesses of this thesis?

There are many methodological strengths in this thesis. The work of exploring the characteristics of usual care, optimal care and variations in care was appropriately undertaken in a scoping review of the literature as well as a qualitative study exploring stakeholder experiences. The Interaction Design lifecycle model and the MRC complex intervention framework provided a strong context for the optimisation of TRAK ACL. The development process followed the behaviour change wheel intervention design process which is robust framework for behaviour change interventions. Both the website development and the trial design were informed by the Normalisation Process theory in order to anticipate potential barriers to implementation. The MRC process guides that feasibility trials are a fundamental step in ascertaining if a future trial would be deliverable. The combination of studies in this thesis provide added value, and together form an important body of work which characterises a

clinical problem and considers ways of addressing it. These strengths are discussed in more detail below.

7.3.1 Theory and frameworks informing design and evaluation

The MRC guidance discusses the importance of making explicit use of theories and frameworks where this can lead to more generalisable findings. The use of theory in intervention design adds to coherence where it can be demonstrated that the theories were applied systematically (254). Selecting appropriate theories to guide both development and evaluation is a challenging process. DHI are created through the intersection of " biomedical, behavioural, computing, and engineering research" so some knowledge from some or all of these disciplines is required (301). The development of TRAK was undertaken with three different theories or frameworks guiding the process. The Behaviour Change Wheel (BCW) Design process was apt to structure the mechanisms of action that would lead to engagement with the target behaviour (35). The physiotherapy theories and guidelines for ACL rehabilitation provided the content of the website through which the mechanisms of action were structured. However, the Behaviour Change Wheel and rehabilitation theory do little to address the minefield of human computer interaction, where mechanism of action may have poor uptake if the interface is not user friendly. The Interaction Design Lifecycle Model (IDLM) was used try and ensure that TRAK ACL was usable and acceptable (392). The MRC process for developing and evaluating complex intervention was the overarching framework of the TRAK development and evaluation. The goals of the Development and Feasibility/Piloting stages informed the objectives of thesis described in Chapters 5 and 6.

As a clinician, I had no prior experience of interaction design, however during previous TRAK research, users had reported that TRAK was "clunky" and it did not meet their technical expectations (30). Embedding the interaction design methods were an essential step in anticipating and problem solving future engagement challenges. This involved synthesis of TRAK ACL user experiences from both previous studies and from the PPI group in order to develop an architecture of TRAK that was more acceptable to users. Establishing requirements, designing alternatives and interacting with prototypes were key steps of the interaction design process (259). The MRC guidance highlighted that not just the intervention mechanisms of action but any links the causal chain may ultimately impact the relationship between intervention and outcome (254) . The design and technical function of TRAK ACL was such a 'link' and incorporating the insights of Interaction Design informed an important part of the causal mechanisms of the intervention where it helped TRAK ACL to meet design and technical expectations of users.

The behaviour change wheel framework was fundamental to understanding and constructing the mechanisms of action for TRAK ACL intervention (35). The process provides a robust template for identifying target behaviours and contextual factors. The identified behaviour and the COM-B (Capability, Opportunity, Motivation, Behaviour) analysis lead to established pathways for interventions and behaviour change techniques that are adapted to the needs of the individual DHI (39). The BCW framework encouraged an in depth look at interventions and behaviour change techniques that are deeply embedded in physiotherapy practice and therefore not easily visualised components of physiotherapy care. Identifying physiotherapist and patient norms also raised questions about the sociological challenges of introducing new models of care.

Identifying potential implementation challenges at an early stage was facilitated by the Normalisation Process Theory (NPT). The NPT is a sociological theory concerned with 'implementing, integrating and embedding (normalising)' new practices or ways of working into clinical practice (256). Where the IDLM predicted usage problems related to TRAK ACL design and functionality, the NPT provided a framework to identify potential barriers to implementation for physiotherapists and patients based on adapting to a new model of care. Digital health interventions are still relatively new in physiotherapy practice in the NHS and although a DHI was created to reflect best physiotherapy practice, physiotherapists and patients would not necessarily have recognised some functions of TRAK ACL in relation to their intended mechanism of actions. Using the NPT facilitated a greater understanding of the interventions clarity of purpose and highlighted areas where improvements could be made such as clarity of message and purpose around TRAK ACL which may impact physiotherapist engagement in future studies.

The MRC process for evaluating interventions describes the components of feasibility as; testing procedures, estimating recruitment and retention, and determining sample size for a future trial (254). This structure informed the objectives of Chapter 6 the feasibility study. Delivering a well-structured feasibility trial is a significant challenge to an early career researcher. The support of a UK registered clinical trials unit helped to navigate the complexities of trial methodology. The standard operating procedures and established pathways for conducting feasibility studies are complex and detailed which helped avoid too many unnecessary errors. The protocol for this feasibility study was published 2 years in advance of the study which also allowed plenty of time for peer feedback and learning. The

support of a trial statistician helped to structure the statistical analysis plan so that methods were known far in advance of the study.

I used the Normalisation Process Theory (NPT) to try and predict challenges of uptake and implementation during the feasibility trial (256). There were significantly important outputs of this process which directly affected trial outcomes. Firstly, we decided not to compare a reduced version of usual care with TRAK ACL to usual care. There was concern that this might have a direct impact on recruitment of post-operative patients who felt too vulnerable to sign up to a study with reduced usual care. This was evidently the right decision as the trial recruitment was successful in achieving its target.

The method used to manage the TRAK ACL usage data during the evaluation process, was the AMUsED framework (347). This sophisticated methodology did much to highlight the limitations of data gathering that TRAK ACL has and highlighted clear aims for future iterations. Ideally, each participant's usage should be traceable down to each click (347). Any interaction they have with a Physiotherapist user should be traceable also. The usage data can then be interpreted on a deeper level with data from the Person Based Approach by mapping user characteristics to the type of usage (274). These functions will be critical for the next stage of TRAK ACL.

Murray et al have argued the importance of achieving a stable intervention and training package for delivery before undertaking a randomised controlled trial to allow for high fidelity delivery and therefore more meaningful outcomes. TRAK ACL is a conceptually stable DHI, however the resources available for its development meant that some of its features had sub-optimal functionality. The research methods were sophisticated but were somewhat limited by the quality of usage data. Fortunately, the data we were able to collect indicates that the TRAK ACL was utilised by most of the patients allocated to it.

7.3.2 Multiple methods. The benefits of using qualitative and quantitative research

Another strength of this thesis was the use of multiple methods, which enabled exploration of a range of research questions. Had I only used quantitative methods I would have been unable to explore the stakeholder experiences of ACL rehabilitation. These experiences ultimately helped to characterise the challenges of providing ACL rehabilitation services, the characteristics of optimal care and develop a rationale for digital solutions to variations in care. I considered a quantitative survey as an alternative to doing a qualitative research study. A survey could reach a larger group of people and I thought I might get a broader idea of what participants thought optimal clinical practice looked like and what

variations they experienced in care. Through the process of brainstorming these ideas, the extraordinary complexity of this topic became clear. The care descriptions were not going to be straight forward and good data would depend on navigating complex matters such as professional identity, clinical expertise, inter-professional relationships and the organisational 'we', meaning Trust and team loyalty. Semi structured interviews were a more suitable methodology to explore not just the descriptive characteristics of usual care and optimal care but the myriad factors contributing to these experiences and how participants related to them.

