

Shared decision-making following anterior cruciate ligament rupture: a mixed methods feasibility study

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ABSTRACT

BACKGROUND

Anterior cruciate ligament (ACL) ruptures are common, affecting over 20,000 people in the UK each year. Treatment may follow a surgical, non-surgical (rehabilitation) or combined pathway whereby patients engage with rehabilitation prior to surgical intervention. Most commonly, surgery is the treatment of choice. Not all patients receive rehabilitation prior to surgery, this may be due to a lack of evidence supporting its efficacy on improving post-operative treatment outcomes. Previous research has also identified that rehabilitation prior to surgery varies. However, all patients in the UK will routinely have rehabilitation after surgery.

Despite increasing rates of ACL surgical procedures over the past two decades (predominately ACL reconstruction, ACLR), only 28% of patients return to their preinjury physical activity levels (a typical goal for most patients) by 18-months. By comparison, 24% of those treated with rehabilitation alone (non-surgical treatment) have returned by the same timeframe. Understanding which patients are appropriate for which treatment pathway is challenging. The sequence of specific treatments also continues to be debated (i.e. when and whether to undergo rehabilitation prior to surgery). Patients' lived experiences of the UK surgical pathway (both prior to and following surgery) are currently unknown.

Development of an evidence-based and theoretically-informed intervention to support decision-making about treatment following an ACL rupture may improve patient outcomes and satisfaction, ensuring the chosen care pathway meets their individual needs. Further, development of clinical recommendations to inform practice following an ACL rupture may address the uncertainty and inconsistency in practice.

AIMS

The primary aims of this research were to:

- Develop an intervention for use with patients post-injury to support decision-making around ACLR
- Understand the interventions acceptability and tolerability among patients and clinicians
- Explore indicators of the intervention's effectiveness and implementation factors in clinical practice

OBJECTIVES

This research involved a three-phase approach to address the above aims.

Objective 1: To understand patients' lived experiences of the treatment pathway following a diagnosis of an ACL rupture and planned surgical management (Phase 1).

Objective 2: To work with patients and stakeholders to develop a novel intervention (Phase 2) to address the patients' unmet needs identified in Phase 1.

Objective 3: To understand feasibility, acceptability and tolerability of the intervention with respect to participants and clinicians in an NHS setting (Phase 3).

METHODS

This project utilised a mixed-methods approach involving three phases of research.

Phase 1: Individual semi-structured interviews with patients at three time-points on the ACLR pathway: (1) up to 3-months before surgery, (2) 3-months post-surgery and (3) 12-months post-surgery.

Phase 2: Nominal group technique consensus study (online) with patients and key stakeholders.

Phase 3: Non-randomised single site feasibility study with embedded qualitative interviews with patients and clinicians.

The design, implementation and refinement of the intervention was underpinned by the Extended Normalisation Process Theory.

RESULTS

Interviews with 18 participants (Phase 1) offered novel insight into the lived experiences of the NHS ACL surgical treatment pathway, both prior to and after surgery. Several gaps in patient support were identified by participants who faced key challenges when: communicating with clinicians, navigating

NHS systems and seeking support for a diagnosis and injury management; making decisions about treatment; receiving personalised care; coping independently in the preoperative period and managing conflicting sources of healthcare advice.

These key issues were combined with the current literature to form an evidence summary provided to participants (n=8) in Phase 2. This supported co-production of a shared decision-making intervention to support treatment decision-making following an ACL rupture and evidence-based recommendations to inform key components of care in the post-injury and/or pre-surgical period. This was achieved through an online nominal group consensus study with patients and key stakeholders including NHS healthcare professionals (physiotherapists, an orthopaedic surgeon and occupational therapist) and an NHS therapy manager.

The shared decision-making intervention was explored in a non-randomised feasibility study with 20 participants at one large acute NHS hospital trust. Feasibility data were collected on recruitment rate, acceptability, fidelity and follow-up questionnaire completion. 94%-100% was achieved across all four outcomes. Embedded qualitative interviews with patients (n=5) and physiotherapists (n=5) supported further exploration of feasibility, acceptability and an understanding of effectiveness and implementation factors. The intervention was acceptable to both patients and clinicians and appeared effective in supporting shared decision-making processes following an ACL rupture. Several implementation factors were identified, mapped to constructs of the Extended Normalisation Process Theory, to consider barriers and enablers to future implementation and normalisation within practice.

CONCLUSION

This mixed-methods study co-developed a shared decision-making intervention and evidence-based consensus recommendations supporting care following an ACL rupture. The shared decision-making intervention was demonstrated to be acceptable, and indicators of effectiveness were identified. Refinements were made to both the intervention and its logic model ready for evaluation in future research. Implementation factors were identified to support planning for a future trial and translation of knowledge into clinical practice, considering barriers and enablers to normalisation.

PUBLICATIONS ARISING FROM THIS THESIS

The qualitative systematic review presented in Chapter 2.5 was published in 2023:

> **Carter, H**., Beard, D., Harvey, A., Leighton, P., Moffatt, F., Smith, B., Webster, K., Logan, P., 2023. Using normalisation process theory for intervention development, implementation and refinement in musculoskeletal and orthopaedic interventions: a qualitative systematic review. Implement Sci Commun 4, 1–25. https://doi.org/10.1186/S43058-023-00499-Z/TABLES/6

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The nominal group technique consensus study presented in Chapter 4 was published in 2024:

> **Carter, H**., Beard, D, Leighton, P, Moffatt, F, Smith, B., Webster, K., Logan, P, 2024. Development of an intervention for patients following an anterior cruciate ligament rupture: an online nominal group technique consensus study. BMJ Open 14, e082387. https://doi.org/10.1136/bmjopen-2023-082387

The protocol for the non-randomised feasibility study presented in Chapter 5 was published in 2024:

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The manuscript reporting the feasibility results presented in Chapter 5 is under review with a peer-reviewed journal:

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The manuscript reporting the implementation results presented in Chapter 5 is also under review with a peer-reviewed journal:

> **Carter, H**., Beard, D., Dodsley, C., Leighton, P., McCallion, J., Moffatt, F., Smith, B., Webster, K., Logan, P., 2024. Exploring implementation of a shared decision-making intervention for patients following an Anterior Cruciate Ligament Rupture: A Qualitative Investigation.

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Developing Complex Interventions to Improve Health, Sheffield Centre for Health and Related Research, *University of Sheffield*

Real World Evaluation: Ten Key Principles for Evaluating Complex Health and Social Interventions, *Sheffield Centre for Health and Related Research, University of Sheffield*

Introduction to Qualitative Research Methods, *University of Oxford*

Knowledge into Action, *University of Oxford*

Introduction to Statistics for Health Care Research, *University of Oxford*

Qualitative Data Analysis and Nvivo, *Scholarly Writing Institute*

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INVOLVE, *National Institute for Health and Care Research*

Ways to Involve the Public in Research, *Cambridge Biomedical Research Centre*

Evaluating PPI, *Cambridge Biomedical Research Centre*

Writing Lay Summaries for Health Research, *Cambridge Biomedical Research Centre*

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LIST OF ABBREVIATIONS

ACL	Anterior Cruciate Ligament
ACLOAS	Anterior Cruciate Ligament Osteoarthritis Score
ACL-QOL	Anterior Cruciate Ligament Quality of Life Questionnaire;
ACL-RSI	Anterior Cruciate Ligament Return to Sport after Injury
ACLR	Anterior Cruciate Ligament Reconstruction
AQoL-8D	Assessment of Quality of Life
ATOCP	Association for Trauma and Orthopaedic Chartered Physiotherapists
BASK	British Association for Surgery of the Knee
BOA	British Orthopaedic Association
BOSTAA	British Orthopaedic Sports Trauma Arthroscopy Association
CASP	Critical Appraisal Skills Programme
CBP	Cross-Bracing Protocol
CDRF	Clinical Doctoral Research Fellowship
CERQual	Confidence in the Evidence from Reviews of Qualitative Research
CFIR	Consolidated Framework for Implementation Research
CI	Confidence Interval

CKRS	Cincinnati Knee Rating System
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated Criteria for Reporting Qualitative Research
COVID-19	Coronavirus Disease
CPD	Continual Professional Development
ED	Emergency Department
ENPT	Extended Normalisation Process Theory
EQ-5D	EuroQol- 5 Dimension
FNCH	Florence Nightingale Community Hospital
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRADE-CERQual	Confidence in the Evidence from Reviews of Qualitative Research
GSM	Grams per Square Meter
HCP	Healthcare Professionals
HRQoL	Health Related Quality of Life
IKDC	International Knee Documentation Committee
IMD	Indices of Multiple Deprivation
IPDAS	International Patient Decision Aid Standards

IQR	Interquartile Range
IRLM	Implementation Research Logic Model
iSoQ	Interactive Summary of Qualitative Findings
JBI	Joanna-Briggs Institute
K-SES	Knee Self Efficacy Scale
KNEES-ACL	Knee Numeric-Entity Evaluation
KOOS	Knee Injury and Osteoarthritis Outcome Score
MMR	Mixed Methods Research
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
MSK	Musculoskeletal
NGT	Nominal Group Technique
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NoMAD	Normalization Measure Development
NPM	Normalisation Process Model
NPT	Normalisation Process Theory
OA	Osteoarthritis

PAS	Physical Activity Scale
PASS	Patient Acceptable Symptomatic State
PCL	Posterior Cruciate Ligament
PDA	Patient Decision Aid
PIS	Participant Information Sheet
POP-ACLR	PreOperative Management of Patients Awaiting Anterior Cruciate Ligament Reconstruction
PPIE	Patient and Public Involvement and Engagement
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROs	Patient Reported Outcomes
PTOA	Post-Traumatic Osteoarthritis
QALY	Quality-Adjusted Life-Year
QHB	Queen's Hospital Burton
QoL	Quality-of-Life
QUIPS	Quality in Prognostic Studies
RCT	Randomised Controlled Trial
RDH	Royal Derby Hospital
REALM-R	Rapid Estimate of Adult Literacy in Medicine, Revised
RTA	Reflexive Thematic Analysis

ROM	Range of Motion
RTPA	Return to Physical Activity
RTS	Return to Sport
RTW	Return to Work
SD	Standard Deviation
SDM	Shared Decision-Making
SF-36	36-Item Short Form Survey
SWD	Satisfaction with Decision
TAS	Tegner Activity Scale/Score
TMG	Trial Management Group
TSC	Trial Steering Committee
TSK-11	Tampa Scale of Kinesiophobia
UHDB	University Hospitals of Derby and Burton NHS Foundation Trust
UK	United Kingdom
UK NLR	UK National Ligament Registry
US	United States
VTE	Venous Thromboembolism
WHO	World Health Organisation

CHAPTER 1 INTRODUCTION

Summary

This chapter introduces the anterior cruciate ligament, relevant anatomy, incidence of injury and treatment options. The justification for research is also presented in addition to an overview of the PhD.

This thesis considers the management of patients who have sustained an anterior cruciate ligament (ACL) rupture. It sets out to understand the current gaps in knowledge of patient experiences following injury in the United Kingdom (UK) National Health Service (NHS). Currently, optimum management for an ACL rupture is unknown and patients will either: (1) engage in rehabilitation (non-surgical treatment), (2) trial non-surgical treatment and convert to surgical intervention if required or, (3) proceed directly to surgical intervention without a period of rehabilitation first (Beard et al., 2022; Frobell et al., 2010; Reijman et al., 2021). It is unclear who is most appropriate for ACL surgery and conversely who may be better managed via non-surgical treatment. Decision-making regarding ACL treatment is therefore unclear, and patients are often uncertain about which treatment is right for them (Grevnerts et al., 2021). This thesis aims to further our understanding of decision-making between patients and clinicians in an NHS setting, understand patient perspectives of treatment and develop an intervention to address the identified gap(s) in care following an ACL rupture diagnosis; with the overall aim of improving patient outcomes and ensuring delivery of cost-effective treatment.

1.1 WHAT IS THE ANTERIOR CRUCIATE LIGAMENT?

The ACL is one of two intra-capsular ligaments, so named for the way it crosses with the posterior cruciate ligament (PCL) in the centre of the knee (Sharma, 2004). The ACL attaches to the anterior tibial spine and blends with the anterior horn of the lateral meniscus. It runs proximally, posteriorly and laterally to attach to the posterior part of the medial surface of the lateral femoral condyle (Palastanga and Soames, 2012; Strandring, 2015), shown in Figure 1.1.

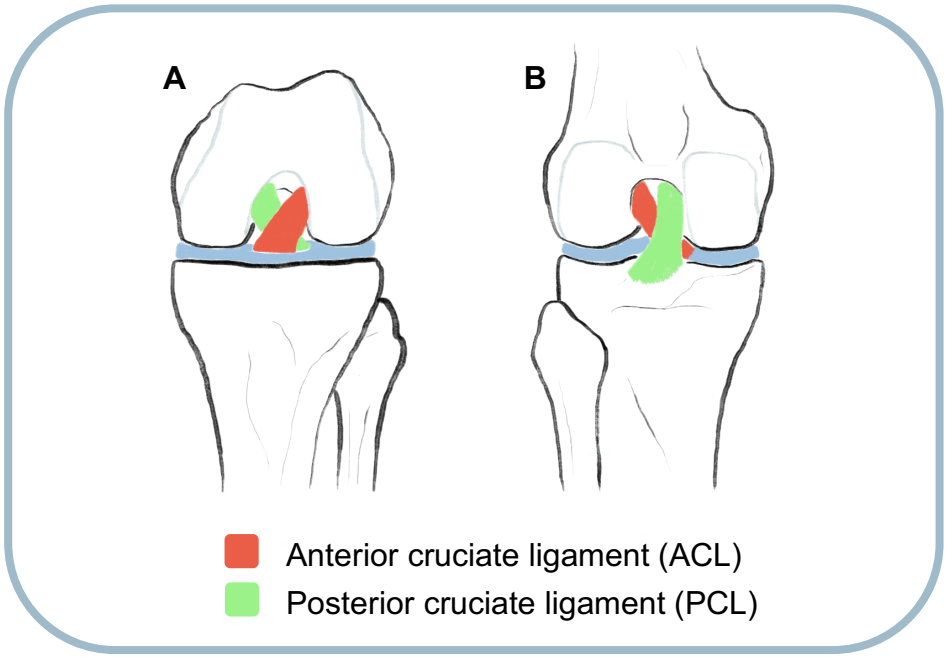


Figure 1.1 – Anatomy of the knee

A. Anterior aspect of the left knee joint in flexion. B. Posterior aspect of the left knee joint in extension.

The ACL prevents forwards translation of the tibia on the femur and provides stability to the knee joint throughout its full range of motion (ROM) (Sharma, 2004).

1.2 ANTERIOR CRUCIATE LIGAMENT INJURIES

The ACL is the most frequently injured knee ligament, thought to account for up to 50% of all knee injuries (Evans et al., 2023; Kaeding et al., 2017; Sanders et al., 2016). It is commonly acknowledged in the orthopaedic and musculoskeletal disciplines that ACL injuries most typically occur as 'non-contact' events; whereby no external force or contact is made with the knee. This has been supported in the literature by video analysis and interviews with patients describing ACL injury events, demonstrating over 70% occur via non-contact mechanisms (Boden et al., 2000; Marshall, 2010; Olsen et al., 2004). This is typically, with the knee near full extension during events such as rapid deceleration or landing manoeuvres (Boden et al., 2000; Marshall, 2010; Olsen et al., 2004). However, rupture can also occur via direct contact, for example during a tackle in rugby (Montgomery et al., 2018). A typical presentation is described as an audible 'pop' and rapid onset of swelling of the knee following injury (Parwaiz et al., 2016).

The consequences of an ACL rupture span a range of physical and psychosocial symptoms, negatively impacting upon an individual's quality of life. Physical symptoms include pain, knee instability, loss of strength and reduced mobility (Kaplan, 2011; Tayfur et al., 2021); with ongoing knee instability being a primary driver for proceeding with surgical treatment (Beard et al., 2022). Whilst there is ample quantitative literature in the ACL evidence base, qualitative studies exploring patient experiences following ACL injury are sparse as most studies report rehabilitation experiences following surgery and return to sport (Filbay et al., 2016). From the limited data available, a number of negative physical, psychological and social experiences are reported.

Typically, patients describe their ACL injury as a life-changing event (Piussi et al., 2023), accounting a loss of identity, frustration and social isolation due to limitations in their physical ability to participate in preinjury activities, mistrust in their knee, increased stress on personal relationships, feeling out of control and experiencing symptoms of depression (Scott et al., 2018; Simonsson et al., 2024).

The most commonly discussed long term consequence following ACL injury is osteoarthritis (OA), referred to as post-traumatic osteoarthritis (PTOA). A 2023 systematic review and meta-regression analysis reported the pooled prevalence of PTOA following ACL reconstruction (ACLR) as 37.9% at a median follow-up of 16.6 years and 40.5% for individuals treated non-operatively at a median follow-up of 15 years (Liukkonen et al., 2023). This is in comparison to a global prevalence of knee OA of 22.9% in individuals aged 40 and over reported in a 2020 meta-analysis of 88 studies including 10,081,952 participants (Cui et al., 2020). The prevalence of other long-term consequences, such as further injury, are dependent on initial injury management and are discussed further in 1.3.2.

ACL tears are common knee injuries affecting more than 20,000 people in the UK each year. A 2012 systematic review of 13 cohort studies (eight countries) reported a median annual incidence of 0.03% in the general population (Moses et al., 2012). However, as not all patients proceed with surgery and there is no standard surveillance of the injury, it is likely the prevalence is higher than that reported (Beard, 2017; Evans and Nielson, 2022). The average age of ACL injury occurrence reported in the literature varies. For example, analysis of knee magnetic resonance imaging (MRI) report data in Sweden (2006-2011,

1421 reports) demonstrated a mean age of rupture diagnosis at 33.9 years (Nicholls et al., 2018). Incidence according to gender was also reported, describing a peak for males in their early twenties and two peaks for females, firstly in their teens and secondly in their forties. In contrast, the 2022 UK National Ligament Registry (UK NLR) report, stated a mean age of 30 at the time of surgery between 2013 and 2021 (no data for age at the time of injury) (National Ligament Registry, 2022). This age mirrors that reported in a United States (US) cohort study (one County in Minnesota) of 1841 patients from 1990-2010 which reported a mean age of 29.1 ± 11 years (Sanders et al., 2016). There is an absence of studies focusing on the adult population alone (as the population of those described above includes those ≤18-years-old) and therefore an accurate understanding of the mean age of occurrence is currently lacking.

Although women are at a greater risk of sustaining an ACL rupture, a higher incidence is reported in the literature for men (Boden et al., 2010). This has been suggested in an Australian epidemiological analysis of knee injuries over a 20-year observation period (1998-2018) to be due to greater participation in 'high risk' sports in males (Maniar et al., 2022). However, with a unified focus to support the expansion of women engaging in physical activity and sport, with campaigns such as 'This Girl Can' launched by Sport England in 2015, it is likely these observations will evolve over the coming years (Sport England, 2021).

There is limited data on racial and ethnic predispositions to ACL injury. A 2021 systematic review aiming to identify gender, racial and ethnic disparities in incidence of ACL tears was only able to report a trend for white athletes in the

Women's National Basketball Association (US) having more than six times the tear rate compared to all other ethnic groups combined (Devana et al., 2022). Further injury surveillance is therefore needed to improve our understanding of injury demographics in addition to age and sex data. This was also recognised in the 2022 (most recent) UK NLR report, acknowledging the need to understand ACL patients' profile further, such as ethnicity and social deprivation, to support a greater understanding of injury epidemiology and outcomes.

1.3 TREATMENT OF ANTERIOR CRUCIATE LIGAMENT RUPTURES

There has been debate within the literature as to the most appropriate treatment for ACL ruptures and currently, there is no standard treatment pathway or 'gold standard' approach (Filbay and Grindem, 2019; Stokes et al., 2022). Typically, patients will either: (1) undergo non-surgical treatment (rehabilitation), (2) trial a period of rehabilitation with a view to progress to surgical intervention if required or, (3) proceed with surgery without trialling rehabilitation first. Most commonly, surgery is the treatment of choice, with or without prior rehabilitation, particularly if an individual aims to return to physical activity (Gokeler et al., 2017; Vaishya et al., 2015). The primary surgical approach is ACLR, which involves replacing the torn ligament with graft tissue (discussed in 1.3.2) (Runer et al., 2023).

In the UK, the age-standardised rate of ACLR, increased 12-fold over a 20-year period from 1997 to 2017 to 24.2 surgeries per 100,000 population (Abram et al., 2020). This increase could be due to a number of reasons

including, increase in injury rate, patient preference for surgical treatment (perhaps due to increase knowledge/exposure of the injury in the media), increase in surgical training/capacity and changes in healthcare commissioning; with some factors corroborated by Abram et al., (2020). In England, an estimated 30,000 primary ACLRs are performed each year, estimated to cost the NHS £63-85 million in 2015 (Beard et al., 2022).

1.3.1 SURGERY VERSUS REHABILITATION

The most up-to-date Cochrane systematic review (2016), including one randomised controlled trial (RCT) (KANON trial, n=141, active adults aged 18-35), reported no difference between a surgical or non-surgical approach for ACL ruptures in knee-related outcomes, health status and return to preinjury activity level at two- or five-year follow up (Monk et al., 2016). The authors of the KANON trial, concluded that surgery may be unnecessary for some, and a trial of pre-surgery rehabilitation reduced the need for ACLR by up to 50% (Frobell et al., 2010). It was also reported that those who had rehabilitation prior to ACLR, had greater knee stability at 2-year follow-up. The rehabilitation protocol used in the study spanned 24-weeks and included objective markers guiding progression from one stage to the next. Whilst exercise examples were offered, there was no specific guidance regarding exercise dose, such as frequency of completion. The protocol was the same for both groups to guide rehabilitation post-injury and post-surgery. However, it is important to note, that by the 5-year follow-up mark, 51% of participants in the non-surgical group underwent ACLR due to ongoing symptomatic instability and 51% of all participants (29 treated with early ACLR and 32 treated with rehabilitation with

the option of a later ACLR) had meniscal surgery (Frobell et al., 2013). Of those who had meniscal surgery, there was no significant difference between treatment groups (p=0.483). Since the Cochrane review's publication, two RCTs have offered further insight into the question of surgical versus non-surgical management.

In 2021, the Netherlands COMPARE trial compared early ACLR (within 6-weeks of randomisation) with rehabilitation and delayed ACLR (minimum of 3-months) for acute ACL ruptures (within 2-months) (Reijman et al., 2021). The study included 167 participants, aged between 18 and 65, and reported a significant difference in patient-reported knee scores (International Knee Documentation Committee [IKDC], Knee Injury and Osteoarthritis Outcome Score [KOOS] and Lysholm) and quality-of-life (QoL) in favour of early reconstruction at 2-year follow-up. The conversion from rehabilitation to surgery, was also reported around 50% at an average of 10.6 months after randomisation.

Most recently, the UK ACL SNNAP pragmatic RCT compared surgery with rehabilitation (with the option of delayed ACLR) for non-acute ACL ruptures (>4-months from injury) in 315 participants (Beard et al., 2022). At 18-month follow-up it was concluded that those who received surgery had substantially better outcomes for self-reported knee outcomes ($KOOS_4$; mean of four KOOS sub-scales), QoL (Anterior Cruciate Ligament Quality of Life Questionnaire [ACLQOL]) and activity level (Tegner) than those in the non-surgical group (including those who had subsequent, necessary surgery). Of those in the rehabilitation arm, 41% went on to have surgery within 18 months. Cost-effectiveness was also estimated based on different threshold values per

quality-adjusted life-year (QALY) gained. The authors reported surgical reconstruction to be the most cost-effective treatment at £30,000 (72% probability) per QALY gained despite higher healthcare costs per individual in the surgical group (£3186 per surgical participant, £2169 per non-surgical participant). However, as there is currently no evidence to support best-practice rehabilitation, ACL SNNAP cannot determine the effectiveness of the rehabilitation received as a standalone treatment or prior to surgery. Those in the rehabilitation arm (n=159), received at least 6 sessions over a 3-month period. If the participant continued with symptoms associated with the ACL rupture (e.g. instability, pain, locking), treatment was considered unsuccessful, and participants were subsequently listed for ACLR following a shared decision made between the patient and clinical team. There were also no results reported for the content and number of rehabilitation sessions received by participants, so it is not clear how rehabilitation was delivered. Thus, uncertainty remains as to how to effectively rehabilitate a patient after an ACL injury regardless of whether they go on to have surgical reconstruction. Those in the KANON trial received a mean of 53 rehabilitation sessions which is a stark contrast to the minimum 6 sessions in ACL SNNAP. This demonstrates the uncertainty around the most effective rehabilitation and highlights the contrast of what is offered in clinical trials (KANON) versus clinical practice (ACL SNNAP, pragmatic RCT).

Interestingly, of 1403 patients screened for ACL SNNAP, 801 were deemed eligible to participate but 61% did not. The predominate reason was due to patient preference (n=391/485) for treatment with 57% opting for surgery and 24% opting for rehabilitation. This highlights the importance of patient

preference in the decision regarding treatment. It is also important to note, the acuteness boundary was relaxed due to difficulties with recruitment and 34% of the population (n=108/315) sustained an ACL injury less than 4-months prior to the point of recruitment. This makes the population slightly less transferable to NHS patients who have often waited more than 4-months.

In 2022, a living systematic review was published aiming to compare the effectiveness of surgery versus rehabilitation (with the option of surgery) for ACL injuries (Saueressig et al., 2022). This review included three studies, two of which are discussed above (KANON and COMPARE trial), and a third trial by Tsoukas and colleagues published in 2016, that compared function and activity levels and manifestations of OA 10 years after surgical or non-surgical treatment (Tsoukas et al., 2016). This concluded that there is very low to low certainty of evidence (according to Grading of Recommendations Assessment, Development and Evaluation [GRADE] scores), for clinically relevant differences in most outcomes between surgery and rehabilitation (with the option of surgery). However, this review did not include the most recent RCT results (ACL SNNAP) and will therefore be important to monitor as the authors update this yearly on their website (https://bit.ly/3ogGYIe). As of November 2024, there has been no further update.

1.3.2 BENEFITS AND NUANCES OF SURGERY

Further debate around the benefits of surgery have centred around its role in protection against further injury. It is a popular belief that surgery acts as a protective mechanism against the development of OA and further meniscal injury (Korpershoek et al., 2020; Wang et al., 2020). However, a 2022 umbrella

systematic review and meta-analysis (n=13, overall moderate level of bias) found surgical treatment to offer no reduction in OA prevalence compared with nonsurgical treatment in the long-term (Webster and Hewett, 2022). This was further supported by the 2022 living systematic review discussed in 1.3.1 (Saueressig et al., 2022). With regards to protection against meniscal injury, there is limited consensus amongst the literature. Anecdotally, it is a commonly reported benefit of ACLR dating back to Kurte Franke of Germany in 1969, who first recommended surgery to avoid further meniscal damage (Hazzard, 2014). A 2019 editorial reported that no high-quality evidence exists to suggest further knee injury rates are reduced in those who undergo ACLR (Filbay, 2019).However, best practice management guidelines for ACL injuries (developed by the British Association for Surgery of the Knee [BASK] and British Orthopaedic Sports Trauma Arthroscopy Association [BOSTAA]) suggests that ACLR protects against further meniscal injury (BOA et al., 2020), which was also reported in a 2020 systematic review (n=28, overall moderate level of bias) (Korpershoek et al., 2020). A 2022 systematic review and meta-analysis however, did report the risk of secondary meniscectomy to be lower in patients who had surgical treatment (risk ratio 0.34, 95% confidence interval (CI) 0.20 to 0.58) (Lien-Iversen et al., 2020). However, this was only supported by two studies (retrospective cohort n=109 [ACLR n=60, conservative treatment n=49] (Kessler et al., 2008) retrospective case series n=80 [ACLR n=40, conservative treatment n=40] (Streich et al., 2011)) and only reports those who went on to have a meniscectomy. Those who sustained a meniscal injury that did not affect function or require further surgery were not included. This review therefore, does not provide sufficient evidence to suggest further

meniscal injury is prevented by ACLR. Despite there being no compelling empirical evidence, it seems a consistent theory that ACLR protects against further meniscal injury. Further high-quality evidence is needed to provide clarity on this point of uncertainty that offers long-term follow up of patients proceeding with surgical or non-surgical treatment following an ACL tear.

In addition to the debate of whether to proceed with surgery, there are many nuances within the surgical procedure itself. First and foremost, the graft of choice. Typically, patients receive an autograft (their own tissue) using the hamstring or patella tendon; with hamstring autografts being the most common in the NHS (UK National Ligament Registry, 2020). Allograft (donor tissue) or synthetic grafts may be used, although these are less common. Further decisions within surgery include: portals of entry for surgical equipment, graft fixation location and device, graft diameter and lateral tenodesis (additional fixation outside the capsule) as an augmentation to the ACLR (BOA et al., 2020; Figueroa et al., 2018; Jurkonis et al., 2018). Although not directly influential to ACL rehabilitation, it is important to note other factors which may contribute to ACLR outcomes.

1.3.3 ALTERNATIVES TO SURGERY AND REHABILITATION

Interest in alternatives to ACLR and rehabilitation have begun to build in recent years, with contemporary evidence considering the potential of the ACL to self-heal following rupture. The ACL has long been considered to have poor healing potential in comparison to other soft tissue structures within the knee. Its healing potential has frequently been discussed, with reasons for poor healing including rupture location, age, altered cell metabolism, insufficient healing

environment due to synovial fluid, intrinsic cell differences and a lack of scaffolding to support ligament remnants to re-bridge (Costa-Paz et al., 2012; Kiapour and Murray, 2014; Murray, 2009; Murray et al., 2007; Pitsillides et al., 2021).

1.3.3.1 SELF-HEALING

In 2022, Filbay et al., published a secondary analysis of the KANON trial (discussed in 1.3.1) to explore evidence of ACL healing on MRI radiographs at two and five years, in participants who received non-surgical treatment (Filbay et al., 2022a).

Evidence of ACL healing was reported in 53% of patients managed with rehabilitation alone at 2-years (n=16) and 58% at 5-years (n=14). However, the results do not detail the site of the healed ligament (for example, whether this is located in its native anatomical position), only that there is continuity in the 'new' ligament. The functional integrity of the structure also remains unknown. There is also limited evidence for important confounding variables, so it is unclear what factors may support or inhibit ACL healing in this group.

The relationship between healing and functional outcomes was also explored and is summarised in Table 1.1.

Patient Reported Outcome measure	Time and healing status	2 years		5 years	
		Evidence of ACL healing	Non-healed	Evidence of ACL healing	Non-healed
KOOS	Sport/Rec	88 (14)	67 (28)	84 (25)	81 (19)
	QoL	76 (17)	54 (25)	77 (18)	61 (22)
	Pain	96 (6)	86 (14)	92 (13)	91 (9)
	Symptoms	94 (6)	81 (18)	91 (16)	87 (19)
Tegner Activity Score		6 (3) (6, 4-9)	6 (3) (6, 4-8)	5 (2) (6, 4-7)	5 (3) (4, 3-7)

Table 1.1 – 2 and 5-year outcomes and ACL healing status, KANON trial secondary analysis

Data displayed as mean (standard deviation, SD) for KOOS subscales and mean (SD) (median, interquartile range [IQR]) for Tegner. KOOS subscales are reported from 0 (extreme knee problems) to 100 (no knee problems). Tegner scores from 0 (sick leave or disability allowance due to knee) to Level 10 (competition in elite sport). Table adapted from Filbay, Roemer, et al., 2022, under the CC BY 4.0 licence.

KOOS sub-scales of Sport/Rec (function in sport and recreation), knee-related QoL, pain and symptoms were reported to be generally higher for those in the group with evidence of ACL healing at 2-years with mean differences from 10 to 22. Although scores remained generally higher at 5-years, mean differences were smaller from 1 to 16. The Tegner Activity Scores (TAS) were similar between groups at both two and five years. Those with evidence of ACL healing also scored on average, higher in each KOOS subscale at both 2- and 5-years than those who had an ACLR within two-years (two groups: (1) rehabilitation and delayed ACLR, (2) early ACLR and rehabilitation) with again smaller mean differences at the 5-year follow-up. The mean TAS remained the same across all groups at both time-points.

The study also reported the Patient Acceptable Symptomatic State (PASS) for KOOS and determined criteria for treatment failure. At 2-years, in those with evidence of ACL healing, 63-94% met the PASS threshold for any given KOOS subscale (sport/rec [81%], QoL [63%], pain [81%] and symptoms [94%]) and no participant met the criteria for treatment failure. In the non-healed group, 29-43% met the PASS threshold for the KOOS subscales (sport/rec [43%], QoL [29%], pain [43%], symptoms [43%]), with the treatment failure criteria met in 7% for KOOS pain, symptoms and sport/Rec and 21% for QoL. Thus, suggesting that those with evidence of ACL healing, experience favourable patient-reported outcomes compared to those who do not spontaneously heal.

This was the first study to report evidence of spontaneous ACL healing over time following rupture and so provides a foundation for further research. However, the study was insufficiently powered for this aim and so there is limited transferability of these results into clinical practice with unclear statistical significance. Research is needed to understand the properties of healing, factors associated with the healing potential of the ACL, whether a spontaneously healed ACL compares functionally to a patient managed with rehabilitation or ACLR, long-term outcomes of spontaneous healing, such as re-rupture and return to sport and finally, economic evaluation of spontaneous ACL healing.

1.3.3.2 CROSS-BRACING

In addition to self-healing, Filbay et al., (2023), published a case series (n=80) reporting the results of a 12-week bracing treatment (cross-bracing protocol, CBP) for the management of acute ACL ruptures (within 4-weeks). The CBP immobilised the knee at 90 degrees of flexion for 4-weeks, followed by 8-weeks

of progressive weekly increases in ROM (in addition to a supervised physiotherapy rehabilitation programme). The rational for the CBP was based upon the distance at which the ACL is at its shortest (between 90 and 135 degrees of knee flexion) and immobilising the knee to facilitate bridging of the torn ligament ends. Treatment outcomes were collected at 3-, 6- and 12-months (detailed in Table 1.2).

Follow-up time-point / **Outcome measure**	3-months	6-months	12-months
MRI (reported using the Anterior Cruciate Ligament OsteoArthritis Score [ACLOAS])*	✓	✓	
Passive knee laxity	✓	✓	
Self-reported knee function (Lysholm)			✓
Knee-related quality of life (Anterior Cruciate Ligament Quality Of Life Questionnaire [ACLQOL])			✓
Return to preinjury sport			✓

*ACLOAS grades; 0: normal ligament with hypointense signal and regular thickness and continuity, 1: thickened ligament and/or high intraligamentous signal with normal cause and continuity, 2: thinned or elongated but continuous ligament, 3: absent ligament or complete discontinuity (Roemer et al., 2014)

Table 1.2 – CBP outcome measures

At 3-months, 90% had a continuous ACL on MRI (ACLOAS grade 1 and 2). Participants with an ACLOAS grade 1 at 3-months (n=40) on MRI reported better self-reported knee function (Lysholm, p=0.01) and knee-related QoL

(ACLQOL, p<0.001) and had reduced passive knee laxity at 3- and 6-months (3 month lachman's [p<0.001], 6 month pivot-shift [p<0.001]) in comparison to those with ACLOAS grades 2-3 (n=40). Return to preinjury level of sport at 12-months was higher for those with ACLOAS grade 1 compared to ACLOAS grade 2-3 (p<0.001).

This supports the results from the KANON study, that signs of ACL healing are present, without surgical intervention, up to 5-years following rupture. Combined, the results identify a spectrum of ACL healing as graded on MRI. However, it remains unknown as to whether a continuous ligament observed on MRI compares functionally to a reconstructed ligament. Further, 11 re-ruptures (14%) were reported at the time of follow-up in the CBP study. It is unclear whether re-injury can be attributed to a reduction in the ligaments integrity as re-rupture rates are similar following ACLR, with a 2022 review reporting 7.2% of patients undergoing revision surgery within 9-years (Randsborg et al., 2022). Longer-term follow-up is warranted to understand subsequent injury rates following CBP management in addition to comparison of CBP against rehabilitation (with the potential of self-healing) and ACLR. This adds to the uncertainty around treatment decision-making following ACL rupture as it is unclear who CBP may be appropriate for.

1.3.3.3 ACL REPAIR

A 2021 systematic review, including 9 studies, reported a correlation between rupture location and healing potential; with a higher healing potential for proximal ligament tears (attributed to the covering sheath remaining intact) (Pitsillides et al., 2021). In addition, a 2022 MRI study of 14 human cadaveric knees supported that the proximal third of the ACL has greatest relative

perfusion at almost two times that of the middle and three times that of the distal third (Lin et al., 2022). Subsequently, in 2023, the National Institute for Health and Care Research (NIHR) in the UK and National Health and Medical Research Council (NHMRC) in Australia funded a multi-centred single-blind RCT to compare ACLR with ACL repair following a proximal ACL injury (March 2024-October 2029) (NHMRC, 2023; NIHR, 2024). This RCT will explore whether ACL repair (reattaching the torn ligament with stitches) is superior to ACLR.

1.3.3.4 ALTERNATIVE TREATMENT SUMMARY

Collectively these studies reveal an evident knowledge gap concerning optimum treatment for patients following an ACL rupture. It is currently unclear which treatment is best suited to individual patients. Whilst this poses a current challenge in ACL rupture management, it may become more problematic as new treatments are explored, reported and become available to patients in the UK, such as the CBP. Research to understand prognostic factors associated with improved outcomes for each management option are also warranted. There is further, very little evidence detailing the perceived and actual involvement of patients in treatment decision-making. Additionally, patients and clinicians' expectations of involvement in decision-making conversations specific to ACL injuries are unknown and so the challenges specific to this patient population are unclear.

1.4 MAKING DECISIONS ABOUT TREATMENT

Given the lack of consensus regarding optimal treatment, shared decision-making (SDM) is an essential component of healthcare conversations between

patients and clinicians regarding ACL injury management. The National Institute for Health and Care Excellence (NICE) and NHS England outline SDM as a core feature of good healthcare; with a commitment to embed SDM practices included in the NHS Long Term Plan (Carmona et al., 2021; National Institute for Health and Care Excellence, 2021a; NHS England and NHS Improvement, 2019a). NHS England describe SDM in their Shared Decision-Making Summary Guide, as “a relationship between people, professionals and the health and care system” (NHS England and NHS Improvement, 2019a). Recognising these three components, the requirements from each and their interaction is key to unpacking SDM.

1.4.1 PEOPLE

The NHS Long Term Plan emphasises the benefit of integrated SDM across the health and care system in ensuring personalised care (National Health Service, 2019). Thus, the person/patient should be at the centre of healthcare decision-making. To make decisions, patients require: (1) adequate information, (2) choice and (3) an understanding of their needs and what matters to them (Elwyn et al., 2012). These components were described in a model for enacting SDM in clinical practice which translated conceptual descriptions of SDM into a 3-step process as the authors of the model acknowledged a lack of literature guiding clinicians on how to do SDM. The model included: (1) choice talk, (2) option talk and (3) decision talk. Choice talk conveys that there is a choice to be made, option talk involves discussing detail with patients about their options, and decision talk ensures patients are supported to understand and communicate their preferences.

SDM practices have been shown to improve patients' knowledge and increase involvement in their care (Arastu et al., 2015). However, motivation to be involved in decision-making is multifaceted and is described to be influenced by personal preferences, level of risk, perceived importance of the decision, fear of a negative outcome and cultural, social and economic factors (Bernhardsson et al. 2017; Grenfell & Soundy 2022; Stenner et al. 2016).

Thus, patients require support from clinicians to move through each step of the model in addition to time to consider the new information, deliberate their choice and consider the outcomes of each option.

1.4.2 PROFESSIONALS

Healthcare professionals are cornerstone in ensuring patients can engage in SDM. As described by Elwyn et al., (2012), the foundations of SDM lie in good clinical communications skills, including the clinician's ability to build rapport and provide structure to consultations. A 2021 qualitative systematic review summarised 14 articles to describe barriers and facilitators to implementing SDM in tertiary care (Waddell et al., 2021). Barriers identified as clinician-related factors were mapped to the theoretical domains framework (Michie et al., 2005) and described under 14 headings. Review findings assessed to have high confidence according to Confidence in the Evidence from Reviews of Qualitative research (CERQual) (Lewin et al., 2018a, 2018b) highlighted barriers defined as clinician-related to include: no or a lack of knowledge of SDM, a lack of time to enact SDM within the constraints of healthcare consultations, self-perception that the clinicians role is to be responsible for making healthcare decisions and to not do so would appear indecisive (with

many clinicians deciding on treatment plans ahead of clinical consultations intending to 'sell' the patient the treatment they have selected) and the belief that patients do not wish to be involved in SDM (Waddell et al., 2021). Some of these barriers have previously been highlighted, in addition to accounts of clinicians who believe they are practicing SDM, but results of patient experience surveys do not support this to be true (Coulter, 2010; Zikmund-Fisher et al., 2010). Thus, the first step for clinicians is ensuring they agree with the underlying principles of SDM and recognising their role in enabling it (Elwyn et al., 2012; Hoffmann et al., 2014). Therefore, appropriate training and support is essential for clinicians to enact and facilitate patients to enact in SDM.