The qualitative methods raised previously unreported issues about the evolution of beliefs when it comes to rehabilitation and the sense that scaled back models of early rehabilitation care and quick discharge have been created and reified within some clinical structures, possibly in response to long term lack of resources. Such data can only come from qualitative methods which provide explanations and context for the rise of digital health. It may require further exploration in future research.

The use of a scoping review methodology rather than a systematic review allowed an alternative analysis of the randomised clinical trial evidence for ACL rehabilitation. A systematic review would have evaluated the strength of the finding of effectiveness however, there would be little scope to observe the impracticality of interventions that require 5 days per week of patient care or are delivered with expensive equipment. For both patients and the health service, the details of these studies are as important as the results. Ultimately the conditions of the trial and its characteristics create important parameters to consider when interpreting results that are not often considered in other review types, hence the strength of the scoping review methodology for this research. Finally, the examination of characteristics of the trial also highlighted the vague descriptions of many exercise based rehabilitation trials. This is problematic when exercise is a primary ingredient of either the control, the intervention or both. This knowledge supports the idea that usual care rehabilitation is a broad church and that variations in care a part of this.

7.3.3 Weaknesses

The primary weakness of the thesis was in the limitations of the TRAK ACL intervention. It was a matter of regret that the TRAK ACL intervention was incomplete and that certain components such as the physiotherapist led 'Achievements' section were not delivered. The absence of this section was a loss to physiotherapists and orthopaedic surgeons and may have affected their sense of the value of TRAK ACL during the trial. Further to this, the intervention had no IT support during the trial. This meant we could not monitor or respond to usage as is indicated in the Person Based Approach, to make live

changes to the intervention. Nor could we respond to problems such as the failings of the prompt email system. Finally, the usage measuring structures of TRAK ACL were not as detailed as they needed to be for an AMUsED framework analysis. This project was low cost and the IT team had a number of branches that were competing for limited resources and so practical factors influenced the development process. Every effort was made by the team to problem solve these challenges and a clear pathway is evident for future research that would need to address these limitations.

7.4 **Implications**

7.4.1 Policy

Digital health interventions should be considered as a solution to variations that occur in evidence based care. Where different levels of access to physiotherapy and equipment and ACL knowledge may be available, TRAK ACL can provide a reflection of optimal care and thereby improve access to care across the UK. However, implementation, even of trial DHI, needs to be considered at a departmental policy level in order to embed the process and formalise support for the intervention.

NHS England normalises the experience of variation in many types of care. Local priorities, new innovations and the pace of implementation and de-implementation across the country can sometimes make variations look wider than they are, and much of the variation we see may be positive and equitable and work in favour of community members (393). In other cases variation can be a more negative experience. For those who may feel they have less access to a particular type of care, NHS Right Care has accepted that it can seem like a 'postcode lottery' (26) .

At a national policy level, NHS Right Care argues the need to reduce unwarranted variations in care, which is defined as any variation that may lead to harmful consequences (393). Local maps of variation were established to monitor care for key health conditions across the boroughs of England (26, 394). Although the NHS Atlases of variation do not currently map musculoskeletal (MSK) conditions, the Public Health England fingertips MSK tool does map area profiles for key MSK indicators such as osteoarthritis, hip fractures and long term MSK problems (395). The National Ligament Registry which is as yet not well subscribed to, measures the outcome of ACL surgery, however since they make no measure of participation in any rehabilitation programme or types of rehabilitation or exercise adherence, little is known about the process of rehabilitation (53). There is also an inherent participation bias to both the private sector and more digitally engaged surgeons. As such, although these structures highlight the need to understand variations in care, none of them facilitate any

knowledge relating to rehabilitation after anterior cruciate ligament reconstruction. This research contributes to the policy debate about variation and the literature on ACL rehabilitation that there is variation in how care is offered across the UK and that some of this variation may be harmless while other findings reveal factors that may contribute to harmful consequences for patients.

In many cases it is not possible to identify the underlying causes of variations in care. This is due to the complexity and the number of variables that are integrated in models of healthcare. However, 'not enough use of high value interventions' is given as one reason (393). Digital healthcare is considered to be a high value intervention in that DHI are known to cost effective (16, 36). Greater use of DHI may therefore contribute to the reduction of variations in care by reducing cost barriers and therefor improving access. TRAK ACL may be cost effective; the feasibility study has shown that this aspect will be possible to assess in a future trial. The NHS cannot afford to implement all new technologies so cost effectiveness is an important component of implementation decisions (396).

7.4.2 Clinical practice

Variations in care, even small ones, provide a rationale for digital health tools. The NHS has built up on line resources over the years and patients who google health information will often look for the NHS accredited information. Within physiotherapy, it makes sense to develop and test digital health interventions for musculoskeletal conditions. ACL rehabilitation is one of the more complex rehabilitation pathways to deliver but it is not the only such. Other rehabilitation pathways could be created as digital tools meaning that any patient can have access to evidence based care for their condition from a trusted source.

TRAK ACL, a DHI to support ACL rehabilitation may have a positive impact on knee outcomes by increasing adherence to exercise behaviour, improving performance of exercise techniques and engaging users to the key learning points at each stage of care. The mechanisms of action of TRAK ACL are reflective of standard care and provide clinicians with opportunities to engage and support their patients in between scheduled appointments.

Overcoming unwanted variations in care is important for clinicians as this may mean that some patients have greater access to knowledge and support during ACL rehabilitation that others. This thesis provides a rationale for the use of digital health tools in clinical practice to improve access to the spectrum of evidence based information and support. Smartphone penetration has reached over 80% in the UK and this can be up to 95% in the younger population (397), who are more likely to

undergo ACL reconstruction. Qualitative study results in Chapter 4 showed that certain patients lean toward self-management after ACLR because of job or family responsibilities that mean they cannot attend rehabilitation classes or one to one appointments. We also know that in the context of the wider NHS some services are unable to fund rehabilitation beyond the early stages. At the moment, it is unknown how these patients would have access to care. The NHS is committed to delivering digital services to improve access to care. NHS Digital recognises that access to DHI can mean better access to health information, improved convenience, and greater control over their healthcare. For clinicians this can mean delivering optimal care; evidence based, patient centred, outcome driven and with increased efficiency.

7.4.3 Teaching and research

Implications for teaching include the importance of expert knowledge cascading in clinical settings, especially where sites and resources are spread out. Some clinicians had moved to on line tools and webinars to facilitate teaching across large teams that are geographically distanced. Further to this, the health psychology theories of behaviour change are not universally understood in physiotherapy and yet form a fundamental part of clinical practice. Understanding of the role and importance of DHI in clinical care may be dependent on a greater understanding of behavioural science.