1.4.3 HEALTH AND CARE SYSTEM

The health and care system provides the opportunity for SDM by ensuring the capacity and potential for its implementation. High and moderate confidence system-level and organisational-level facilitators to SDM, as reported by Waddell et al., (2021), include changing clinical guidelines to promote SDM, display of leaders engaging in SDM and a presence of a culture that supports clinicians to engage in SDM. Moderate confidence findings for barriers to SDM include a lack of formal training, noisy or busy ward environments to conduct SDM conversations and a lack of private space for consultations. The health and care system is therefore a key component in enabling SDM.

1.4.4 SHARED DECISION-MAKING MODELS AND TOOLS

In 2019, Bomhof-Roordink et al., completed a systematic review of 40 articles describing 40 SDM models to outline key components of SDM. In total, 53 elements were identified which were clustered in 24 components (Bomhof-Roordink et al., 2019). The five most common components included: (1) describe treatment options (88%), (2) make the decision (75%), (3) patient preferences (65%) and tailor information (65%), (4) deliberate (58%), (5) create choice awareness (55%). However, although many similarities between the models were described, the authors highlighted significant heterogeneity in line with that previously reported by Makoul and Clayman (2006). Furthermore, although patient preferences were the third most common component, views of patients and/or clinicians were only considered to inform 14 of the 40 models. Thus, highlighting the disconnect between those developing SDM models and those enacting it in clinical practice.

To provide further understanding to the enactment of SDM, Waldron et al., (2020) explored contributors to engagement through a realist synthesis. They produced a program theory outlining engagement in SDM (depicted as the outcome) comprising of three contexts and eight mechanisms, to consider how SDM works, for whom, in which circumstance and why. The identified contexts included pre-existing relationship, difficulty of decision and health system support. The eight mechanisms included perception of other party capacity, anxiety, perception of time, trust, self-efficacy, world view, perception of capacity to access external support and recognition of decision. Each concept was identified to positively or negatively impact upon engagement in SDM,

recognising that more than one may operate to influence the outcome and may manifest in both the patient and clinician.

In addition to the barriers and facilitators discussed above, SDM practices can further be supported by patient decision aids (PDAs) or SDM tools. NICE emphasise the need for these to be evidence-based, relevant to the patient and the context and be used as part of a toolkit. A 2017 Cochrane review of decision aids for people facing healthcare decisions summarised 105 RCTs evaluating PDAs for 50 different decisions (Stacey et al., 2017). The review reported high-quality evidence that, in comparison to usual care, PDAs were more effective: (1) on knowledge scores, (2) in reducing patients 'feeling uninformed' about options, benefits and harms and (3) reduced patients 'feeling unclear about values'. Moderate quality evidence supported the use of PDAs for transmitting accurate risk perceptions and reducing clinician-controlled decision-making when compared to usual care. Low quality evidence was found in favour of PDAs for selecting an option congruent with an individual's values. Further, a significantly lower proportion of patients remained undecided after exposure to a PDA (n=22) and reported higher satisfaction with choice (n=4). Although the review included only four studies in the orthopaedic/musculoskeletal field (knee and/or hip osteoarthritis), a statistically significant reduction in the number of patients choosing major elective surgery was reported in the groups receiving a PDA compared to usual care (across specialties and after removal of one study in women carrying the BRCA1/2 gene who were offered a prophylactic mastectomy). In addition, consultation length was reported in 10 studies, with two reporting significantly longer consultations and eight reporting no statistically significant difference in

length. This addresses the pragmatic concerns highlighted by clinicians identifying time constraints as a barrier to SDM (Waddell et al., 2021). Total cost was assessed in only five studies, with two reporting no statistically significant difference, two reporting a higher cost in the PDA group (when accounting for interactive video disc equipment) and one reporting a mean total saving in the PDA group. Thus, the use of PDAs seems to have a positive effect on multiple areas of clinical practice.

SDM enables patients to have a voice, be heard by healthcare professionals and connected to the healthcare system and their own health. SDM must therefore, be embedded within the treatment pathway and be responsive to the requirements of the patient, professional and healthcare system/organisation in which it operates.

1.4.5 SHARED DECISION-MAKING IN ACL INJURY MANAGEMENT

The 2019 Panther Symposium ACL Treatment Consensus Group released 11 statements agreed upon for the management of ACL injuries; of which two relate to treatment decision-making (Diermeier et al., 2021). The first, reaching 100% agreement, was that “operative and non-operative treatments are both acceptable treatment options for ACL injury” and second, reaching 82.6% agreement, was that “operative versus non-operative treatment should be reached via a shared decision-making process that considers the patient’s presentation, goals and expectations as well as a balanced presentation of the available evidence-based literature” (Diermeier et al., 2021). However, two recent qualitative studies exploring Swedish patients’ experiences of rehabilitation following ACL rupture suggest that this does not mirror decision-

making in clinical practice (Piussi et al., 2023; Simonsson et al., 2024). Although the primary aim of the studies was not to describe decision-making practices, the authors reported experiences of several patients reflecting that: (1) treatment decisions were viewed by patients to be the responsibility of the orthopaedic surgeon and (2) when a 'wait and see' approach was recommended (i.e. a trial of rehabilitation prior to proceeding with surgical intervention) this was perceived by patients as the clinician's inability to decide on appropriate treatment (Piussi et al., 2023; Simonsson et al., 2024). There is no current evidence describing patients' involvement in decision-making regarding ACL treatment in the UK.

It is therefore clear that an evidence gap exists presenting multiple challenges in relation to shared decision-making for patients following an ACL rupture. Firstly, translating the need for shared decision-making into clinical practice to both patients and clinicians, second in understanding patients' experiences relevant to a UK context and finally, understanding how shared decision-making operates in UK practice and how this is perceived by patients and clinicians.

1.5 OUTCOMES OF ANTERIOR CRUCIATE LIGAMENT SURGERY

There is no standard set of outcomes determined to define the success of ACLR and there are a wide range of validated outcome tools (Svantesson et al., 2020). Often, surgeons aim for a successful procedure with minimal post-operative complications, rehabilitation professionals aim to optimise function and facilitate return to activity, and patients most commonly aim to return to

their preinjury level of activity (varying from return to work [RTW] through to elite sport).

Cohort studies in Germany (2016, n=181) and Australia (2019, n=675) have revealed that 88-91% of patients expect to return to their preinjury level of activity following ACLR (Feucht et al., 2016; Webster and Feller, 2019b). This is unsurprising, given the key driver for the decision to proceed with surgery is to facilitate return to preinjury activity levels (Webb et al., 1998). However, this outcome is frequently documented to be sub-optimal. For example, a 2014 systematic review reported a return to sport (RTS) rate of 55% (pooled data from 30 studies) following ACL surgery (primary and revision ACLR) at an average follow-up of 40 months (range 12-156 months) (Ardern et al., 2014b). However, research reporting the true return to preinjury activity levels is much lower, with only 24% achieving this at 1 year (cohort study, n=675, 2019) (Webster and Feller, 2019a), 28% at 18-months (RCT, n=316, 2022) (Beard et al., 2022), and less than 45% returning at 2 years (multi-centred cohort, n=446, 2010; case series, n=122, 2015) (Ardern et al., 2015; Dunn and Spindler, 2010). Psychological factors are the most commonly cited reason for failing to return to preinjury levels after ACLR (Ardern et al., 2014a; Flanigan et al., 2013; Kvist et al., 2005). Those who fail to return may cease engagement in physical activity completely and experience negative impacts to their quality of life, physical and mental health (Filbay et al., 2016, 2017).

A 2017 survey of 125 Dutch adults reported a full RTW in a median timeframe of 78 days post-surgery (IQR 49-112 days). A return beyond 78 days was most likely for those performing knee-heavy work and those who required crutches to facilitate walking for a greater number of weeks following surgery (Groot et

al., 2017). Similarly, a 2022 Finnish study reported a mean RTW of 65 days post-ACLR with longer periods of absenteeism reported for those returning to manual work, aged 40 and older or who had a period of sickness preoperatively (Arimaa et al., 2022). As there is no evidence-based advice available for RTW after ACLR and no standard outcome of measurement, it is difficult to determine the impact and burden of ACL injuries on society beyond treatment costs in the NHS. However, a recent systematic review, including three European studies, assessing the economic burden of ACL injuries reported large direct and indirect costs to healthcare and society in addition to costs associated with absences from work and reduced productivity (Filbay et al., 2022b). For example, one RCT reported that per QALY gained there was a cost of over 48,000 euros from a healthcare perspective and over 78,000 from a societal perspective for early ACLR compared with rehabilitation and the option of delayed ACLR (Eggerding et al., 2022). Although early ACLR was not deemed to be cost effective, this demonstrates the large healthcare and societal costs. At present, there is no systematic review of cost-effectiveness studies to understand the long-term costs of ACL injury managed with or without surgical intervention.

As there is no universally agreed set of outcome measures, several are currently used (Meta et al., 2017). The most recent consensus statement (2020, modified Delphi exercise) suggested the use of outcomes in four categories, shown in Table 1.3, with a minimum two-year follow-up (Svantesson et al., 2020).

Category	Example Outcomes	Example Measurement Tools
1. Adverse events	• Intraoperative complications • Surgery of device related complications • Infections • Venous thromboembolism (VTE) • Re-operation	Recommendation for these outcomes to be collected within the first year with adverse events reported as soon as possible.
2. Patient Reported Outcome (PRO)	• Validated knee-specific outcome score • Psychological measures • Health related quality of life (HRQoL) • Activity level • Return to sport	36-Item Short Form Survey (SF-36); EuroQol- 5 Dimension (EQ-5D); Assessment of Quality of Life (AQoL-8D); ACLQOL; ACL Return to Sport after Injury (ACL-RSI); Knee Self Efficacy Scale (K-SES); Tampa Scale of Kinesiophobia (TSK-11); KOOS; IKDC; Cincinnati Knee Rating System (CKRS); Knee numeric-entity evaluation score (KNEES-ACL); Marx Scale; TAS.
3. ACL graft failure/ recurrent ligament disruption	• Graft rupture/failure • ACL revision • Contralateral ACL injury	
4. Clinical measures of knee function	• Strength • Hop testing • Performance • Knee joint laxity • Range of movement • Imaging • Osteoarthritis • Concomitant knee joint injuries	Muscle strength (e.g. quadriceps, hamstrings); single hop; triple hop; crossover hop; six-meter timed hop; KT-1000; Kellgren and Lawrence

Table 1.3 – Outcomes of ACLR

Table adapted from Svantesson et al., 2020 under the CC BY 4.0 Licence.

Although these categories were suggested, no specific tools have been agreed upon to assess each domain. Furthermore, the consensus group

acknowledged that there is a fine line between multiple outcome measures and responder burden (Svantesson et al., 2020). Further work is needed to migrate these agreed outcome domains into research trials to determine a key set of core outcome measures to support standardised reporting and collation of evidence.

1.5.1 PREOPERATIVE PREDICTORS OF RETURNING TO PHYSICAL ACTIVITY

Returning to physical activity (RTPA) is the primary goal for most patients following ACLR. A 2023 systematic review summarised the modifiable preoperative predictors of this outcome (Carter et al., 2023b). The population of focus was adults aged 18-65 who had undergone primary ACLR. Eight studies were included in the review, investigating a total of 715 participants, reporting 18 preoperative predictors categorised as physical (7), psychosocial (6) or demographic/clinical factors (5). Four were found to be predictive of RTPA including quadriceps strength, psychological profile, patient estimated ability to return and graft type (bone-patella tendon-bone graft). Physical activity was reported using five different outcome measures (Tegner, Marx, Physical Activity Scale [PAS], return to play at elite level and return to preinjury level) at a range of time-points from 1 to 10 years post-operatively. A risk of bias assessment, using the Quality in Prognostic Studies (QUIPS) tool, identified five studies as high risk and three as moderate risk of bias. The GRADE system was also used to rate each predictive variable. All 18 preoperative predictive factors were reported to be of very low quality. Thus,

the available evidence describing modifiable factors for areas of focus prior to surgery is poor in both quantity and quality.

However, in absence of guidance for the preoperative phase of care (discussed in 1.6.1), the review findings offer a foundation for future work. The review highlighted that, where rehabilitation before surgery has previously focused on physical components alone, there may also be benefit in targeting psychosocial and clinical/demographic factors. Two psychosocial factors, high psychovitality (psychological profile) and patients' positive estimation of their ability to return, were identified to be positively associated with returning to physical activity following ACLR. Psychovitality was measured by a bespoke questionnaire with the aim of assessing a patient's expectations of treatment and motivation to resume physical activity. Preoperative expectations are an important area of focus given they have previously been associated with motivation to engage in rehabilitation and satisfaction (Jain et al., 2017; Smith and Choma, 2017; Sonesson et al., 2017). Further, patient expectations of ACLR are frequently reported to be high and are in contrast to reported outcomes (El-Haddad et al., 2020; Feucht et al., 2016; Webster and Feller, 2019a). Findings from the review suggest that those with low expectations and motivation (reported as low psychovitality) are less likely to return to physical activity following ACLR. Thus, ensuring expectations are realistic and in-line with evidence-based data is essential, in addition to addressing patients' motivation levels.

In addition to modifiable factors, there are some non-modifiable factors described in the literature to be predictive of postoperative ACLR outcomes. Fewer years of education, lower mental health and higher preinjury Marx

activity scores were reported to be predictive of the inability to return to preinjury activity levels in a US cohort study of 1188 patients (MOON Knee Group et al., 2023). Younger age has also been shown to support a return to preinjury activity levels (Ardern et al., 2012a). Research regarding the influence of sex and/or gender (often used interchangeably) has however been contradictory, with some studies reporting males as more likely to return (Ardern et al., 2011; Glasgow et al., 1993; Thing, 2006) and others demonstrating similar RTS rates (Shelbourne et al., 2008). Most recently, a 2023 Australian cohort study (n=1080) reported RTS rates in men and woman 2-7 years after ACLR (Klemm et al., 2023). Although woman had a significantly lower RTS rate compared to men (overall 9.5% lower rate), when grouped by age, significance was only reached for those in the 20-29 age group (p=0.01). Geographical location was also reported to influence RTS rates with a lower rate of return reported for women living in metropolitan areas compared to those in rural locations. A 2023 systematic review and meta-analysis further reported very-low quality evidence (using GRADE) that females (women/girls) had inferior self-reported activity compared to males (men/boys) and reduced odds, of approximately 25%, of returning to sport after injury/reconstruction within 1-year, 1-5 years and 5-10 years (Bruder et al., 2023).

1.6 THE ROLE OF REHABILITATION

Rehabilitation for an ACL injury and subsequent reconstructive surgery can be defined at two stages: (1) prior to surgery, known as preoperative rehabilitation or prehabilitation, (2) after surgery, known as postoperative rehabilitation.

1.6.1 PREOPERATIVE REHABILITATION (PREHABILITATION)

Guidance regarding prehabilitation is limited (Carter et al., 2021, 2020). A 2020 worldwide survey of physiotherapeutic practice explored the preoperative management of patients awaiting ACLR; 183 respondents replied (122 complete responses) from 20 countries (geographic spread shown in Table 1.4) across 3 settings (public and private health services and sports) (Carter et al., 2021).

Country	Number of Responses
Australia	8
Austria	1
Denmark	1
Finland	1
Ghana	1
Hong Kong (S.A.R.)	1
India	4
Ireland	7
Israel	1
Italy	3
Netherlands	1
New Zealand	1
Norway	1
Poland	1
South Africa	1
Sweden	2
Switzerland	1
Turkey	1
United Kingdom of Great Britain and Northern Ireland	67
United States of America	18

Table 1.4 – Geographical spread of survey responses

The results indicated that advice, education and exercise (variety of exercise types) comprised the mainstay of treatment during prehabilitation, however there was disparity in reporting for exercise frequency and treatment length. A

range of other interventions were also reported (e.g. manual therapy, electrotherapy, bracing), supporting the notion that prehabilitation lacks consensus.

A 2019 narrative review on ACL rupture recommendations suggests prehabilitation completion, starting as soon as possible after diagnosis, to improve postoperative outcomes (Filbay and Grindem, 2019). These recommendations advise that the main goals of this phase are: no knee joint swelling, full active and passive ROM and 90% quadriceps strength symmetry. However, the authors fail to refer to any evidence to support their proposal of these goals. Instead, they suggest that prehabilitation is led by an experienced clinician. Despite psychological factors being cited as the most common reason for failing to return to preinjury levels of activity, they are not addressed in these recommendations. This is in contrast to other published recommendations (2016 and 2017) which suggest that the function of prehabilitation is to physically and mentally prepare patients for surgery and postoperative rehabilitation (Gokeler et al., 2017; Wilk and Arrigo, 2016). Furthermore, research has supported the need to consider psychological factors with associations found between pre- and post-operative psychological responses and returning to sport/preinjury levels of physical activity (Ardern et al., 2012a, 2013, 2014a, 2015).An individual's psychological readiness has also been shown to predict return to performance following ACLR (Webster et al., 2018). It has been highlighted that an individual's response to injury, surgery and rehabilitation is an important consideration in ACL treatment and that the role of psychological factors has been undervalued (Ardern et al.,

2011b, 2012b; Brand and Nyland, 2009; Kvist et al., 2005; Langford et al., 2009; McCullough et al., 2012; Webster et al., 2008).

Not only is the content of prehabilitation debated, but evidence supporting its effectiveness is also unclear. A 2020 systematic review explored the effectiveness of prehabilitation on postoperative outcomes following ACLR (Carter et al., 2020).The review included three, low-quality, RCTs of prehabilitation programmes that varied in content, frequency and length and evaluated the effects on muscle strength (n=1), function (n=2), pain (n=1) and RTS (n=1). Results concluded that prehabilitation including strength, balance and perturbation training, when compared to no prehabilitation (n=2) offers small benefits (established through effect size calculations) to quadriceps strength and single leg hop distance (a commonly used postoperative functional test) three months after ACLR. The remaining three studies in the evidence base were excluded from the review due to study design (not RCT) but did report positive effects of prehabilitation on postoperative objective and subjective outcomes (Failla et al., 2016; Grindem et al., 2015; Logerstedt et al., 2013). However, the study designs introduce high levels of risk of bias and thus generalisability is limited. The evidence base lacks evaluation of prehabilitation on psychosocial factors and outcomes; paradoxically, these are key components highlighted in the literature to predict postoperative outcomes and influence return to preinjury levels of activity (Ardern et al., 2014a, 2013; Langford et al., 2009; Webster et al., 2008).

A 2022 evidence synthesis of systematic reviews (OPTIKNEE consensus) exploring effectiveness of rehabilitation interventions following ACL tears further confirmed that there is little consensus amongst the literature regarding

optimal components of ACL rehabilitation (both prior to and after surgery) leading to marked heterogeneity in practice (Culvenor et al., 2022). In the wider orthopaedic and surgical literature, prehabilitation has been described to improve: functional recovery, fear avoidance beliefs, coping strategies, patient satisfaction, overall outcomes, mental preparation for surgery, patient involvement, sense of control and trust in staff members whilst reducing length of stay and complication rates. This however, is in a range of populations (including spinal, total knee replacement, total hip replacement, abdominal, cancer, cardiac and vascular surgery) and so transference of results to the surgical ACL population is limited (Conradsen et al., 2016; Gometz et al., 2018; McIsaac et al., 2022).

1.6.2 POSTOPERATIVE REHABILITATION

Postoperative rehabilitation is lengthy, lasting up-to and beyond 12-months for most individuals. Early rehabilitation focuses on regaining movement, reducing swelling, improving gait, and beginning lower limb strengthening (Filbay and Grindem, 2019). As previously discussed, dependent upon occupation, RTW is often achieved by 12-weeks (and may be earlier in less labour-intensive roles) (Groot et al., 2017), as is return to running (in those aiming to do so) (Rambaud et al., 2018). Return to higher level activities progressing from restricted activity (e.g. drills including changing direction) to unrestricted participation is typically delayed until 6-12 months post-surgery (Filbay and Grindem, 2019; Nagelli and Hewett, 2017).

Whilst outline timescales are often provided to patients, there is considerable heterogeneity in the rehabilitation protocols available online and in the

literature (Greenberg et al., 2018; Makhni et al., 2016; Thrush et al., 2018). The NHS website (Knee ligament surgery - Recovery - NHS, n.d.), for example, suggests RTS may be possible after 6 months, but this is well-regarded in the ACL evidence base as much too early, in-fact putting the patient at increased risk of re-injury (Meredith et al., 2020). Post-operative progression has previously been measured against time-based criterion alone, considering the biological healing of the ACL graft in isolation of other factors (Filbay and Grindem, 2019). However, over the last decade, emphasis has been placed on measuring progression against objective markers (such as quadriceps strength, hop test symmetry and psychological outcomes), with rehabilitation individualised to each patient (Andrade et al., 2020; Filbay and Grindem, 2019a). In fact, progression against time-based criterion alone, is now considered insufficient (Dingenen and Gokeler, 2017; Grindem et al., 2016).

Further, the burden of postoperative rehabilitation is often accounted with patients frequently reporting to be unprepared for the length and content of treatment (Heijne et al., 2007). A 2021 cross-sectional survey of adults (>90% residing in Australia) between 1 and 20 years post-ACLR identified barriers to completing recommended rehabilitation following ACLR (Walker et al., 2021). Fear of reinjury was the highest rated barrier (>60% indicated this affected their ability to complete recommended rehabilitation ‘quite a bit’, ‘a lot’ or ‘some’) followed by the length of and commitment required for rehabilitation (>45%).

A 2020 scoping review identified 36 articles (n=10 review, n=26 primary research) describing barriers and facilitators to ACLR rehabilitation (Walker et

al., 2020). Fifteen primary research studies described patient perceived barriers to rehabilitation in the categories of environmental (including social and societal), personal (including psychological, physiological and behavioural) and treatment-related (including delivery of care, provider factors, digital health, and group rehabilitation). A frequency count identified delivery of care factors as the most commonly identified barrier (n=18, such as length and commitment of rehabilitation, non-sport specific exercise and restrictions in activities) followed by psychological factors (n=16, such as fear, self-motivation and unmet expectations), provider factors (n=12, such as therapeutic relationship and information availability) and physiological, behavioural and social factors (n=6, such as pain, weakness and illness, organisation/lack of time and interaction with friends/family/team/coaches).

A 2022 Australian qualitative study comprising of three focus groups with 6-7 participants (n=20) between 1- and 20-years post ACLR explored patient-reported barriers to ACLR rehabilitation (Walker et al., 2022). Several factors were identified to inhibit engagement with rehabilitation similar to those reported in previous research including the length of treatment and time commitment required, competing life demands, treatment cost, and plateaus, slow progress and setbacks in rehabilitation. Further, participants described difficulty with understanding what was required of them during rehabilitation as prescribing therapists where unclear with instructions and overused technical language. Participants also discussed the absence of adequate information during rehabilitation and thus, the need to seek external sources to understand their progress, answer questions and offer motivation whilst also expressing concern about the validity of the information they found. Finally, consistent with

other interview and online questionnaire studies exploring psychological responses after ACLR (Ardern et al., 2013; Mahood et al., 2020), fear of reinjury and kinesiophobia presented significant barriers to completing rehabilitation (particularly towards the latter stages when returning to jumping and change of direction activities) and returning to sport.

In addition, there is also controversary around the decision making to support patients to RTS and the terminology that is used (Meredith et al., 2020). What is known, is that RTS decision making is complex and multi-factorial (Ardern et al., 2016). A 'test battery' is commonly used which comprises of several clinical tests. However, it is well documented that, typically, the proportion of patients who pass these test batteries, and are therefore deemed 'safe' to return, is low (Webster and Feller, 2019b). A 2016 consensus statement on RTS outlines the process as a continuum comprising of 3 stages: (1) Return to participation (2) Return to sport (3) Return to performance (Ardern et al., 2016). It was further recognised by the Panther return to sport consensus group in 2020 that RTS can vary significantly among individuals and may take some, up to 2-years (Meredith et al., 2020).

1.7 RATIONAL FOR FURTHER RESEARCH AND PHD OVERVIEW

At present, the evidence does not provide consensus for clinical practice regarding the management of patients following ACL rupture. The care currently provided in the NHS therefore varies widely and may not be clinically or cost effective. The evidence gaps support the need to develop an intervention that is implementable within an NHS setting to support patients following ACL rupture.

This PhD therefore set out to develop an intervention for use post-injury and/or prior to ACLR surgery and was funded by HEE/NIHR Clinical Doctoral Research Fellowship (CDRF). The proposal was peer-reviewed as part of the CDRF application and funding process.

1.8 PROJECT AIMS

The primary aims of this research were to:

- Develop an intervention for use with patients post-injury to support decision-making around ACLR
- Understand the interventions acceptability and tolerability among patients and clinicians
- Explore indicators of the intervention's effectiveness and implementation factors in clinical practice

1.9 PROJECT OBJECTIVES

This research involved a three-phase approach to address the above aims.

Objective 1: To understand patients' lived experiences of the treatment pathway following a diagnosis of an ACL rupture and planned surgical management (Phase 1).

Objective 2: To work with patients and stakeholders to develop a novel intervention (Phase 2) to address the patients' unmet needs identified in Phase 1.

Objective 3: To understand feasibility, acceptability and tolerability of the intervention with respect to participants and clinicians in an NHS setting (Phase 3).

1.10 PROGRAMME OF WORK

The planned programme of work is summarised in Figure 1.2, demonstrating an overall study flow chart. On application for NIHR funding and ethical approval, the study title was 'The **P**re**O**perative Management of **P**atients Awaiting **A**nterior **C**ruciate **L**igament **R**econstruction: The **POP-ACLR** Study'.

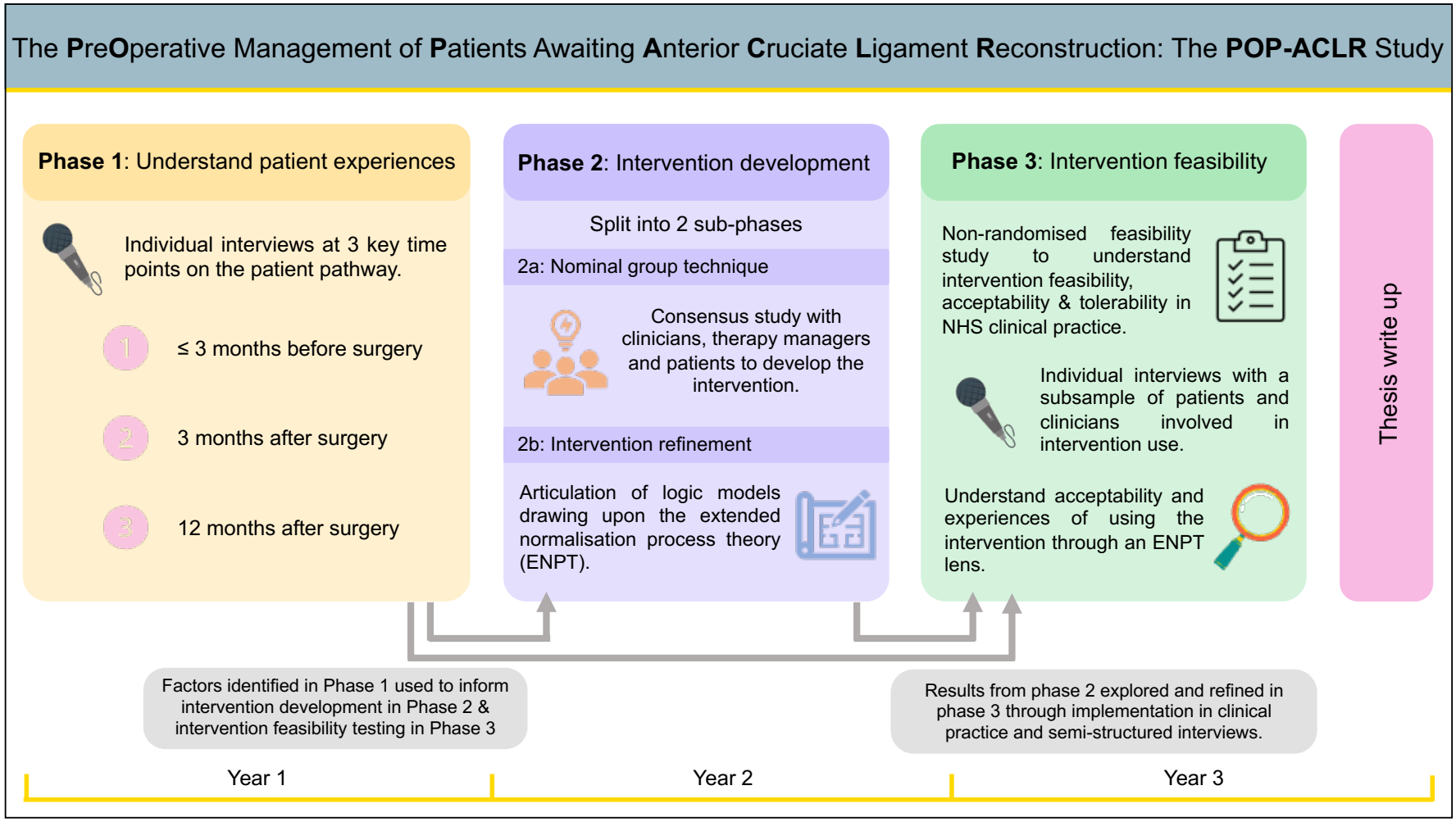


Figure 1.2 – POP-ACLR study flow chart

The proposed intervention was developed in response to need, as identified during the qualitative interviews (Phase 1). Given the prior work completed and the identified gap within the evidence base, the underlying theoretical basis for the intervention was a biopsychosocial rehabilitation intervention supporting patients to both physically and mentally prepare for surgery. However, during the qualitative interviews (Phase 1) a need became apparent to take a step back in the patient pathway to consider decision-making about treatment following an ACL injury (discussed further in Chapter 3). The co-designed intervention (Phase 2) therefore took the shape of an SDM tool, discussed in Chapter 4. The overall programme of work did not change, nor did the methodology or research method used in each phase.

Chapter 2 presents methodology for the research, Chapters 3-5 present the results of each phase (as described above) with an overall discussion and conclusion in Chapter 6.

CHAPTER 2 METHODOLOGY

Summary

This chapter presents the methodological approach to the research in addition to an overview of complex intervention development and the underpinning theory, Normalisation Process Theory.

The studies presented in this PhD thesis used a mixed methods approach to reflect the research objectives presented in Chapter 1. As suggested in the Medical Research Council (MRC) framework (Skivington et al., 2021) and O'Cathain et al's (2019a) guidance for complex intervention development, a theoretical framework was also chosen to underpin this work; the Normalisation Process Theory (NPT) (May and Finch, 2009).

2.1 PHILOSOPHICAL ASSUMPTIONS

Crotty (1998), outlines four levels in the evolution of a research enquiry, shown in Figure 2.1.

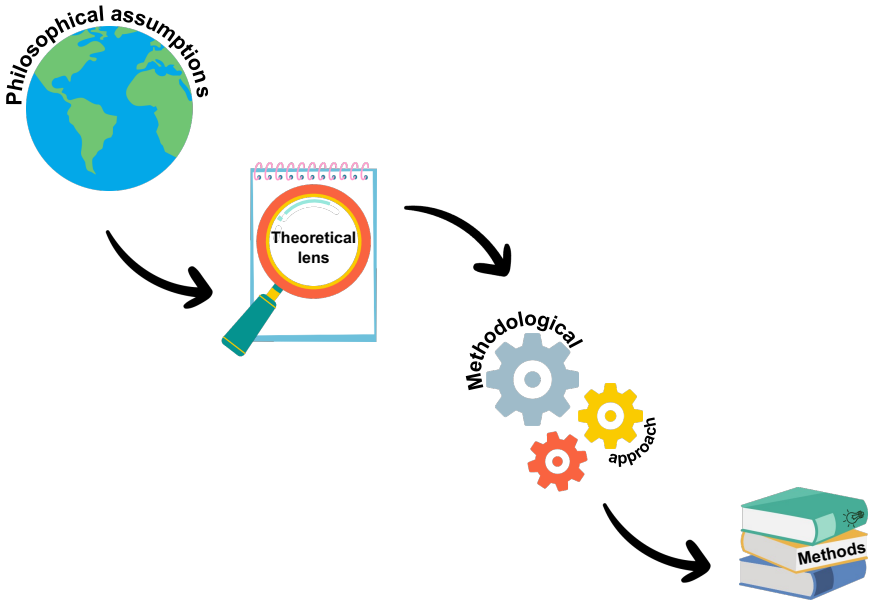


Figure 2.1 – Evolution of research enquiry

Foundational philosophical assumptions, typically referred to as a researcher's 'worldview', describe a broad set of beliefs that guides the line of enquiry (Creswell and Clark, 2018). These are often discussed in relation to an individual's ontological and epistemological beliefs. Ontology refers to beliefs about the nature of existence and study of being, with realism and idealism as the two primary contrasting perspectives (Benton and Craig, 2010). Realism represents the idea of a single external reality which can be objectively studied, whereas idealism captures the idea that no single external reality exists; rather multiple realities exist and are only bought to life by what one perceives and thus constructs via mental processes (Blackburn, 2016). The contrasting views are often related to knowledge that is objective (realist) versus that which is subjective (idealist). Epistemology is the theory of knowledge and spans a spectrum between positivism, describing knowledge that can be discovered (typically through quantitative methods), and interpretivism where knowledge is subjectively interpreted (Benton and Craig, 2010).

Crotty (1998) further describes that in turn these assumptions influence the theoretical lens the researcher may use, which subsequently informs the methodological approach and selected methods. There are four worldviews described by Creswell and Clark (2018) to be most useful in informing mixed methods research including: (1) post-positivism, (2) constructivism, (3) transformative approach and (4) pragmatism. Most recently, critical realism (which combines a realist ontology with a constructivist epistemology) has also been described by Maxwell and Mittapalli in the SAGE Handbook of Mixed Methods of Social and Behavioural Research as an informative worldview for mixed methods research (Tashakkori and Teddlie, 2010).

Post-positivism emerged following dissatisfaction with the positivist approach to human science in the 1950s; it's predominantly concerned with quantitative methods underpinned by deterministic thinking, reductionism, empirical observation, and measurement for the purpose of theory verification (Creswell and Clark, 2018; Teddlie and Tashakkori, 2009). Constructivism centres around theory generation with researchers constructing the meaning of the phenomena under investigation and is predominantly associated with qualitative methods (Creswell and Clark, 2018; Teddlie and Tashakkori, 2009). The transformative approach is a variant of critical theory taking a political, activist approach placing central importance on social justice and emancipatory research (Creswell and Clark, 2018; Teddlie and Tashakkori, 2009). Finally, pragmatism is described as a problem centred approach, oriented around real-world practice with a focus on "what works". It abandons the dichotomy of post-positivism and constructivism and values both qualitative and quantitative research within the same study. Pragmatism

focuses less on ontology (the nature of existence and study of being) and epistemology (the theory of knowledge) and instead draws on diverse approaches to research questions, allowing the selection of methods that best suit the problem at hand (Creswell and Clark, 2018; Teddlie and Tashakkori, 2009). As this PhD encompassed a mixed methods approach involving both qualitative and quantitative research with convergence of results to answer the primary aim, a pragmatic approach was taken.

There are examples throughout this thesis (particularly Chapters 3-5) of decision making in line with the pragmatic philosophy. One such example is the decision to cease interviews during Phase 1 of this research (described in Chapter 3). The sample size was based on a framework anticipating thematic saturation to be reached by 12 interviews (Guest et al., 2006; Hennink et al., 2017), similar to qualitative interview studies of patients with shoulder and knee pain of musculoskeletal origin (Cuff and Littlewood, 2018; Smith et al., 2018). Interviews were planned with patients at three time-points on the surgical pathway following an ACL rupture to capture experiences before surgery (time-point 1), 3-months after surgery (time-point 2) and 12-months after surgery (time-point 3). The estimated sample size was therefore 36 participants (12 at each identified time-point). On commencing the study however, it became apparent that although there were some unique experiences at each time-point, the distinctions were not as apparent as anticipated prior to commencing the study. In addition, recruiting participants at the 12-month time point proved challenging. After consulting with Physiotherapy and Orthopaedic colleagues, it was felt this difficulty was most likely due to patients being discharged from hospital services prior to the 12-

month time point. Code analysis further revealed that 75% of codes had been generated by interview 6, with 100% of codes reached by interview 16. A pragmatic philosophy guided the decision to cease interviewing as the research objectives had been met through the completed interviews. Two further interviews had already been arranged and so it was agreed with the lead researchers' supervisory team that it was appropriate to conduct these and ensure no new codes were determined. Nothing further was added to the codebook after transcript analysis and this further consolidated the decision to end the study after 18 interviews.

2.2 MIXED METHOD RESEARCH

Mixed methods research (MMR) integrates both qualitative and quantitative methods, and draws interpretations to understand the research problem, based on the combined strengths of both sets of data (Creswell and Clark, 2018). There are a number of classifications available in the field of MMR, however, the simplified typology described in the third edition of Creswell and Clarks' book (Creswell and Clark, 2018), outlines three core designs. The evolution of their typology since 2003 is shown in Table 2.1.

2003 Typology	2007 Typology	2011 Typology	2018 Typology
Sequential explanatory	Explanatory design	Explanatory sequential design	Explanatory sequential design
Sequential exploratory	Exploratory design	Exploratory sequential design	Exploratory sequential design
Sequential transformative		Transformative design	
Concurrent triangulation	Triangulation design	Convergent parallel design	Convergent design
Concurrent nested	Embedded design	Embedded design	
Concurrent transformative		Transformative design	
		Multiphase design	

Table 2.1 – Creswell and Clarke typologies 2003-2018

Adapted from 'Designing and conducting mixed methods research', Creswell and Clark, (2018).

In the POP-ACLR study, Phases 1 and 2 were combined to form an exploratory sequential design (with ethical approval sought for the two phases concurrently). Phase 3 was a convergent design, non-randomised feasibility trial with embedded individual qualitative interviews with patients and clinicians. The results of all three phases are discussed individually in Chapters 3-5 in addition to the convergence of results in Chapter 6.

2.3 COMPLEX INTERVENTION DEVELOPMENT

The MRC guidance has been supporting the development and evaluation of complex interventions in healthcare since its first iteration in 2000 (Shahsavari et al., 2020), and subsequent revision in 2006 (Craig et al., 2006). In 2021, the guidance was further updated to give further consideration as to how interventions interact within the context they are implemented to bring about

change (Skivington et al., 2021). The most recent iteration divides complex intervention research into four phases: development or identification of the intervention, feasibility, evaluation and implementation, shown in Figure 2.2. Each phase is underpinned by a common set of six core elements, to be considered and revisited throughout the research process. The framework promotes intervention research as an iterative cycle that may begin at any phase.

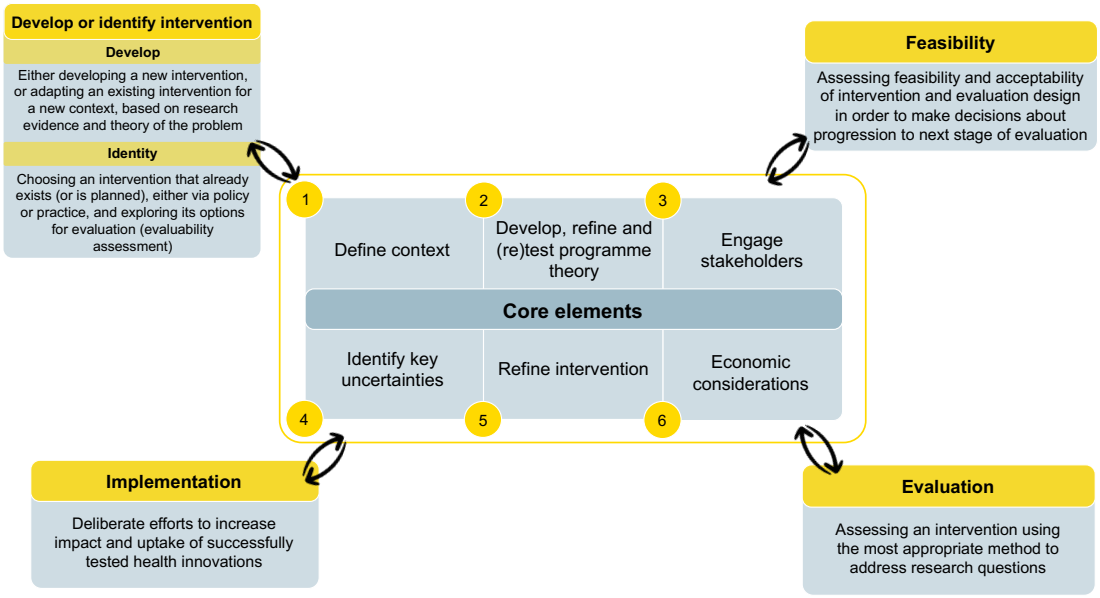


Figure 2.2 –– Framework for developing and evaluating complex interventions

Adapted from 'A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance', Skivington et al., (2021) under the CC BY 4.0 licence.