Developers of new technologies for healthcare must take into account the needs of those who may be digitally excluded. There is some evidence lower income people and those who already suffer health Inequalities like lower level education, poor housing may be less likely to have access to the DHI (305). NHS hospitals around the UK care patients from a wide spectrum of social and economic conditions (305). Indeed the feasibility trial of this PhD took place in a London borough that is seventh most deprived in the country (308) and where the digital divide has been amongst the worst in London (282) At the second trial site local government reports highlight that digital exclusion is compounded by decreased internet access related to market forces and geographical variation (398). A knowledge of these issues could help to avoid digital exclusion from a future TRAK ACL study. NHS Digital's definition of 'digital inclusion' includes having the digital skills (the technical ability), connectivity (internet and device) and accessibility (available to those who are blind, deaf or otherwise use assistive technology) to use digital health (305). A further iteration of TRAK ACL would need to increase the usage measurement capacity to allow for analysis of individual characteristics and demographics relative to uptake and access of the DHI. Some NHS trust have implemented digital heroes as a means to increasing learning opportunities and digital confidence for patients (305). Any future TRAK ACL study could include PPI to consider how best to overcome the divide with TRAK ACL. A range of

community partners available through social prescribing are also available as resources to tackle the digital exclusion (398).

Learning for future clinical trial studies should include the need for a more detailed report of the resources used in RCTs. Accurate reporting of exercise interventions, their resources and the skill of the person delivering the intervention would help healthcare decision makers to effectively manage resources when implementing evidence based care. The feasibility trial results inform future research by confirming the KOOS^4 as a suitable primary outcome for a future trial and by calculating a suitable sample size for a future clinical trial as 108 patient per arm, 216 in total. Finally, future researchers in DHI development should note the challenges of delivering DHI functionality and consider timelines and costs carefully.

7.5 **Reflections**

I suspected that there was a lot of variation in ACL rehabilitation practice. I had experienced it in my career as had colleagues and patients that I encountered. When I wanted to discuss the implications of this, I often found that I lacked the details of how variations in care occurred. In this sense I feel I have achieved something useful with this work. The map of variation in care is a starting point for discussions about what is warranted and what is unwarranted variation and how, as a profession, physiotherapists should manage variations in care. Perhaps we can accept that variations in care are the norm and consider how we should be monitoring variations.

The PhD student who worked on TRAK ACL was lost to the project and unfortunately Cardiff IT infrastructure could not find someone to take over the work at short notice. With the support of NIHR, I reallocated £8000 funds to pay someone extra to do it but once again no one within the team had capacity for the work. The option of exporting TRAK ACL to UCL was explored but it became complex as we tried to unpick the intellectual property and we were running out of time so we decided as a team it was not a good option.

The intervention that was taken to trial contained many of the well thought out behaviour change techniques and mechanisms of action, many of which were well utilised by patients. I feel satisfied that intervention as it is now is conceptually stable but requires a final stepping stone to be fully realised. As yet, I am aware of nothing like it on the internet or in the App market.

It is worth noting that since the COVID19 pandemic occurred, the Chartered Society of Physiotherapists featured TRAK ACL on their list of digital resources. I created an email account and an infographs to inform physiotherapists or patients directly that they could use it if they wished for no cost. I circulated it through social media. I then signed up 6 different hospital Trusts including my own. I personally registered over 100 - patients. Much more than during the trial. I look forward to reviewing the data in due course as a measure of impact.

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Appendices

Appendix A: Abstract

Background

The Anterior Cruciate Ligament (ACL) stabilises the knee and is commonly injured in sport. Surgical repair and rehabilitation are common. However, rehabilitation randomised controlled trials do not always report the resources used to deliver ACL rehabilitation. This may lead to suboptimal availability of resources for evidence based care.

Objective

To identify the resources used to deliver multimodal ACL rehabilitation in randomised controlled trials

Methods

Comprehensive searches, combining 'anterior cruciate ligament', and 'rehabilitation' with the Cochrane RCT filter, were conducted of Medline, Embase, Cinahl, PeDro, Sports Discus and the Cochrane Library. Adults, post-ACL reconstruction, were included. The intervention and comparator were physiotherapy for post-operative rehabilitation. Outcomes were the resources required to deliver rehabilitation, and study type was randomised controlled trials. Papers were screened against the criteria; data were charted and narrative synthesis applied.

Results

Fourteen studies reported on 599 patients. The interventions ranged from four to 36 weeks. Physiotherapy was typically an hour and ranged from 1-5 sessions/week. Resources included a gym environment with rehabilitation equipment such as resistance machines, free weights, cardiovascular and neuromuscular control equipment, and an experienced physiotherapist.

Conclusions

Implications for future studies include the need for a more detailed report of the resources used in RCTs. Accurate reporting would help healthcare decision makers to effectively manage resources when implementing evidence based care. Findings can be considered as criteria against which to audit resource provision.

Appendix B: Information Request Letter

University College London

UCL Research Department of Primary care & Population Health

eHealth Unit

UCL Research Department of Primary Care & Population Health

Royal Free Hospital

Rowland Hill Street

London

NW3 2PF

emma.dunphy@ucl.ac.uk

Dear Dr …….

Regarding your publication: …….

My name is Emma Dunphy. I am a physiotherapist and a PhD student at University College London. I am writing to you regarding your publication in the field of anterior cruciate ligament (ACL) research. I came upon it while doing a systematic review entitled; a systematic review of the resources needed to deliver ACL rehabilitation in randomised control trials of Anterior Cruciate Ligament Rehabilitation. A systematic review of the evidence.

I would like to include your article but in order to do this, I wonder if you would kindly provide me with some further information'.

I want to be certain about the amount of physiotherapy consultation (face to face) time that was used to deliver both the intervention arm and the control arm of your study/the experience or skill level of the physiotherapists delivery the standard care component of rehabilitation/ the environment (gym/office/cubicle) that you used and equipment that you used. If possible could you clarify this?

I would be most grateful to hear from you about this study within 6 weeks of receiving this email. I am sure you can understand the time sensitivity. It would be great to include the study in the review. If you have any questions or would like to discuss this further, please do not hesitate to contact me.

Yours faithfully,

Emma Dunphy BSc MPhil MCSP

Senior Musculoskeletal Physiotherapist

********** NHS Trust

NIHR Clinical Doctoral Research Fellow

University College London

Appendix C: Topic Guide

Toward criteria for optimal management of Anterior Cruciate Ligament rehabilitation programmes. A qualitative study of key stakeholder opinion

About how many ACL patients does your service see?

What is your ACL rehabilitation service like? Pathway

How do patients come to your service? Via Ortho/ via GP/via A&E

Do you have an opinion on the skill level of clinicians who run classes? What is the skill level required?

Does it have a structure? (Stages, goals, criteria)

How soon post operatively do you see patients?

Do you follow a protocol?

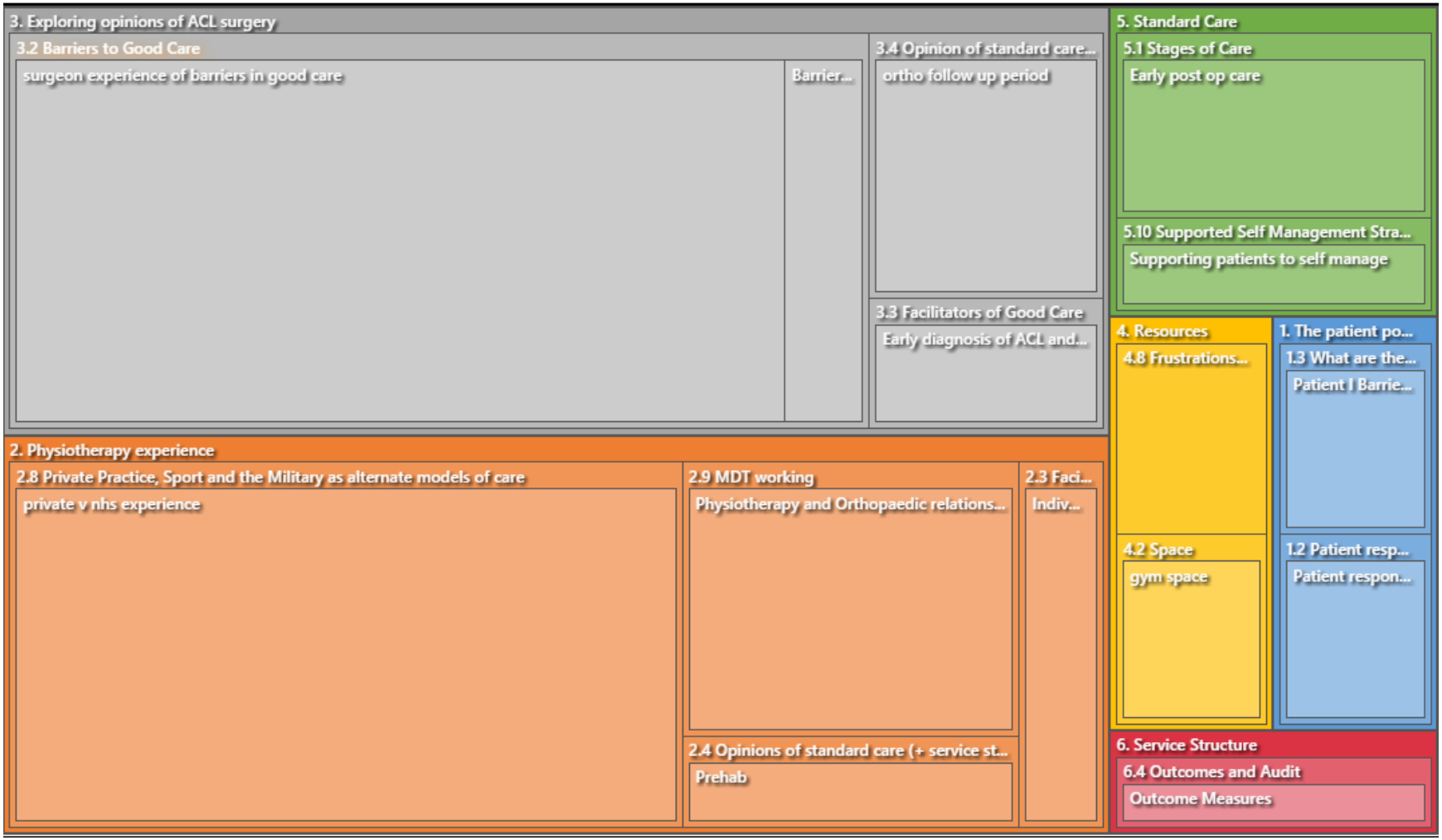
What facilities do you have? Do you have a budget for equipment?

Can you say how often patients are seen? How long are patients seen over months? How long per individual session?

What influences that answer?

Do you see rehabilitation changing in line with financial pressures in the current NHS climate?

Appendix D: NVIVO coding chart



Appendix E: Participant Information Sheet

Participant Information Sheet

What is the feasibility of a Randomised Controlled Trial investigating TRAK, a digital tool to support the self-management component of rehabilitation following Anterior Cruciate Ligament reconstruction?

IRAS: 215998

You are being invited to take part in a research study because you have had an ACL reconstruction. This study is taking place in 2 London NHS Hospitals in collaboration with University College London and Cardiff University. We are looking for a total of 75 individuals to take part. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. One of our team will go through the information sheet with you. Ask us if there is anything that is not clear or if you would like more information. Discuss it with others if you wish, before you decide whether or not you wish to participate.

It is up to you to whether or not to take part. If you do decide to participate you will be given this information sheet to keep and after you have had enough time to read through it, you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision not to take part or to withdraw at any time will not affect the care you receive in any way. Should you decide not to take part, you do not have to provide a reason for this decision.

What is the purpose of this trial?

The aim of this research is to see if we can recruit people to take part in a study comparing their usual care pathway to the usual care plus the TRAK website. It aims to see if we can engage people to use the TRAK website and to find it useful throughout their rehabilitation until the rehabilitation or the study, are complete. We also want to know will the participants be willing to fill in the outcome measures at the beginning and end that will tell us about their experiences and how their knee is.

TRAK has certain features to help you with your physiotherapy; information sections and videos, individualised exercise plans made by your physio that change throughout your rehabilitation and ways of recording your progress such as an exercise log and a dashboard. It will also email you reminders to engage with your rehabilitation plan.

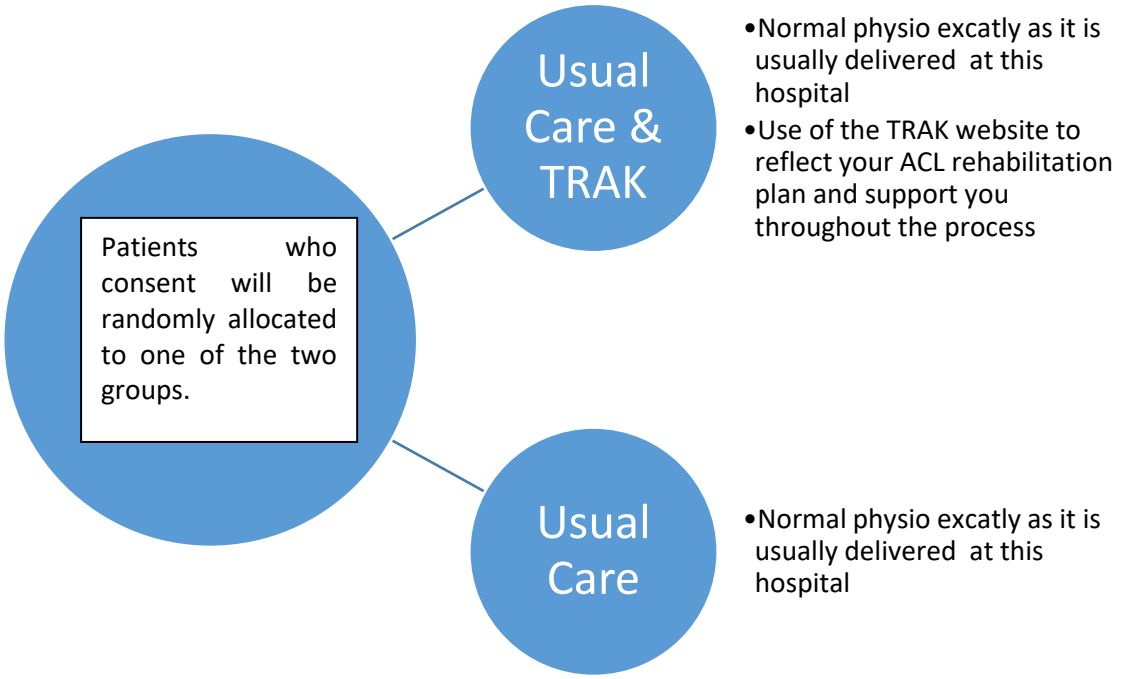


Figure 1. Randomisation

This study is needed because ACL reconstructions are a common occurrence. Rehabilitation can help individuals from doing what they want during their everyday lives long term and there is a high demand for treatment. Therefore new efficient and beneficial ways of delivering physiotherapy, that support individuals long term goals and treatment are required.