To complement the MRC guidance and add detail to the intervention development phase, O'Cathain et al., (2019b) undertook a systematic review (including literature where intervention development approaches were described in a book, journal article or website after 2007 or cited in a primary research article in 2015 or 2016). Eight categories of approach to intervention

development were outlined (Figure 2.3), followed by an e-Delphi consensus exercise with intervention developers and stakeholders.

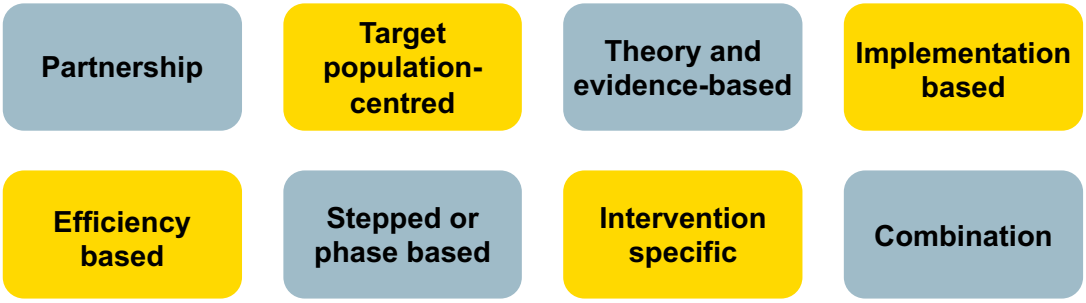


Figure 2.3 – Eight categories of approach to intervention development.

As described in 'Taxonomy of approaches to developing interventions to improve health: A systematic methods overview', (O'Cathain et al., 2019b).

These two programmes of work led to the development of additional guidance to provide researchers with key actions for consideration in intervention development underpinned by a set of key principles, outlined in Table 2.2 (O'Cathain et al., 2019a).

Actions	Principles
Plan the development process	Intervention development is: 1) Dynamic 2) Iterative 3) Creative 4) Open to change 5) Forward looking to future evaluation and implementation
Involve stakeholders, including those who will deliver, use and benefit from the intervention	
Bring together a team and establish decision-making processes	
Review published research evidence	
Draw on existing theory	
Articulate programme theory	
Undertake primary data collection	
Understand context	
Pay attention to future implementation of the intervention in the real world	
Design and refine the intervention	
End the development phase	

Table 2.2 – Key actions and principles for consideration in complex intervention development

Adapted from 'Guidance on how to develop complex intervention to improve health and healthcare communication' (O'Cathain et al., 2019a) under the CC BY 4.0 Licence.

Two key actions which support an implementation-based approach to intervention development are to 'draw on existing theory' and 'pay attention to future implementation of the intervention in the real world'; the use of implementation science theories, such as NPT, has therefore been an area of interest to intervention developers. Nilsen (2015) outlines several theories in a narrative review that support the prioritisation of 'the how and why' of implementation. No single theory has been identified as superior to another and researchers have previously commented on the difficulties of choosing an appropriate approach (Birken et al., 2017; Martinez et al., 2014; Nilsen, 2015).

NPT has been a prominent choice among healthcare research with the key paper outlining the theory cited over 500 times in Scopus (May et al., 2009).

2.4 NORMALISATION PROCESS THEORY

NPT originated as an applied theoretical model, known as the Normalisation Process Model (NPM) (May, 2006; May et al., 2007). NPM aimed to facilitate the understanding and evaluation of factors that facilitate or inhibit the routine integration of complex interventions in healthcare (Finch et al., 2012). Empirical application of NPM identified its utility in describing concepts related to the work participants do to enact the intervention in practice, termed 'collective action' in the next iteration of the theory (May et al., 2007).

NPT was later developed by May and Finch in 2009, extending the model to a middle-range theory, a term first developed in the 1940s by Robert Merton to define the connection between high level social theory and empirical observational patterns (Merton, 1968). NPT's extension was deemed necessary as it was recognised that NPM had limited scope in explaining factors beyond collective action. This led to the development of three further constructs: (1) coherence (meaning and sense making), (2) cognitive participation (commitment and engagement) and (3) reflexive monitoring (reflection or appraisal). NPT was defined by May and Finch (2009;538), to be *'concerned with the social organization of the work (implementation), of making practices routine elements of everyday life (embedding), and of sustaining embedded practices in their social contexts (integration)'*. NPT therefore provides researchers with a set of tools to support the understanding of the implementation, normalisation, and sustainment of an intervention in

practice (May et al., 2022). It focuses on the work that participants do (collective action) and presents the idea that a way of working only becomes normalised if:

1. A need is perceived, it's seen as meaningful and is understood by those adopting it (coherence),
2. Those adopting it have the resources to fulfil its need (cognitive participation),
3. Its impact can be demonstrated through appraisal (reflexive monitoring).

Most recently (2013 onwards) the theory expanded to consider dynamic implementation contexts in which the intervention operates (May, 2013; May et al., 2016). Four further constructs were defined, shown in Figure 2.4, described as the 'Extended Normalisation Process Theory' (ENPT) (May, 2013).

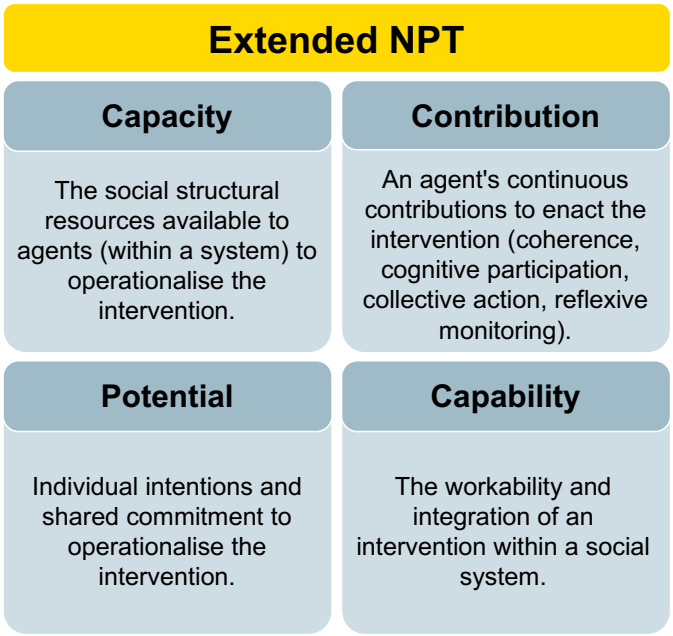


Figure 2.4 – Extended Normalisation Process Theory

ENPT links NPT with relevant constructs from sociological theories of social systems and social cognitive theories in psychology (Figure 2.5). It aims to provide a more detailed explanation of the implementation process by describing the interactions between (1) agency (i.e., the work that people do and the ways they work with components of the complex intervention) and (2) context (the resources people draw on to realise agency) (May, 2013).

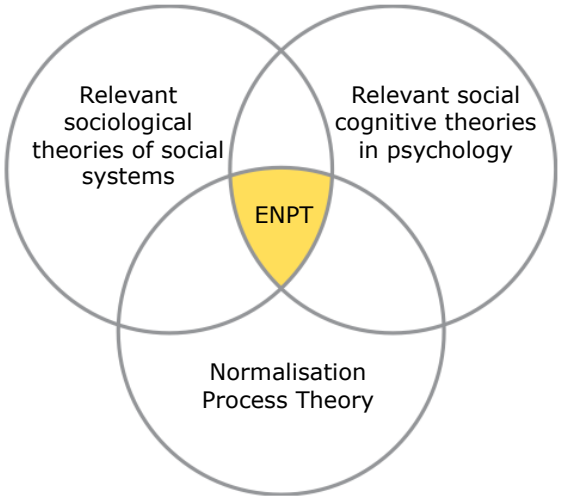


Figure 2.5 – ENPT construction

The constructs of capability and contribution sit within agency, and potential and capacity sit within context. The constructs of NPT sit within 'contribution', therefore focusing on expressions of agency independent of the context. This is shown in Figure 2.6.

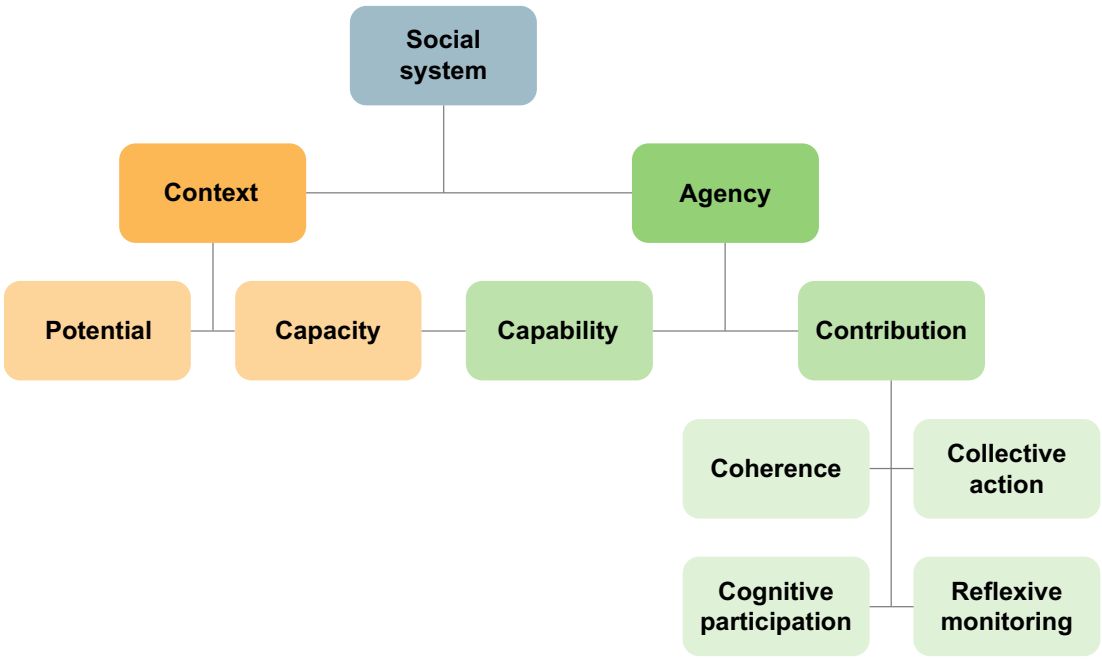


Figure 2.6 – Organisation of ENPT and NPT

Adapted from 'Towards a general theory of implementation' May, (2013) under the CC BY 2.0 Licence.

Most recently, in 2018, a 23-item instrument was developed, based on NPT, to explore implementation factors affecting normalisation of an intervention; the Normalization Measure Development (NoMAD) tool (Rapley et al., 2018). Specifically, the NoMAD's focus is on the experiences of those delivering or receiving the intervention. Finch et al., (2018) suggest utilising the tool as a pragmatic measure to meet research and practice needs.

2.5 EXPLORING NPT IN ORTHOPAEDIC AND/OR MUSCULOSKELETAL INTERVENTIONAL RESEARCH

In addition to the original plan set out during the application phase of this PhD, a qualitative evidence synthesis to explore NPTs use in supporting intervention research in orthopaedic and musculoskeletal conditions was deemed

important to conduct to facilitate the lead researchers (HC) understanding of NPT and its use in the context specific to the planned research.

The review question was:

> How has the Normalisation Process Theory been used in intervention research targeting adults (≥18 years old) with an orthopaedic and/or musculoskeletal condition in a healthcare setting?

The review objectives were to:

1) Identify how NPT had been used (e.g. in the process of intervention development, implementation and/or refinement)
2) Explore insight generated in the use of NPT
3) Understand the benefits and disadvantages of using NPT as critiqued by researchers

As previously described by O'Cathain et al., (2019a), the terms "design" and "develop" are often used interchangeably in the literature when describing intervention development processes. For example, a previous review in 2018, led by the theory's developers, explored the use of NPT in feasibility studies and process evaluation of complex healthcare interventions (May et al., 2018a). Only one study (n=1/13) was described to use NPT to support intervention design. However, a review by Huddlestone et al., (2020) described five studies (n=5/35) using NPT as a framework for intervention development. Two of these studies were included in the previous review by May et al,. but were categorised as using NPT as a tool for 'organisation and delivery' rather than intervention design. Not only do these two reviews differ in their use of terminology, employing "design" and "development" to discuss intervention

development processes, but they also classify NPT's use differently. It is therefore clear that the language used across the literature varies, and perhaps lacks clarity. For the purpose of the review, it was felt important to define the terms used to describe intervention development processes, which where are follows:

Development Any process related to the inception and design of a novel intervention. This can be anywhere on the continuum from initial scoping work, to determine the need for the intervention, through to the developed prototype.

Implementation The process of embedding the intervention within the setting/context of its intended use.

Refinement The process of refining or adapting an already existing intervention.

2.5.1 METHODS

The protocol was prospectively registered with PROSPERO (CRD42022358558, https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022358558) and the review was published in Implementation Science Communications, June 2023 (Carter et al., 2023a).

2.5.1.1 DESIGN

The review was designed following guidance from the Cochrane Handbook (Chapter 21) and the Joanna-Briggs Institute (JBI) Manual for Evidence Synthesis (Aromataris and Munn, 2020; Noyes et al., 2023).

When designing the review, several factors were considered to ensure the findings supported the lead researchers understanding of NPT specific to the planned research in addition to contributing useful insight within the field of orthopaedic/musculoskeletal (MSK) research. Firstly, the population in question was focused on adults with an orthopaedic and/or MSK condition. In previous reviews of NPT's use by May et al., (2018) and Huddlestone et al., (2020), only two papers (across both reviews) included a similar population of osteoarthritis (n=1) and hip fracture (n=1) and offered no discussion specific to NPT's use in this cohort. In addition, scoping work carried out prior to the formal search identified interventional research in patients with a relevant condition where the intervention targeted a different condition or disease within the cohort. For example, a longitudinal prospective study describing the effectiveness of implementing a preventative urinary catheter care bundle for patients hospitalised following a hip fracture (Frödin et al., 2019) referenced the 2013 paper by May (May, 2013). This helped refine the search strategy to identify relevant intervention research targeting the orthopaedic/MSK condition as opposed to an intervention targeting any condition in the target population. A focus specifically on interventions targeting orthopaedic/MSK conditions was necessary to support the review's objectives and be most applicable to the planned research (as described in Chapter 1).

Secondly, the search strategy was considered to ensure all relevant literature were captured. HC reflected on work by May et al., (2018) and Kirk et al., (2016) who explored the use of theory (NPT and consolidated framework for implementation research, CFIR) in implementation research and utilised citation searching for literature referencing key papers relating to the theory.

Whilst acknowledging that the finalised strategy would only capture work citing the articles, it was deemed unlikely that a paper using NPT as a guiding theory during intervention development, implementation or refinement would fail to reference at least one of the papers describing NPT, related methods or tools. A pragmatic view helped with this decision-making during construction of the review's protocol.

2.5.1.2 SEARCH STRATEGY

The search strategy designed a priori and described in the PROSPERO record was followed. The **PICo** approach (**P**opulation, **I**nterest, **Co**ntext) was used to support the search, defined as:

Population	Adults (≥18 years-old) with an orthopaedic or musculoskeletal condition
Interest	Normalisation Process Theory
Context	Any healthcare setting (including primary, secondary, tertiary, community)

Similar to the search strategy outlined by May et al., (2018a) and Kirk et al., (2016), the search focused on citations of key papers relating to NPT. 12 papers were selected which described the development of NPT, related methods or tools in addition to the web-based toolkit for NoMAD (Table 2.3). Citations of these 12 papers were searched in two bibliographic databases (Scopus and Web of Science) and a search engine (Google Scholar) from inception to November 2022. The keywords of 'orthopaedic' and 'musculoskeletal' were also applied to narrow the results of the studies citing the key articles.

Author	Year	Title
May C	2006	A rational model for assessing and evaluating complex interventions in health care
May C, Finch T, Mair F, et al.	2007	Understanding the implementation of complex interventions in health care: the normalization process model
May CR, Mair FS, Dowrick CF, Finch TL	2007	Process evaluation for complex interventions in primary care: understanding trials using the normalization process model.
May C, Finch T	2009	Implementation, embedding, and integration: an outline of normalization process theory
May C, Mair FS, Finch T, et al.	2009	Development of a theory of implementation and integration: normalization process theory
Murray E, Treweek S, Pope C, et al.	2010	Normalisation process theory: a framework for developing, evaluating and implementing complex interventions
May C, Finch T, Ballini L, et al.	2011	Evaluating complex interventions and health technologies using normalization process theory: development of a simplified approach and web-enabled toolkit
Finch T, Mair F, O'Donnell C, et al.	2012	From theory to 'measurement' in complex interventions: methodological lessons from the development of an e-health normalisation instrument
May C	2013	Towards a general theory of implementation
May C	2013	Agency and implementation: understanding the embedding of healthcare innovations in practice
Finch TL, Rapley T, Girling M, et al.	2013	Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol
May C, Albers B, Bracher M, et al.	2022	Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development

Table 2.3 – Citations searched

2.5.1.3 ELIGIBILITY CRITERIA

Inclusion Criteria

1) Peer reviewed journal articles where NPT was used in the intervention development, implementation or refinement process
2) Any healthcare setting
3) Any intervention targeted at an orthopaedic or musculoskeletal condition e.g. exercise, leaflet, website, screening tool
4) Any method, including protocols, provided there was a clear explanation of how NPT will be or has been used
5) Any paper that used NPT as a stand-alone theory or in combination with other theories
    a. It must be clear how NPT has specifically contributed to the process alongside the other theory/theories used
6) Any language where it is feasible and pragmatic to translate the article into English

Exclusion Criteria

1) NPT influence not clearly explained
2) Intervention implemented outside of a healthcare setting
3) Intervention not targeted at an orthopaedic or musculoskeletal condition

2.5.1.4 STUDY SCREENING AND DATA EXTRACTION

The results of each search were collated in an Excel spreadsheet (Microsoft Cop., Redmon, WA, USA). Firstly, study titles were screened against the eligibility criteria, followed by abstracts and full texts. Where the lead

researcher was uncertain about the relevance of a study, it progressed to the next round of screening for further assessment. Where uncertainty remained on full text screening, this was discussed at monthly PhD supervision meetings. Data were extracted by HC and a second reviewer, Alison Harvey (AH, a musculoskeletal physiotherapist). A bespoke data extraction tool was developed to extract data on: authors, year of study, study type, population/study setting/condition, intervention, use of NPT (intervention development, implementation or refinement), insight generated in the use of NPT and author critique of NPT.

2.5.1.5 DATA ANALYSIS

Framework analysis was used to explore the data in relation to the research question and objectives and was felt to be appropriate to meet the review aims. Clear objectives were identified to explore NPT's use, insight generated into its use and identified advantages and disadvantages of its use which were appropriate to map to matrices facilitating the generation of structured outputs of summarised data (Gale et al., 2013; Goldsmith, 2021). The collection of homogenous data was anticipated that described the use of NPT in interventional research specific to the orthopaedic/MSK population which suits the methodological process adopted in the framework method (Gale et al., 2013). Further, this review was completed alongside undertaking individual semi-structured interviews analysed using the reflexive thematic analysis approach (described in Chapter 3). The reflexivity required during both analyses enabled HC to consider the use of both methods, the differences in data analysis and generated data. Whilst a deductive approach was appropriate to draw out important data to map to each objective, it was also

felt that allowing room for the generation of unexpected data would be beneficial. As the framework approach allows for research on the inductive-deductive continuum and combined types of analysis, it aligned well to this evidence synthesis (Goldsmith, 2021). Finally, as the framework method does not have a particular philosophical underpinning and is not aligned to a single epistemological and ontological view, it aligned to the researchers pragmatic stance (Gale et al., 2013).

Two matrices were developed a priori and described in the protocol. Matrix one mapped to objectives (1) and (3); (1) Identify how NPT had been used, (3) Understand the benefits and disadvantages of using NPT as critiqued by researchers, and matrix two mapped to objective (2); Explore insight generated in the use of NPT. The topics included in the a priori matrices are shown in Figure 2.7.

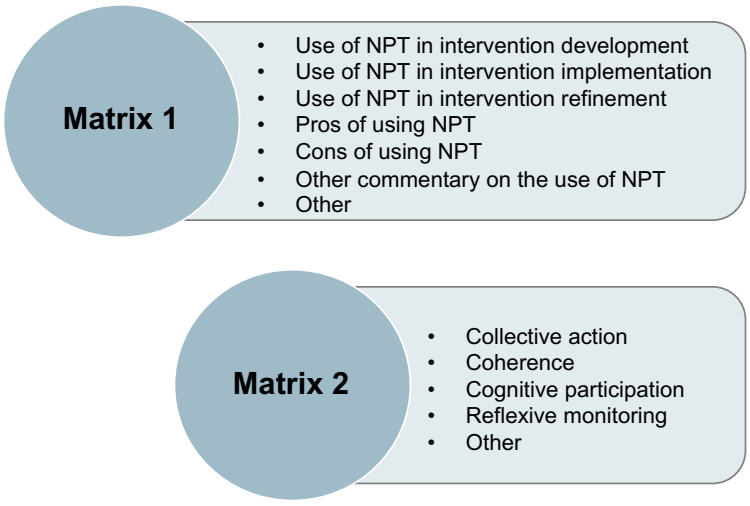


Figure 2.7 – Topics included in the a priori matrices

Initial analysis focused on matrix one, aiming to understand and identify how NPT had been used in each study. The a priori headings fit well with the objectives of the review and no refinement of this matrix was required.

Secondly, focus shifted to the individual constructs of NPT in matrix two. The pre-defined headings only included the constructs of collective action, cognitive participation, coherence and reflexive monitoring, in response to scoping work identifying a focus on these constructs. However, four of the 14 papers utilised the constructs of ENPT and so the matrix was expanded to include capacity, potential, capability and contribution. One study also employed the NoMAD questionnaire and so this was also included as an item in the matrix. After this initial mapping to matrix two, charting was completed for 25% of the dataset. The items were reviewed and covered all aspects of NPT's use and the remainder of the dataset was mapped to the refined matrices, shown in Figure 2.8.

Matrix 1

- Use of NPT in intervention development
- Use of NPT in intervention implementation
- Use of NPT in intervention refinement
- Pros of using NPT
- Cons of using NPT
- Other commentary on the use of NPT
- Other

Matrix 2

- Collective action
- Cognitive participation
- Coherence
- Reflexive monitoring
- Capacity
- Potential
- Capability
- Contribution
- NoMAD

Figure 2.8 – Amended and final matrices

Following data mapping onto the two matrices, data were organised into three themes: (1) What was NPT used to support? (2) NPT use, justification and insight generated, (3) Critique and commentary of NPT use.

2.5.1.6 QUALITY APPRAISAL AND ASSESSMENT OF CONFIDENCE

Quality appraisal of included articles was carried out using the Critical Appraisal Skills Programme (CASP) checklist (CASP, 2018) with guidance

from the Cochrane Handbook (Chapter 21) (Noyes et al., 2023) and Long et al., (2020). There is debate as to what constitutes 'quality' in qualitative research due to the broad range of methods encompassed within the qualitative paradigm and disagreement between the those who argue that (1) qualitative research represents a distinctive paradigm generating different types of knowledge to that of quantitative research and (2) there is no separate philosophy and so the same general criteria that is applied to quantitative research can be applied to qualitative research (Mays and Pope, 2020). The CASP tool is the most frequently used checklist in qualitative evidence syntheses for health and social care research likely due to its pragmatic application and endorsement by the World Health Organisation (WHO) and Cochrane (Dalton et al., 2017; Hannes and Macaitis, 2012; Noyes et al., 2018a). Further, the guidance offered by Long et al., (2020) suggests solutions for potential challenges when using the CASP tool in addition to proposing pragmatic modifications to the tool to improve its suitability and usability, thus optimising its value. The CASP tool is also praised for its suitability for novice researchers and so HC felt this tool was appropriate for use in this study (Hannes and Bennett, 2017; Long et al., 2020).

GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) was used to assess the confidence of each of the review findings (Lewin et al., 2018a, 2018b). The interactive Summary of Qualitative Findings (iSoQ) tool was used to facilitate its application (Norwegian Institute of Public Health, 2022) in addition to guidance from the GRADE-CERQual paper series (Colvin et al., 2018; Glenton et al., 2018; Lewin et al., 2018a; Munthe-Kaas et al., 2018; Noyes et al., 2018b). The GRADE-CERQual approach allows for a

systematic assessment of confidence to ensure explicit and transparent review findings (Lewin et al., 2018b).

2.5.2 RESULTS

2.5.2.1 SEARCH RESULTS

Citation searching of the 12 key studies revealed a total of 10,420 citations across the two databases and search engine. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow diagram is shown in Figure 2.9.

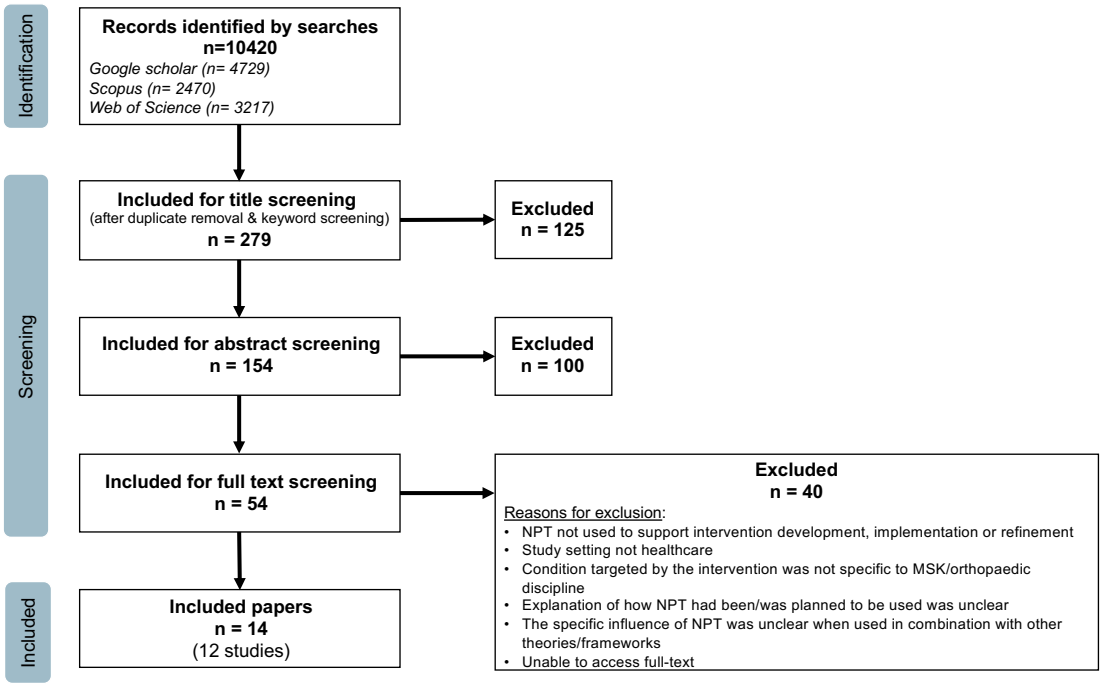


Figure 2.9 – PRISMA flow diagram

Key words of ‘orthopaedic’ and ‘musculoskeletal’ were applied to the search which narrowed the results to 755 citations. A further 476 articles were removed for duplication leaving 279 titles eligible for inclusion. Of these, 125 were excluded following title screening and 154 abstracts were read. 100 further studies were excluded leaving 54 full texts to be screened. Finally, 40

texts were excluded to leave 14 papers describing the results from 12 different studies for inclusion in the review.

It is important to acknowledge that ten studies were excluded from the review due to limited description of NPT/ENPT's use. It was common that a single statement was made, referencing the use of NPT with little further detail offered. For example:

> "Individual agency and reflexive monitoring played an important part in the successful implementation of VC." (Gilbert et al., 2020)

Further, four of the ten studies were excluded as they used NPT alongside another theory but described little detail for the specific use of NPT. For example:

> "Training and educational packages were developed for GPs and practice nurses by drawing on the work of May et al, Grol and Michie et al" (Dziedzic et al., 2018)

2.5.2.2 TYPES OF STUDIES

Included articles were of a qualitative (n=9) (Drew et al., 2015; Gilbert et al., 2022, 2019, 2018; Peng et al., 2020; Sanders et al., 2011; Saunders et al., 2022, 2020; Volkmer et al., 2021) and mixed methods design (n=4) (Foster et al., 2020; Hay et al., 2018; Judge et al., 2016; Wylde et al., 2018), with one commentary included to support the justification of NPT use in one study (Ong et al., 2014). Among the qualitative studies, semi-structured interviews were the most common method (n=8) (Drew et al., 2015; Gilbert et al., 2022, 2019, 2018; Judge et al., 2016; Sanders et al., 2011; Saunders et al., 2020; Volkmer et al., 2021) with two studies utilising semi-structured interviews alongside

observations (Peng et al., 2020) or focus groups (Saunders et al., 2022).The studies utilising a mixed methods design incorporated multiple workstreams. In these instances (n=4), only the stage incorporating NPT was extracted. Qualitative methods were used in three of the mixed methods studies (semi-structured interviews (Foster et al., 2020; Judge et al., 2016), observations and interviews (Hay et al., 2018)) and one study used a quantitative online questionnaire (Wylde et al., 2018).

The data extraction table is shown in Table 2.4**.**

Authors	Year	Study Type	Population/study setting/condition	Intervention	Use of NPT	Insight generated in the use of NPT	Author (of the included study) critique of NPT
Drew et al.,	2015	Qualitative, semi-structured interviews	**Population the intervention targets**: no specific population described other than 'hip fracture patients' **Setting**: Secondary care, UK (11 hospitals) **Condition**: hip fractures	Secondary fracture prevention service	**Implementation** 'Authors describe the aim of using ENPT was to *"Understand how and why secondary fracture prevention services can be implemented in secondary care"*. ENPT was described to be used to support development of the topic guide and analysis of the interview data (codes transposed onto the four constructs).	Four constructs of ENPT: (1) Capacity (2) Potential (3) Capability (4) Contribution No insight gained into the use of ENPT. The authors only related the interview data to each of the four constructs.	3 challenges in the application of ENPT are described: 1) The overlapping nature of the constructs meaning that data could be coded into more than one construct 2) Being certain that data was categorised into the 'correct' construct 3) Potential for tension with undertaking an abductive analysis whilst

							ensuring data are not forced into pre-defined constructs.
Foster et al., and Saunders et al., (1)	2020	Foster et al., - RCT with nested qualitative study Saunders et al., - Qualitative, semi-structured interview data presented from Foster et al., RCT	**Population the intervention targets**: individuals with sciatica. RCT population: mean age 52.1 years, n=476 (50% female) **Setting**: primary care, community physiotherapy and spinal interface services between primary and secondary care, UK **Condition**: Sciatica	Stratified care approach for sciatica (combines information on the risk of persistent disability with information about sciatica clinical severity)	**Implementation** NPT used alongside the 'boundary objects concepts' to guide qualitative study (the influence of both theoretical frameworks was clearly explained). The concept of 'coherence' was used as a lens to interpret the interview findings. Themes were described to be mapped onto this construct.	Only 'coherence' construct used. No new insight gained into this construct.	The authors report that the use of NPT (and boundary objects concepts) enabled the team to develop a more robust understanding of the identified issues.

Gilbert et al., (1)	2018	Qualitative, semi-structured interviews	**Population the intervention targets**: patients aged over 18 **Setting**: Tertiary orthopaedic hospital, UK **Condition**: Shoulder pain/dysfunction	Multiple Joint (MUJO) system (rehabilitation device)	**Implementation** ENPT was used to explore the underlying reasons behind the MUJO System's acceptability. The interview schedule was described to be developed in 'accordance with NPT'. A directed content analysis was undertaken to organise the qualitative data against the ENPT constructs.	Four constructs used (ENPT): (1) Capacity (2) Potential (3) Capability (4) Contribution No insight gained into construct use.	Nil
Gilbert et al., (2)	2019	Qualitative, semi-structured interviews	**Population the intervention targets**: patients over 18, attending	Video-conferencing	**Implementation** The interview structure was	Four constructs used (ENPT): (1) Capacity (2) Potential	The authors state that "the use of supplementary

			the hospital for shoulder rehabilitation for shoulder instability **Setting**: Tertiary orthopaedic hospital, UK **Condition**: Atraumatic shoulder instability		based on the constructs of NPT. A directed content analysis was undertaken analysing the factors in accord with NPT. Coding of data was undertaken using a previously published NPT coding framework.	(3) Capability (4) Contribution No insight gained into construct use.	theoretical models or a combination of open and directed content analysis might have gleaned additional data which could have informed the results", however no direct critique of NPT was offered.
Gilbert et al., (3)	2022	Qualitative, semi-structured interviews	**Population the intervention targets**: patients over age 18 years, attending the specialist orthopaedic hospital for physiotherapy or occupational therapy for an	Virtual consultations (VC)	**Implementation** NPT used to underpin the line of enquiry into the implementation of VC. Preference theory also used but the use of	Four concepts used: (1) Coherence (2) Cognitive participation (3) Collective action (4) Reflexive monitoring	The authors state that "the use of normalisation process theory provided focused attention towards key implementation factors that feed

			orthopaedic/musculoskeletal condition **Setting**: Tertiary orthopaedic hospital, UK **Condition**: Any orthopaedic/musculoskeletal condition		NPT is clearly explained. The interview schedule and coding frame was developed based on NPT.		into the formation of preference". No other critique of the theory itself was offered.
Hay et al., & Ong et al., MOSAIC interventi on	2018 2014	Hay et al., Mixed methods study. NPT used in workstream 2: qualitative evaluation - observations and interviews Ong et al.,: description of the conceptual underpinning of the	**Population the intervention targets**: ≥ 45 years old **Setting**: primary care, UK **Condition**: osteoarthritis	Model osteoarthritis consultation (MOSAIC)	**Implementation** The authors describe the use of NPT in 2 ways: 1) To provide a structure to identify factors facilitating implementation and overcoming barriers to delivering the intervention. 2) To provide a framework for analysing and	Although NPT was referenced to be used with all four constructs described, in the paper by Ong et al., the construct of 'coherence' was the only one mentioned.	Nil

		approach in the MOSAIC study (commentary)			evaluating the process of intervention implementation a. Coherence construct used as an 'organising device' for group interviews with GPs and nurses who had undertaken intervention training b. Themes developed from data analysis were compared to the NPT construct of coherence.		
Judge et al.,	2016	Mixed methods study. NPT used in	**Population the intervention targets**: ' hip fracture patients', no specific age	Secondary fracture prevention service	**Implementation** The authors described use of ENPT in 2 ways:	Four constructs used (ENPT): (1) Capacity (2) Potential (3) Capability	The authors discussed the challenge of analysing data using ENPT with

		Objective 2 - Qualitative, semi-structured interviews	given **Setting**: Secondary care (11 hospitals), UK **Condition**: hip fracture		1) Interview topic guide based on four core elements 2) Codes from interview data were transposed onto the four constructs	(4) Contribution No insight gained into construct use.	a concern of coding data into the theories constructs whilst ensuring they're not 'forced' into pre-defined categories. They explained to have avoided this problem by performing an initial step of inductive analysis prior to transposing the developed codes into the theory. They explained to feel that this meant any factors that did not ‘fit’ within the theory would have been identified but also felt that the theory was able to account for all

							of the issues relating to service implementation.
Peng et al.,	2020	Process evaluation - Qualitative, semi-structured interviews & observations	**Population the intervention targets**: 'older hip fracture patients', no specific age given **Setting**: Orthopaedic hospital, China **Condition**: hip fracture	Multidisciplinary co-management programme	**Implementation** The authors described use of NPT in 2 ways: 1) Interview guide based on NPT 2) Key themes were mapped onto the NPT constructs	Four concepts used: (1) Coherence (2) Cognitive participation (3) Collective action (4) Reflexive monitoring	The authors describe to have found the use of NPT helpful in systematically identifying barriers to implementation which allowed for consistent responses to be collected across interviews.
Sanders, Foster and Ong	2011	Qualitative, semi-structured interviews	**Population the intervention targets**: 'back pain patients' **Setting**: Primary care, UK **Condition**: back pain	Subgrouping tool	**Implementation** The authors described use of NPT in 3 ways: 1) Semi-structured interviews 'organised' around the 4	All four concepts were described to be used, with a focus on the concept of 'coherence'. No insight generated into NPT use.	The authors stated to have found very little evidence that the constructs of collective action, cognitive participation and reflexive monitoring accurately

					NPT dimensions 2) NPT used as a guiding theoretical framework for emerging themes and concepts 3) Key themes from the analysis of second stage interviews were mapped onto the 'coherence' construct		reflected the behaviours and attitudes of their study population (GPs).
Saunders et al., (2)	2022	Qualitative, semi-structured interviews & focus groups	**Population the intervention targets**: no clear description other than 'employed patients consulting a first contact practitioner with MSK pain' **Setting**: Primary care, UK	Vocational advice	**Implementation** 1) Mapping interview themes onto the four components (themes where then explored in relation to how well they 'fit' the four NPT components).	Four concepts used: (1) Coherence (2) Cognitive participation (3) Collective action (4) Reflexive monitoring	The authors described NPT to have enabled development of a more robust understanding of the implementation potential. Further, a strong level of ‘fit’ was

			Condition: MSK pain				described between the authors themes and the NPT components (ie none of the findings fell outside of the parameters of NPT, and the identified themes could be usefully explained through the lens of NPT).
Wylde et al.,	2018	Mixed methods study. NPT used in stage 4 - online questionnaire	**Population the intervention targets**: people with chronic knee pain after total knee replacement **Setting**: Secondary care, UK **Condition**: Total knee replacement	Assessment clinic - STAR care pathway	**Implementation** 1) NoMAD instrument used to measure implementation processes from the perspectives of stakeholders	NoMAD instrument used (23-item instrument with 20 core construct items that reflect the four core constructs of NPT).	Nil

Volkmer et al.,	2021	Qualitative, semi-structured interviews	**Population the intervention targets**: postoperative hip fracture patients **Setting**: Secondary care, UK **Condition**: Hip fracture	Postoperative physiotherapy	**Implementation** 1) NPT drawn upon to aid interpretation of interview findings (themes)	Four concepts used: (1) Coherence (2) Cognitive participation (3) Collective action (4) Reflexive monitoring	Nil

Table 2.4 – Data extraction table

2.5.2.3 WHAT WAS NPT USED TO SUPPORT?

INTERVENTION DEVELOPMENT, IMPLEMENTATION AND REFINEMENT

NPT was used to support intervention implementation in all 12 studies included in the review. There was no evidence of its use for intervention development or refinement. One study reported to have used the results from the NoMAD instrument to evaluate the implementation of an intervention (in addition to results from the three other elements of multi-phase study) to support its refinement in future work (Wylde et al., 2018).

In two studies, NPT was used alongside another theory: boundary objects concepts (Foster et al., 2020) and preference theory (Gilbert et al., 2022).

INTERVENTIONS AND CONDITIONS

Of the 12 studies, five interventions were a new clinic pathway, service or consultation (Drew et al., 2015; Hay et al., 2018; Judge et al., 2016; Peng et al., 2020; Wylde et al., 2018), two were interventions related to rehabilitation (Gilbert et al., 2018; Volkmer et al., 2021) or an assessment tool for a specific condition (Foster et al., 2020; Sanders et al., 2011), two were a consultation medium (Gilbert et al., 2022, 2019) and one was a vocational advice intervention (Saunders et al., 2022).

The condition most commonly addressed by an intervention was hip fractures (n=4) (Drew et al., 2015; Judge et al., 2016; Peng et al., 2020; Volkmer et al., 2021) followed by conditions related to the shoulder (n=2) (Gilbert et al., 2019, 2018) and lower back (n=2) (Foster et al., 2020; Sanders et al., 2011). Two interventions targeted generic musculoskeletal and/or orthopaedic conditions

(Gilbert et al., 2022; Saunders et al., 2022), one intervention targeted a knee specific condition (chronic knee pain after total knee replacement) (Wylde et al., 2018) and one intervention addressed the condition of osteoarthritis (Hay et al., 2018).

A summary is shown in Table 2.5.

		Original NPT Constructs				Extended NPT Constructs				NoMAD
		Collective action	Cognitive participation	Coherence	Reflexive monitoring	Capacity	Potential	Capability	Contribution	
Intervention	Clinic pathway, service or consultation	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Consultation medium	✓	✓	✓	✓	✓	✓	✓	✓	
	Rehabilitation	✓	✓	✓	✓	✓	✓	✓	✓	
	Vocational advice	✓	✓	✓						
	Assessment tool			✓						
Condition / body part targeted	Hip fracture	✓	✓	✓	✓	✓	✓	✓	✓	
	Generalised orthopaedic / musculoskeletal condition	✓	✓	✓	✓					
	Shoulder					✓	✓	✓	✓	
	Osteoarthritis			✓						
	Lower back			✓						
	Knee									✓

Table 2.5 – Interventions and conditions summary

2.5.2.4 NPT USE, JUSTIFICATION AND INSIGHT GENERATED

The frequency of use for each NPT/ENPT construct is shown in Figure 2.10.

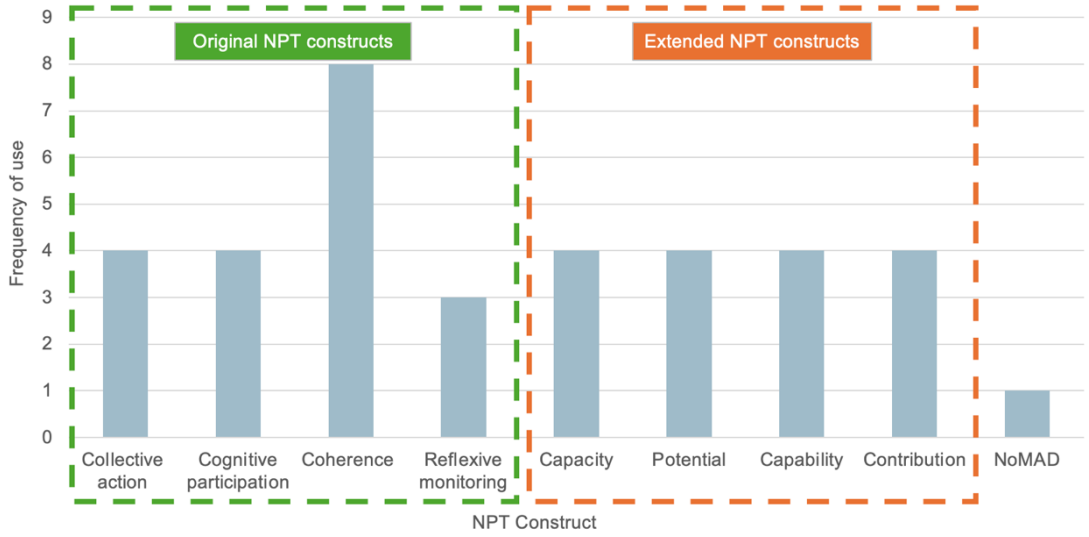


Figure 2.10 – NPT construct frequency

Coherence was the most frequently utilised construct, cited in eight papers (seven studies) (Foster et al., 2020; Gilbert et al., 2022; Ong et al., 2014; Peng et al., 2020; Sanders et al., 2011; Saunders et al., 2022, 2020; Volkmer et al., 2021). Only 25% of the included studies used all four constructs of the original theory (Gilbert et al., 2022; Peng et al., 2020; Volkmer et al., 2021). One study reported to use all four constructs of NPT but there was no evidence of the use of reflexive monitoring in the results (Saunders et al., 2022). Where ENPT was used (four studies), all four constructs were employed (Drew et al., 2015; Gilbert et al., 2019, 2018; Judge et al., 2016). No study utilised any of the original constructs in combination with one or more construct from the extended version of the theory. Yet 13 papers were published after the introduction of ENPT in 2013. There was limited justification across all studies for selection of NPT an/or individual construct use. Instead, authors made statements such as:

> "We used qualitative methodology to explore the underlying reasons behind the MUJO System's acceptability and this work was informed by Normalisation Process Theory (NPT)." (Gilbert et al., 2018)

> "we drew on Normalisation Process Theory (NPT), which provides a framework both for planning and understanding the implementation of healthcare initiatives, in particular, why some are accepted and more successfully embedded in routine practice than others. NPT comprises four components, which provide a lens through which to interpret our findings" (Saunders et al., 2022)

COHERENCE

Coherence was suggested to be a fundamental first step in intervention implementation by several authors. Examples include:

> "The mechanism of 'coherence', which is concerned with sense-making and giving meaning to a new intervention, is a pivotal first stage for implementation, and a focal point of our study" (Ong et al., 2014)

> "The meaning attached to a clinical intervention and whether or not clinicians and patients 'buy in' to a new way of working is key to its early adoption and implementation" (Foster et al., 2020)

> "we chose to adopt the conceptual idea of 'coherence', used to explain the initial stages of implementation" (Sanders et al., 2011)

This construct was explained, in all studies, to support 'sense making' and understanding of the intervention amongst patients and/or clinicians. In three

papers (Foster et al., 2020; Ong et al., 2014; Saunders et al., 2020), it was also employed to understand the degree of meaning of the intervention. One study described to have chosen this concept alone, as they found little evidence to support the use of any other constructs for their population (Sanders et al., 2011).

> “We were interested in explaining the obstacles to the early adoption of the new system, which fitted in with the concept of ‘coherence’, and because we found little evidence that the other NPT constructs (for example, cognitive participation, collective action, and reflexive monitoring) accurately reflected the behaviours and attitudes of the GPs in this study." (Sanders et al., 2011)

There was no new insight gained into the utility of this construct from that already reported in the literature by May and Finch (May and Finch, 2009). All results reported under the heading of coherence, related to understanding/sense making of the intervention by patients/clinicians.

COGNITIVE PARTICIPATION, COLLECTIVE ACTION AND REFLEXIVE MONITORING

Cognitive participation and collective action were used in four studies and reflexive monitoring was used in three studies; there was no discussion describing the reason for their use. In all studies, results were reported against each construct, for example:

> "Shared decision-making and effective communication strategies were suggested as mechanisms to overcome barriers to engagement in physiotherapy, as well as the need to tailor approaches to

accommodate differing individual needs (collective action)." (Volkmer et al., 2021)

"**Cognitive participation: Investment in co-management program**

Receiving strong support from the hospital management and willingness to participate were key drivers of the intervention program. Participants who were less motivated to contribute to the program were likely to have a negative effect on the delivery of the intervention. The primary reason for those who had less motivation to participate in the program was due to lack of financial incentives for doing additional work. Six participants provided information related to cognitive participation construct, and two subthemes were identified." (Peng et al., 2020)

"**Reflexive monitoring**

Patients were forthcoming with feedback about their experiences"

(Gilbert et al., 2022)

The interventions being implemented were: a consultation medium for patients with an orthopaedic/musculoskeletal condition (Gilbert et al., 2022), a multi-disciplinary care management programme for patients following a hip fracture (Peng et al., 2020), a vocational advice intervention for patients with MSK pain (Saunders et al., 2022) and physiotherapy for postoperative hip fracture patients (Volkmer et al., 2021).

There was no new insight gained into the use of these three constructs from that already documented in the literature (May and Finch, 2009).

The four papers citing the constructs of ENPT (Drew et al., 2015; Gilbert et al., 2019, 2018; Judge et al., 2016), utilised all four concepts and no study used one concept in isolation of the remaining three.

All four studies utilised each construct as a heading to present their results against and described these against their original descriptions outlined by May in 2013. Examples include:

> "**Capacity – Social structural resources available to patients and clinicians**
>
> The accessibility of the equipment for patients and clinicians was identified as the main barrier to using the device" (Gilbert et al., 2018)

> "**Potential – Social cognitive resources available to agents.**
>
> Clinicians see a face-to-face follow-up as the 'gold standard' but there was awareness that VC might be preferable to patients. Clinicians distinguished when a face to face would be required" (Gilbert et al., 2019)

> "The capability of users to enact the components of a fracture prevention service depends on their potential for workability and integration in their everyday practice.
>
> We have already emphasised that participants were enthusiastic about introducing the fracture prevention service because it introduced dedicated specialist nurses who delivered a new layer of service

> provision that centred on co-ordination and support, but at the same time, freed up the capacity of others who had previously been engaged in this work. In this sense, the service intervention was apparently highly workable and easily integrated into practice. But there were also important problems." (Drew et al., 2015)

> "Participants' contributions to enacting a fracture prevention service depend on them investing in meaning, commitment, effort and appraisal.
>
> Fracture prevention co-ordinators did not change the clinical work that was undertaken. Rather, their introduction changed the way the work was organised and delivered. Multidisciplinary meetings were used to sustain the potential and capacity of professionals involved in service delivery." (Judge et al., 2016)

The interventions being implemented in the studies that utilised these constructs were: a rehabilitation device to treat shoulder pain/dysfunction (Gilbert et al., 2018), videoconferencing for atraumatic shoulder instability (Gilbert et al., 2019) and a fracture prevention service for patients following a hip fracture (Drew et al., 2015; Judge et al., 2016).

NOMAD

The NoMAD instrument was used in one study to assess health professional stakeholders' views (involved in the development or future delivery of the intervention) about implementation of a care pathway for people with chronic

knee pain after total knee replacement (Wylde et al., 2018). Results from the survey were collated and presented as a descriptive summary. Examples of results statements are shown below:

> "Stakeholders' opinions varied about how different the STAR care pathway was to usual patient care. This may reflect diversity in current practice for assessment, management and treatment of chronic post-surgical pain"
>
> "All stakeholders were aware of the proposed benefits of the intervention for patients, and most thought that their colleagues felt the STAR care pathway was worthwhile. However, some were less certain about this, which indicates that further work may be needed to promote the new practices among colleagues. Stakeholders thought that the intervention would have a valuable effect on their work." (Wylde et al., 2018)

2.5.2.5 CRITIQUE AND COMMENTARY OF NPT USE

Six studies (seven papers) commented on the benefits of using NPT/ENPT to:

1) Focus attention towards key implementation factors (Gilbert et al., 2022; Peng et al., 2020)
2) Produce more robust understanding of identified issues (Foster et al., 2020; Saunders et al., 2022, 2020)
3) Draw attention to specific elements of sense-making and community of practice (Hay et al., 2018)
4) Account for all issues relating to implementation during data analysis (Judge et al., 2016)

Negative aspects of NPT use were less frequently documented, with only two studies reporting difficulties with employing NPT (Drew et al., 2015; Sanders et al., 2011). One study commented on the overlapping nature of ENPT constructs and resultant uncertainty as to whether data were coded correctly.

> "A challenge in the application of extended Normalization Process Theory was the overlapping nature of the constructs, meaning that data could be coded into more than one construct" (Drew et al., 2015)

The second study described the lack of available evidence to support use of three NPT constructs (collective action, cognitive participation and reflexive monitoring) to reflect the data for their studies population (behaviours and attitudes of GPs), and subsequently justified the use of only one construct (coherence) (Sanders et al., 2011).

> "We were interested in explaining the obstacles to the early adoption of the new system, which fitted in with the concept of 'coherence', and because we found little evidence that the other NPT constructs (for example, cognitive participation, collective action, and reflexive monitoring) accurately reflected the behaviours and attitudes of the GPs in this study." (Sanders et al., 2011)

Three research teams used an abductive approach to analyse data due to concern that NPT, used to develop a framework approach, may not capture all important data elements (Drew et al., 2015; Judge et al., 2016; Saunders et al., 2022). To address this, the authors outlined a preliminary step of analysing data inductively prior to data mapping onto the NPT framework. However, two

teams commented that NPT was able to account for all issues relating to implementation (Judge et al., 2016; Saunders et al., 2022).

> "Undertaking an abductive analysis, to enable us to use extended NPT, is potentially challenging, as data must be coded into constructs while it is ensured that they are not 'forced' into pre-defined categories. We avoided this problem by performing an initial inductive analysis to identify factors that may impact on the implementation of services and then transposing them onto the theory. Doing so meant that any factors that did not 'fit' within the theory would have been identified. However, we found that the theory was able to account for all of the issues relating to service implementation." (Judge et al., 2016)

One study commented that where NPT was used to support analysis, this was primarily as a guide to ensure data were not restricted.

> "NPT was adopted as the guiding theoretical framework underpinning emerging themes and concepts. However, NPT was used primarily to guide analysis, and not to restrict the exploration of other possible theoretical insights." (Sanders et al., 2011)

Other commentary of its use was related more closely to the utility of theory in understanding implementation in complex healthcare environments rather than specific commentary about NPT.

> "Fracture liaison services are complex interventions, and a strength of the study is the use of NPT as a theoretical framework in order to help to understand something of the complexity of change within health services." (Judge et al., 2016)

No study utilised the original four constructs of NPT (cognitive participation, collective action, coherence and reflexive monitoring) in combination with those in the extended version (capability, capacity, potential and contribution). However, one could argue that those utilising ENPT are inadvertently including the original four constructs within the construct of contribution; although this distinction was not discussed in any of the studies that utilised ENPT.

2.5.2.6 QUALITY APPRAISAL

The CASP qualitative tool was used to assess 12 of the 14 articles. Guidance was sought from the lead researchers PhD supervisory team and an expert at the University of Nottingham (Professor Catrin Evans) on applying the CASP tool to the two papers describing one study. For the SCOPIC trial by Foster et al., (2020), NPT was only used in the nested qualitative study; of which, the results were reported separately by Saunders et al., (2020). It was deemed appropriate that only appraisal of the qualitative study was necessary and so the CASP qualitative checklist was applied to the study by Saunders et al., (2020). The MOSAIC trial (Workstream 2) by Hay et al., (2018) was discussed in a programme grant report as part of a larger study in addition to further commentary on the use of NPT detailed in a separate paper by Ong et al., (2014). It was deemed appropriate that the qualitative CASP tool would be applied to the section of the programme report detailing the results of Workstream 2 in addition to referring to Ong et al., for additional detail of NPT's use where necessary.

Of the 12 papers that were appraised, all were deemed to be of sufficient quality according to the CASP tool. In general, there was limited evidence in six studies (Drew et al., 2015; Judge et al., 2016; Peng et al., 2020; Sanders

et al., 2011; Saunders et al., 2022; Wylde et al., 2018), to support the appraisal of question six regarding the relationship between the researcher and the participants. The lack of evidence to answer this question, is likely due to limitations with manuscript word count and reflexivity of researchers not being a formal requirement from journals for publication; as previously acknowledged by Olmos-Vega et al., (2023). However, appraisal against the remainder of the questions was felt to be sufficient to support the rigour of the articles.

2.5.2.7 ASSESSMENT OF CONFIDENCE

There were eight key findings assessed against the GRADE-CERQUAL criteria. The results of the assessment are shown in Table 2.6, presenting five findings of a high confidence and three of a moderate confidence.

Summary of review finding	Studies contributing to this review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence
1. Coherence is the most commonly utilised construct to understand intervention implementation and is seen as a fundamental first step	Foster et al. 2020; Gilbert et al. 2022; Ong et al. 2014; Peng et al. 2020; Sanders et al. 2011; Saunders et al. 2020; Saunders et al. 2022; Volkmer et al. 2021;	**No/Very minor concerns** (CASP scoring used to support assessment of this criterion)	**Moderate concerns** (The construct of coherence is the most frequently used construct of NPT across the dataset. However, only 3 studies [4 papers] used coherence in isolation. The remaining 4 studies therefore do not utilise coherence (construct) as a first step and so there are moderate concerns regarding	**Moderate concerns** (The 3 studies utilising coherence as a first step offered limited rationale for this and so there are concerns regarding the richness of data supporting this review finding)	**No/Very minor concerns** (8 studies of relevance to the review question, objectives and eligibility criteria. Range of interventions and MSK/orthopaedic conditions across the studies)	**Moderate confidence**

			coherence (assessment criterion) for this review finding)			
2. To date, only evidence of NPT (including ENPT) use to support the implementation of MSK/orthopaedic interventions is available and so it is unclear how NPT can be used to support intervention development and refinement	Drew et al. 2015; Foster et al. 2020; Gilbert et al. 2018; Gilbert et al. 2019; Gilbert et al. 2022; Hay et al. 2018; Judge et al. 2016; Ong et al. 2014; Peng et al. 2020; Sanders et al. 2011; Saunders et al. 2020; Saunders et al. 2022; Volkmer et al. 2021; Wylde et al. 2018;	**No/Very minor concerns** (CASP scoring used to support assessment of this criterion)	**No/Very minor concerns** (The review finding is coherent with the underlying data)	**Minor concerns** (Minor concerns as although NPT is used to support implementation across all 12 studies [14 papers] there is limited discussion offering further detail and insight into its use. Data richness therefore limited)	**No/Very minor concerns** (12 studies of relevance to the review question, objectives and eligibility criteria. Range of interventions, MSK/orthopaedic conditions and healthcare settings across the studies)	**High confidence**

3. There is no evidence that the intervention or MSK/orthopaedic condition being targeted affects the utility of NPT/ENPT	Drew et al. 2015; Foster et al. 2020; Gilbert et al. 2018; Gilbert et al. 2019; Gilbert et al. 2022; Hay et al. 2018; Judge et al. 2016; Ong et al. 2014; Peng et al. 2020; Sanders et al. 2011; Saunders et al. 2020; Saunders et al. 2022; Volkmer et al. 2021; Wylde et al. 2018;	**No/Very minor concerns** (CASP scoring used to support assessment of this criterion)	**No/Very minor concerns** (The review finding is coherent with the underlying data. No issues were reported in any paper regarding the suitability of NPT for MSK/orthopaedic conditions)	**Minor concerns** (No discussion in any study regarding the suitability of NPT for any MSK/orthopaedic condition. Data richness to support NPTs use for any MSK/orthopaedic condition is limited, however data to refute its use is non-evident)	**No/Very minor concerns** (12 studies of relevance to the review question, objectives and eligibility criteria. Range of interventions, MSK/orthopaedic conditions and healthcare settings across the studies)	**High confidence**
4. It is unclear when utilisation of the original constructs of NPT may be	Drew et al. 2015; Foster et al. 2020; Gilbert et al. 2018; Gilbert	**No/Very minor concerns** (CASP scoring used to support	**No/Very minor concerns** (This review finding is	**No/Very minor concerns** (No discussion in any study	**No/Very Minor concerns** (12 studies of relevance to the	**High confidence**

more appropriate to those than ENPT and vice versa	et al. 2019; Gilbert et al. 2022; Hay et al. 2018; Judge et al. 2016; Ong et al. 2014; Peng et al. 2020; Sanders et al. 2011; Saunders et al. 2020; Saunders et al. 2022; Volkmer et al. 2021; Wylde et al. 2018;	assessment of this criterion)	coherent with the underlying data as there is limited to no discussion to support the use of NPT over ENPT and vice versa)	regarding the appropriateness of either version of the theory and so there are no/very minor concerns regarding this review findings)	review question, objectives and eligibility criteria. Range of interventions, MSK/orthopaedic conditions and healthcare settings across the studies)	
5. There is limited evidence to support the NoMAD instruments' utility	Wylde et al. 2018	**No/Very minor concerns**	**No/Very minor concerns** (only one study utilising NoMAD. The instrument is not referred to in any other study and so this review finding is	**Minor concerns** (Data richness to support NoMADs use is limited, however data to refute it's use is non-evident)	**Minor concerns** (1 study and therefore only 1 condition [total knee replacement], intervention type [clinic pathway] and setting	**High confidence**

			coherence with the underlying data)		[secondary care])	
6. NPT/ENPT is a useful analytical lens to focus researcher's attention to understanding implementation factors more robustly and accounting for a range of identified issues	Foster et al. 2020; Gilbert et al. 2022; Hay et al. 2018; Judge et al. 2016; Peng et al. 2020; Saunders et al. 2020; Saunders et al. 2022	**No/Very minor concerns**	**No/Very minor concerns** (The review finding is coherent with the underlying data)	**Minor concerns** (7 papers discussing the usefulness of NPT in implementation however further detail to offer greater insight into its use would have been beneficial. This would have added a greater degree of richness to support this review finding)	**No/Very minor concerns** (6 studies [7 papers] of relevance to the review question, objectives and eligibility criteria. Range of interventions, MSK/orthopaedic conditions and healthcare settings across the studies)	**High confidence**
7. The application of ENPT may pose a challenge for researcher's due to the overlapping	Drew et al. 2015	**No/Very minor concerns**	**No/Very minor concerns** (Although only one study supports this	**Moderate concerns** (Only 1 study supporting this review finding.	**Minor concerns** (1 study and therefore only 1 condition [hip fracture],	**Moderate confidence**

nature of constructs			review finding, there were no data to challenge it. The finding is therefore coherent with the underlying data)	Further detail would have added greater insight to support the understanding of the challenges in ENPT's application)	intervention type [service] and setting [secondary care])	
8. There is limited evidence that the population targeted by the intervention limits the use of particular NPT constructs	Sanders et al. 2011	**No/Very minor concerns**	**Moderate concerns** (Moderate concerns with this finding as only one study reported limited evidence to support the use of 3 NPT constructs for their population. However, no issues were reported in all other studies. An alternative	**Moderate concerns** (Only 1 study questioned the utility of NPT (3 constructs) in a specific population. There was limited discussion as to why the authors felt the constructs didn't reflect the population in question and evidence of this would have	**Minor concerns** (1 study and therefore only 1 condition [back pain], intervention type [assessment tool] and setting [primary care])	**Moderate confidence**

			explanation may be that although there was no empirical evidence supporting the constructs use in the studies population, it does not necessarily mean that NPT is not suitable for use).	provided a greater depth of understanding)		

Table 2.6 – GRADE-CERQUAL assessment of key findings

2.5.3 DISCUSSION

2.5.3.1 KEY RESULTS

In this review, 12 studies were identified to utilise NPT/ENPT during intervention implementation. These studies were reported or discussed in 14 peer-reviewed journal articles. Eight key findings were assessed using GRADE-CERQual with five of high and three of moderate confidence.

The use of NPT/ENPT was most prevalent in qualitative study designs. It was used to support intervention implementation across primary, secondary, and tertiary care settings for a range of MSK and orthopaedic conditions including specific conditions such as hip fractures, sciatica and atraumatic shoulder instability and more generically described conditions such as MSK pain.

The constructs and theory (NPT/ENPT) were used in line with that which has previously been described by May and Finch (May, 2013; May and Finch, 2009; May et al., 2016).

A summary of recommendations is shown in Table 2.7.

Recommendations based on review findings	
1	NPT/ENPT can be used to support and understand implementation of orthopaedics/MSK interventions.
2	Consider NPT/ENPT to support intervention development and refinement. Offer detail of its use and usability to inform future research in this area.
3	NPT/ENPT seems appropriate for use across all orthopaedic/MSK conditions and target populations.
4	Consider the additional constructs offered by ENPT to support greater exploration of contextual factors but be cautious of the potential challenges with the overlapping concepts. Inviting a researcher familiar with NPT/ENPT may support this.
5	Report on the challenges of using NPT/ENPT to inform future researchers.
6	Consider using the NoMAD tool and reporting on the instruments utility to add to the evidence base and inform future researchers.

Table 2.7 – Summary of recommendations for NPT/ENPT based on review findings

2.5.3.2 RESULTS IN CONTEXT

Implementation of complex interventions should be visioned as an iterative process (May et al., 2016; O'Cathain et al., 2019a; Skivington et al., 2021). However, predominant use of a single construct (coherence) and the suggestion that this is a fundamental first step in the implementation process is indicative that, for interventions specific to orthopaedic/MSK conditions included in this review, implementation using NPT is still seen as linear. Viewing implementation as a one-directional process is problematic. Coherence is concerned with agents perceiving a need for the intervention and seeing it as meaningful. If this is considered to be met, with no other elements explored, there is potential for research teams to miss factors that could instantly disrupt intervention adoption at the next stage, examples include:

(1) Lack of resources available to support workability of the intervention (collective action)

(2) Lack of outcomes recorded to evaluate the interventions use and thus lack of evidence to demonstrate its benefit to service commissioners (reflexive monitoring)

Further, if the next step is reached along this linear process, it is implied that factors relating to coherence are not revisited. As the intervention and research evolves, key issues relating to coherence may be missed that subsequently affects intervention normalisation further down the line. Therefore, considering coherence in isolation of other factors, seems to narrow the practice for complex intervention implementation in healthcare. Viewing implementation as linear, may only be one account for the use of coherence as a standalone construct. However, in the absence of reflexive accounts from authors offering further insight into this, alternative explanations are limited.

In addition, the use of NPT in isolation, without the additional elements outlined in the updated ENPT, may result in key contextual facilitators or inhibitors being missed (Skivington et al., 2021). The context in which the intervention is to be implemented is an important consideration, given that it will exert its influence by altering existing practices, changing resource utility and impacting upon user and deliverer relationships. Context is described by Skivington et al., (2021) to be considered as both dynamic and multi-dimensional to include physical, spatial, organisational, social, cultural, political, or economic features. However context has been acknowledged as an important but poorly understood aspect of implementation (Fitzgerald et al., 2005; Nilsen, 2015). This is perhaps because a universally accepted explanation of context has yet

to be established; as recognised in a recent systematic review which summarised 64 studies in aim of defining and assessing context in healthcare implementation studies (Rogers et al., 2020). The review encouraged the development of an operational definition to support consistency in future research studies and to allow for context to be appropriately accounted for. In the absence of a unified definition, the constructs offered in ENPT support the consideration of contextual elements (including social norms, social roles, cognitive resources and material resources [capacity] and individual intentions and shared commitments [potential]) (May, 2013). Whilst a single tool/theory may not capture and account for all relevant elements, lack of any consideration of the context is not supported by the current evidence base. Use of the original constructs of NPT alone, could therefore be considered insufficient. However, as the studies included in this review did not report or discuss this, NPT's utility to address contextual factors is unclear.

The use of NPT in supporting implementation was demonstrated across a range of healthcare settings for interventions targeting several different orthopaedic/MSK interventions. There was consistent stability of each NPT construct across the studies, used against their description in the literature, demonstrating NPT's ability to be applied successfully to a range of intervention research projects. The original developers suggest that the optimal way to employ NPT is to adapt it, specific to the research goal to support workability (Nilsen and Birken, 2020). This review supports that NPT can be used to meet the needs of a range of interventions for several different conditions in the field of MSK/orthopaedics, however there is limited evidence to support its adaptation. There was also no evidence for NPT's utility in

intervention development despite the use of theory being highlighted as a key action in this phase (O'Cathain et al., 2019a). Reserving NPT for use solely in the implementation phase may delay identification of key inhibiting and/or facilitatory factors. This practice also promotes a linear stepwise process which has been discussed above and identified to be problematic. NPT's utility in supporting the iterative development process therefore remains hypothetical as there is currently no evidence to evaluate its use.

There was a concern in three studies that NPT, when used to support framework analysis, may not account for all captured data (Drew et al., 2015; Judge et al., 2016; Saunders et al., 2022). This was addressed by the introduction of a preliminary stage of inductive analysis before data was subsequently mapped onto NPT constructs. However, two study teams reflected that NPT was able to account for all issues relating to implementation, providing reassurance for future studies that an initial inductive stage may not be necessary (Judge et al., 2016; Saunders et al., 2022). Despite the two study teams being satisfied that analysis using NPT was sufficient, it could be argued that these interpretations could be expanded upon using ENPT. As suggested above, the original constructs may not cover all important aspects of implementation and so, some elements may have been missed through the sole use of NPT.

There was a lack of justification, by study authors, for NPT's use across the included studies. Despite this, benefits of its use were accounted in six of the included 12 studies. Further discussion detailing reflexive decision-making would have added deeper insight and clarity for the selection of NPT amongst other theories and for individual construct use. This would support future

researchers to understand the usability of NPT and appropriateness of its choice. Negative aspects of theory use were sparsely reported. This could be due to the user friendliness of the theory and thus minimal issues experienced, or due to the limitations to manuscript publication meaning this level of detail was edited out during manuscript preparation/publication process. In addition to journal word count limitations, there is no requirement for this detail to be evidenced according to reporting guidelines such as COnsolidated criteria for REporting Qualitative (COREQ) (Tong et al., 2007) and Consolidated Standards of Reporting Trails (CONSORT) (Schulz et al., 2010). This may result in pitfalls of theory use encountered by one research team being avoidably repeated by another. To improve the use of theory among researchers and in the interest of research waste and efficiency, evidence of insight into its use would be beneficial. Ten studies were also excluded from this review due to the limited description of NPT use. This contributes to the argument for sufficient detail to be documented to support other researchers in utilising NPT. Finally, some healthcare research continues to be funded, conducted and published without clear consideration of underpinning theory. Without author insight, the benefits of theory use therefore remain unclear.

2.5.3.3 WIDER EVIDENCE

This review contributes to the evidence of NPT's use in the implementation process and can be supplemented by the work of May et al., (2018a) and Huddlestone et al., (2020). In May et al's., systematic review, 130 reports of 108 NPT studies demonstrated its use to support intervention design, implementation planning and understanding of implementation, embedding and integration in feasibility studies and process evaluations (May et al.,

2018a). All included studies utilised NPM, NPT or ENPT; with NPT most commonly reported. Similar to the present review, May et al., found that some researchers utilised the theory in a linear manner, with sense-making seen as the preliminary step. It was also concluded that critique of NPT was rare, not all included studies justified its use and typically, NPT was used as a conceptual framework structuring study design and data analysis.

Huddlestone et al's., systematic review explored the application of NPT specific to UK primary care settings (Huddlestone et al., 2020). This review included 31 papers detailing the use of the original four constructs of NPT. The authors concluded that the theory provides a flexible framework for intervention development and evaluation and supported its use in the primary care setting. Similar to this and May et al's review, Huddlestone et al., encouraged future NPT users to document justifications for its use as there was limited evidence of this in the included studies. There were however, 12 categories of author reflections documented regarding NPT use, of which three were similar to that discussed in this review:

1) Useful way of understanding the experience of the implementation of innovation, from multiple perspectives
2) Risk of artificially imposing ("shoehorning") constructs onto data collection and analysis and
3) Potential for cross-over of NPT constructs.

The ability of NPT to complement other theory use was also reflected upon in three studies in Huddlestone et al's review. Although this was not directly stated by the two research teams utilising other theory in addition to NPT in

this review, it could be implied that given the research was completed and published, NPT was compatible with other theories (boundary objects concepts (Foster et al., 2020) and preference theory (Gilbert et al., 2022)).

2.5.3.4 STRENGTHS AND LIMITATIONS

This review contributes to the literature in supporting the use of NPT in MSK/orthopaedic intervention research. A thorough search produced 14 studies for discussion which covered a range of interventions and conditions. Non-English articles were included in the search which widened the scope, however, none were found to be appropriate for inclusion. Although a comprehensive search was undertaken in two bibliographic databases and one search engine, it is possible that some studies were missed. The use of Google Scholar was also challenging as it produced multiple versions of the same reference creating additional work in eliminating duplications. The choice to narrow the context of interventions in the field of MSK/orthopaedic conditions also potentially reduces the transferability of results to other areas of healthcare. Although framework analysis was used and analysis using this method is likely repeatable by another research team, it is possible different conclusions could be drawn from the data by other researchers due to the subjective nature of qualitative data. The robustness of the review findings has been maximised by refining the a priori matrices with a formal review after 25% of the data were charted and through continual discussions of the results with the lead researcher's supervisors. The supervisory team included those with experience of using NPT in addition to those with minimal experience; ensuring the process was transparent and comprehensible.

2.5.4 CONCLUSION

The use of NPT/ENPT to support intervention development and refinement among the orthopaedic/MSK evidence-base is sparse. Reviewing the theory's utility in implementation however, has demonstrated its potential in supporting these processes. Its use in future research can therefore be advocated for, based on the results of this review.

The construct of coherence appears most popular with limited insight into construct selection. The specific benefits of using NPT/ENPT over another or no theory is limited, and further work is needed to define this. As context is a key factor in the intervention development and implementation process, the use of NPT alone is perhaps no longer sufficient. NPT's utility in understanding contextual factors was unclear in the orthopaedic/MSK studies included in this review. However, evidence of the additional benefits of ENPT use is sparse. NPT/ENPT appears suitable for implementation research across a range of healthcare settings and for differing types of interventions targeting several different orthopaedic/MSK conditions. Future researchers are encouraged to offer clear justification for NPT's use in their methodology.

NEXT STEPS

In the field of MSK/orthopaedic conditions, researchers need to consider utilising NPT/ENPT in an iterative intervention implementation process, with multiple feedback loops rather than a linear stepwise approach. Further, attention to context is important to ensure key factors are not missed. Deeper insight into the usability of NPT is encouraged to support transparency of its use.

As defined in objective (1), the review aimed to identify the use of NPT in the process of intervention development, implementation and/or refinement. In this review, NPT's utility has only been identified in the implementation phase. The use of NPT to support intervention development and refinement therefore remains unknown and further research is needed to determine its benefit in orthopaedic/MSK research.

Relevant to this PhD, the review has offered insight into implementation processes and developed the lead researchers understanding of NPT/ENPT. It was encouraging to find use of the theory across several different conditions and no findings called to question its suitability for use as an underpinning theory in this research. Further, exploring the use of NPT versus ENPT has ensured consideration as to which version of the theory was most appropriate for use. During the PhD funding application process, HC considered the use of NPT but not ENPT. However, individual reflexive practices and those facilitated by the supervisory team whilst undertaking this review has led to the decision to utilise the constructs of ENPT. As the original constructs are encompassed with contribution (one construct of ENPT), the use of ENPT would allow for further exploration of contextual factors whilst allowing for consideration of factors related to agency independent of context. A pragmatic philosophy helped interpret the review findings and guide decision making as to the selection of ENPT and translation of key findings to this thesis. The use of ENPT further aligns with the underpinning philosophy of the research, supporting Phases 1-3.

2.6 CONCLUSION

This Chapter has presented the philosophical assumptions, theoretical underpinning and methodology used in this PhD. An overview of complex intervention development and NPT has been discussed in addition to deeper exploration of NPT/ENPT's use in orthopaedic/musculoskeletal intervention research.

Chapters 3-5 report the findings of each Phase undertaken in this mixed-methods study, demonstrate the use of pragmatic philosophy in guiding this research and discuss ENPT's utility in supporting the development, implementation and refinement of the intervention. Chapter 6 summarises the main findings, discusses recommendations for clinical practice and future research and reflects upon the planned aims and objectives outlined in Chapter 1.

CHAPTER 3 UNDERSTANDING PATIENT EXPERIENCES (PHASE 1)

Summary

Phase 1 aims to understand patient experiences, through qualitative individual interviews, at three time-points on the ACL treatment pathway; (1) pre-operative, (2) 3-months post-operative, (3) 12-months post-operative.

The results will contribute to intervention development in Phase 2 (Chapter 4) and support the exploration of the interventions acceptability in Phase 3 (Chapter 5).

Chapter 1 presented the mechanisms and prevalence of ACL ruptures, injury consequences and available treatment options. The difficulties with treatment decision-making between patients and clinicians were also discussed as currently, there is no optimum treatment pathway. The current knowledge gaps were presented, one of which was understanding patient experiences in a UK NHS setting. This chapter reports the findings of a qualitative, individual interview study, exploring patient experiences of the ACL pathway in the UK.

3.1 INTRODUCTION

In 2020, the British Orthopaedic Association (BOA), BASK and BOSTAA jointly published best practice guidelines for the management of ACL ruptures in the UK (BOA et al., 2020). The guidelines describe management across the pathway from diagnosis to post-operative care and follow-up. Diagnosing an

ACL rupture should therefore be somewhat uncomplicated. Patients typically report an audible ‘pop’, pain, rapid onset of knee swelling, limitation to knee function and/or grabbing the knee after the injury event (Parwaiz et al., 2016). A clinician’s index of suspicion for an ACL rupture should therefore be raised when presented with some features of this typical history, and a referral for urgent assessment in an acute knee injury clinic should be completed (BOA et al., 2020). However, it is acknowledged that presence of pain, guarding and effusion can present challenges to diagnosis in an acutely injured knee (Guillodo et al., 2008). MRI is the modality of choice to assess for ACL injury, demonstrating high accuracy for complete ACL tears of >87% (Li et al., 2022; Zhao et al., 2020). Accuracy is reduced for chronic tears and so ‘getting it right first time’ is particularly important for this patient group (Vahey et al., 1991; Xu et al., 2018). However, analysis of retrospective UK data has recognised that diagnosis rate from initial presentation is poor (Decary et al., 2018; Parwaiz et al., 2016). Patients’ experience of the diagnosis pathway are currently unknown.

Once diagnosed, treatment may follow a non-surgical or surgical approach (discussed in 1.3.1). Regardless of the pathway followed, rehabilitation is recommended, however guidance supporting clinicians in delivering evidence-based rehabilitation is limited and thus clinical practice varies widely (Carter et al., 2021; Filbay and Grindem, 2019). Rehabilitation is also completed post-surgery, although the breadth of research in this area is vast and protocols are consistently reported to be heterogeneous with no consensus on the most clinically-effective approach (Andrade et al., 2020b; Culvenor et al., 2022).

As discussed in Chapter 1.4, patient-centred care is a core ethos of the NHS, outlined in the Long Term Plan as a key deliverable (National Health Service, 2019). Limited research exists to describe the patient experience of sustaining an ACL injury and navigating the ACLR pathway and so our ability to deliver patient-centred care is sub-optimal. To date, only quantitative measures collected from cohort studies have reported patients' preoperative expectations of RTS following ACLR (Feucht et al., 2016; Webster and Feller, 2019a). Postoperative perspectives from 6-months to 10-years post-surgery have however, been explored through semi-structured interviews (Heijne et al., 2007; Kaur et al., 2019; Scott et al., 2018). Collectively, these studies, reveal that patients have unrealistic preoperative expectations of returning to physical activity post-surgery and are faced with a post-operative rehabilitation burden that requires an unexpected level of commitment; with participants describing a lack of mental preparation for the rehabilitation process that was longer and more intense than expected (Heijne et al., 2007; Scott et al., 2018; Webster and Feller, 2019a). Patients further report ongoing issues, requiring them to seek healthcare professionals' advice up to 10-years post-surgery (Heijne et al., 2007; Kaur et al., 2019). There is an absence of knowledge to understand patients lived experience of this phenomena, particularly prior to surgical intervention. Further, there is a paucity of evidence to understand where patients seek healthcare advice following an ACL rupture diagnosis.

The aim of the study was to understand patients' lived experiences of the treatment pathway following a diagnosis of an ACL rupture and agreed surgical management. Study objectives were (1) to explore lived experiences at pre- and post-operative time points, (2) to explore patients' views and involvement

in prehabilitation and (3) to understand patients' sources and consistency of healthcare advice prior to surgery.

3.2 METHODS

3.2.1 DESIGN

This study utilised semi-structured individual interviews to achieve the aims and objectives discussed below. It was designed with input from the POP-ACLR study patient and public involvement and engagement (PPIE) group who helped to identify priorities of inquiry. Further, two patient representatives sat on the Trial Management Group (TMG) supporting study oversight.

This research was reviewed and given favourable opinion by the North East - Newcastle & North Tyneside 1 Research Ethics Committee on 27th July 2022 (reference number: 22/NE/0119). The study was registered on clinicaltrials.gov (ID: NCT05529511) on 2nd September 2022.

3.2.2 AIMS AND OBJECTIVES

The main aim of this phase was to understand patients' lived experiences at three time points on the patient pathway from receiving an ACL rupture diagnosis, having surgery and returning to sport/physical activity. The exploration of patients' sources and consistency of healthcare advice was added as an aim following consultations with patients during PPIE workshops.

Phase 1 objectives are shown in Table 3.1.

Objective (a)	To interview approximately 36 participants at three time points: 1) 12 participants up to 2 weeks before surgery 2) 12 participants 3 months after surgery 3) 12 participants 12 months after surgery These time points were determined in collaboration with patients and stakeholders and reflect important points within the patients' journey (for example, at 3 months patients are able to begin impact exercises such as running, after 9 months most patients have begun to return to unrestricted physical activity and thus by 12 months, have the opportunity to return to preinjury activity levels).
Objective (b)	To explore patients' lived experiences of ACL injury, rehabilitation and returning to physical activity following ACLR
Objective (c)	To explore patients' involvement in and views of prehabilitation
Objective (d)	To understand patients' sources and consistency of healthcare advice prior to surgery

Table 3.1 – Phase 1 objectives

Objective (a) was amended following field visits to the orthopaedic consultants and their secretary at the Royal Derby Hospital (RDH) after discussing the difficulties with planning surgical procedures following coronavirus disease (COVID-19), the number of patients currently awaiting surgery and how several procedures were scheduled ‘last minute’. It was felt that a 2-week window was no longer appropriate as it may exclude many patients who were due for imminent surgery (within the next 2-3 months) but were still awaiting a

set date. This timeframe was therefore amended to ‘up to 3 months before surgery’ with an amendment submitted on 10th August 2022.