Do I have to take part?

It is up to you to whether or not to take part. If you do decide to participate you will be given this information sheet to keep and after you have had enough time to read through it, be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time. A decision not to take part or to withdraw at any time will not affect the standard of care you receive. Should you decide not to take part, you do not have to provide a reason for this decision.

What would taking part involve?

- You will be given time to think if you want to participate.
- You will be asked to sign a consent form on your next clinic appointment
- You will fill in questionnaires that measure your knee symptoms, how active you are, what health care resources you use and how you believe you can treat your knee. This will be done at the beginning and end of the study.
- You will continue to receive face-to-face physiotherapy exactly as it is usually delivered at this hospital.

- You will be trained how to use the TRAK website on your phone or at home.
- We will monitor and analyse how you use the website to learn what is more popular and useful to you. We will monitor the remote interactions you have with your physiotherapist and check that these are addressing your needs.
- We will ask up to 75 individuals to take part in this study in two different hospitals. A group of approximately 20 of these patients will be asked to participate in an interview to discuss their experiences of using the website as part of their rehabilitation. The questions will evaluate your experience of TRAK, if this met your needs, how useful it was and future requirements.
- The interviews will be audio-recorded.
- We will also be learning how physiotherapists use TRAK so we will also be making an audio recordings of approximately 5 patient/physio interactions where the physio is teaching the patient how to use TRAK. Once again, the process for the patient and physio will be fully anonymised but we will learn a lot about how physiotherapists use TRAK.
- TRAK security and storage of data will be explained to you. No personal data will be stored on the website.

Data will be kept securely for a minimum of 15 years in accordance with good research practice and data protection regulations imposed by Cardiff University and University College London in accordance with the Data Protection Act 1998. All data obtained during the study will remain confidential. Access to data will only be available to the investigators attached to this study from Cardiff University and University College London.

What are the possible benefits of taking part?

We cannot guarantee any specific treatment benefits from taking part in this study. We do hope to obtain a better understanding of how online treatment could be a better treatment option in the future. An indirect benefit is that by using TRAK individuals will have access to resources that are not currently available when you attend physiotherapy i.e. videos of information and exercise and tools to encourage you to do the exercises. At the end of the study period individuals in the usual care group will also be given access to these resources should they wish.

Are there any risks in participating in this trial?

Individuals will still receive usual care physiotherapy, so there are no additional risks with participating in the study. All individuals will be required to complete questionnaires that are beyond their normal care, which will take approximately 15 minutes of their time at the beginning and end of the study period.

What if something goes wrong?

If you are harmed by taking part in this research there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any

aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

What to expect during the consent process?

A member of your clinical team will have checked if you are eligible to be involved in the study and asked you if you are willing to talk to a member of the research team. They will explain the study to you and go through the information sheet, which you will also take away. You will be given at least 24 hours to consider if you want to take part. If you agree, then at your clinic appointment a member of the research team will explain the study to you again, answer any questions you have and then you will be asked to sign a consent form.

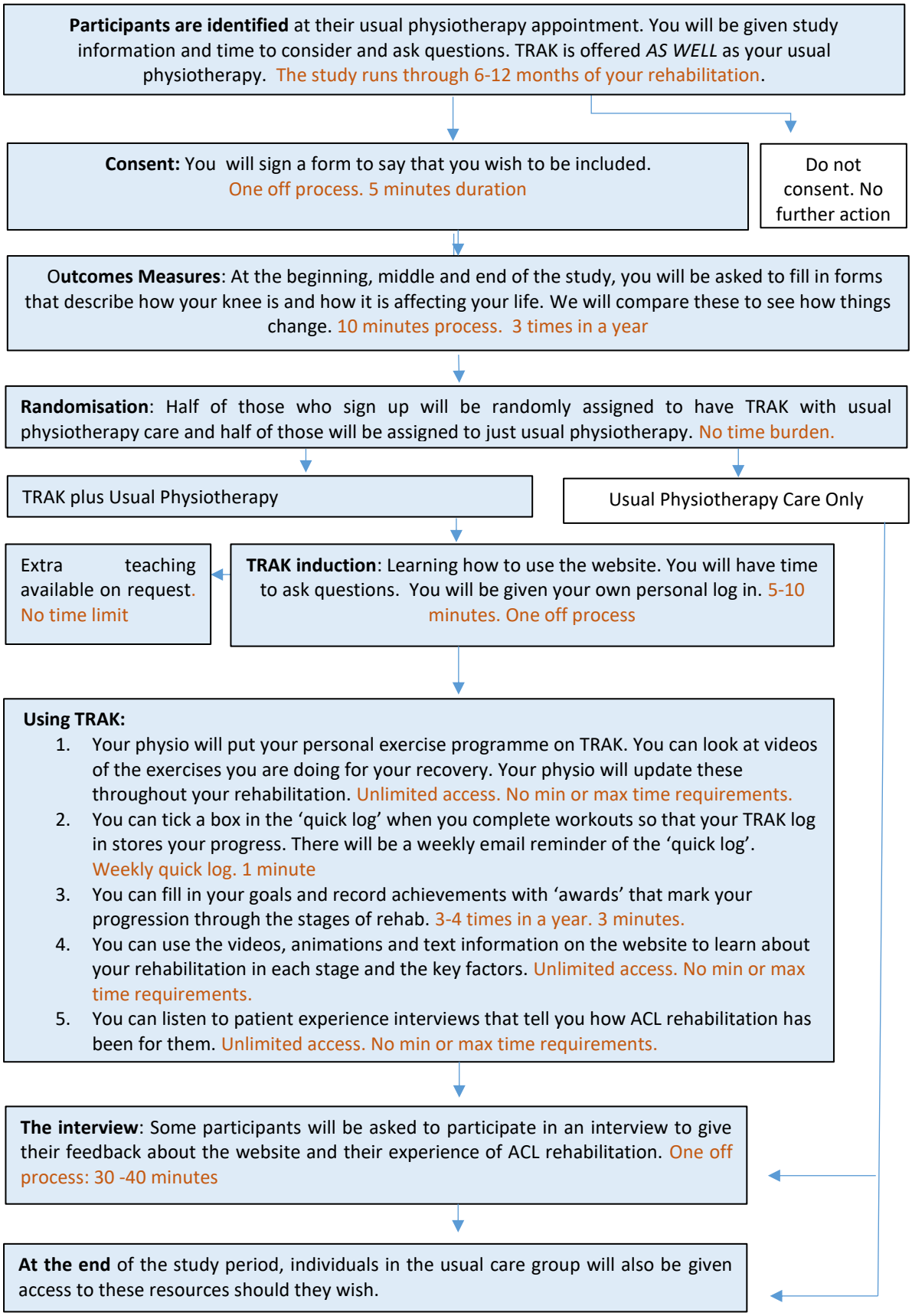


Figure 2. Flow Chart of Patient Participation

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

If you withdraw from the study, we will erase all identifiable material, but we will need to use the data collected up to your withdrawal.