3.2.3 SAMPLE SIZE AND ELIGIBILITY CRITERIA

The sampling framework aimed to interview participants to the point where no new themes arose. This was anticipated to be reached by approximately 12 interviews (at each of the three time-points) (Guest et al., 2006; Hennink et al., 2017).

The eligibility criteria are shown in Table 3.2**.**

Inclusion
1) ≥ 18-years old
2) Patient who is awaiting or has previously had an ACLR

Exclusion
1) Concomitant injuries requiring surgical intervention that will significantly alter the postoperative rehabilitation protocol e.g., meniscal repair requiring a non-weight bearing period
2) Previous knee surgery to the affected limb
3) Co-existing injuries requiring surgical intervention impacting on the individual’s participation in pre- or post-operative rehabilitation
4) Pregnancy

Table 3.2 – Eligibility criteria

Pregnant participants were excluded due to the impact of pregnancy on experiences of the ACLR pathway such as the timing of surgical intervention and engagement with and progression through rehabilitation protocols.

3.2.4 RECRUITMENT

The aim was to recruit approximately 12 patients at each of the three time-points (3-months prior to surgery, 3-months after surgery and 1-year after surgery) estimating that this would be sufficient to reach data saturation and mirrored similar research of musculoskeletal/orthopaedic conditions (Cuff and Littlewood, 2018; Hennink et al., 2017; Littlewood et al., 2014; Smith et al., 2018). A range of participant characteristics, including age, sex, physical activity type and level and prehabilitation engagement, were sought to be included.

Participants were identified by the clinician in charge of their care and recruited from physiotherapy and orthopaedic waiting lists at the University Hospitals of Derby and Burton NHS Foundation Trust (UHDB). Orthopaedic waiting lists were screened for two lower limb consultants at UHDB and all outpatient MSK physiotherapists working at the Florence Nightingale Community Hospital (FNCH). All patients had received an MRI and had a consultation with an orthopaedic clinician to determine the extent of concomitant injuries. Clinicians were aware of the study eligibility criteria and highlighted all those appropriate for inclusion in the study. They were subsequently contacted by the lead researcher (HC) via mail, telephone or introduced in person. Eligibility for inclusion was checked prior to consent being gained for participation in the study.

Recruitment at the 12-month time-point was particularly challenging. On discussion with healthcare professionals at UHDB, surgeons and physiotherapists reported discharging postoperative ACLR patients (with an

open appointment) at six and nine months respectively. This was discussed at Trial Steering Committee (TSC) and TMG meetings where the following suggestions were made: (1) design business cards for clinicians to provide to patients at their last hospital appointment to advertise the study and act as an aide-memoire for contact around the 1-year time point; (2) discuss with clinicians at UHDB/other hospitals to explore alternative ways of contacting patients. Subsequently, business cards were designed and printed, shown in Figure 3.1A, which were provided to clinicians at UHDB. They were also distributed at the BOA Congress in September 2022 to clinicians during a presentation describing the POP-ACLR study. Pens with the study logo and website address were also created and distributed at UHDB and BOA (Figure 3.1B). Difficulties with recruitment of patients at the 12-month time point within and outside of UHDB was discussed and several clinicians (therapists and surgeons) showed interest at BOA. On discussion, clinicians agreed that 12-months post-surgery may be difficult due to reduced contact from the hospital but felt confident they were able to signpost appropriate patients.

A



B



Figure 3.1 – POP-ACLR study promotion material

A. POP-ACLR study recruitment business card. B. POP-ACLR study pen

3.2.5 DATA COLLECTION

Participants were offered choice of interview location and medium (face-to-face/telephone/video). Eight participants opted for a face-to-face interview conducted in a hospital setting and the remainder opted for a telephone interview. Interviews were carried out between August and November 2022. Prior to recording at the start of each the lead researcher introduced herself as a Physiotherapist working at UHDB and as a researcher conducting a PhD at the University of Nottingham. The aims of the study were explained, with the opportunity for any final questions to be answered. Consent was subsequently taken to start the interview and recording.

Semi-structured interviews were conducted using a topic guide, developed at TMG meetings using the literature and PPIE input (Appendix A). This interview style allowed the interview structure to remain flexible, whilst permitting avenues of questioning, relevant to the research aims, to be freely explored.

The lead researcher also maintained a reflexive journal to document thoughts after each interview, in addition to revisiting initial interview recordings to review interview and questioning technique. This practice helped to identify areas where the researcher was hesitant to prompt for further clarification and supported deeper exploration of concepts in later interviews. It also acted as a basis for discussion during TSC meetings and allowed for participant characteristics to be recognised ensuring recruitment was responsive to data collection.

3.2.6 DATA ANALYSIS

Reflexive thematic analysis (RTA) was chosen to analyse the data, aligning to the philosophical underpinnings of pragmatism (Braun and Clarke, 2021). The results are reported in line with the COREQ checklist (Tong et al., 2007).

RTA is described to offer “robust process guidelines, not rigid rules” (Braun and Clarke, 2021), facilitating rich engagement with the data to allow for knowledge production. The process and procedures of RTA operate within the qualitative paradigm where researchers accept a partly knowable world where practice is situated in meaning and interpretation, rather than experiments and systematic observation. Pragmatism allows for this line of enquiry with a focus on the research question and appropriate methods of answering this, rather than ontological and epistemological debates.

Audio files were sent for transcription to an approved third-party vendor by UHDB. On receipt, transcriptions were reviewed against the audio recording for accuracy. The transcripts were read several times to support data immersion and then coded, with code generation discussed at TSC meetings.

Data were organised and coded in NVivo V.12 (released 2017). After initial coding, themes were developed in Microsoft Excel (Microsoft Cop., Redmon, WA, USA). 75% of codes were generated by interview six and 100% of codes were reached by interview 16, offering reassurance that no new codes were arising in the latter stages of recruitment (Figure 3.2).

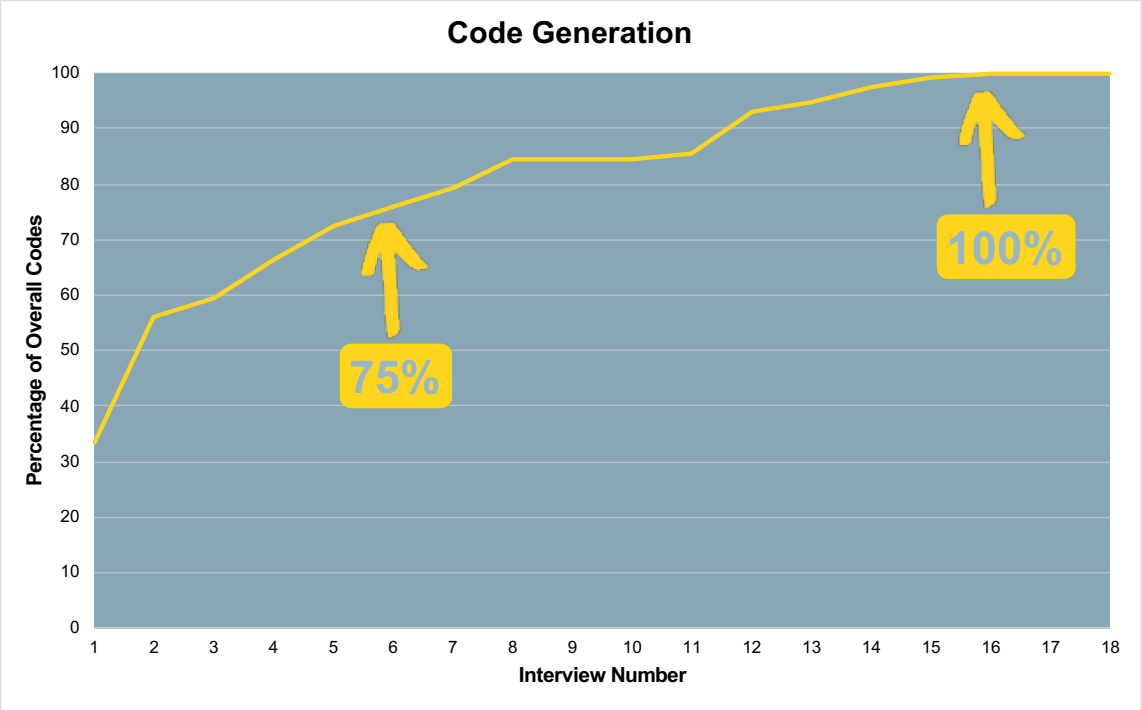


Figure 3.2 – Code generation graph

Recruitment closed after 18 interviews for several reasons. Firstly, the a priori assumption that 12 participants were needed from each time point revealed to be unnecessary as the study progressed. Whilst participants had different experiences relevant to the time-point at which they were interviewed, distinct differences relevant to the research aims and objectives were less apparent; this was supported by the code generation graph. Secondly, as discussed above, recruitment of participants at the one-year time-point proved challenging. As code generation began to stabilise, it was considered whether participants at the 1-year time-point may present data that generated new

codes. However, the two interviews with participants at the 1-year time point took place after 75% of the codes had been generated. After transcript analysis, the codebook remained stable with 100% of codes reached by interview 16. From a pragmatic perspective, continuing to seek patients at the 1-year time-point did not seem necessary. Finally, following discussions at TSC meetings, it was agreed that further recruitment and interviews were not necessary to meet the research aims and objectives.

The codes were organised into five themes to match the research objectives. These themes and supporting extracts were discussed at TSC and TMG meetings and were felt to offer a rich and clear insight of the data, individually representing an organising concept whilst contributing to the narrative of other themes and thus the entire dataset. The questions show in Figure 3.3 from Braun and Clarke were used to support the refinement of each theme (Braun and Clarke, 2021):

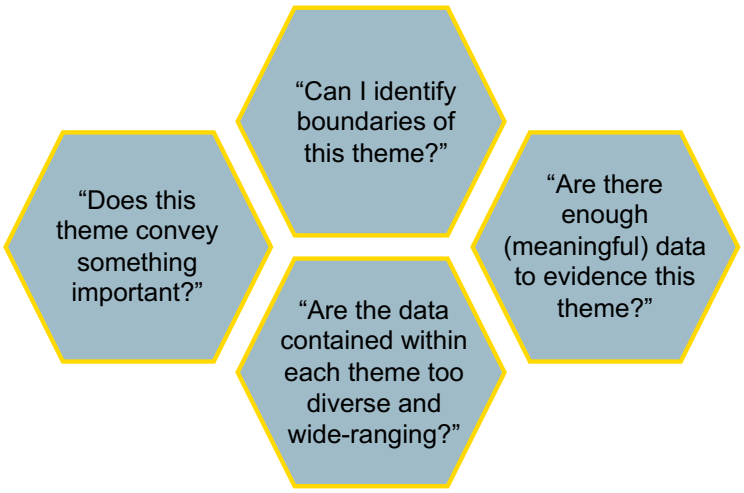


Figure 3.3 – Theme refinement questions

The codebook is available in Appendix B.

3.3 RESULTS

A purposive sample of 18 participants with a diagnosis of an ACL rupture who were awaiting or had undergone an ACLR were recruited from the NHS physiotherapy and orthopaedic waiting and clinic list. The study was discussed with 26 potential participants, four declined to participate and four did not respond after initial discussion. Participant characteristics are shown in Table 3.3.

Participant Number	Age	Sex	Time-Point on ACLR Pathway	Prehabilitation (Y/N)	Average number of days physically active		Returned to preinjury activity level (Y/N)
					Preinjury	At point of interview	
001	27	M	3-months postoperative	N	4	4	N
002	29	M	Preoperative	Y	4	3	N
003	28	M	Preoperative	Y	3	1	N
004	45	F	Preoperative	Y	3	4	Y
005	29	M	Preoperative	Y	4	1	N
006	29	M	Preoperative	Y	4	2	N
007	30	M	Preoperative	Y	7	7	N
008	28	M	3-months postoperative	Y	6	7	N
009	35	M	Preoperative	Y	4	4	N
010	27	F	Preoperative	Y	3	1	N
011	26	M	3-months postoperative	N	5	5	N
012	32	M	3-months postoperative	N	4	4	N
013	37	M	Preoperative	Y	5	0	Y
014	37	M	Preoperative	Y	3	2	N

015	32	F	1-year postoperative	N	5	5	N
016	28	M	3-months postoperative	N	7	6	N
017	35	M	1-year postoperative	N	4	2	N
018	18	M	3-months postoperative	Y	6	3	N

Table 3.3 – Participant characteristics

Participants ranged from 18 to 45 years of age (median: 29 years), three identified as female (16.7%) with the remainder identifying as male (83.3%). Ethnic origin of participants was predominantly white (n=14, of which one participant also described themselves as Lithuanian), followed by Indian (n=2), British Asian (n=1) and Pakistani (n=1). Ten participants were awaiting ACLR, six were 3-month post-surgery and two were 1-year post-surgery. Injuries were sustained predominantly during a sporting activity (n=12) with the remainder occurring from a slip (n=2), landing from a jump (n=2), a motorcycle incident (n=1) and road traffic collision (n=1). All participants engaged in more than one activity type prior to injury, with 22 different types reported. Football was the most common activity (n=8), followed by attending the gym for resistance training alone (n=7) or cardiovascular and resistance training (n=5), swimming (n=4), rugby (n=3), running (n=3) and cricket (n=3). Other activity types are shown in Table 3.4. The physical activity types participants were engaged in at the time of interview spanned a smaller variety with resistance training the most commonly reported activity (n=7) followed by walking (n=5) and cardiovascular and resistance training at a gym (n=5). Activity types are shown in Table 3.4. Twelve participants engaged in prehabilitation (varied treatment length, type, frequency) at different sites across the midlands. The average number of days participants where physically active prior to injury was 4.5 days compared with 3.4 days at the time of interview.

Activity Type	Number of participants engaging in the activity	
	Preinjury	At point of interview
Badminton	1	
Basketball	1	
Cricket	3	
Cycling	1	1
Football	8	
Golf	1	1
Gym (cardiovascular and resistance training)	5	5
Hiking	1	
Indoor cycling	1	1
Judo	1	
Mountain biking	2	
Netball	2	
Resistance training	7	7
Road cycling		1
Rugby	3	
Running	3	3
Snowboarding	1	
Squash	1	
Swimming	4	1
Tennis	2	
Volleyball	1	
Wakeboarding	1	
Walking	2	5
Yoga		1

Table 3.4 – Activity types

Five themes were identified from the interview data. The first theme: injury experience, impact and support describes participants' injury and diagnosis experience, their beliefs and knowledge of ACL injuries, impact of the injury and journeys of gaining support to deal with injury consequences. Subsequent

themes explore participants' experiences of navigating the ACL treatment pathway and difficulties with utilising resources, making decisions about their care and the challenges of communicating with healthcare professionals in the current NHS climate. Expectations and realities of post-surgical treatment are explored and the value of prehabilitation is also discussed alongside the importance of personalised treatment and information.

3.3.1 THEME 1: INJURY EXPERIENCE, IMPACT AND SUPPORT

Half of the participants reported an intuitive response to injuring their knee. Explaining an instinctive sense of its seriousness, reporting:

> "I think immediately I sort of knew what I had done, even though I had never done it before" [P8, 3-months postoperative]

Following injury, route to diagnosis varied. Some participants described a seamless pathway where a direct referral was made from the Emergency Department (ED) to an acute knee clinic for specialist assessment and MRI. Others were advised to self-manage for an arbitrary period (typically 12-weeks) before seeking advice from a general practitioner (GP) or returning to ED if symptoms remained. This considerably delayed diagnosis, added unnecessary steps to the pathway and resulted in repeat interactions with medical professionals (e.g. ED practitioner, GP, physiotherapist). This is consistent with the literature reporting a median of three different healthcare professionals (HCPs) to be consulted before an ACL diagnosis is made (Parwaiz et al., 2016).

Once diagnosed, several participants described this to be a difficult and distressing time. A lack of knowledge about the injury and its severity contributed to worry and catastrophising thoughts.

> “During that early stage, I was panicking about what is happening … I was just assuming that my life is gone" [P14, preoperative]

Beliefs about the injury and recovery were typically negative, with a consistent thought that surgery was essential for knee function to improve and to allow for a return to normal activities.

> “nothing is going to fix it … until you have the surgery” [P8, 3-months postoperative]

The burden of ACL injury was prevalent across all interviews with detailed accounts of its impact on self and self-identity, family, social and working life. The injury was described to have a profound impact upon engagement in physical activity with several participants explaining to have ceased or significantly reduced participation. The concern of causing further damage and that physical activity was dangerous was the predominant reason for limiting participation.

> " I had to wait two years from when I found out it was an ACL rupture to trying to get surgery. …. I couldn’t do football. It was dangerous. Quit gym. I couldn’t go gym. …. I gained weight." [P17, 1-year postoperative]

Many described having to alter their working duties to less physically demanding roles, finding alternative work in a different occupation or to be on

long-term sick due to their ACL rupture. This resulted in social and financial loss as participants were unable to work and engage in activities with friends and family at preinjury levels. Several participants also described the physical and mental challenges of the injury, such as difficulty accepting changes to their body image as a result of reduced exercise frequency and subsequent weight gain. Participants reflected upon feeling disabled and described several symptoms of depression.

> “I have struggled really, really sort of deeply to the point where I didn’t want to go to work, didn’t want to get out of bed” [P6, preoperative]

Existing personal support networks were valued by participants who described their benefit in accepting the injury and managing its consequences. Support from individuals/groups with injury experience seemed important with suggestions that HCPs fail to fully understand the patient experience and therefore cannot offer truly holistic care. It was further felt that mental wellbeing was not addressed by clinicians.

> “When I went to the GP,… physio and the surgical consultant, there was no questions mentally there. … That’s something that I feel should be addressed. Because significant injuries like this are life changing and anything that’s life changing is very mentally draining" [P7. preoperative]

3.3.2 THEME 2: NAVIGATING THE TREATMENT PATHWAY

Participants gave a detailed description of their journey, commonly referring to this as a “process” [P2, P3]. Engagement from participants was described to be passive as though “you’re just going through the motions” [P3]. The

pathway was further described as prescriptive and lacking personalisation; this led to participants feeling burdensome to clinicians and the healthcare system.

> "yes a little bit of a burden because you know that you are not their priority to say, because you are not the only person they see" [P8, 3-months postoperative]

Participants commonly reported the inconvenience of limited notice for appointments and surgery dates, in addition to frustration with delays and waiting times across the pathway, which contributed to their perception that care was not individualised. Feelings of loneliness were also common, in addition to feeling undervalued due to clinician busyness and restricted appointment times. Communication with healthcare professionals was described to be challenging as participants struggled to gain rapport with clinicians during short appointments in addition to limited opportunities to consider and ask questions about their care. Participants listed honesty, transparency and empathy as important traits in HCPs and failure to display these qualities contributed to feelings of distress.

> "I had to wait a long time so that made my anxiety worse as well. But then actually getting into the room, she could see I was quite distressed, but she just had no kind of emotion at all." [P10, preoperative]

Further, there were multiple accounts of disjointed interactions that caused frustration and a lack of confidence in HCPs. Participants described inter-disciplinary communication as fragmented, with some feeling as though they were responsible for coordinating all those involved in their care.

> “I still don’t think there is that communication if I am honest … everything is on a database … even the physio … the first two or three times he kept going “remind me what you have done” … obviously there has been no communication with the surgeon” [P8, 3-months postoperative]

Whilst some explained the importance of being an active participant in the communication loop, others felt this was disorganised and were frustrated with repeating their story. Those happy to feedback previous conversations to the next HCP felt this contributed to a sense of control over their care which supported decision-making processes.

The primary decision discussed amongst participants was whether to proceed with surgical treatment. This decision-making process was described in three ways by participants, who: (1) were not presented with an opportunity to partake in decision-making i.e. the decision was made for them (2) attempted to avoid decision-making in fear of feeling responsible should an incorrect decision be made and (3) were presented with unbalanced information regarding treatment and felt there was no decision to be made as advice favoured surgical intervention to support a return to physical activity/sport. Two participants explained to have decided upon surgery, to support their role as parents enabling them to be active, without restriction in their children’s lives. Several participants reflected upon the lack of support with decision-making which resulted in feelings of helplessness and caused decision paralysis.

> "I did not get a clear recommendation from the specialist on whether I should go for surgery, they gave me the personal choice. As a non-medical background person, I got the information from the internet and

> I am unable to make the decision. So, from my point of view, I was not able to make the decisions because I don't know the severeness of the problem that I have." [P14, preoperative]

Unsurprisingly, many participants referenced COVID-19 to justify short falls in their care, it was the predominant reason referenced for the delay to surgery with participants offering some leniency because of this. Participants also reflected on the priority of their injury in comparison to others requiring medical attention during the pandemic. Understanding capacity within the hospital was typically measured against reports in the media, with participants starting to avoid attending the hospital when, perhaps, prior to COVID-19 they may have presented sooner.

3.3.3 THEME 3: SENSE MAKING IN THE PREOPERATIVE PERIOD

Despite all participants being on the waiting list for or having had ACLR, some still recalled questioning the necessity of surgery during the preoperative period.

> "I feel like I've just been on a pendulum – I want it done, no I don't want it done, I want it done, no I don't want it done, I want it done – and I'm still a bit like that, and a bit apprehensive" [P4, preoperative]

Participants described feeling unsupported whilst awaiting surgery with several concerns and unanswered questions. Typically, these were related to knowing what to do whilst awaiting surgery, the surgical procedure itself or the postoperative recovery period. Examples are shown in Figure 3.4.

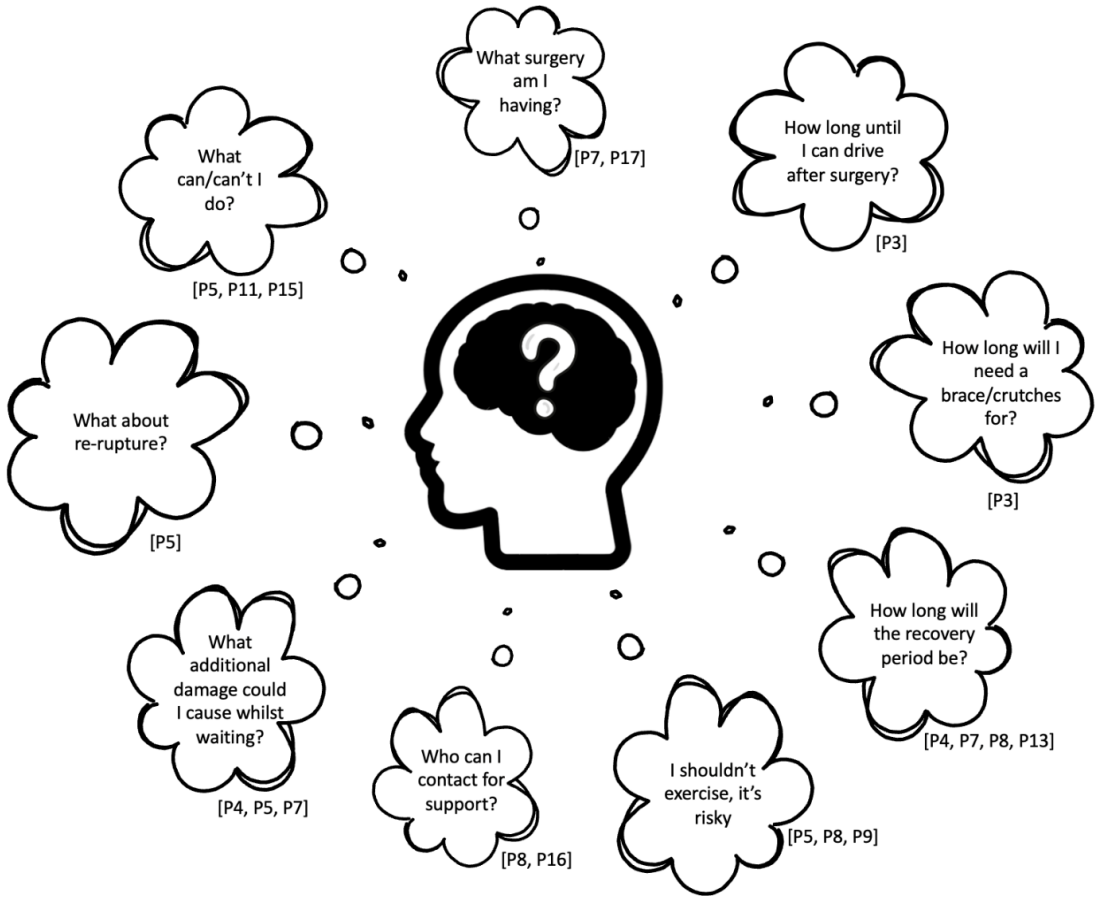


Figure 3.4 – Concerns and questions raised during the preoperative period
Supporting quotes are shown in Appendix C.

Participants battled with several emotions during the preoperative period. Many described frustration with a lack of communication regarding a potential surgery date but were equally discouraged when offered an estimated date that was not met. Many expressed feeling desperate for surgery, but when called with an operation date (often 2 weeks or less) were frustrated with the hindrance of re-prioritising their commitments. Others were conflicted between blindly waiting and repetitively chasing the orthopaedic team for information; battling with self-doubt about what a lack of communication may mean. Participants described lacking confidence during the preoperative period in: (1) their decision making, (2) ability to exercise, (3) understanding their identity as they adjust to their new lifestyle with their injury and (4) healthcare

professionals/hospital procedures running as expected i.e. concern of being missed off the waiting list.

Support through prehabilitation before surgery was valued highly amongst participants, regardless of whether they had received it. It was perceived to offer an advantage to recovery, post-operative rehabilitation and support a faster RTS. Participants also felt it supported psychological wellbeing and increased their knowledge of the injury and its management. Where participants engaged in exercise with physiotherapy guidance it was described to develop confidence and offer reassurance that post-surgery exercise was achievable and may perhaps be easier. Prehabilitation's utility in decision making regarding surgery was also discussed. One participant explained to have only felt comfortable proceeding with surgery after exhausting their potential during prehabilitation.

> "More a decision tool really, so, yes, I tried it and tried to push my boundaries with it but didn't get where I want to be so, yes, it was more a decision tool for me." [P2, preoperative]

One participant felt they had nothing to lose by engaging in rehabilitation prior to surgery, describing desperation of trying anything to improve their knee function. However, there were concerns amongst some that prehabilitation lacked specificity, with participants describing disappointment when prescribed what felt like generic exercises. Where this was the case, participants struggled to understand the value of prehabilitation in their journey.

> “I don’t really know what I expected from it. But I thought that it would be a little bit more personalised and there would be a little bit more of a road to recovery really, [I thought] there would be a little bit more of a personalised service, but I just felt it was just very generic really” [P10, preoperative]

One participant expressed concern that prehabilitation would be a waste of time and resources, after it was explained that post-surgery physiotherapy would be intense and that their knee would not improve without an ACLR. The language and phrasing used during their consultation was influential on their decision to not engage in preoperative rehabilitation.

> “I thought there was no point in me wasting more time at the physio until the issue was resolved. And then I can work on it and getting back to a standard when I can start playing sports again.” [P6, preoperative]

Two participants, who were HCPs by profession, explained to have found benefit from seeking physiotherapy support pre-surgery, despite their own professional knowledge of musculoskeletal injuries. Many participants wanted support transitioning from an un-restricted active lifestyle to managing the consequences of their knee injury, however most felt that this need was or would be unmet by current NHS services. Participants viewed prehabilitation as safe and valued the security of direction provided by a physiotherapist. Where prehabilitation wasn’t offered, many described concerns about engaging in physical activity due to fear of their knee giving way, worry of causing further damage or experiencing pain and/or swelling.

3.3.4 THEME 4: UNCERTAINTY, EXPECTATIONS AND REALITY OF THE POST-SURGICAL PERIOD

Those at post-surgical time-points, typically reflected on the busyness of the hospital environment and delays experienced during their inpatient stay. One participant accounted feeling overwhelmed, rushed and confused due to the limited amount of time spent with medical staff on the ward and a lack of clarity over their treatment plan.

> "It is really quite confusing and overwhelming, you never really quite know what the plan is." [P15, 1-year postoperative]

The early postoperative period (≤3 weeks) was described to be a particularly difficult time, due to unexpectedly high levels of pain, challenges caused by a lack of mobility, struggles maintaining morale and motivation and difficulties with managing thoughts/feelings independently.

> "It's about two weeks [before you] see anybody about it. So having that period where you're expected to crack on with the exercises, in a lot of pain … and all you're left is a booklet to read." [P1, 3-months postoperative]

Participants further described battling anxiety in the first 3-months post-surgery, concerned about the progress they were making, levels of pain and contemplating the success of surgery. Participants' mental wellbeing seemed to reflect their physical progress. When pain levels and physical function began to improve, participants described feeling more positive about the procedure and were hopeful for future rehabilitation prospects.

> “Oh my, it was ten times worse than before, it was awful, the pain is like agonising, I couldn’t sleep, I couldn’t do anything, they gave me oral morphine and that was still like, even when I took that I couldn’t even tell. It was so painful, it was awful but I was like, it’s never going to end.” [P18, 3-months postoperative]

Participants reflected on the intensity of postoperative physiotherapy and the challenge of balancing this against work and social commitments. Those progressing through postoperative rehabilitation described it to be more structured than their experiences of preoperative rehabilitation, which was viewed positively. Postoperative physiotherapy was also typically described as face-to-face interactions. Whilst one participant preferred this, another reflected on the lack of flexibility that this offered, with a preference for increased frequency of appointments and the option of virtual consultations. The common narrative was that personalised care was important.

There was a range of expectations regarding return to work following surgery. Typically, these expectations were not addressed by HCPs and were developed by the participant with little to no support. This is shown in Table 3.5 with supporting quotes.

Return to work expectations	Supporting quote
Following day after surgery	Yes I'll have to [work from home immediately], I'm self-employed. I've got people who work for me but most of the money comes from me doing stuff so I have no choice." [P3, preoperative]
Few days	I did tell work that I was going for surgery. And I told them, "Oh I just need like two days, no sorry, three, four days to recover because it's the weekend and then I'll be back at work on Monday." [P17, 1-year postoperative]
6-weeks to 3-months	"I think realistically I'll be back to work in six weeks to three months" [P2, preoperative]
2-years	"in my head I am just kind of going well I am going to be out for two years, I am not going to be able to work … I am just going to the worst possible scenario" [P7, preoperative]
80% better	"I'll just wait until it's better, if it works then about 80% alright, then I'll try it, but there's no point in rushing it, is there, in case you damage it even more" [P13, preoperative]

Table 3.5 – Return to work expectations

Expectations of return to work did not match reality post-surgery. One participant described having no information about the impact of surgery on their working ability and so expected to only need the weekend to recover. When provided with a sick note for six weeks, they explained feeling shocked and found navigating subsequent conversations with their employer difficult.

Expectations of returning to physical activity also formed a spectrum of assumptions with respect to time and ability to return. Time to return ranged from participants wishes for 'as soon as possible' through to questioning whether they wished to return at all. There were a range of expectations

between the 6- and 12-month mark, with some feeling the time to return was based upon their commitment to rehabilitation whereas others felt a measurement against time was the best indicator. When considering a return to physical activity, some questioned their confidence to return whilst others considered their ability to cope with and the impact of a subsequent ACL injury to their work and social life. Others were adamant to return with their confidence of being able to do so stemming from advice given by a HCP:

> “I was always set on it because the success rate that Mr. X gave was very high, like 95 plus to get my preinjury levels. And I do believe that as well” [P17, 1-year postoperative]

The level of ability participants felt they would be able to return to also varied. Some participants felt they would not be able to return at all, some described accepting they would only be able to return at a sub-injury level, whilst others expected a full return to their preinjury level.

3.3.5 THEME 5: BALANCING RESOURCES, ADVICE AND OPINIONS

There was a common narrative among participants that resources were difficult to navigate. Several participants stated mistrust with the internet and discussed the prevalence of contradictory information. Others avoided searching the internet, in anticipation that information would be inaccurate and conclude catastrophizing outcomes.

> “You know what Google is like, you look at knee surgeries and it turns out you are dying of something with the lungs, you know, don’t trust the internet." [P7, preoperative]

The preference for using forums to explore the lived experiences of the condition was accounted by some, as opposed to reading standardised medical information. Many referenced searching the NHS website, although views of this resource were conflicting. Whilst many seemed to view this as a reputable website, some felt it lacked specificity whereas others described using it as a primary source for all their healthcare information.

Several participants had not been provided with or signposted towards any resources for further information about their condition. Those that were provided with leaflets recalled difficulties in engaging with this resource due to the timing it was given (typically at the end of consultations) and lack of personalisation. A need for a reliable resource that HCPs could recommend, was described as a simple solution that would offer reassurance and support mental wellbeing.

The consequences of the lack of information were profound across many interviews. Participants described difficulty with their mental wellbeing and feeling "in the dark" [P7] due to absent information regarding surgery, how to prepare for it and what to expect post-reconstruction.

> "it's very demoralising when you don't hear anything. And that simple little phone call would make the world of difference" [P7, preoperative]

One participant, with a professional background as a Physiotherapist, emphasised the importance of educational material to be delivered by a HCP, supplemented by written resources. They felt that verbal information lacked depth and information leaflets were too generic leaving ambiguity around the focus of rehabilitation. For example, weight bearing is encouraged immediately

after surgery (as pain allows), however one participant reflected this not to be clear and only felt informed to weight bear on their leg because of their background knowledge as a Physiotherapist.

> “If I didn’t have that physio background I probably wouldn’t have put as much weight on initially (after surgery), probably would have been more walking mostly on my uninjured leg and then the exercise I wouldn’t have stuck to as well" [P1, 3-months postoperative]

Information regarding timelines was a common frustration, with many feeling to be left to manage independently for the prolonged preoperative period. Whilst awaiting a formal date for their operation and in absence of support, participants considered several hypothetical scenarios of how surgery and the subsequent recovery may impact their work, social and family life.

> “Could my recovery time be six months plus or even longer, which if so, I could lose my job over that. I could really be up the creek if that’s the situation because I have got a child, a ten-month-old now as I said, and I have got a mortgage and my partner is still a full time mum, so we are relying purely on my income. And not knowing what’s happening with the surgery is really putting my stomach in my throat with regards to the future of myself and my family” [P7, preoperative]

A key message summarising this was relayed by one participant who explained “knowledge is power” [P9].

Advice regarding pre-surgery preparation was mixed. Some participants recalled the surgical team recommending physiotherapy and strengthening

exercises whilst others were advised that this was not necessary and were instead advised against types of activity, for example road running and swimming. Advice given by physiotherapists seemed more consistent with a narrative that strengthening exercises were beneficial. Advice regarding surgery was unsurprisingly mixed, given the disparity in evidence. Surgical teams typically recommended surgery whereas physiotherapists were more likely to consider a non-surgical approach as a viable option. Participants relayed the emphasis placed on engagement with post-operative rehabilitation by the surgical team but the details of what this entailed for pre-operative participants, was typically poorly understood.

> "They said to me, you have to do all the rehabilitation or the operation won't work, they have said that but they haven't actually said what it is" [P11, 3-months postoperative]

Where differing opinions and advice were offered, participants explained feeling confused, as they battled with deciding who to believe and trust.

> "Well I don't know who to believe now, do I believe the senior physio or do I believe the orthopaedic consultant?" [P4, preoperative]

Some tackled this by only seeking advice from those they deemed reliable (predominantly surgeons and/or physiotherapists), which helped to keep the number of opinions they received low. Others gave descriptions of seeking confirmation bias of either their beliefs or beliefs of HCPs they felt they could trust.

Two participants, with an interest in football, described the influence of the media on their journey. They related to famous elite athletes who they had

seen rupture their ACL and return to football. This seemed to offer some reassurance and direction for participants, as they recognised the injury in a relevant context. This also influenced their expectations of recovery.

> "I am a Liverpool fan. I have seen Van Dyke it took him a year to get back to playing football and he's got the best physios and best coaches around him in the world, so I am not expecting to be kicking a football any time soon" [P8, 3-months postoperative]

An important reflection from this study, is the impact of culture, with a unique viewpoint offered by two participants who compared UK NHS treatment to that offered in Lithuania and India. One participant described discussing the injury with a surgeon based in Lithuania where it was advised that optimal treatment was surgical intervention at 6-weeks post injury:

> "So, in six weeks, that was his words, when the swelling goes down and starts healing then you get your surgery." [P12, 3-months postoperative]

They explained feeling frustrated as they were unable to seek surgery that quickly in the UK and in hindsight reflected that knowledge of treatment in their home country was not particularly helpful. The second participant described being recommended ACLR by a surgeon when visiting India in addition to the use of alternative medicine (such as herbal oils) to support healing, pain management and muscle strength by a physiotherapist. They further reflected on the conflicting advice from clinicians in their home country compared to that offered in the UK. These reflections are an important consideration in the treatment of patients who may come from cultures with different health beliefs

and/or have access to care in a different health system with alternative views and practices.

3.4 DISCUSSION

This study is the first published qualitative exploration of patient experiences specific to the NHS ACLR pathway.

A key finding from this empirical work was the difficulty experienced by participants when navigating the NHS treatment pathway, demonstrating inconsistencies in clinical practice and pathway routes. This was evident at pivotal points from initial injury management to surgery. Challenges were highlighted with: (1) referrals to appropriate clinicians to support a timely diagnosis and appropriate injury management, (2) coping independently in the preoperative period, (3) communicating with HCPs (e.g. liaising with multiple professions, gaining support with concerns/questions/updates on treatment timeframes), (4) making decisions about injury management and (5) patient-centred, personalised care.

Patient experience has been identified to be positively associated with treatment outcomes and patient safety across a range of conditions, settings and patient groups (Doyle et al., 2013). A common narrative in this study, was the lack of consistent information and reliable resources regarding ACL treatment and outcomes; this has previously been identified to affect patient experience outcomes (Cole et al., 2017). As of 2020, the Office for National Statistics reported 92% of UK adults to be internet users (Internet users, UK - Office for National Statistics, 2021). Almost 70% of orthopaedic patients with access to the internet search their condition online (Fraval et al., 2012).

However, a 2016 review highlighted the overall poor quality and readability of available online patient orthopaedic information, which contributes to poor understanding and misconceptions of conditions and treatment by the public (Cassidy and Baker, 2016). ACL information available on the NHS website is not consistent with the evidence base. Accessed in April 2024, the NHS website states: “ACL surgery fully restores the functioning of the knee in more than 80% of cases” (NHS, 2021). There is no reference supporting this claim and ‘functioning of the knee’ is unclear and open to interpretation. It further states that recovery following surgery “usually takes around 6 months, but it could be up to a year before you're able to return to full training for your sport”. This does not match the literature which no longer recommends a return based upon time-alone and it is commonly acknowledged that a return may take up to 2-years (Meredith et al., 2020). Surplus amounts of information has further been identified to contribute to poor patient satisfaction and the importance of supporting consultations with written patient information has previously been identified as important (Cole et al., 2017; Nielsen et al., 2005). This empirical work highlights this gap in clinical care and the need for consistent information for the ACL population that is comprehensive, readable and viewed to be reliable. It may further benefit patient understanding and thus satisfaction, for clinicians to directly address patients’ internet findings to ensure they are correctly informed. This would further support shared decision-making, of which there was limited evidence of in this study.

Secondly, four participants were HCPs. Despite their medical training, all valued receiving treatment in line with patients of a non-medical background. Where prior knowledge of the injury and its management were assumed,

participants reflected poorly on receiving less information. Health literacy is an important consideration in patient care, defined by WHO as an individual's characteristics and social resources to access, understand, appraise and use information to make decisions about health (World Health Organization, 2014). In England, 42% of working-age adults are unable to understand everyday health information (Public Health England, 2015). Recognising that health literacy is an important prognostic factor of health outcomes, ensuring patients have appropriate resources to support understanding of their condition and its treatment is essential. A US study of 210 individuals (orthopaedic patients without a knee condition, undergraduate university students and general public) reported 65% of respondents to rate their ACL knowledge to be "little" or "none"; with 27% of respondents employed in a health-care setting (Matava et al., 2014). This supports that HCPs should not assume a patient's health literacy based upon their profession. Clinicians should take time to understand individual needs to ensure appropriate information and support is offered to enable patients to make fully informed choices.

Finally, a key element highlighted by participants was the importance of tailored, patient-centred care. This was in reference to treatment discussions, provision of written information and rehabilitation programmes. Whilst the importance of shared decision-making and the provision of resources has been discussed, it is important to consider personalisation of rehabilitation, particularly prior to ACLR. The description of generic exercise prescription perhaps mirrors the lack of consensus in the literature to guide this stage of treatment (Carter et al., 2020, 2021). Inconsistencies in care were evident in this study, despite all participants receiving treatment within the same UK

region, predominantly at one hospital. With widespread financial restrictions across NHS services, understanding optimum treatment is important to inform clinicians and financial stakeholders as services that lack clear guidance are likely to be cost inefficient.