Will my GP be informed of my involvement in the study?

With your permission your GP will be notified that you are participating in this study.

Who is organising and funding the research?

This study was organised and carried out by Emma Dunphy, Senior Physiotherapist at XXXXXX University Hospital and research fellow at University College London. It is based on an application developed XXXXXX by XXXXXXX with computing experts and researchers XXXXXXX. This study is being funded by the National Institute for Health Research (NIHR) Clinical Doctoral Research Fellowship fund. There are no commercial sources of funding.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the investigation. If this happens, the lead researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, it will not affect your continuing care in the NHS. If you decide to continue, you will be asked to sign an updated consent form.

How will my information be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. We will be using the computing infrastructure that already exists within the participating NHS Hospitals that meets local and national standards for security and confidentiality. Any information about you which leaves the hospital will have your details removed, such as name and contact details removed so that you cannot be recognised from it. No personal identifiable data will be stored on the TRAK website

What will happen to the results?

The results of the study will be presented at scientific meetings and published in journals for healthcare professionals and computer scientists. We will summarise findings on the TRAK website and the NIHR website. You will not be identified in any report/publication.

Who has reviewed this study?

This study has been reviewed by the Research Ethics Committee (REC) for England.

How have patients and public been involved?

We have asked patients and physiotherapists their viewpoint on using online treatment for knee conditions. We asked patients to help design the website and to inform the content. This has been taken into consideration when designing this study.

What if I wish to lodge a complaint?

If you wish to make a complaint regarding the way you were approached or treated during the trial, please contact Emma Dunphy using the contact details below or you can contact the hospital Patient advice and liaison service (PALS) at 02085107315.

Contact for further information

Emma Dunphy

Physiotherapy Department

****

Tel: 02085107835

Email: emma.dunphy@nhs.net

Appendix F: The Client Service Receipt Inventory

GP AND COMMUNITY CARE						
Utilities	**Baseline**		**3 Month**		**6 month**	
	TAU	**TRAK**	**TAU**	**TRAK**	**TAU**	**TRAK**
	N=25	N=26	N=19	N=25	N=17	N=23
Seen GP at surgery						
0	10	10	14	16	14	18
Yes	15	17	5	9	3	5
Obs, no. of times mean (SD)	14, 1.43 (.85)	16, 2 (1.41)	5, 1.2 (.45)	7, 1.7 (1.1)	2, 1 (0)	4, 2.25 (1.5)
Cost	???	???	???	???	???	???
Missing	1	1	0	2	1	1
Seen GP at home						
0	23	25	19	25	17	23
Yes	2	1	0	0	0	0
Obs, no. of times mean (SD)	2, 1.5 (.71)	1, 2 (.)	-	-	-	-
Cost	????	???	-	-	-	-
Missing	0	0	0	0	0	0
Phoned GP for advice						
0	19	22	18	23	16	21
Yes	6	4	1	2	1	2
Obs, no. of times mean (SD)	5, 1 (0)	3, 1.33 (.58)	1, 2 (.)	1, 1 (.)	1, 1 (.)	2, 1 (0)
Cost	???	???	????	???	???	???
Missing	1	1	0	1	0	0
Seen practice nurse at the surgery						
0	13	12	14	19	15	22
Yes	12	14	5	6	2	1
Obs, no. of times mean (SD)	11, 1.27(.47)	14, 1.58 (.85)	5, 4 (6.16)	5, 1.6 (1.3)	2 1 (0)	1, 1 (.)
Cost	???	???	???	???	???	???
Missing	1	0	0	1	0	0
Phoned practice nurse for advice						
0	23	26	19	24	17	23
Yes	2	0	0	1	0	0
Obs, no. of times mean (SD)	1, 1 (.)	-	-	-	-	-
Cost	???	-	-	???	-	-
Missing	1	0	0	1	0	0

Got meals on wheels						
0	25	26	18	24	17	23
Yes	0	0	1	1	0	0
Obs, no. of times mean (SD)	-	-	1, 5 (.)	-	-	-
Cost	-	-	???	???	-	-
Missing	0	0	0	1	0	0
Home help						
0	25	26	19	25	17	23
Cost	-	-	-	-	-	-
Missing	0	0	0	0	0	0
Seen social worker						
0	25	26	19	25	17	23
Cost	-	-	-	-	-	-
Missing	0	0	0	0	0	0
Phone social worker						
0	25	26	19	25	17	23
Cost	-	-	-	-	-	-
Missing	0	0	0	0	0	0

PHYSIOTHERAPY AND OTHER THERAPIES

Utilities	Baseline		3 Month		6 month	
	TAU	TRAK	TAU	TRAK	TAU	TRAK
	N=25	N=26	N=19	N=25	N=17	N=23
Physiotherapist at hospital (NHS)						
0	0	5	4	6	7	8
Yes	25	21	15	19	10	15
Obs, no. of times mean (SD)	24, 4.75 (4.0)	19, 4.31 (2.76)	11, 8.1(5.39)	12, 13.83(11.62)	9, 5.1 (3.3)	10, 11.4 (4.5)
Cost	???	???	???	???	???	???
Missing	1	2	4	7	1	5
Seen at home (NHS)						
0	25	26	19	25	17	23
Yes	0	0	0	0	0	0
Obs, no. of times mean (SD)	-	-	-	-	-	-
Cost	-	-	-	-	-	-
Missing	0	0	0	0	0	0
Seen at the GP surgery or a clinic (NHS)						
0	21	21	19	24	17	22
Yes	4	5	0	1	0	1