3.4.1 CLINICAL IMPLICATIONS

There are several messages important for clinical practice arising from this research. Firstly, failure to recognise a suspected ACL rupture and referral onto an appropriate management pathway remains an issue. Getting it right first time is a current national initiative in the UK (Getting It Right First Time - GIRFT, 2021). Sub-optimal management results in delays to diagnosis and treatment in addition to increased healthcare and economic costs (Arastu et al., 2015). It may be appropriate to improve awareness and education of clinicians assessing musculoskeletal knee injuries in addition to considering staff awareness of hospital treatment pathways. A retrospective study of one NHS surgeon's caseload between 2004 and 2011 reported a reduction in days to diagnosis and treatment following implementation of an acute knee clinic (Parwaiz et al., 2016); demonstrating the success in getting it right first time.

Secondly, greater attention needs to be paid to decision-making regarding injury management. Shared decision-making has been shown to improve patients' knowledge, help patients and clinicians to understand preferences for treatment, reduce decisional conflict, help to clarify and set realistic expectations, and increase patients' involvement in their care (Légaré et al., 2008). Findings from this study demonstrated variation in patient involvement in decision-making conversations. Motivation to be involved in decision-

making is multifaceted, influenced by individual preferences, level of risk, fear of a negative outcome, perceived importance of the decision and cultural, social and economic factors (Bernhardsson et al., 2017; Grenfell and Soundy, 2022; Stenner et al., 2016). In the absence of a tool specific to the ACL population, these research findings support that clinicians may benefit from understanding patients' treatment preferences, values and beliefs, preferences to be involved in decision-making and factors that may affect this. Utilising up-to-date evidence to educate patients on their options to support informed, shared decision-making is also essential.

Further, it was felt that mental wellbeing was not addressed by clinicians; despite musculoskeletal and orthopaedic injuries being commonly linked to poorer mental health outcomes (Muscatelli et al., 2017). Lower psychological scores have previously been associated with poorer outcomes following ACLR (Hamrin Senorski et al., 2017; Nwachukwu et al., 2019) in addition to significant symptoms of depression reported in over 40% of patients awaiting ACLR (Garcia et al., 2015). This could be considered by clinicians to ensure appropriate support and signposting is provided to patients to manage their condition and aid decision-making about their care.

Thirdly, signposting patients towards reliable information resources should be considered to support face-to-face discussions and patient education conversations. Educating patients on the specificities of their condition and how this differs from 'generic' advice is another important reflection from this study. Encouraging patients to present contradictory advice/information may also support patient understanding of their condition and consolidate their ability to make clear, informed decisions. Findings from this study suggest

allowing participants time to reflect upon information they are given to consider questions they have about their treatment. Patients should further be provided with a point of contact should questions arise post-consultation.

Further, it is important to ensure expectations are realistic and that physical and mental health concerns are addressed during the preoperative period. Several participants highlighted the loneliness of the preoperative period with limited understanding of available support. Some further felt there was little to no attention paid to their mental wellbeing during consultations; this should form an integral part of clinical assessment with onward referral where necessary.

In summary clinicians should: (1) ensure they are aware of appropriate treatment pathways for patients presenting with a potential ACL rupture, (2) adopt the principles of shared decision-making during consultations with patients regarding ACL treatment, (3) consider face-to-face patient education that is supported by personalised written information, (4) offer a number of opportunities and clear points of contact for patients to seek support for questions and concerns regarding their treatment, (5) address expectations of treatment timelines and (6) assess the mental wellbeing of ACL patients and consider referring for psychological support where indicated.

3.4.2 RESEARCH IMPLICATIONS

This research highlights the perceived benefit of preoperative rehabilitation and support amongst ACL patients. Current evidence supporting preoperative care is limited (Carter et al., 2021, 2020), and so further exploration of this phase of treatment is warranted. The development and evaluation of

preoperative interventions that address patients' understanding of their condition, decision-making ability and optimal physical and mental preparation for surgery is needed. Understanding what warrants optimal preparation also needs further consideration, with input from both patients and clinicians. The evaluation of these interventions on patient reported outcomes, clinical measures and cost-effectiveness would further support the delivery of optimal and cost-effective treatment pathways.

The absence of a decision support tool for this patient group was also identified. A 2021 systematic review highlighted that shared decision-making implementation research in hospital settings is an emerging field and important area for further work (Waddell et al., 2021). Implementation factors are an important consideration to ensure decision support tools are developed with their context of use in mind. The potential benefits of implementing such a tool to patient and clinical outcomes have been discussed; further work to develop and evaluate this would be a novel area for future exploration.

This research also recognised the importance of high-quality patient information resources which are currently lacking for this patient population. Future co-development work to produce these resources may also be beneficial.

In summary, implications highlighted from this research that may warrant further investigation include: (1) the need for clear preoperative treatment guidance to support consistent and cost-effective care, (2) the development of a decision support tool to aid informed and shared decision-making practices, (3) co-development of reliable, readable and consistent patient

information resources that give voice to patient experiences, (4) understanding optimal pathways for ACL patients and implementation factors affecting this and (5) formally evaluating the impact of preoperative interventions on patient satisfaction and outcomes.

3.4.3 STRENGTHS, LIMITATIONS AND REFLEXIVE CONSIDERATIONS

It is important to highlight that the researcher (HC) was a clinician at UHDB and there is potential that the results were limited due to familiarity amongst some participants in the study. The researcher's active role in data collection is also important to acknowledge. Although the same topic guide was used across each interview, HC was responsible for guiding questioning and probing topics for further exploration. The researcher's experience as a clinician, rehabilitating patients both prior to (+/- surgical intervention) and after ACLR in a sporting and NHS context, is likely to have influenced the results. Into each interview, HC brings known and subconscious biases and experiences from previous patient interactions and awareness of some commonly occurring issues in the study population. Maintenance of a reflexive journal to account experiences and initial responses after each interview supported awareness towards the channelling of questions.

Another consideration is the medium in which the interviews were undertaken. Participants were given the choice of a face-to-face or virtual interview to allow for flexibility to participate in the research study, an element consulted with the PPIE group during study design. During study planning, PPIE members felt a virtual interview may allow participants to feel more comfortable to discuss their experiences behind the anonymity of a telephone whist acknowledging

that some may prefer the personalisation of a face-to-face interview. In-person interviews were carried out in a hospital setting. Whilst private rooms were arranged and participants were reassured of anonymity on publication of the manuscript, participants may have felt less comfortable to recount negative experiences when physically present in front of a researcher who also identifies as a member of the clinical team. These points were considered during data analysis and mitigated by collaboration with the research team, TMG and TSC which included patients and stakeholders.

In addition, an observation of recruitment was that only three women participated in the study. Although this mirrors data reported in the UK NLR; that more men proceed with surgery following ACL rupture (UK National Ligament Registry, 2020), this is an important point of reflection to consider the recruitment strategies success at reaching both sexes and if alternative methods may be needed in future studies.

An important factor to consider, impacting patient experience on the surgical pathway, is the timing of this research study. Interviews were carried out in August-November 2022; two and a half years after the COVID-19 pandemic reached the UK. COVID-19 had a profound impact on NHS services with many face-to-face procedures delayed and the rapid implementation of virtual consultations (Gilbert et al., 2020). Although the NHS recovery plan for tackling the backlog of elective procedures was rolled out in February 2022 (NHS England, 2022), service demand and capacity remained unevenly balanced.

Finally, the study population were treated within hospitals in one region of the UK (Midlands) but received rehabilitation at a range of different sites within the

Midlands. Data detailing all hospital departments at which patients received rehabilitation treatment was not collected. Whilst it is not the aim of qualitative research to be generalisable, these findings may not represent the experiences of those treated in other UK regions and outside of an NHS setting. However, a purposive technique was employed which allowed sampling to be responsive to emerging data. Further, there was an inconsistent number of participants at the three identified time-points for the study. There were a greater number of participants at the preoperative time-point which is likely to have resulted in greater richness of data regarding the preoperative pathway than that of the postoperative pathway (particularly at the one-year time point where only two participants were interviewed).

3.5 CONCLUSION AND CONSIDERATIONS FOR PHASE 2

This study has reported patient experiences of the NHS ACL surgical treatment pathway, novel to the ACL evidence base.

It highlights the gaps in patient support and magnitude of issues patients face when: navigating the NHS system, communicating with clinicians, making decisions about their treatment and managing conflicting sources of healthcare advice. These issues have not previously been recognised in the literature.

This study provided novel insight into the lived experiences of patients both prior to and after an ACLR in the NHS. The results were used to facilitate development of an intervention for patients post-injury/pre-surgery alongside a systematic review exploring the effectiveness of prehabilitation (Carter et al., 2020), a worldwide survey of physiotherapy practice (Carter et al., 2021), and a predictors review of modifiable preoperative factors associated with a return

to physical activity after ACLR (Carter et al., 2023b). This was combined with relevant, up-to-date literature and distributed to participants involved in the intervention development process (pre-elicitation technique) described in Chapter 4.

CHAPTER 4 INTERVENTION DEVELOPMENT (PHASE 2)

Summary

Phase 2 aims to:

1) Develop an intervention for use with patients post-ACL rupture to support treatment decision-making
2) Determine treatment recommendations for patients proceeding with rehabilitation and/or surgical intervention following an ACL rupture

The developed intervention will be implemented in UK NHS clinical practice in a non-randomised feasibility study (Phase 3).

Chapter 3 presented the findings from a qualitative individual interview study exploring patient experiences of the ACLR pathway. The study provided novel insight relevant to the UK NHS setting and highlighted challenges faced by patients when: (1) making decision about treatment, (2) navigating the NHS pathway, (3) communicating with clinicians, (4) receiving, seeking and interpreting medical advice and information and (5) coping independently in the preoperative period.

Phase 1 helped to inform the requirements of the intervention to be co-developed with patients in Phase 2. As discussed in Chapter 1.10, the underlying theoretical basis for the intervention was a biopsychosocial rehabilitation intervention supporting patients to both physically and mentally

prepare for surgery. However, during the qualitative interviews (Phase 1) a need became apparent to take a step back in the patient pathway to consider decision-making about treatment following an ACL injury and further, to gain consensus on optimum treatment in aim of standardising practice post-injury/pre-surgery.

4.1 INTRODUCTION

As discussed in Chapter 1.3, ACL injury management can follow a surgical (ACLR), non-surgical (rehabilitation) or combined (rehabilitation followed by surgical intervention) pathway. The results of three RCTs were presented which concluded that:

1) Early surgery may be better than delayed surgery (although there is limited transferability of this finding to an NHS setting where expediting surgery is not currently feasible due to the backlog in elective orthopaedic procedures following COVID-19) – Netherlands, Reijman et al., (2021).
2) Surgery may not be appropriate for everyone and engaging in rehabilitation as first line treatment may avoid unnecessary surgical intervention – Sweden, Frobell et al., (2010).
3) Surgery resulted in improved outcomes at 18-months for self-reported knee outcomes, quality of life and activity level when compared to non-operative treatment – UK, Beard et al., (2022).

Understanding which patients are appropriate for surgical or non-surgical management is challenging and creates uncertainty over treatment decision

making, the sequence of specific treatments and any related temporal factors (i.e. when to undergo specific treatments) continue to be debated.

SDM tools are a decision aid that may help patients make decisions about their health and treatment. SDM regarding treatment for ACL tears is especially important given the uncertainty about efficacy of treatment in the literature and the starkly contrasting options. Some with more risk than others.

The purpose of this study was to develop a theoretically informed SDM intervention, using an online video chat nominal group technique, to support patients with decision-making regarding treatment post-ACL rupture. The study also aimed to define treatment recommendations for patients proceeding with rehabilitation and/or surgical intervention to support standardisation of treatment across the UK. The developed SDM intervention was later tested in a feasibility trial (Phase 3).

4.2 METHODS

Ethical approval was sought concurrently with Phase 1 (Chapter 3). The study was reviewed and given favourable opinion by the North East - Newcastle & North Tyneside 1 Research Ethics Committee on 27th July 2022 (reference number: 22/NE/0119). The study was registered on clinicaltrials.gov (ID: NCT05529511) on 2nd September 2022.

4.2.1 DESIGN

This study used the nominal group technique (NGT) method to:

1) Develop an SDM intervention for use with patients following diagnosis of an ACL rupture.
2) Gain consensus for treatment recommendations covering five domains: advice and education, exercise guidance, delivery method, outcome measure use and shared decision-making.

NGT uses group meetings comprising of appropriate experts to gain consensus on a topic area (Jones and Hunter, 1995). This approach has commonly been utilised in healthcare intervention development (Jones and Hunter, 1995; Potter et al., 2004). NGT was chosen over other consensus methods, such as Delphi, as it offers a pragmatic way of exploring ideas with experts, patients and stakeholders (McMillan et al., 2016). Attrition is highlighted as a concern with the Delphi technique (Trevelyan and Robinson, 2015), which has also been suggested to better suit the development of clinical guidelines (McMillan et al., 2016). During patient and public engagement, patients also felt that NGT was less burdensome than Delphi methods. NGT follows the basic outline of (1) idea generation, (2) idea ranking, (3) rankings discussed, and (4) re-ranking. This can be repeated several times until an acceptable level of consensus is achieved.

Although usually face-to-face, the NGT method was adapted to be conducted online via video teleconference to support collaboration from participants in a spread of geographical locations. This has previously been identified as a pragmatic concern of the face-to-face method (Murphy et al., 1998).

Successful online NGT studies have also been described elsewhere (Bateman et al., 2021). The online NGT process followed the same structure as described for face-to-face, this is shown in Figure 4.1.



Figure 4.1 – Nominal Group Technique process

4.2.2 AIMS AND OBJECTIVES

The primary aim of this phase was to develop an intervention, using an online video chat nominal group technique, for use with patients post-ACL rupture to support treatment decision-making.

The secondary aim was to determine treatment recommendations for patients proceeding with rehabilitation and/or surgical intervention to support the standardisation of treatment across the UK. This aim was added as Phase 1 highlighted variation in treatment in the post-rupture/pre-surgical period from a patient's perspective; with this finding also corroborated by a survey of worldwide physiotherapy practice (Carter et al., 2021).

4.2.3 SAMPLE SIZE AND ELIGIBILITY CRITERIA

NGT was originally developed in 1971 and since, there has been debate around the optimal sample size for meetings (Delbecq and van de Ven, 1971). More recent literature has proposed 6-12 participants with suggestions that below six will reduce reliability and above 12 will diminish the improvements in reliability (Harvey and Holmes, 2012; Murphy et al., 1998). A sample of 6-12

participants was therefore aimed to be recruited, with a minimum of one participant from each identified professional or patient group.

Participants eligible for inclusion included NHS healthcare professionals with a special interest/expertise in treating ACL injuries, therapy managers of an NHS musculoskeletal outpatient department and patients who were awaiting or who had undergone an ACLR. Eligibility criteria is shown in Table 4.1.

Inclusion
1) NHS healthcare professionals with a special interest/expertise in treating ACL injuries or 2) Therapy managers of an NHS musculoskeletal outpatient department or 3) Patients awaiting or who have undergone an ACLR

Table 4.1 – Phase 2 eligibility criteria

The consensus group also included non-voting participants to support with group discussion and facilitation. Non-voters did not partake in voting due to engagement in the wider POP-ACLR project. Voting participants had no previous involvement in the study.

4.2.4 RECRUITMENT AND PARTICIPANTS

Participants volunteered to take part in response to study material advertised via professional and special interest networks (Association for Trauma and Orthopaedic Chartered Physiotherapists [ATOCP]) and through interested clinicians, social media (Twitter: @POP_ACLR) and an existing PPIE group. At least one therapist and therapy manager were recruited from UHDB, as this

was felt to be important as the primary site for feasibility testing of the intervention in Phase 3. Where more than one potential participant volunteered, their characteristics were considered to ensure variation in group expertise and experience. For example, healthcare professionals from different backgrounds such as medical and allied health professionals were sought for inclusion.

Overall, there were 13 participants. The voting participants included: one orthopaedic consultant, three orthopaedic/musculoskeletal physiotherapists, one occupational therapist specialised in vocational rehabilitation in a musculoskeletal outpatient therapy department, one outpatient therapy manager who was also a physiotherapist and had lived experience of an ACLR and two patients with lived experience of an ACL rupture and reconstructive treatment. The non-voting participants included: one clinical academic with expertise in orthopaedic and musculoskeletal research including ACL injuries and treatment (Professor David Beard, the lead researchers mentor and project collaborator); two PhD supervisors (one with experience of conducting NGT studies [Dr Paul Leighton] and one clinical academic musculoskeletal physiotherapist [Dr Benjamin Smith]) and two patient representatives who had been involved in the wider study and it's set up. Professor David Beard was included to support communication of the most up-to-date literature. Dr Paul Leighton and Dr Benjamin Smith were present to observe the group, providing oversight to methodological rigour and to support reflexive practices. The patient representatives were involved to support patient participants as they had experience of discussing their views at TSC meetings and PPIE workshops with patients and clinicians.

HC chaired the meetings and explained to participants at the start her role as the lead researcher undertaking a PhD and a practicing MSK physiotherapist at UHDB. Three voting participants (surgeon, therapy manager and patient) and one facilitator (Dr Benjamin Smith) were unable to make the second meeting due to other commitments. These participants were still included in the pre-meeting voting ahead of the second meeting and all email communications.

4.2.5 DATA COLLECTION

Two meetings were held via Microsoft Teams. All participants gave consent to participate in the meetings which were also recorded for study purposes. The first meeting lasted 1 hour 51 minutes, the second meeting lasted 2 hours.

The pre-elicitation technique was used to provide participants with relevant, up-to-date literature in addition to the unpublished results from Phase 1 prior to the first meeting. All participants received the same information (Appendix D), with a lay document provided to non-clinical participants. In addition to the information document, pre-meeting voting was conducted to support discussions at the first meeting via Microsoft Forms (Appendix E). Participants were asked to vote on a 5-point Likert scale whether components were ‘very important’, ‘important’, ‘neither important nor not important’, ‘not important’ or ‘not at all important’ for inclusion. Participants voted on five components: (1) advice and education, (2) exercise guidance, (3) delivery method, (4) outcome measures, and (5) decision-making. Free text responses were also permitted to stimulate further thought and discussion points to allow room for additional

components and topics to be added. This supported the first two stages of the NGT process: explanation and silent generation of ideas.

The purpose of the first meeting was to gain consensus on core components for the recommendations and SDM intervention. During the meetings Mentimeter (www.mentimeter.com) was used for anonymous voting and idea sharing. An example of Mentimeter idea sharing from the first consensus meeting is shown in Figure 4.2.

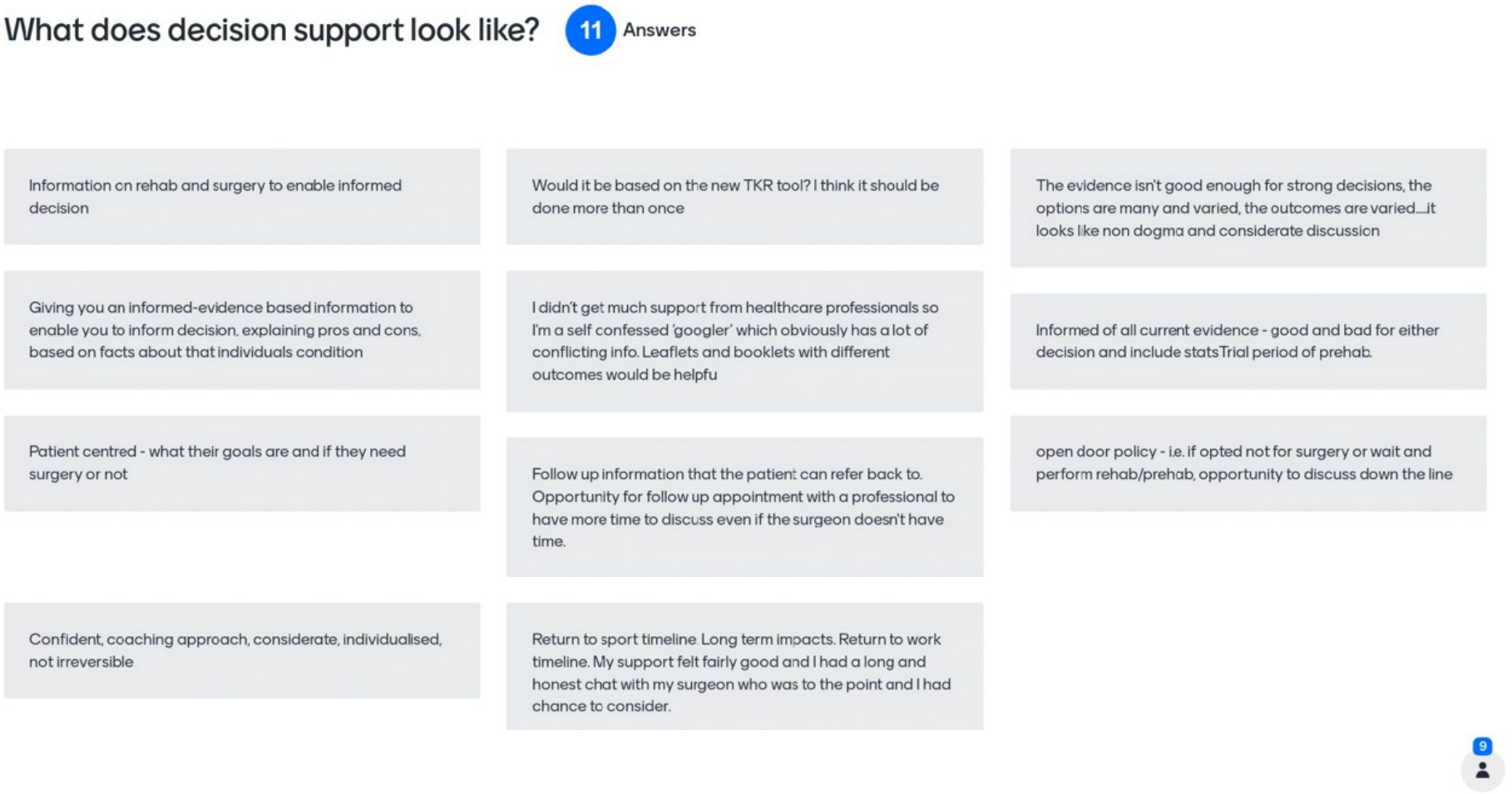


Figure 4.2 – Mentimeter idea sharing example (Meeting 1)

The first meeting consolidated the five components of the recommendations, with no additional components suggested for inclusion. The 'very important components' were considered to be essential, whilst the 'important' components were recommended to support the personalisation of care. The recommendations aimed to offer pragmatic guidance to ensure they were achievable, applicable and relevant to the UK NHS setting. The decision-making discussions were split into elements to be included in the recommendations and specific design of the SDM intervention. The need for the recommendations was felt to be important as a direct impact for clinical practice ahead of future feasibility testing of the SDM intervention.

A draft version of the recommendations and SDM intervention was shared with participants ahead of meeting two to provide a basis for group discussion. A second round of voting amongst NGT group participants was conducted prior to the second meeting to support idea sharing and to generate discussion (Appendix F). Stakeholder engagement with SDM intervention developers, academic experts and clinicians was conducted between the two meetings to gain feedback and thoughts on the developing interveion and recommendations. These were discussed at the second meeting. The second meeting was conducted to agree on specific elements of each component to finalise the recommendations and SDM intervention. At the end of the second meeting, the overall components and specific elements for the SDM intervention and recommendations were finalised.

The final version of the SDM intervention and treatment recommendations were communicated with all NGT group participants after meeting two (including those who were unable to attend). No concerns were raised by any

participant, so the final versions were considered representative of the discussions and voting across both meetings.

An overview of the study process is shown in Figure 4.3.

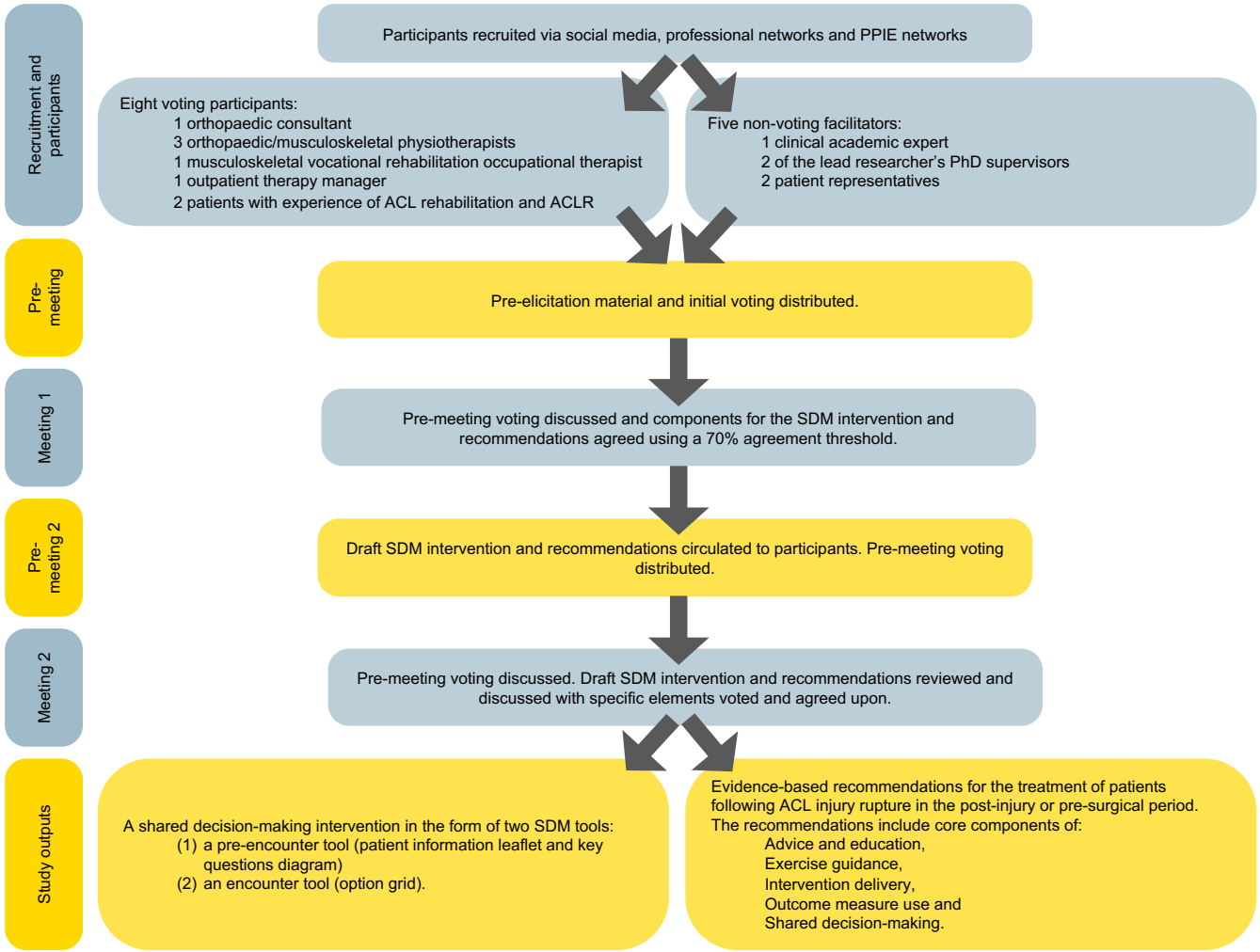


Figure 4.3 – Overview of study process

4.2.6 DATA ANALYSIS

In line with other consensus recommendations, a 70% agreement threshold was used (Tugwell et al., 2007; Williamson et al., 2012). This was also discussed and agreed by the study team at TMG meetings. A 70% cut-off was used to include components that were considered 'very important'. Components were deemed 'important' if 70% was reached combining scores of very important and important voting. Components below 30% were excluded and those not reaching the 70% inclusion cut off nor the 30% exclusion were discussed.

The International Patient Decision Aid Standards (IPDAS) criteria and option grid development guidelines were used to support the development of the SDM intervention (Coulter et al., 2013; Elwyn et al., 2006; Marrin et al., 2013). The NICE framework for development of decision aids was also used (National Institute for Health and Care Excellence, 2021b). Visual representation of how these were used is available in Appendix G.

The Implementation Research Logic Model (IRLM) was used to support visual representation of the SDM intervention considering future implementation and evaluation in a feasibility study (Phase 3, Chapter 5) (Smith et al., 2020). ENPT was used to stimulate discussions during NGT meetings about implementation to embed these considerations in the development process. The four constructs of ENPT were utilised to consider how the intervention would integrate with current NHS systems/pathways (capability), the users' (i.e. clinicians and patients) ability to engage with and deliver the intervention (e.g. considering their resources and skillset) (capacity and potential) and the work

and ability of the users to continue engaging with the intervention to allow it to become part of normal practice (contribution). The implementation strategies as part of the IRLM were also mapped to ENPT. The IRLM for the study and mapping of implementation strategies to ENPT is shown in Figure 4.4 and Figure 4.5.

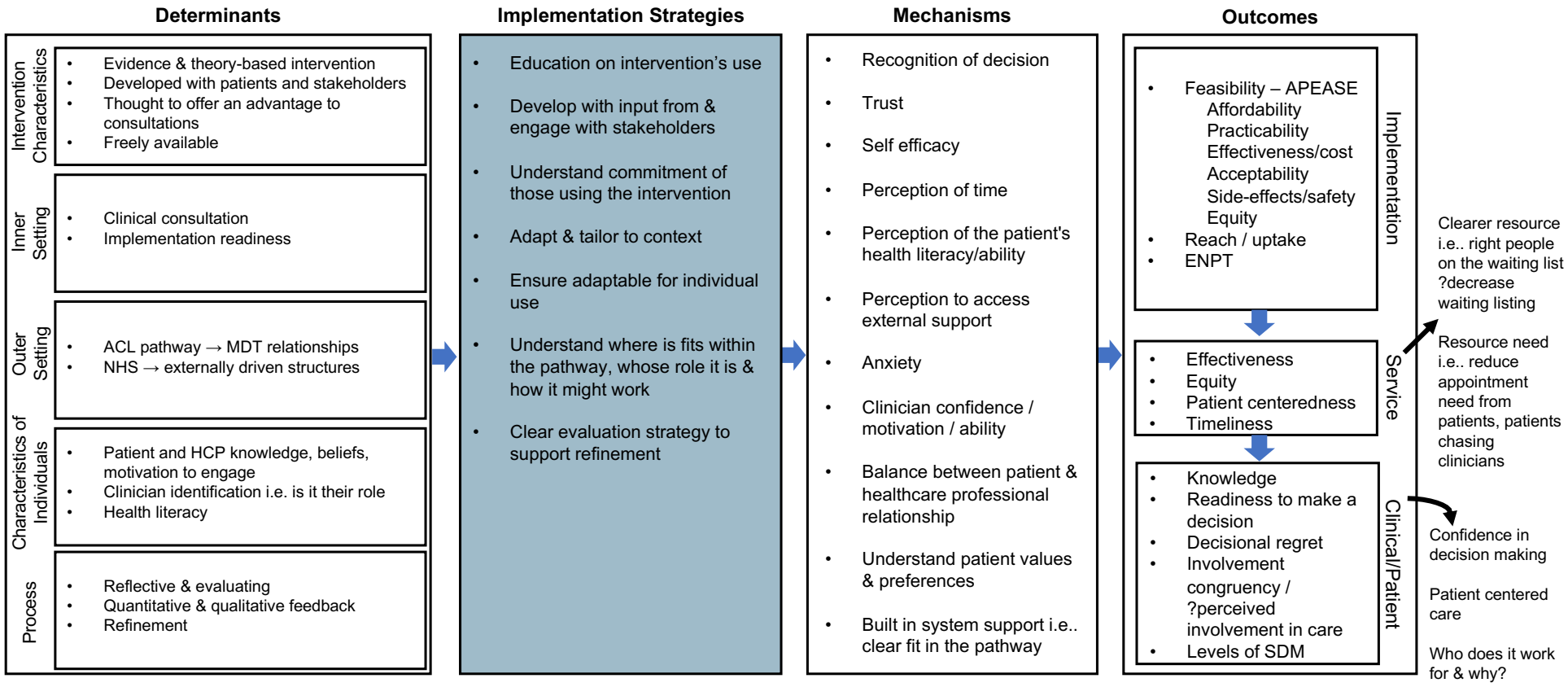


Figure 4.4 – Implementation Research Logic Model

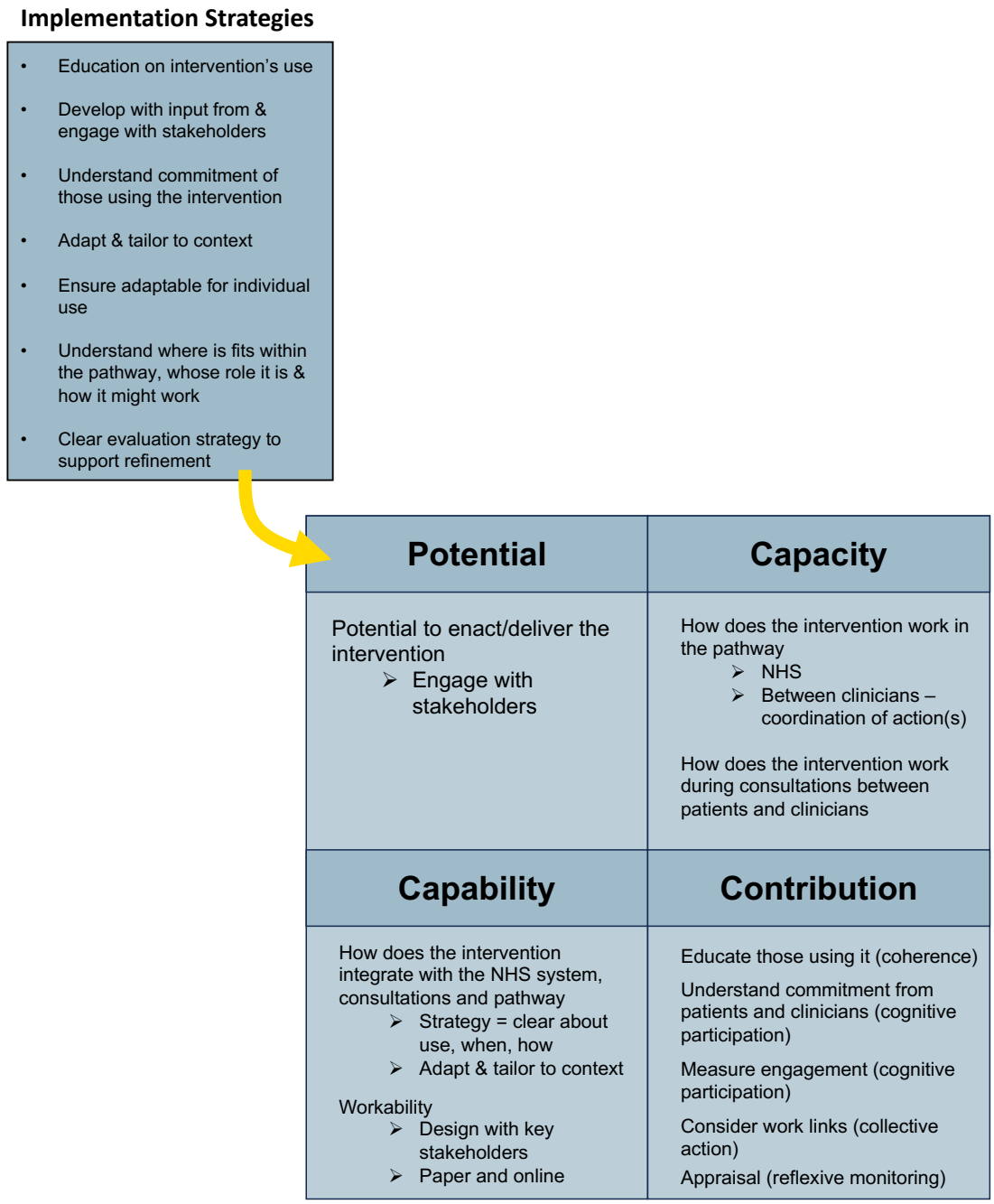


Figure 4.5 – Implementation strategies (from IRLM) mapped to ENPT constructs

4.3 RESULTS

The results for the SDM intervention and treatment recommendations are presented below.

The SDM intervention (Chapter 4.4) comprises of two components:

Component A	Pre-encounter tool (patient information leaflet and key questions diagram) – Appendix H
Component B	Encounter tool (option grid) – Appendix I

The evidence-based recommendations (Chapter 4.5), outline key components of treatment for patients following ACL injury rupture. This includes advice and education, exercise guidance, intervention delivery, outcome measure use and SDM principles.

4.4 SHARED DECISION-MAKING INTERVENTION

The NGT meeting focused on designing an intervention to support SDM regarding treatment following an ACL rupture. The SDM intervention was split into two components: (A) pre-encounter and (B) encounter. Two pre-encounter tools were developed, designed for use by patients prior to a clinical consultation. The pre-encounter tool comprises of a patient information leaflet and a diagram to support patients to consider key questions about their treatment. The key questions diagram was included in the patient information leaflet to form one tool. The encounter tool, an option grid, was designed for use during clinical consultations by patients and HCPs. The tools were developed using the agreed SDM recommendations by the group in meeting one (presented in Chapter 4.5.5).

Prior to meeting two, participants were sent drafts of the three tools for comments, with suggested amendments discussed and voted on during the second meeting. The tools were also mapped to the IRLM to support consideration of the key determinants, implementation strategies,

mechanisms and outputs (Smith et al., 2020). This was presented to participants at meeting two (shown in Figure 4.4 and Figure 4.5 above). Key areas that were refined included adding: (1) detail to the information leaflet about the physical and mental effort of ACL injury treatment (Appendix H, page 3), (2) information about the increased risk of osteoarthritis following ACL injury to the information leaflet (Appendix H, page 6), (3) questions about the potential loss of income, employer sickness policy and how treatment may impact an individual's life to the key questions diagram (Appendix H, page 8), (4) information about fitness management to the option grid (Appendix I, page 2), and (5) a blank box for the 'clinician recommendation' section of the option grid (Appendix I, page 2). The final SDM intervention comprised of two components:

Component A Patient information leaflet, including the key questions diagram

Component B Option grid

4.5 TREATMENT RECOMMENDATIONS

The treatment recommendations are available in Appendix J.

4.5.1 ADVICE AND EDUCATION

There were 20 advice and education topics voted on ahead of and discussed during the meeting. Five reached the 70% threshold to be considered as 'very important' for inclusion and the remaining 15 reached the threshold to be considered 'important'. A free text comment suggested the inclusion of spontaneous ACL healing. Following discussion amongst the group and

Mentimeter voting, this was considered to be ‘important’ and so 16 topics were considered to be ‘important’. An overview of the scoring for each statement across the study is shown in Table 4.2.

Component	Statement	Pre-meeting 1	Meeting 1	Pre-meeting 2	Meeting 2
Advice & education	Knee anatomy and injury	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Surgical procedure	>70% very important or important			
	Evidence-based information regarding graft choice	>70% very important or important			
	Risks of surgery	>70% very important or important			
	ACL injury management - surgery versus rehabilitation	>70% very important			
	Pathway milestones, expected appointments and timeframes e.g. physiotherapy, surgery, orthopaedic follow-up	>70% very important			
	Evidence based information on injury outcomes e.g. re-rupture, return to work, return to physical activity	>70% very important			
	Expected timeline specific to the patient e.g. considering prognostic factors that may delay a return to physical activity/work	>70% very important			
	Evidence-based information regarding outcomes of surgical and non-surgical treatment	>70% very important			
	Prehabilitation's e.g. purpose, importance, timeframe	>70% very important or important			
	Discussing the postoperative period	>70% very important or important			
	What to expect during the inpatient stay	>70% very important or important			
	Common issues pre- and post-surgery	>70% very important or important			
	Pain management	>70% very important or important			
	Managing work and home preparations e.g. expected absence from work, expectations for return to work, childcare, driving	>70% very important or important			
	Common psychological difficulties associated with ACL injury	>70% very important or important			
	Signposting towards relevant services for mental health support	>70% very important or important		Free text comment highlighted concern mental health should be 'very important'	>70% very important or important
	Weight management and nutrition	>70% very important or important		Agreement that draft document represents discussions at meeting 1	No further discussion required
	Smoking cessation	>70% very important or important			
	Goal setting	>70% very important or important			
	Spontaneous ACL healing	Suggested addition	>70% very important or important		
	Delivery method for advice & education e.g. when and by whom	Suggested addition	Discussed and refined, agreed for inclusion as very important.		Discussed initial consensus from meeting 1, no further refinement

Table 4.2 – Voting scores for advice and education statements

The final recommendations are shown in Figure 4.6.