Obs, no. of times mean (SD)	3, 2.66 (2.08)	4, 3(2.16)	-	-	-	-
Cost	???	???	-	???	-	-
Missing	1	1	0	1	0	1
PRIVATE Physiotherapist at home						
0	24	26	19	25	17	23
Yes	1	0	0	0	0	0
Obs, no. of times mean (SD)	1, 1 (.)	-	-	-	-	-
Cost	???	-	-	-	-	-
Missing	0	0	0	0	0	0
PRIVATE Physiotherapist Outpatient						
0	22	25	19	24	17	23
Yes	3	1	0	1	0	2
Obs, no. of times mean (SD)	3, 1.66 (1.15)	1, 2(.)	-	1, 4 (.)	-	2, 10 (0)
Cost	???	???	-	???	-	???
Missing	0	0	0	0	0	0
PRIVATE Physiotherapist hospital						
0	25	26	19	24	17	23
Yes	0	0	0	1	0	0
Obs, no. of times mean (SD)	-	-	-	1, 10 (.)	-	-
Cost	-	-	-	????	-	-
Missing	0	0	0	0	0	0
Occupational Therapist (OT) seen at hospital						
0	24	26	18	25	17	23
Yes	1	0	1	0	0	0
Private	1	-	1	-	-	-
Obs, no. of times mean (SD)	1, 1(.)	-	-	-	-	-
Cost	??	-	???	-	-	-
Missing	0	0	1	0	0	0
OT Seen at Home						
0	25	26	19	25	16	23
Yes	0	0	0	0	1	0
Private	-	-	-	-	1	-
Obs, no. of times mean (SD)	-	-	-	-	1, 2 (.)	-
Cost	-	-	-	-	???	-
Missing	0	0	0	0	0	0
Other Described	**Osteopathy, Work based**	**CBT, OT at work**	**Sports massage**	**CBT, Chiropractor**	**Osteopath,**	**Chiropractor**

	rehab centre				**ACL Class , P Trainer**	
0	23	24	18	23	14	22
Yes	2	2	1	2	3	1
Private	1	1	0	2	2	1
Obs, no. of times mean (SD)	2, 6.5 (4.95)	2, 1.5 (.71)	-	2, 2.5(2.12)	3, 7.66 (5.8)	1, 1 (.)
Cost	???	???	???	???	???	???
Missing	0	0	1	0	0	0
Other Service				**Counselling**	**S. Massage**	
0	25	26	19	24	16	23
Yes	0	0	0	1	1	0
Private	-	-	-	1	0	-
Obs, hours mean (SD)	-	-	-	-	1, 2 (.)	-
Cost	-	-	-	???	???	-
Missing	0	0	0	1	0	0
HOSPITAL						
Utilities	**Baseline**		**3 Month**		**6 month**	
	TAU	**TRAK**	**TAU**	**TRAK**	**TAU**	**TRAK**
	N=25	N=26	N=19	N=25	N=17	N=23
Been to accident and emergency						
0	20	16	18	23	16	23
Yes	5	10	1	2	1	0
Obs, hours mean (SD)	4, 1.5(1)	8, 1.38(.52)	1, 1 (.)	2, 1.5 (.71)	1, 1(.)	-
Cost	???	???	???	???	???	-
Missing	1	2	0	0	0	0
Elective hospital overnight stay						
0	24	24	19	25	17	23
Yes	1	2	0	0	0	0
Obs, days mean (SD)	-	1, 1 (.)	-	-	-	-
Cost	???	???	-	-	-	-
Missing	0	1	0	0	0	0
Non-elective hospital overnight stay						
0	25	21	19	24	17	23
Yes	0	5	0	1	0	0

Obs, days mean (SD)	-	4, 2.25 (1.5)	-	1, 3 (.)	-	-
Cost	???	???	-	???	-	-
Missing	0	1	0	0	0	0
Overnight hospital stay in intensive care/ high dependency unit						
0	25	25	19	25	17	12
Yes	0	1	0	0	0	0
Obs, hours mean (SD)	-	-	-	-	-	-
Cost	-	??	-	-	-	-
Missing	0	1	0	0	0	0
Had a hospital outpatient appointment						
0	11	14	17	18	14	21
Yes	14	12	2	7	3	2
Obs, hours mean (SD)	14, 1.57(.76)	11, 2 (1.67)	2, 1.5(.71)	5, 2(1)	3, 4.66 (6.4)	2, 1.5(.71)
Cost	??	???	???	???	???	???
Missing	0	1	0	0	0	0
Day patient procedure/test						
0	12	13	18	23	17	22
Yes	13	13	1	2	0	1
Obs, hours mean (SD)	12, 1.08(.29)	11, 1.09(.30)	1, 7 (.)	1, 2(.)	-	1, 2(.)
Cost	???	???	???	???	-	???
Missing	1	2	0	1	0	0

EMPLOYING EXTRA HELP

Utilities	**Baseline**		**3 Month**		**6 month**	
	TAU	**TRAK**	**TAU**	**TRAK**	**TAU**	**TRAK**
	N=25	N=26	N=19	N=25	N=17	N=23
Employing extra help (e.g. cleaning)						
0	25	26	19	25	17	23
Yes	0	0	0	0	0	0
Who paid	-	-	-	-	-	-
Obs, cost mean (SD)	-	-	-	-	-	-
Missing	0	0	0	0	0	0
Transport to get to healthcare appointments (e.g. to go to your GP surgery or hospital)						
0	10	15	10	17	17	22
Yes	15	11	9	8	0	1

Who paid	0 (11), patient (13) mum (1)	0 (17), patient (8)	0 (11), patient(8)	0 (20), patient(5)	-	0 (22), patient(1)
Obs, cost mean (SD)	14, 80.35(96.52)	9, 161.6 (214.7)	9, 64.66 (42.61)	4, 96.75(71)	-	1, 40(.)
Missing	1	2	1	4	0	0
Transport to get to self-help groups						
0	24	26	19	25	17	23
Yes	1	0	0	0	0	0
Who paid	0 (24), patient (1)	-	-	-	-	-
Obs, cost mean (SD)	1, 10(.)	-	-	-	-	-
Missing	0	0	0	0	0	0
Health care (e.g. private or alternative treatments						
0	21	23	19	24	17	22
Yes	4	3	0	1	0	1
Who paid	0(21), patient(30), parent(1)	0(24), patient(2)	-	0(24), patient(1)	-	0 (22), dad (1)
Obs, cost mean (SD)	4, 66.25(90.31)	2, 165(190.91)	-	1, 150(.)	-	1, 9(.)
Missing	0	1	0	0	0	0
Special equipment (e.g. kitchen equipment)						
0	24	26	19	25	17	23
Yes	1	0	0	0	0	0
Who paid		-	-	-	-	-
Obs, cost mean (SD)	1, 30(.)	-	-	-	-	-
Missing	0	0	0	0	0	0
Changes to your home (e.g.stairlift)						
0	25	26	19	25	17	23
Yes	0	0	0	0	0	0
Who paid	-	-	-	-	-	-
Obs, cost mean (SD)	-	-	-	-	-	-
Missing	0	0	0	0	0	0

Financial support (please do not include state benefits)						
0	24	25	19	25	17	23
Yes	1	1	0	0	0	0
Who paid	0(24), parent(1)	0(25), family (1)	-	-	-	-
Obs, cost mean (SD)	1, 360(.)	1, 600(.)	-	-	-	-
Missing	0	0	0	0	0	0
List other costs						
0	23	25	19	24	17	22
Yes	2	1	0	2	0	1
Describe	0(23), takeaway (1), work travel (1)	0(25), work travel (1)	-	0(24), medicine (1) gym for rehab (1)	-	0(22), medicine (1)
Who paid	0(23), patient (1.5), work(.5)	0(25), work(1)	-	0(24), Patient (2)	-	0(22), Patient (1)
Obs, hours mean (SD)	2, 350(353.55)	1 200(.)	-	2, 75(7.07)	-	1, 10(.)
Missing	0	0	0	0	0	0
Any time off work						
0	1	4	9	10	14	13
Yes	19	16	8	10	1	6
Not Employed	5	6	2	5	2	4
Took sick leave from work						
0	8	14	13	22	16	23
Yes	17	12	6	3	1	0
Obs, mean days(SD)	16, 9.26(6.4)	11, 12.27 (13.94)	6, 13.16 (5.63)	3, 25(20)	-	-
Obs, mean hours(SD)		1, 8(.)	-	-	-	-
Cost?	???	???	???	???		-
Missing	-	0	0	0	1	0
Used your paid holiday time						
0	19	21	16	23	17	21
Yes	6	5	3	3	0	2