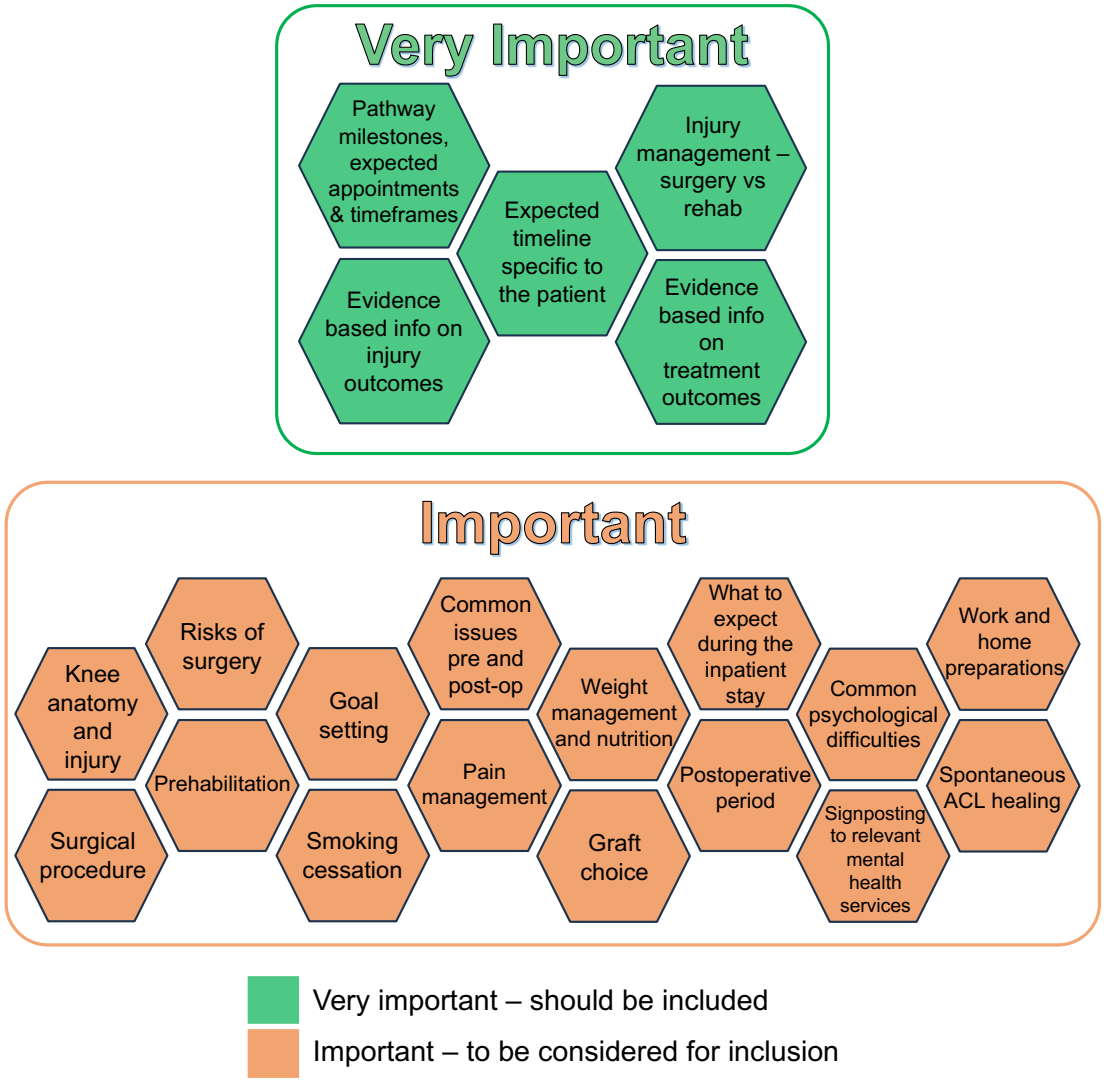


Figure 4.6 – Advice and education topics

The group further discussed delivery of advice and education, considering it 'very important' that it is delivered: (1) in a one-to-one session, (2) by any clinician with expertise and knowledge to do so and (3) consistently by the healthcare team across the patients care.

4.5.2 EXERCISE GUIDANCE

There were nine exercise topics voted on ahead of and discussed during the first meeting. These included that exercise guidance should include: at least 1

session with a rehabilitation/exercise therapist, 2-6 sessions with a rehabilitation/exercise therapist, more than 6 sessions with a rehabilitation/exercise therapist, exercise type(s), frequency of exercise completion, exercise programme length, time-period to be completed, delivery method and guidance on exercise/types of activity to avoid. One reached the 70% threshold considered as 'very important' for inclusion, that as a minimum, at least one session should be offered with a rehabilitation/exercise therapist within 3-months of ACL injury diagnosis. It was considered 'important' that clinicians offer further sessions based on individual patient need, considering specific goals and waiting times for surgery (if appropriate). Specific exercise components were discussed including exercise type, exercise programme frequency and length, and dos and don'ts. It was agreed specific exercise types should not be recommended to be completed by every patient following ACL injury. Instead, the group offered suggestions of exercise types for considerations by clinicians as appropriate to individual patients and their specific goals. An overview of the scoring for each statement related to exercise guidance across the study is shown in Table 4.3.

Component	Statement	Pre-meeting 1	Meeting 1	Pre-meeting 2	Meeting 2
Exercise guidance	At least 1 session with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	>70% very important or important	Discussed and refined with agreement to not limit session number and instead suggest at least 1 session to be offered within 3-months of injury diagnosis	Agreement that draft document represents discussions at meeting 1, no additions	Further discussion of wording, agreement in line with meeting 1
	2-6 sessions with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	>70% very important or important			Excluded & not discussed
	More than 6 sessions with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	No consensus			Excluded & not discussed
	Exercise type(s)	>70% very important or important	Discussed and further refined e.g. specifics of exercise types such as strength, mobility	Further voting on specific exercise types, consensus not achieved	Specific exercise types discussed with agreement reached on those to be recommended
	Frequency of exercise completion	>70% very important or important	Discussed and further refined, agreement achieved for frequency of exercise completion to be 2-3 times per week	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Exercise programme length	>70% very important or important	Discussed and further refined, agreement achieved for exercise programme to be continuous		
	time-period to be completed e.g immediately after injury, 30months prior to surgery, continuous	>70% very important or important	Discussed and further refined, agreement achieved for exercise programme to be continuous		
	Delivery method e.g. virtual, group, individual, guided by a healthcare professional, self-directed	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Guidance on exercise/ types of activity to avoid	>70% very important or important	Further discussed and refined to 'risks and considerations', consensus not gained on specific elements	Refinements voted upon and free text comments added for specific elements	Further discussed with refinement of wording and elements agreed upon, >70% consensus to be very important for inclusion

Table 4.3 – Voting scores for exercise guidance statements

Exercise type suggestions are shown in Figure 4.7.

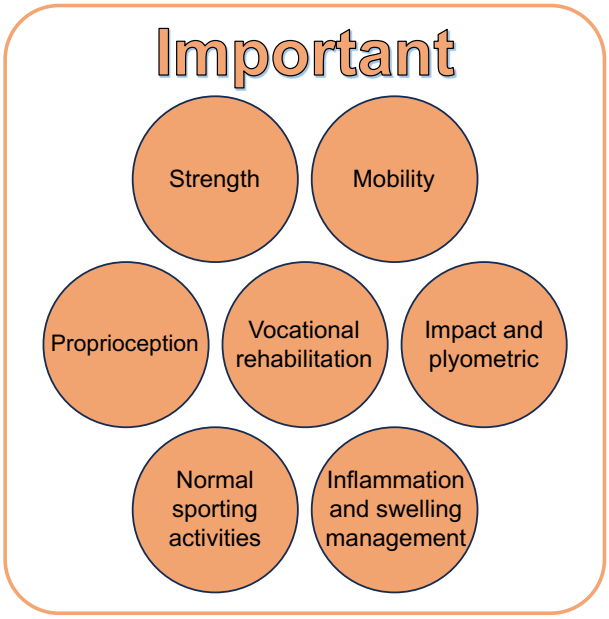


Figure 4.7 – Exercise types to be considered by clinicians

It was considered very important that exercise programmes are completed a minimum of 2-3 times a week and continuously for the preoperative period or until a non-surgically managed patient meets their aims/goals. The group considered ‘dos and don’ts’ at the second meeting following a number of suggestions at meeting one. Several considerations and scenarios were discussed. It was agreed that exercise should be guided by the appropriate professional and be within the limits of the individual. Whilst it is acknowledged that activities that provoke knee swelling and instability and cause intolerable amounts of pain may need to be limited, the group recommended progressive and graded exposure to activities, working towards the patients’ individual goals. It was further considered very important that the risks of engaging in physical activity are discussed with each patient. This discussion should be based on the patients' goals to allow them to make educated decisions about engaging in physical activity after their ACL injury. The group discussed the importance of this conversation empowering patients to engage in physical

activity within the scope of risk deemed acceptable to them and their treating clinician(s). The discussion should be a balanced presentation of the evidence considering potential risks and benefits of engaging in different activities/exercise types. For patients proceeding with surgery, the group recommended considering the risk of further injury and subsequent consequences for the planned surgical procedure. Expression of caution to return to cutting/pivoting activities may therefore be greater with this patient group. The group subsequently agreed to rename these recommendations to 'risks and considerations' as opposed to 'dos and don'ts' to reflect the nature of these conversations more accurately. These recommendations are summarised in Figure 4.8.

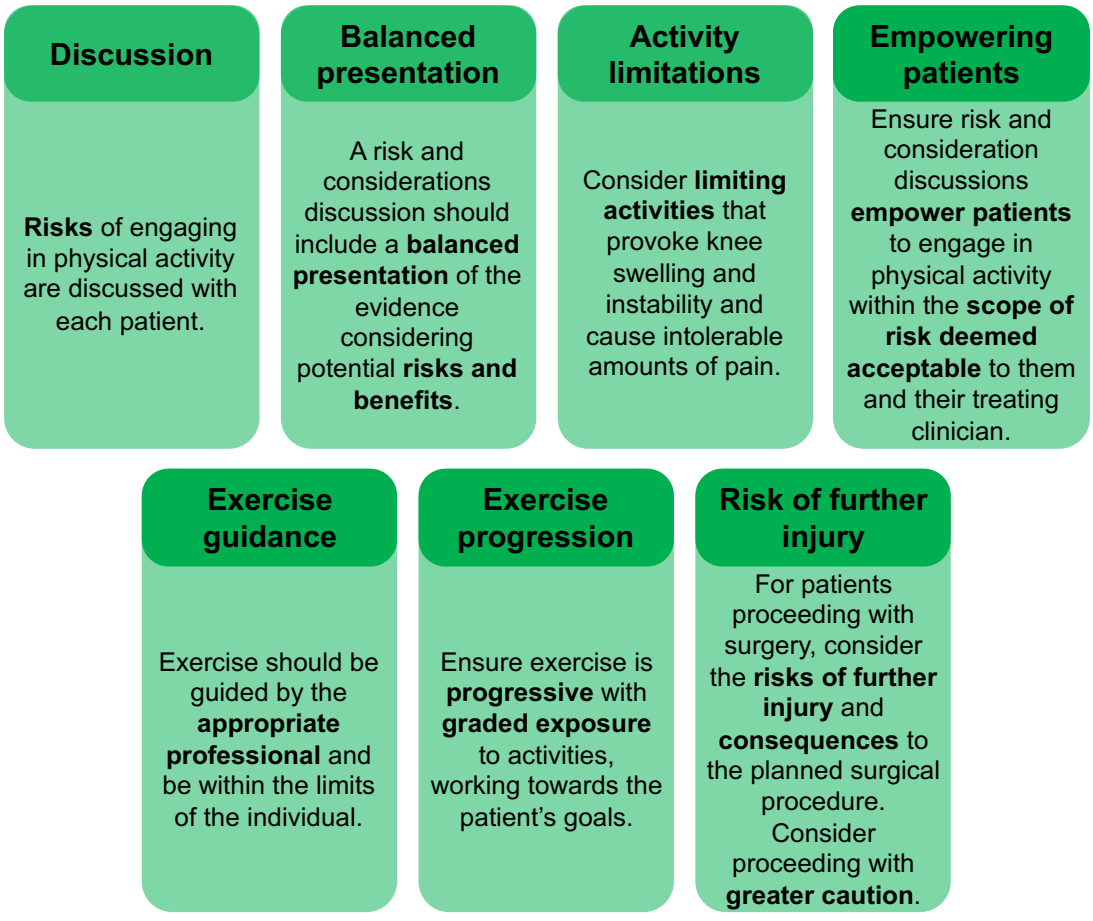


Figure 4.8 – Risks and considerations

4.5.3 DELIVERY METHOD

The delivery method of interventions post-ACL injury/pre-ACLR were discussed. It was considered important that the following six mediums are considered by clinicians: (1) booklet, (2) website, (3) face-to-face, (4) one-to-one, (5) peer support and (6) combination of face-to-face and digital or printed resources. The importance of the delivery method meeting the needs of the individual was discussed and considered a priority for choosing the appropriate method. It was recommended that an initial one-to-one session is offered to ensure specific needs are met and considered when selecting an appropriate medium for intervention delivery. An overview of the scoring for each statement related to delivery method across the study is shown in Table 4.4.

Component	Statement	Pre-meeting 1	Meeting 1	Pre-meeting 2	Meeting 2
Delivery method	Booklet	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Website	>70% very important or important			
	Face-to-face	>70% very important or important			
	Forum	No consensus	Discussed and excluded		
	Group	No consensus	Discussed and excluded		
	1:1	>70% very important or important	Discussed & wording refined		
	Peer support	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	By a single healthcare professional	No consensus	Discussed and excluded		
	By a team of healthcare professionals	No consensus	Discussed and excluded		
	Combination of face-to-face interactions and printed/digital resources	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Dependent upon patient	Suggested addition	Discussed and refined, agreed for inclusion in context of other elements		

Table 4.4 – Voting scores for delivery method statements

4.5.4 OUTCOME MEASURES

The fourth element presents recommendations for the use of outcome measures for patients following ACL injury. Three measures were considered to be very important, and the group recommended for these to be used, as a minimum, with all patients post-injury regardless of the treatment decision of rehabilitation or surgery. These include: (1) knee specific outcome measures, (2) psychological outcome measures and (3) current level of activity including occupation. Six further outcome measures were considered to be important and were advised to be used as appropriate to individual patients. Outcome measures to be considered for use include: (1) patient estimated ability to return to their preinjury level of activity, (2) patient expectations of treatment and outcomes, (3) preinjury level of activity, (4) patient satisfaction, (5) weight screening and (6) clinical assessment. The group agreed upon the recommendation of these outcome measure groups, rather than selecting a specific measure for each category. This was decided to ensure outcome measure selection is most appropriate for individual patients. It further aligns with the ACL literature where several different outcome measures are recommended for use in this population (Svantesson et al., 2020). The group agreed that outcome measures should not differ based on the expected treatment of surgery or rehabilitation. Clinicians should consider assessing all patients at baseline to help with future treatment planning and progress tracking. An overview of the scoring for each statement related to outcome measures across the study is shown in Table 4.5.

Component	Statement	Pre-meeting 1	Meeting 1	Pre-meeting 2	Meeting 2
Outcome measures	Knee-specific outcome score e.g. Knee injury and Osteoarthritis Outcome Score (KOOS)	>70% very important	Discussed initial consensus from pre-meeting voting, no further refinement	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Psychological measures e.g. anxiety and depression screening	>70% very important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Clinical assessment e.g. knee range of motion, muscle strength	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Weight screening	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Patient satisfaction	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Pre-injury level of activity	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Current level of activity	>70% very important or important	Discussed and refined to combine with occupation		
	Expectation screening	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Patient estimation of ability to return to preinjury activity levels	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Occupation	>70% very important	Discussed and refined to include as ‘very important’		
	Baseline strength and jump testing on uninjured leg	Suggested addition	Discussed and agreed included under ‘clinical assessment’		
	Current level of activity including occupation	-	Suggested addition, discussed & two measures combined (as above)		
	Ideal speed of return to sport	-	Suggested addition, discussed and agreed included under ‘clinical assessment’		
	Outcome measures to differ for those proceeding with surgery	-	Suggested consideration	Consensus agreed for no difference	

Table 4.5 – Voting scores for outcome measure statements

4.5.5 SHARED DECISION MAKING

The group discussed the principles of SDM in aim of determining important components to be included in an SDM tool and/or during a clinical consultation.

Six principles were considered to be very important and seven were considered important. These are presented in Figure 4.9.

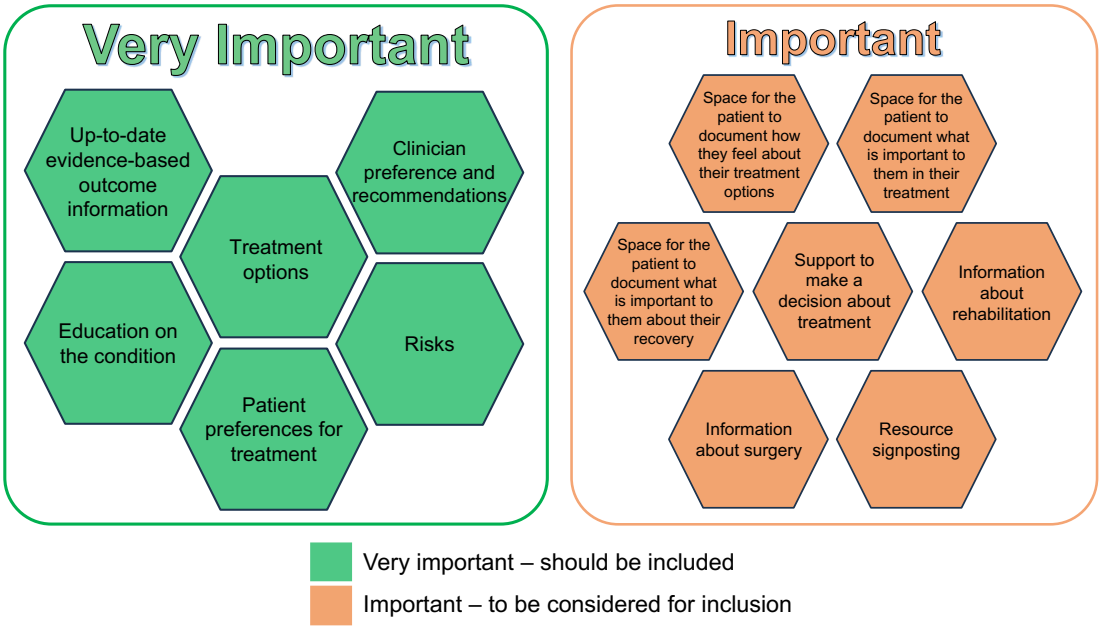


Figure 4.9 – Shared decision-making recommendations

Whilst a specific SDM intervention has been developed, it was agreed amongst the group to be beneficial to consider recommendations for SDM principles directly applicable to clinical practice. The need for these recommendations was felt to be important as a direct impact for clinical practice ahead of future feasibility testing of the SDM intervention in Phase 3.

It was considered important that the SDM tool be designed for completion by the HCP and patient together, be available online and via paper, and include a diagram of key questions to help the patient consider their treatment options.

Participants were asked to vote ahead of the second meeting whether the drafted recommendations were representative of discussions at meeting 1. 100% of participants agreed they represented previous discussions. Only minor amendments were made at meeting 2 including: (1) elaboration of the

importance of individualised mental health support as part of the advice and education recommendations, (2) consideration of exercise type selection and (3) addition of risks and considerations in place of ‘dos and don’ts’. An overview of the scoring for each statement related to shared decision-making across the study is shown in Table 4.6.

Component	Statement	Pre-meeting 1	Meeting 1	Pre-meeting 2	Meeting 2
Shared decision-making	Primarily for the patient in the form of an information sheet with interactive components for them to bring to consultations e.g. sections to fill in / questions to respond to	No consensus	Discussed and agreed to exclude	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	For both the healthcare professional and the patient to complete together	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	In the form of a paper document	No consensus	Discussed and agreed to exclude		
	In the form of an online tool	No consensus	Discussed and agreed to exclude		
	Both a paper and online tool	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	A flow-chart of key questions to help consider treatment options	>70% very important or important			
	Education on the condition	>70% very important			
	Treatment options	>70% very important	Specifics further discussed		
	Patient preference for treatment	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement		
	Clinician preference / recommendation for treatment	>70% very important or important	Discussed initial consensus from pre-meeting voting, no further refinement	Suggestion to remove lined space for a recommendation about treatment from a clinician	Further discussed and agreed amendment for a blank box instead of lined space
	Space for the patient to document/consider what is important to them about the recovery of their knee injury e.g. reduced pain, improved mobility, return to work	>70% very important or important		Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Space for the patient to document/consider what is important to them in their treatment	>70% very important or important			
	Information about rehabilitation	>70% very important or important			
	Information about surgery	>70% very important or important			
	Space for the patient to document/consider how they feel about their treatment options	>70% very important or important			
	Support to make a decision about treatment	>70% very important or important			
	Resource signposting	>70% very important or important	Discussion of specific resources/services to signpost too	Further suggestions made	Suggestions discussed, specific resources/services agreed e.g. talking therapy
	Up-to-date and evidence-based outcome information e.g. percentage of those who return to physical activity following surgery	>70% very important	Discussion of specific outcomes for inclusion	Agreement that draft document represents discussions at meeting 1, no additions	No further discussion required
	Include consultant and family	Suggested addition	Discussed and agreed included within the other statements, excluded	Agreement that draft document represents discussions at meeting 1, no additions	
	Impact upon employment & potential timeframes for sickness absence	-	-	Suggested addition	Discussed and agreed inclusion

Table 4.6 – Voting scores for shared decision-making statements

The recommendations have been summarised in a single document including a 3-page summary (Appendix J).

4.6 DISCUSSION

This consensus study has led to the development of:

1. An SDM intervention comprising of two components:

   Component A: Patient information leaflet and key questions diagram (pre-encounter tool)

   Component B: Option grid (encounter tool)

2. Evidence-based recommendations for the treatment of patients following ACL injury rupture in the post-injury and/or pre-surgical period. These recommendations cover core components of advice and education, exercise guidance, intervention delivery, outcome measure use and SDM.

The SDM intervention is a novel development to support injury management decisions for patients following ACL rupture. The patient information leaflet and key questions diagram was designed in aim of improving patient knowledge; a previously recognised benefit of pre-encounter tools (O'Connor et al., 2007). As previous research has reported that pre-encounter tools fail to influence SDM practices (Aubree Shay and Lafata, 2015; Stacey et al., 2017), an encounter tool was also developed in the form of an option grid. A 2015 stepped wedge trial explored the impact of an option grid for patients diagnosed with knee osteoarthritis in a UK interface clinic for patients with musculoskeletal problems (Elwyn et al., 2016). Use of the option grid led to

significantly increased patient knowledge and readiness to decide on treatment. It was also reported that use of the tool did not lead to an increase in clinical consultation length and was successfully used with translators for patients whose first language was not English. A potential barrier to SDM practices at present may be a pragmatic concern of time constraints during consultations. During stakeholder engagement and NGT meeting discussions, clinicians reflected positively that previous research has demonstrated no additional burden of using an SDM tool. Two essential elements of SDM include: (1) knowledge exchange between parties and (2) patient preferences (Elwyn et al., 2000; Légaré et al., 2010; Makoul and Clayman, 2006b; Stacey et al., 2010; Waldron et al., 2020). It is hoped that use of the pre-encounter tool will support increases in knowledge and the encounter tool will support patients to consider and express their treatment preferences, resulting in informed decision making and SDM practices during consultations.

The development of the treatment recommendations supports those previously published by Filbay and Grindem, (2019). Filbay and Grindem's evidence-based recommendations provide information on injury diagnosis, management, rehabilitation and criteria to inform return to sport. Whilst these previously published recommendations cover a number of areas and summarise current evidence they do not: (1) offer clear topics to be included in advice and education information, (2) offer very important and important elements to guide exercise, (3) consider the delivery method of rehabilitation, (4) recommend outcome measures to be used in clinical practice or (5) recommend very important principles of SDM. These recommendations were also published prior to two RCTs comparing surgery versus rehabilitation for

the treatment of ACL injuries and therefore warrant updating (Beard et al., 2022; Reijman et al., 2021). This study combined this evidence with the voice of key stakeholders ensuring the co-production of clinically relevant recommendations in the key areas of advice and education, exercise guidance, intervention delivery, outcome measure use and SDM principles. They go further to present essential components for inclusion and components to be considered to allow tailoring for individual care. These recommendations are the first step towards standardising practice in the UK. Whilst the recommendations were developed for use in the UK NHS service, they may be appropriate for use elsewhere in other health settings.

4.6.1 STRENGTHS, LIMITATIONS AND REFLEXIVE CONSIDERATIONS

This study included a range of different stakeholders involved in the care of ACL patients and future implementation of the SDM tools. Patients who may benefit from the SDM tools were also involved as participants and facilitators of the NGT meetings. The involvement of these key stakeholders will support the implementation and acceptability of tools in clinical practice (discussed in Chapter 5).

As a range of stakeholders were involved in the study, it is important to consider the power dynamic amongst the group and how this may have influenced the final results. It is acknowledged that there were more HCPs involved in the study than patients. Patients involved in the wider study were invited as facilitators to support the voting patient participants. The patient facilitators have experience of discussing their views at TSC meetings and PPIE workshops with patients and clinicians. Their inclusion was intended to

reduce the potential for the patient voice to be lost. As the lead researcher chairing the meetings was aware of this, every effort was made to ensure patient participants were active in group discussions. Patients also had the opportunity to offer anonymous feedback via Mentimeter should they have not felt comfortable to share ideas aloud. An introduction round was also conducted at the start of both meetings to ensure participants were comfortable speaking in front of the group. The use of virtual meetings may have been a barrier for some (patients and HCPs) to participating in discussions but an enabler for others who may have felt less comfortable talking in front of an in-person group. Further, both patients included in the study had experience of ACLR. This may have influenced patient perspectives on important information to be included in the SDM intervention and treatment recommendations, with a potential preference for surgical intervention. The addition of patient participants with experience of non-surgical management may have offered different perspectives and influenced group discussions and study outputs.

In addition, two HCPs (surgeon and therapy manager) and one patient were unable to attend the second meeting. Whilst no major changes were made during the second meeting, it is important to acknowledge that the results may have differed if those unable to attend were present. Although the final recommendations and SDM tools were shared with the group after the second meeting, and no concerns were raised, it is recognised that one of the pros of utilising the NGT method, for example over Delphi, is idea sharing during group discussion. Alternative views and considerations may have been raised by the participants unable to attend the second meeting which may have added to

discussions and subsequently changed group decisions. However, the patient voice was still present with three other patients in the meeting and the clinical academic expert involved as a facilitator has experience of working on surgical ACL trials so was able to offer a surgical perspective. Finally, the absence of the therapy manager may have meant practical/policy considerations were missed. However, this was discussed amongst the group with senior clinical and academic experts offering opinions and thoughts regarding this. This was also discussed at TMG and TSC meetings.

A strength of this study was the inclusion of participants in differing geographical locations, ensuring historical practices at one organisation did not dominate discussions and voting. Further, the consensus thresholds set are consistent with established consensus recommendations adding robustness to study procedure (Tugwell et al., 2007; Williamson et al., 2012). The recommendations produced are based on the current evidence base and expert consensus of patients and HCPs, ready for adoption in clinical practice in the UK. It is important to acknowledge that further evidence published after study completion may alter the recommendations.

ENPT was used as the underpinning theory in this study. A previous systematic review outlined that ENPT is suited to support the development of MSK/orthopaedic interventions however report of its use is sparse (Carter et al., 2023a). Author reflexivity of its use has also previously been recognised to be limited (Carter et al., 2023a; May et al., 2018a). Reflexive practices of the lead researcher were supported by observations of NGT meetings by Dr Paul Leighton (PhD supervisor with experience of NGT methods). A reflexive journal was also maintained. This helped HC to reflect on experiences of

chairing the first meeting to consider things to repeat or improve upon ahead of the next meeting. HC also asked for specific feedback from Dr Leighton on communication and facilitation skills to ensure her approach could be adapted for meeting two as necessary. For example, Dr Leighton highlighted that whilst HC was able to manage appropriate periods of silence to allow for idea generation and individual thinking, she could have been more direct with individuals to seek comments/questions from group members who had audibly contributed less. HC subsequently made a crib sheet with key points identified during discussions and used this as a prompt during Meeting 2. This individual and supported reflexive practice also facilitated reflection of ENPT's use. HC identified that ENPT enabled greater attention to be paid to implementation factors during the design process. Embedding the theory into the intervention development process has also allowed for ease of transition towards feasibility planning and it is hoped that some implementation barriers were considered and addressed prior to feasibility testing. Ahead of the meetings the lead researcher was concerned about communicating the theory to participants who were likely to not be familiar ENPT or any implementation theory. HC took a pragmatic approach to ensure discussions were in plain English and supplemented explanation of the theory with questions aligning to each component of ENPT. For example, for capacity and capability questions were posed such as 'Where does it [the intervention] fit in the pathway?', 'How does it integrate in the NHS system?' and 'Who is needed to make it work?'. ENPT worked as a pragmatic toolkit supporting intervention development and also facilitated the completion of the IRLM (shown in Figure 4.4). Mapping the implementation strategies to ENPT ensured multiple constructs of

implementation were considered and discussed amongst the group. For example, when discussing 'capacity' it was identified that consideration for how the intervention would work during clinical consultations was needed. This was discussed amongst participants to consider mechanisms of action such as, 'built in system support' to ensure seamless experiences for both participants and clinicians. Ensuring the intervention was available online and paper and that clinicians had adequate training and support to deliver the intervention were some strategies discussed by the group to address this. Further considerations and strategies are discussed in Chapter 5. These discussions also facilitated development of the topic guide and intervention training package for Phase 3, which is also discussed further in Chapter 5.

4.7 CONCLUSION AND CONSIDERATIONS FOR PHASE 3

This study successfully developed an SDM intervention to support ACL treatment decision-making. Evidence-based recommendations for the treatment of patients following ACL injury, ready for testing in a UK NHS setting, were also defined. Core components include: (1) advice and education, (2) exercise guidance, (3) delivery method, (4) outcome measure use and (5) SDM principles.

Moving forward to Phase 3, Chapter 5 will present the results of a non-randomised single site feasibility study with embedded individual qualitative interviews exploring the acceptability and feasibility of the SDM intervention in addition to indicators of effectiveness and implementation factors.

CHAPTER 5 INTERVENTION FEASIBILITY (PHASE 3)

Summary

Phase 3 aimed to:

1) Understand feasibility and acceptability of the SDM intervention with patients following an ACL rupture diagnosis in an NHS setting
2) Explore indicators of effectiveness of the SDM intervention
3) Understand implementation factors of the SDM intervention using ENPT

The intervention will further be refined at the end of the study utilising both quantitative and qualitative data.

Chapter 3 presented the results of an individual qualitative interview study exploring patient experiences on the ACLR pathway; providing novel insight that supported the intervention development process in Phase 2, Chapter 4. Chapter 4 outlined the consensus study where an SDM intervention was co-produced with patients and key stakeholders. This chapter presents the results of a non-randomised feasibility study exploring implementation of the intervention in a UK NHS ACL pathway.

5.1 INTRODUCTION

As discussed in Chapter 1.3, three RCTs to date have compared surgical and non-surgical treatment of ACL ruptures and reported conflicting findings regarding optimal management (Beard et al., 2022; Frobell et al., 2010; Reijman et al., 2021). Given the uncertainty in the literature, it is unsurprising

that patients also report uncertainty with their decision-making about treatment (Chapter 3.3.2).

As discussed in Chapter 1.4.4, SDM tools can support decision-making about treatment. They have been shown to improve knowledge, reduce patients 'feeling uninformed' and 'unclear about values', lower the proportion of patients undecided about treatment and result in higher satisfaction (Stacey et al., 2017). As outlined in Chapter 4.1, SDM in the management of ACL ruptures is particularly important given the lack of clarity on treatment efficacy. An evidence-based and theoretically informed SDM intervention was therefore co-developed and presented in Chapter 4.

The purpose of this study was to understand feasibility and acceptability of the SDM intervention, explore indicators of effectiveness and implementation factors through the lens of ENPT.

5.2 METHODS

This study was approved by East Midlands - Nottingham 1 Research Ethics Committee (REC reference: 23/EM/0263) and sponsored by the University Hospitals of Derby and Burton NHS Foundation Trust. The study was registered with ISRCTN (ISRCTN17801081, https://doi.org/10.1186/ISRCTN17801081).

5.2.1 DESIGN

A non-randomised single site feasibility study with embedded qualitative interviews. A study flow-chart is shown in Figure 5.1.

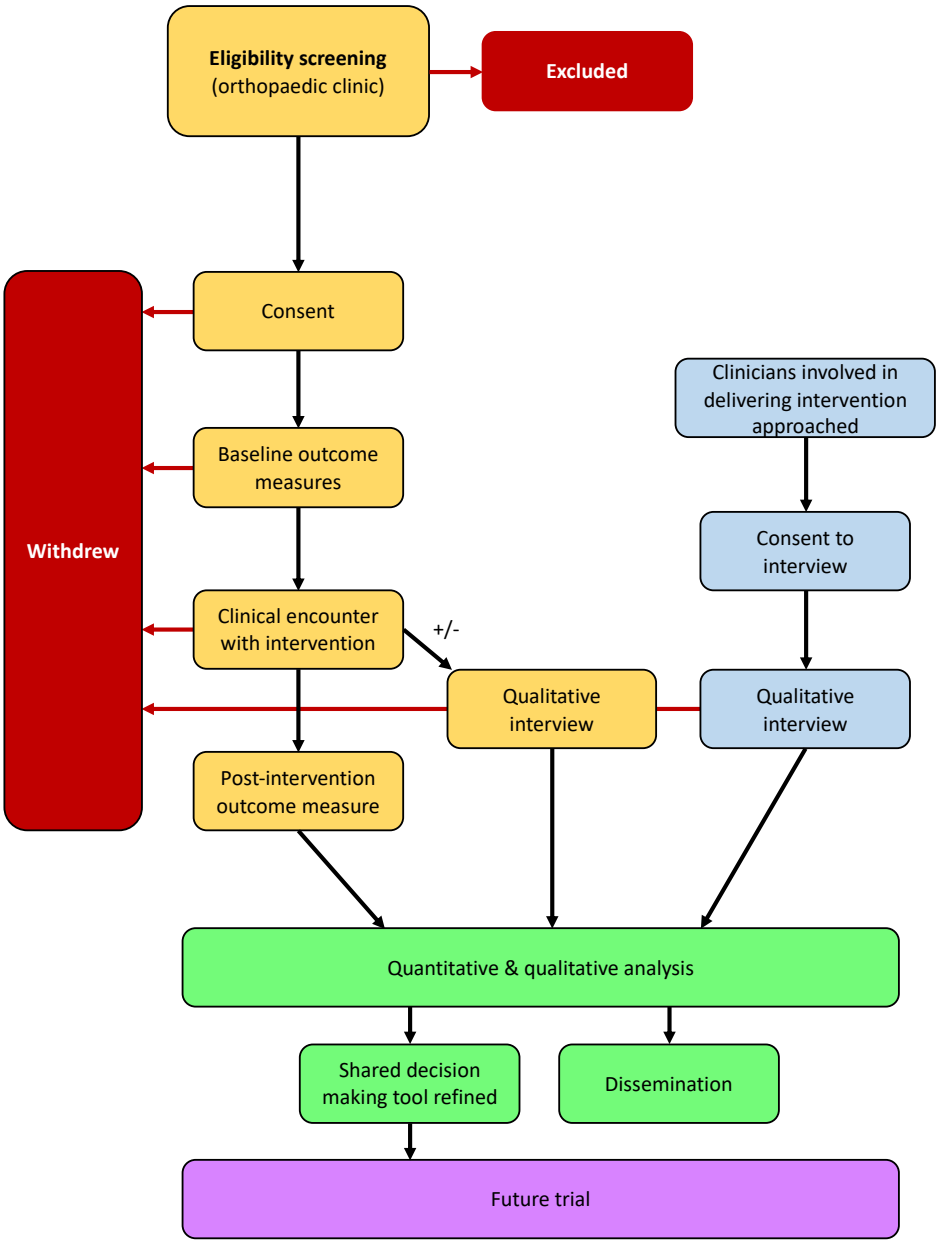


Figure 5.1 – Study flowchart

The study was conducted at one NHS trust (UHDB), across three sites (RDH, FNCH and Queen's Hospital Burton [QHB]), providing orthopaedic and outpatient musculoskeletal physiotherapy for adults with an ACL rupture. Two physiotherapy services, at FNCH and QHB, delivered the intervention.

5.2.2 AIMS AND OBJECTIVES

The aims and objectives for this mixed-methods feasibility study are shown in Figure 5.2.

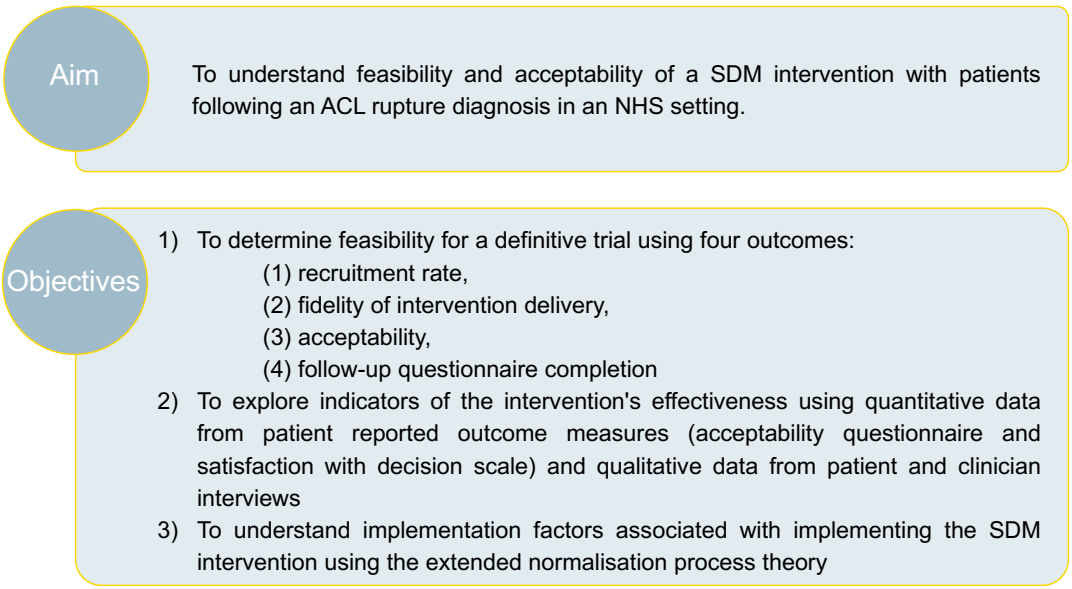


Figure 5.2 – Study aims and objectives

5.2.3 SAMPLE SIZE AND ELIGIBILITY CRITERIA

Twenty participants were planned to be recruited into the feasibility study with a maximum 6-month recruitment window. Data observed at UHDB between 2020-2023 reported on average, 135 ACL procedures to be performed each year (inclusive of any ACL procedure such as revision surgery following graft failure). Detail of specific primary ACLRs performed was not available. A 6-month window was therefore felt to be sufficient. This sample is consistent with other UK feasibility studies and was felt to be appropriate to meet the pragmatic objectives of the study (Billingham et al., 2013). A purposive sample of approximately six patients and six treating physiotherapists were planned to be interviewed in the embedded qualitative component, anticipating this would

be sufficient to reach data saturation and meet study objectives (Hennink et al., 2017).

Participants were eligible for inclusion if they were: aged 18 or over and had been diagnosed with an ACL rupture, for the first time in that limb, confirmed by an MRI scan. They were excluded if they: had a concomitant injury requiring surgical intervention anticipated to significantly alter usual treatment, e.g. fracture, bucket handle meniscal tear requiring immediate surgical intervention prior to ACLR, had previous surgery to the affected limb or were pregnant (as this would affect decision-making regarding surgical treatment and rehabilitation).

Physiotherapists involved in delivering the SDM intervention were purposively sampled (based on clinical grade, number of participants treated, hospital site) to take part in the interviews in addition to purposive sampling of patient participants with varying characteristics (such as age, sex, education level, site receiving treatment) and responses to follow-up questionnaire data.

5.2.4 RECRUITMENT

Potential participants were identified by clinicians from the orthopaedic and/or outpatient musculoskeletal physiotherapy service at UHDB. Consent was gained from potential participants meeting the eligibility criteria to be contacted by the lead researcher (HC). The lead researcher made contact via telephone or was introduced in person. Potential participants were invited to participate in the study, provided with the participant information sheet (PIS), consent documents and opportunity to ask any questions and discuss or clarify information in the PIS.

Information relating to the interviews was included in the PIS and an option to provide consent to be contacted for the interview was included on the consent form. After completion of the clinical consultation, if prior consent was provided, participants were contacted to confirm interest to participate in the interview and a suitable date/time/location was arranged.