Obs, mean days(SD)	6, 7.66(3.66)	3, 7.66 (4.04)	3, 5.33(4.50)	2, 7.5(3.5)	-	2, 5.5(.71)
Obs, mean hours(SD)	-	-	-	-	-	-
Cost?	???	???	???	???	-	???
Missing	0	0	1	1	0	0
Took unpaid leave from work						
0	22	22	19	23	17	21
Yes	3	4	0	2	0	2
Obs, mean days(SD)	3, 11(9.53)	3, 18.33 (18.77)	-	1, 18(.)	-	2, 8(2.82)
Obs, mean hours(SD)	-	-	-	1, 210(.)	-	-
Cost?	???	???	???	???	-	???
Missing	0	1	0	0	0	0
Just made up the time at work						
0	25	25	16	23	17	21
Yes	0	1	3	2	0	2
Obs, mean days(SD)	-	-	1, 2 (.)	4, 3.5(3)	-	2, 5(4.2)
Obs, mean hours(SD)	-	1 850(.)	2, 11.5(6.36)	1, 850(.)	-	-
Cost?	-	???	???	???	-	???
Missing	0	1	0	-3	0	0
Other arrangement (please describe)						
0	22	24	19	24	17	23
Yes	1	2	0	1	0	0
Describe	0 (22), Less work, work from home (1)	0(24), Working from home (2)	-	0(24), Less work, work from home (1)	-	-
Obs, mean days(SD)	1, 25(.)	-	-	-	-	-
Obs, mean hours(SD)	-	-	-	-	-	-
Cost?	???	???	-	???	-	-
Missing	2	2	0	1	0	0
Gross Income						
Obs, Mean income (SD)	7, 4961.86 (10623.38)	9, 10974 (21061.69)	4, 12113.25	5, 712.2 (724.13)	3, 1616.66	4, 941 (772.31)

			(22593.85)		(860.72)	
Missing	18	17	15	20	14	19
FRIENDS & RELATIVES HELPED						
Utilities	**Baseline**		**3 Month**		**6 month**	
	TAU	**TRAK**	**TAU**	**TRAK**	**TAU**	**TRAK**
	N=25	N=26	N=19	N=25	N=17	N=23
Friends and relatives helped						
0	4	8	8	17	17	22
Yes	21	18	11	8	0	1
Cost?	???	???	???	???	???	???
Personal care (e.g. bathing, dressing)						
0	13	15	15	23	17	23
Yes	12	11	4	2	-	-
Obs, mean hours p week (SD)	8, 4.375 (2.82)	8, 4.875 (2.23)	2, 1(0)	2, 5.5(.71)	-	-
Cost?	???	???	???	???	-	-
Missing	4	3	2	0	0	0
Housework / laundry						
0	4	12	12	22	17	22
Yes	21	14	7	3	0	1
Obs, mean hours p week (SD)	15, 3.53(2, 16)	6, 3.83(2.48)	4, 4.75(3.78)	2, 2(0)	-	1, 4(.)
Cost?	???	???	???	???	-	???
Missing	6	8	3	1	0	0
Providing transport/taking you out						
O	6	11	11	23	17	23
Yes	19	15	8	2	0	0
Obs, mean hours p week (SD)	15, 3.46(3.33)	9, 4.88(4.23)	5, 6.6(2.07)	2, 3(1.41)	-	-
Cost?	???	???	???	???	-	-
Missing	4	6	3	0	0	0
Preparing meals						
O	8	9	15	23	17	23
Yes	17	17	4	2	0	0
Obs, mean hours p week (SD)	12, 5.91(3.28)	7, 8(4.39)	1, 10(.)	-	-	-
Cost?	???	???	???	-	-	-
Missing	5	10	3	2	0	0
Gardening						

0	23	22	18	24	17	23
Yes	2	4	1	1	0	0
Obs, mean hours p week (SD)	1, 1(.)	2, 4(1.41)	1, 1(.)	-	-	-
Cost?	???	???	???	???	???	???
Missing	1	2	0	1	0	0
Shopping						
0	12	11	13	23	17	23
Yes	13	15	6	2	0	0
Obs, mean hours p week (SD)	9, 4.44(6.24)	5, 4.8(5.16)	4, 1.75(.5)	1, 1(.)	-	-
Cost?		???	???	???	???	???
Missing	4	10	2	1	0	0
Looking after pets						
0	23	24	19	24	17	23
Yes	2	2	0	1	0	0
Obs, mean hours p week (SD)	1, 7(.)	3, 6.66(3.51	-	-	-	-
Cost?					??	??
Missing	1	-1	0	1	0	0
DIY/home improvements						
0	21	24	15	24	17	23
Yes	4	2	4	1	0	0
Obs, mean hours p week (SD)	2, 1 (0)	1, 2(.)	2 , 1.5 (.71)	-	-	-
Cost?	???	???	???	-	-	-
Missing	2	1	2	0	0	0
Other (Please describe)						
0	24	26	18	25	17	23
Yes	1	0	1	0	0	0
Decribe	Childcare (1)	-	Moving house (1)	-	-	-
Obs, mean hours p week (SD)	-	-	-	-	-	-
Cost?	???	-	???	-	-	-
Missing	1	0	1	0	0	0
Friends and relatives stayed off work						
0	15	15	18	20	17	23
Yes	10	11	1	5	0	0

Obs, mean hours (SD)	9, 3.66(2.78)	11, 8.9(7.94)	1, 2(.)	5, 24.4 (48.99)	-	-
Missing	1	0	0	0	0	0
Your current situation						
Full time work >30 hours	17	12	16	15	14	11
Job training/apprentice	0	0	1	0	1	0
Other	4	7	2	7	2	5
Part time work <30 hours	1	1	0	1	0	4
Unable to work	3	6	0	1	0	1
Unemployed looking for work	0	0	0	1	0	2
Missing	0	0	0	0	0	0
Other						
0	17	13	17	17	15	17
Education	4	6	2	7	2	6
Self employed	0	1	0	0	0	0
Bank shifts	0	0	0	0	0	0
Missing	0	0	0	0	0	0
How long have you been unable to work						
0	21	18	19	23	17	23
Yes	4	8	0	2	0	0
Obs, mean time (SD)	4, 6.5(5.44)	8, 12(12.24)	-	2, 2.5(.71)	-	-
Missing	0	0	0	0	0	0
Benefits						
0	25	26	19	24	17	23
Yes	0	0	0	1	0	0
Type	-	-	-	Job seekers (1)	-	-
Other	-	-	-	-	0	0