Provision was in place to translate study material into a potential participants preferred language via a translator using the normal procedures and in-house translation service at UHDB.

5.2.5 DATA COLLECTION

Once consented, baseline data were collected on patient demographics, mechanism of injury, pre-injury and current physical activity level/frequency and any received treatment recommendation(s). Participants postcode was used to calculate the Indices of Multiple Deprivation (IMD) 2019 Decile which represents ten equal sized groups from one (most deprived 10% of areas nationally) to ten (least deprived 10% of areas nationally) (Stefan Noble et al., 2019). The Rapid Estimate of Adult Literacy in Medicine, Revised (REALM-R) was also recorded. REALM-R is an 11-item word recognition assessment used to identify people at risk of poor literacy skills (Bass et al., 2003). The first three words aim to lower test anxiety and improve reader confidence and are unscored. There is a maximum score of eight and a score of six or less is considered to identify adults to be at risk for poor health literacy.

Participants were given the choice of receiving the follow-up questionnaires online (via email and/or text message) or via paper. Reminders were sent once a week (via the preferred method) for three further weeks until the

questionnaires were completed. On completion, participants received a £20 voucher of their choice.

Following baseline data collection, participants were referred to the physiotherapy department of their choice (of those participating in the trial) and were offered a telephone or face-to-face consultation with a trial trained physiotherapist. Referrals were prioritised as urgent, to be seen within 2-weeks, where appointments were available within the pragmatic constraints of the physiotherapy teams waiting list. Normal procedures were followed at each site for booking an appointment. Once booked, a note was placed against the appointment indicating to the physiotherapist that the patient was participating in the study.

Semi-structured interviews were completed in person or virtually according to the participant's preference. Virtual interviews were completed via telephone or Microsoft Teams. The topic guides were informed by ENPT and PPIE input.

Where interviews took place in person, travel and reasonable childcare expenses were reimbursed. Participants received a second £20 voucher of their choice on completion of the interview.

5.2.6 INTERVENTION

As presented in Chapter 4, the SDM intervention comprised of two components:

(A) Patient information leaflet (Appendix H)

(B) Option grid (Appendix I)

This was printed into a ten-page booklet and two-sided A4 sheet and was also made available digitally.

5.2.6.1 TRAINING OF THE PHYSIOTHERAPISTS

The paper and/or digital intervention was provided to patients (according to preference) on consenting to take part in the trial. The digital intervention was delivered via the study website (www.pop-aclr.co.uk) on a password protected page allowing patients to download pdf versions of the paper documents. The intervention was subsequently discussed with patients at an outpatient appointment with a trained physiotherapist.

The pragmatic training package was designed to be deliverable via in-person or online methods in a short timeframe to meet the demands of busy outpatient physiotherapy teams and fit within usual continual professional development (CPD) in-service training schedules. The training consisted of a one-hour session and included: study background, intervention development process, trial overview, schedule of events and participant flow, intervention components, intervention delivery and outcome measure data collection.

Following training, teams were provided with a one-sided information document summarising key points of the trial and access to a restricted page on the trial website. The restricted page included: key study information, downloadable versions of the protocol, case report form, intervention and participant information sheets for patients in the feasibility trial and clinician interviews.

All physiotherapists were supported via email or informal conversation where required. A key contact was identified at the two participating physiotherapy

sites to support face-to-face discussion where needed. Individual physiotherapists also received a summary of trial procedures via email ahead of the planned consultation with a patient participating in the trial.

5.2.7 OUTCOMES

The study collected outcomes attaining to feasibility and indicators of intervention effectiveness. Implementation factors were also explored using ENPT.

5.2.7.1 FEASIBILITY OUTCOMES

There were four main feasibility outcomes: (1) recruitment rate, (2) fidelity, (3) acceptability and (4) follow-up questionnaire completion.

Feasibility was also evaluated through qualitative interviews, retention rates and reasons for withdrawal.

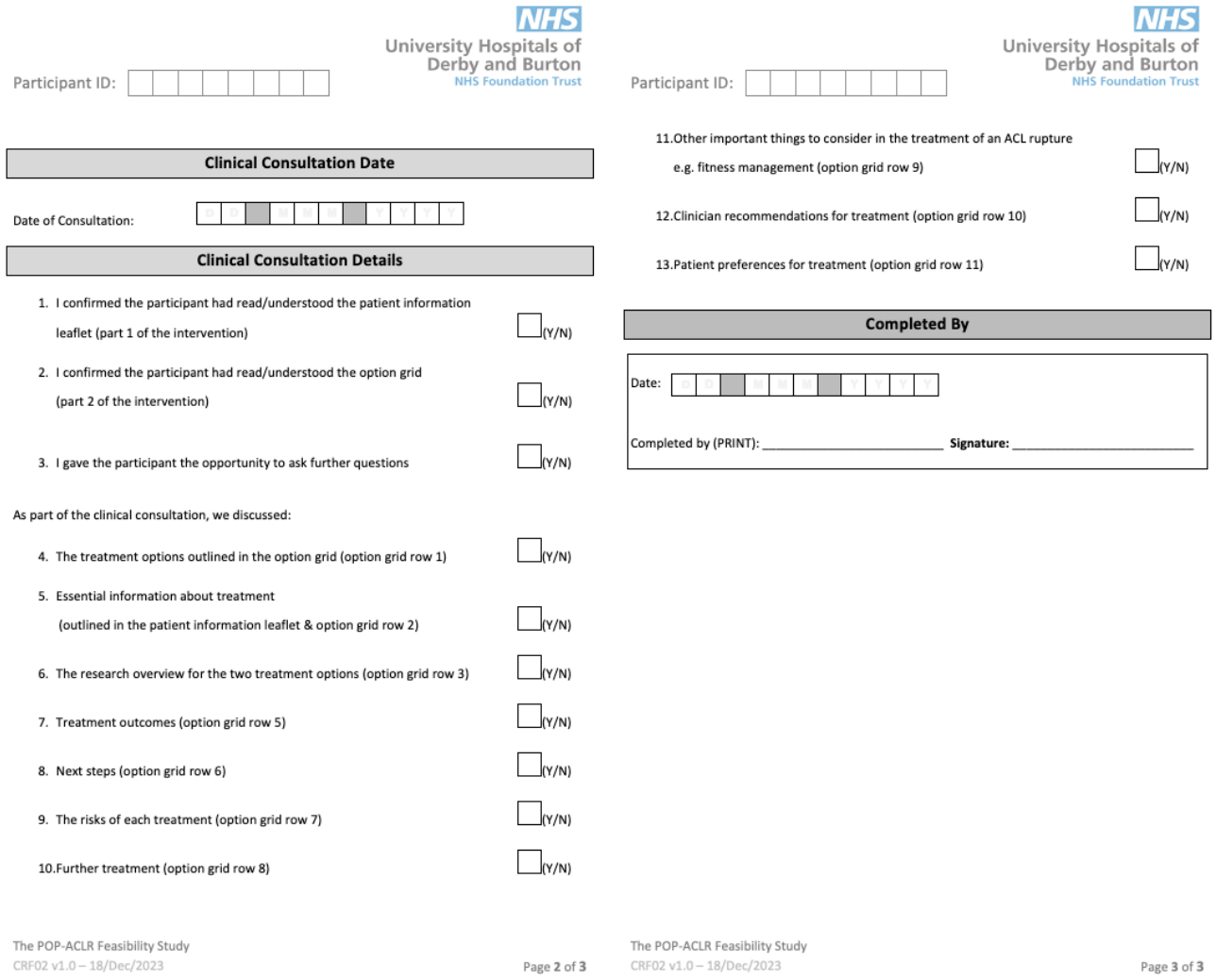
(1) Recruitment rate

Recruitment rates were recorded and defined as the percentage of patients approached to participate in the study following confirmation of eligibility.

(2) Intervention fidelity

Fidelity was defined as adherence to intervention delivery by the treating physiotherapist. This was evaluated using a case report form completed by the treating physiotherapist detailing the clinical consultation where the SDM intervention was discussed. This was measured against components of the important details of the SDM intervention delivered in the training package.

The case report form included 13 statements with a ‘yes’ or ‘no’ response. A blank copy of the case report form is shown in Figure 5.3.



Participant ID:

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Clinical Consultation Date

Date of Consultation: D D M M M Y Y Y Y

Clinical Consultation Details

1. I confirmed the participant had read/understood the patient information leaflet (part 1 of the intervention) (Y/N)
2. I confirmed the participant had read/understood the option grid (part 2 of the intervention) (Y/N)
3. I gave the participant the opportunity to ask further questions (Y/N)

As part of the clinical consultation, we discussed:

4. The treatment options outlined in the option grid (option grid row 1) (Y/N)
5. Essential information about treatment (outlined in the patient information leaflet & option grid row 2) (Y/N)
6. The research overview for the two treatment options (option grid row 3) (Y/N)
7. Treatment outcomes (option grid row 5) (Y/N)
8. Next steps (option grid row 6) (Y/N)
9. The risks of each treatment (option grid row 7) (Y/N)
10. Further treatment (option grid row 8) (Y/N)

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Participant ID:

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

11. Other important things to consider in the treatment of an ACL rupture e.g. fitness management (option grid row 9) (Y/N)
12. Clinician recommendations for treatment (option grid row 10) (Y/N)
13. Patient preferences for treatment (option grid row 11) (Y/N)

Completed By

Date: D D M M M Y Y Y Y

Completed by (PRINT): _____ **Signature:** _____

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Figure 5.3 – CRF02, case report form intervention fidelity

(3) Acceptability

Acceptability was measured using both quantitative and qualitative data. All patients participating in the study were asked to complete an acceptability questionnaire after receiving the SDM intervention. Acceptability was presented as percentages of agreement to each statement in the questionnaire, in addition to an overall mean acceptability percentage (detailed below). Acceptability was further explored during individual qualitative interviews with both patients and clinicians.

(4) Follow-up questionnaire completion

Follow-up questionnaire completion was defined as the percentage of returned patient reported outcomes at four-weeks. The percentage of missing data was also recorded.

5.2.7.2 PATIENT REPORTED OUTCOMES

Clinical outcome measures were collected at baseline and up to four-weeks following the physiotherapy consultation where the SDM intervention was discussed. Two PROs were collected at follow-up: (1) acceptability, (2) Satisfaction with Decision (SWD) scale.

(1) Acceptability questionnaire

A bespoke acceptability questionnaire was designed and included 15 statements pertaining to key elements thought to determine acceptability (presented in Appendix K). These statements were discussed with participants of the consensus study where the intervention was developed, in addition to

discussion with patients during PPIE consultations. Feedback was therefore gained from clinicians, a therapy manager, patients and academic experts.

(2) SWD scale

The SWD scale comprises of six items scored on a five-point Likert scale to determine a patients' satisfaction with a healthcare decision (Holmes-Rovner et al., 1996; Wills and Holmes-Rovner, 2003). For each item a level of satisfaction is reported from strongly agree (5) to strongly disagree (1) with an overall level of satisfaction reported between 5 (low satisfaction with decision) to 30 (high satisfaction with decision) (presented in Appendix L).

5.2.8 NESTED QUALITATIVE INTERVIEWS

Semi-structured interviews were conducted using a topic guide developed at TMG meetings using results from Phase 1 and 2 and PPIE input (Appendix M). Participants (patients and clinicians) were offered an interview at a time and via a medium convenient for them (in-person, telephone or Microsoft Teams).

5.2.9 DATA ANALYSIS

Data analysis for both quantitative and qualitative elements were completed concurrently. Electronic quantitative study data were collected and managed using REDCap electronic data capture tools hosted at the University of Nottingham (Harris et al., 2019a, 2019b). Statistical analysis was undertaken using SPSS Statistics for Mac, version 29.0.1.0 (SPSS Inc., Chicago, Ill., USA). Qualitative data was stored and managed in NVivo V.14 (released

2023). Data were mapped onto pre-defined matrices in Microsoft Excel (Microsoft Cop., Redmon, WA, USA).

5.2.9.1 QUANTITATIVE DATA

Descriptive statistics were used to summarise the baseline data. The continuous baseline variables (e.g. age) were reported with means, SDs and 95% CIs where appropriate, if shown to be normally distributed, otherwise were reported with medians and IQRs. The categorical variables (e.g. sex) were reported with frequencies and percentages.

5.2.9.2 QUALITATIVE DATA

The qualitative component followed a framework approach underpinned by ENPT. Two data matrices were developed to meet the study objectives to understand acceptability, effectiveness (and contamination for clinician participants) and implementation. Topics included in the data matrices are show in Figure 5.4.

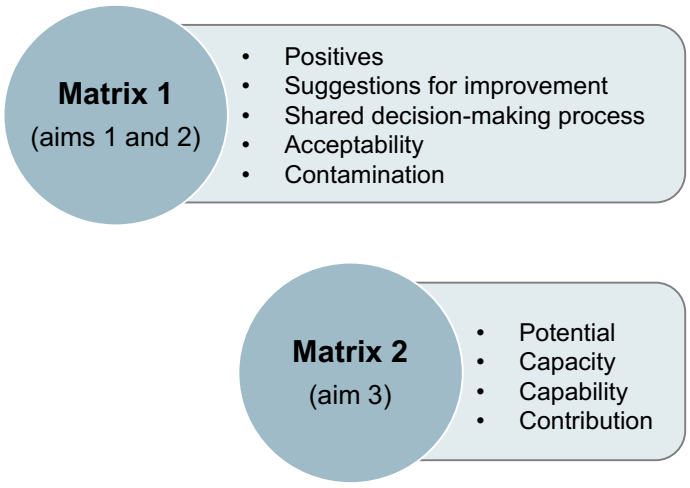


Figure 5.4 – Topics included in qualitative data matrices

Interviews were recorded and transcribed verbatim using an approved third-party transcription service (TP transcription, https://tptranscription.co.uk). All

transcriptions were checked for accuracy against original recordings. The researcher also maintained a reflexive journal to document thoughts after each interview, on initial reading of the transcripts and during data analysis.

Matrices were discussed with the study team during TMG meetings after charting was completed for 25% of the dataset. Following data mapping onto the two matrices, data were organised into two broad topics. Topic 1: acceptability, indicators of effectiveness and feasibility. Topic 2: implementation of the intervention and considerations for future implementation and normalisation.

A pragmatic philosophy supported the purposive sampling strategy for qualitative interviews. Participants (both patients and clinicians) were interviewed after follow-up outcome questionnaires had been completed to support identification of patients reporting varying acceptability and SWD scores. Patient participants were interviewed as desired characteristics were identified, such as age, sex and responses to follow-up questionnaires, whereas physiotherapists were identified after all physiotherapy appointments had been booked for patient participants. This was to ensure all physiotherapists involved in the trial were considered for interview.

Coding of four patient transcripts had been completed before any clinician interviews had begun and so the data were discussed at TMG meetings based on patient interviews alone. The coding framework had also been reorganised to support mapping of data to the ENPT principles (where previously codes where not organised under ENPT constructs). On coding of the physiotherapy transcripts, only codes to separate clinician from patient data were added.

After coding of five patient interviews, it was felt further interviews would not offer additional insight into trial processes, acceptability or implementation factors from a patient perspective. The lead researcher (HC) undertaking the interviews acknowledged that later interviews began to focus on discussions about effectiveness as patients were keen to appraise the SDM intervention and its utility in supporting them to make decisions about treatment. Whilst this supported appraisal of the intervention's effectiveness, it was not the primary focus of the study. A similar phenomenon was experienced when undertaking clinician interviews, however reflexive practices supported the lead researcher to remain focused towards acceptability and implementation factors. This was likely because of their experience as a clinician at UHDB and familiarity with working practices in both departments (FNCH and QHB). After coding of the five physiotherapy transcripts, it was considered that further interviews would not offer additional information to support understanding in line with the research aims and objectives. After discussion at TMG meetings, it was agreed that further interviews were not necessary, and no further participants were invited to interview. A further discussion with the lead researcher's PhD supervisor supported iterative data analysis and organisation of the data into the two defined topics described in Chapter 5.3.3.

5.3 RESULTS

A total of 20 participants we recruited into the study. The mean age was 32.2 (SD 9.7, range 18-57), eight were of female sex at birth (40%) and all participants reported their gender identity to be the same as their sex registered at birth. Ethnic origin was predominantly white British (n=18, 90%)

followed by Asian Pakistani (n=1, 5%) and British Indian (n=1, 5%). The number of participants living in the 50% most deprived areas (IMD ≤ 5) was four (20%). Over 50% of participants (n=11, 55%) reported to have a level 3 education qualification (A-level or equivalent) or below. Three participants (20%) scored a six or below on the REALM-R score, indicating risk of poor health literacy. All three participants at risk of poor health literacy also reported a level 3 or below education qualification. Two of the three participants were also living in 50% of the most deprived neighbourhoods in the UK. Most participants reported working full-time (n=16, 80%), two were full or part-time students, one worked part-time, and one participant was a full-time carer.

The predominant mechanism of injury was through a non-contact event (n=14, 70%) whilst playing football, hockey or netball, experiencing a fall when skiing or during a motorbike accident. The time to diagnosis ranged from five days to approximately six years. All participants engaged in physical activity prior to their injury at varying levels and frequencies, from occasional participation to national level competition, and between one and more than seven times a week. At the time of participating in the study, over half of participants were unable to engage in physical activity due to their knee injury. Baseline data are shown in Table 5.1.

Baseline Data Summary	
Age (years), mean (SD, range)	32.2 (9.7, 18-57)
Sex at birth, n (%) Female Male	 8 (40) 12 (60)
Gender, n (%) Identity the same as sex registered at birth	 20 (100)
Ethnicity, n (%) White British Asian Pakistani British Indian	 18 (90) 1 (5) 1 (5)
Index of Multiple Deprivation Decile, n (%) 2 3 5 6 7 8 9 10	 1 (5) 1 (5) 2 (10) 1 (5) 3 (15) 6 (30) 3 (15) 3 (15)
Highest level of education, n (%) No formal qualifications Level 2 Level 3 Level 4 Level 5 Level 6	 1 (5) 4 (20) 6 (30) 1 (5) 2 (10) 6 (30)
REALM-R, n (%) 3 5 6 7 8	 1 (5) 1 (5) 1 (5) 7 (35) 10 (50)
Employment status, n (%) Full time Part time Full or part time student Full time carer	 16 (80) 1 (5) 2 (10) 1 (5)
Days between injury and diagnosis, median (range, IQR values)	38 (5-2191, 8-65.5)
Mechanism of Injury, n (%) Contact Non-contact Activity engaged in at the time of injury, n (%) Football Skiing Hockey Netball Motorbike accident	 6 (30) 14 (70) 13 (65) 4 (20) 1 (5) 1 (5) 1 (5)

Treatment recommended by orthopaedic surgeon, n (%)	
Surgery	12 (60)
Non-surgery (rehabilitation)	3 (15)
Provided with the option for surgical or non-surgical intervention and placed on the waiting listing	5 (25)
Preinjury physical activity level, n (%)	
Competitive - national level	1 (5)
Competitive – regional level	3 (15)
Competitive – local level	9 (45)
Recreational/Leisure	6 (30)
Occasional participation	1 (5)
Preinjury physical activity frequency, n (%)	
Once a week	1 (5)
2-4 times a week	11 (55)
5-7 times a week	7 (35)
More than 7 times a week	1 (5)
Current physical activity level, n (%)	
Recreational/Leisure	2 (10)
Occasional participation	7 (35)
Unable to participate due to knee injury	11 (55)
Current physical activity frequency, n (%)	
Once a week	2 (10)
2-4 times a week	7 (35)
Unable to participate	11 (55)

Table 5.1 – Baseline data summary

A CONSORT diagram is shown in Figure 5.5.

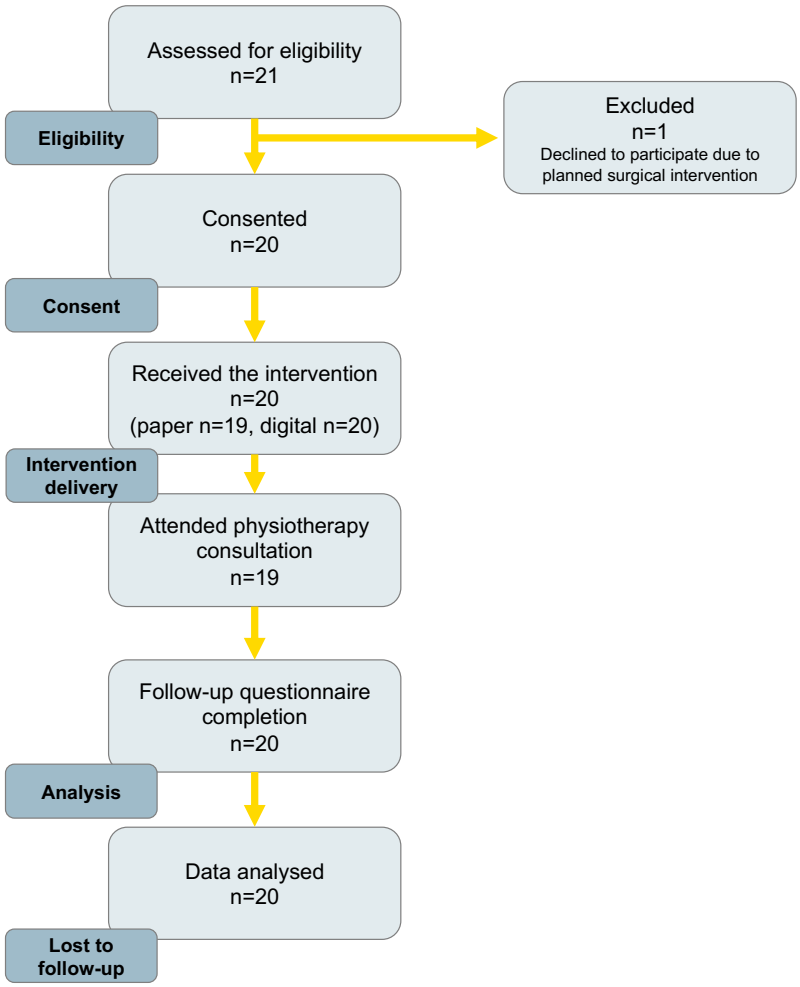


Figure 5.5 – CONSORT diagram

5.3.1 FEASIBILITY

5.3.1.1 RECRUITMENT RATE

There were 21 patients meeting the inclusion criteria who were approached about the study. 20 consented to take part, between 29 January and 5 June 2024, resulting in a recruitment rate of 95.2%. The recruitment graph is shown in Figure 5.6.

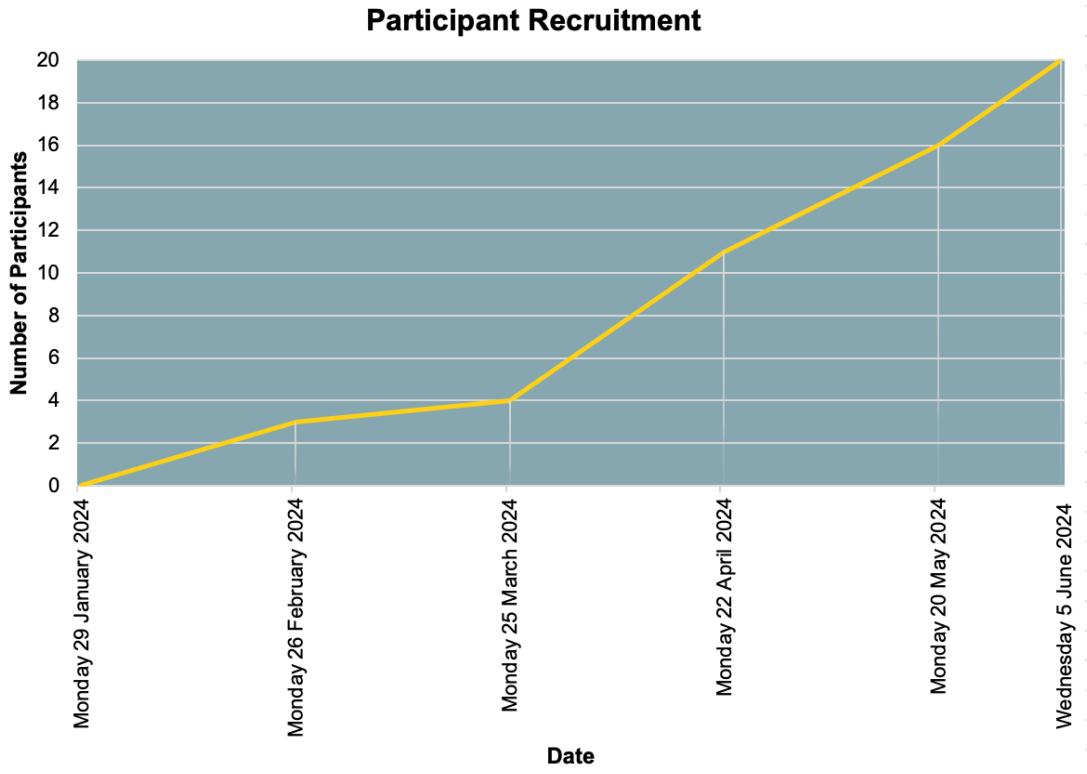


Figure 5.6 – Participant recruitment graph

Most patients were recruited at the time of diagnosis of their ACL rupture during an orthopaedic clinic appointment. Three patients were contacted via telephone after their orthopaedic appointment and prior to their initial physiotherapy appointment. No participants withdrew from the trial. One participant was identified to be eligible but did not consent. This was because, ahead of their MRI result, they had booked a provisional date to have an ACLR in the private sector. On discussing the study with the lead researcher, they expressed their desire to take part to determine whether they needed an ACLR but subsequently found out they would not be able to cancel their upcoming, private surgical procedure without financial implications. They expressed feeling unable to take part and engage in SDM as not proceeding with surgical intervention was no longer an option they could consider. They therefore did not provide consent to participate in the study.

All participants received a link to access the intervention via the study website, 19 participants also received a paper copy of the intervention, one participant chose to access the online version only. One participant did not attend their booked physiotherapy appointment. They received the paper intervention and completed the follow-up PROs.

5.3.1.2 FIDELITY

All participating therapists completed a case report form detailing important components of the appointment where the SDM intervention was discussed. All forms were completed in full and indicated 100% intervention fidelity. Across both sites, there were eleven physiotherapists who delivered the intervention.

5.3.1.3 ACCEPTABILITY

20 participants completed the acceptability questionnaire. Overall acceptability across the 15-items was 94%. Results for responses to each statement are shown in Table 5.2 and discussed further in 5.3.2.1.

Acceptability Statement	Agree n (%)	Disagree n (%)	Level of agreement (%)
The information in the shared decision-making tools was helpful	19 (95)	1 (5)	95
The information helped me to understand my ACL tear	20 (100)	0 (0)	100
The information helped me to understand my treatment options	20 (100)	0 (0)	100
The diagram on page 8 of the information leaflet was helpful in getting me to think about key questions to discuss with my healthcare professional	19 (95)	1 (5)	95
The option grid helped me to make a decision	18 (90)	2 (10)	90
I am aware of the advantages of each treatment option for my ACL injury	20 (100)	0 (0)	100
I am aware of the disadvantages of each treatment option for my ACL injury	19 (95)	1 (5)	95
I understood all the information in the shared decision-making tools	20 (100)	0 (0)	100
The length of the shared decision-making tools was 'just right'	19 (95)	1 (5)	95
The length of the shared decision-making tools was 'too short'	3 (15)	17 (85)	85
The length of the shared decision-making tools was 'too long'	3 (15)	17 (85)	85
The presentation of information seemed in favour of having surgery	4 (20)	16 (80)	80
The presentation of information seemed in favour of not having surgery	3 (15)	17 (85)	85
The presentation of information was 'balanced' and fair towards each treatment option	20 (100)	0 (0)	100
I would recommend the shared decision-making tools to other patients in a similar position to me	20 (100)	0 (0)	100
	Average agreement across all statements (%)		94

Table 5.2 – Acceptability questionnaire

5.3.1.4 FOLLOW-UP QUESTIONNAIRE COMPLETION

All 20 participants completed both PROs (acceptability and SWD scale) resulting in a completion rate of 100%. All questionnaires were completed online via email or text message links. Most participants (n=16) completed both questionnaires within the first week following their physiotherapy appointment, three participants received one reminder (via their preferred method) and one participant received two reminders.

5.3.2 OUTCOME MEASURES

5.3.2.1 ACCEPTABILITY

The overall level of acceptability was 94% (Table 5.2, chapter 5.3.1.3). All acceptability statements achieved over 80% agreement (or disagreement where this was the desired response). Six statements achieved 100% agreement, four achieved 95% agreement, one achieved 90% agreement, three achieved 85% agreement and one achieved 80% agreement. Four participants agreed that '*the presentation of information seemed in favour of having surgery*', this statement achieved the lowest agreement (of disagreeing with this statement [desired response]) percentage of 80%. However, all four participants also agreed that '*the presentation of information was 'balanced' and fair towards each treatment option*'.

Acceptability was also explored during individual qualitative interviews (discussed in Chapter 5.3.3) where discrepancies, such as that described above were further explored.

5.3.2.2 SATISFACTION WITH DECISION

The mean SWD score across all 20 participants was 24.85 (95% CI 23.06-26.64, SD 3.82). The lowest score was 17, whilst the highest (reported by two participants) was the maximum score of 30. SWD data is shown Table 5.3.

Participant	SWD score
0002	25
0003	24
0004	28
0005	24
0006	25
0007	24
0008	26
0009	18
0010	29
0011	30
0012	30
0013	25
0014	17
0015	25
0016	23
0017	19
0018	21
0019	28
0020	27
0021	29

Table 5.3 – Satisfaction with decision (SWD) scale scores

Further, SWD data was grouped by response, this is shown in Table 5.4.

	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly Agree n (%)
I was adequately informed about the different treatments available for my ACL injury	0 (0)	1 (5)	1 (5)	14 (70)	4 (20)
The decision I made was the best decision possible for me personally	0 (0)	0 (0)	5 (25)	8 (40)	7 (35)
My decision was consistent with my personal values	0 (0)	0 (0)	3 (15)	10 (50)	7 (35)
I expect to successfully carry out (or continue to carry out) the decision I made	0 (0)	0 (0)	5 (25)	6 (30)	9 (45)
I had as much input as I wanted in the choice of treatment for my ACL injury	0 (0)	0 (0)	5 (25)	8 (40)	7 (35)
I am satisfied with the decision that was made about treatment for my ACL injury	0 (0)	0 (0)	4 (20)	8 (40)	8 (40)

*Likert scale from strongly disagree (1) to strongly agree (5).

Table 5.4 – SWD grouped responses

5.3.2.3 SOCIOECONOMIC FACTORS

To determine utility of the SDM intervention amongst those from a lower socioeconomic background, at risk of poor health literacy and with a lower level of education, consideration was given to compare acceptability and SWD scores against these three variables.

IMD

Participants with an IMD of 5 or below (n=4, 20%) had an overall lower percentage agreement on the acceptability questionnaire (92%) and lower mean SWD score (24.5) than those with an IMD > 5 (acceptability 94%, SWD 24.95).

REALM-R

Three participants (15%) were identified to be at risk of poor health literacy, scoring six or below on REALM-R. Those at risk of poor health literacy had an overall lower percentage agreement on the acceptability questionnaire (91%) and lower mean SWD score (24.33) than those not at risk of poor health literacy (acceptability 94%, SWD 24.94).

LEVEL OF EDUCATION

Over 50% of participants reported to hold a qualification at level 3 or below (n=11, 55%). Participants with a level 3 qualification or below had an overall higher percentage agreement on the acceptability questionnaire (91%) and lower mean SWD score (24.33) than those with a level 4 qualification or above (acceptability 92%, SWD 23.9).

5.3.3 EMBEDDED QUALITATIVE INTERVIEWS

Individual semi-structured interviews were completed with five patient participants and five physiotherapy participants.

Of the 20 participants, 15 provided consent to be contacted. Purposive sampling identified seven participants who were invited to interview. One

participant initially expressed they did not wish to be interviewed but later changed their mind and contacted the lead researcher to discuss their experiences. Three did not reply to the interview invitation via email. The median age of participants was 32 (range 20-57), two were female, one identified as Asian Pakistani and four identified as white British. Participants level of education ranged from level 2 to 6, and all scored above six on the REALM-R (indicating a low risk of poor health literacy). All participants at risk of low health literacy (n=3) did not provide consent on initial recruitment to be contacted for interview. Participants included those who injured their ACL via a contact injury and those with a non-contact mechanism, with a median time between injury and diagnosis of 2-months (range five days to six years). A range of physical activity levels and frequencies were reported prior to injury (lowest: recreational activity 2-4 times a week, highest: competitive national level competition 5-7 times a week). Employment status included three participants working full-time, one working part-time and one student. Demographic data of participants is shown in Table 5.5.

Participant	Age	Sex
0002	32	Male
0009	57	Female
0011	30	Male
0012	20	Male
0015	32	Female

Table 5.5 – Patient participant demographics

In addition, five physiotherapists involved in intervention delivery were purposively sampled to interview. They had a range of years' experience as qualified physiotherapists at Agenda for Change Bands 5-7 (Band 5 – newly

qualified/junior physiotherapist, Band 6 – senior physiotherapist, Band 7 – specialist physiotherapist) and treated a varying number of patients participating in the trial (range: 1-3) at either site (FNCH and QHB) with different appointment lengths (30 or 60 minutes) and mediums (face-to-face and telephone call). Demographic data is shown in Table 5.6.

Participant	Agenda for Change Grade	Treating site	Consultation length and medium
0022	Band 6	FNCH	30 minutes, face-to-face
0023	Band 6	QHB	30 and 60 minutes, face-to-face
0024	Band 5	FNCH	30 minutes, face-to-face
0025	Band 7	QHB	60 minutes, telephone call
0026	Band 6	FNCH	30 minutes, telephone call

Table 5.6 – Physiotherapist participant demographics

Interview data were mapped to two topics to support understanding in relation to two key questions:

Question 1: **What was the outcome of delivering the intervention?**

(study objectives 1 and 2)

a. Was it acceptable?
b. Did it appear to be effective?
c. Was it feasible?

Question 2: **How was the intervention operationalised?**

(study objective 3)

a. What are the considerations for future implementation?

Topic 1 seeks to answer question 1 and describes acceptability of the intervention (theme 1), indicators of effectiveness (theme 2) and feedback on trial procedures (theme 3).

Topic 2 seeks to address question 2 and describes operationalisation of the intervention and reflections of future normalisation within NHS practice under four themes mapped to each construct of ENPT: potential (theme 1), capacity (theme 2), capability (theme 3) and contribution (theme 4).

5.3.3.1 TOPIC 1, THEME 1: ACCEPTABILITY

The SDM intervention was positively received by both patients and physiotherapists and overall deemed to be acceptable with respect to its content and delivery.

Patients reflected positively on the intervention's length, colour scheme, font size, level of detail, paper quality and availability of the paper and online version. Participants suggested that the intervention struck an appropriate balance of offering relevant information without excessive, lengthy and confusing medical detail.

> "It's very precise. There's not masses of information that aren't relevant, but then I also think it tailors to everyone" [P0012, patient]

Patients further liked the layout of the documents, commenting on the mix of text, figures and tables that were presented in a logical order which ensured the content was manageable to read and not overwhelming. The medical language and lay terminology used was also deemed acceptable to patients.

> “The size of the font, it’s not too little where you’re reading loads of words on a page and it’s really clear and it’s set out in little chunks, so it’s not super overwhelming … It’s laid out nice and … in a logical order, rather than just a page of A4 text which is really busy and it’s on black and white paper and it’s stressful to read.” [P0015, patient]

Two participants explained to be disappointed by some of the data as most expected the outcomes of ACLR to be higher than that reported in the literature. However, they went on to reflect positively about their inclusion as it offered transparency of outcomes for the available treatment options.

> “the main thing that stands out in my mind is the chance of re-rupture … You know, it’s quite a scary statistic, and also the stats about people getting back to playing sport. I mean, quite worrying. But I understand that, you know, those are figures and you can't lie about them, and to be honest I’m grateful to have seen it early on because there’s no smoke and mirrors” [P0012, patient]

Patient participants valued the availability of the intervention as a paper resource in addition to the option of viewing it online. Some favoured use of the paper version, as this allowed them to make notes in relevant places, highlight key information and use it to communicate information with friends, family and employers.

> “I just want something tangible to be able to hold and read when I’m watching TV without making it look like I’m on my phone. I want to read an actual document and be able to write on it or highlight little bits or if

> I've got questions just write little notes at the bottom of the page" [P0015, patient]

Others reflected that whilst they preferred paper, availability online supported convenience of use and liked the option of both mediums. Two participants stated that they did not find the online version particularly helpful, with one reporting difficulty accessing the website on their mobile phone.

Both patients and clinicians reflected positively on the timing at which the intervention was delivered in the hospital pathway. Patients reported the importance of the SDM intervention being provided at the point of diagnosis, followed by an appointment where it was expected that the material would be discussed. This allowed them to have time to process the information and consider relevant questions. All participants further felt the physiotherapist was an appropriate healthcare professional to be discussing decision-making about treatment with.

> "my physio was like really good … I went away from the first time seeing him like I opened the book of knowledge … anything I asked him, he just explained in depth and made me understand" [P0011, patient]

One patient reflected on the importance of the healthcare professional to be interested in the area and not "just going through the motions" [0012, patient]. Another commented on their preference for delivery by a "knee specialist" and whilst this did not need to be the surgeon, felt it was important that the clinician "could have tolerated a little bit of silence while I was trying to work things out and think up the questions I needed to know" [P0009, patient]. Another participant suggested a one-to-one appointment may not be necessary. They

felt the SDM intervention contained sufficient detail to support decision-making about treatment, particularly where ACLR was seen to be inevitable for young patients looking to return to high level cutting and pivoting sports.

Physiotherapists reported the intervention to be acceptable describing it to be non-burdensome, compatible with usual practice, low risk and within the scope of a qualified physiotherapist's skillset. The intervention was low/minimal cost to participants apart from the time taken to engage with it which was reported to be acceptable to both patients and clinicians. Only one therapist had experience of a 60- and 30-minute consultation. They reflected that although achievable within 30 minutes, the increased time allowed for more in-depth conversations which they perceived to improve patient understanding of their injury and treatment options. In contrast, some clinicians with experience of a 30-minute consultation only, felt the intervention supported a reduction in consultation time and greater time at the first appointment was not needed. They explained to have utilised time in subsequent appointments where necessary to revisit information and answer questions raised by patients. A 30- and 60-minute consultation, with carry-over of discussions into future sessions as needed, therefore appeared acceptable to physiotherapists.

5.3.3.2 TOPIC 1, THEME 2: EFFECTIVENESS

The SDM intervention was perceived to be effective in several areas of practice by both patients and physiotherapists. Patients reported the intervention to increase their knowledge of the injury and the treatment options available to them which supported them to engage in decision-making.

> “If I wasn’t given this leaflet, I think I would be quite clueless at to what’s happening… I feel like I’m in a position where I can make a decision” [P0015, patient]

In contrast, one participant reflected on the lack of compelling evidence available and reported in the SDM intervention and suggested this added difficulty to the decision-making process.

> “If it'd been more conclusive like, oh yes, it’s a hundred percent success rate, that would've been easier … if the outcomes had been more compelling, but they are what they are.” [P0009, patient]

All patients commented on the inclusion of the statistical data which was seen to add value to the intervention and medical information. They were viewed as evidence-based and relevant to what happens in real life with several patients commenting on their use in supporting an individual assessment of the pros and cons of treatment. This subsequently allowed them to consider treatment options in line with what was important to them.

> “It’s got some really good statistics in as well that are helping me see. It’s not a one-size-fits-all approach.” [P0015, patient]

Physiotherapists also reported the level of detail, statistical data and information included in the intervention to be appropriate, relevant and useful. They felt the statistics were valued by patients and acknowledged that without the intervention, they would not have been able to offer the same level of evidence-based information as keeping up-to-date with the literature is challenging in the current NHS climate.

> "these are a lot of the questions that patients ask you. We should have been able to answer before, but this gave clarity and data to those conversations, which was useful for patients." [P0022, physiotherapist]

The intervention was also perceived to be effective in supporting communication between patients and physiotherapists. Further, all patients reported to use the intervention outside of the trial, with friends, family members, healthcare professionals and employers to help communicate their injury and gain support to manage its consequences. Both clinicians and patients deemed the intervention to be trustworthy as it was derived from research and included references to the literature that were easy to locate should participants want to seek further information. As a result, some patients suggested to have not needed to research their injury further, saving them time from reading (or watching) unwanted levels of detail.

> "I haven't Googled it, no. I've literally just stuck to the information which I've been given in the booklet … Because when you YouTube surgeries *[previous experience of doing so for another orthopaedic surgery]* you just get the full in-depth and it's normally an American site, and you see them cut you open and get hammers and chisels out, and all sorts. And it's a bit like, oh, maybe I shouldn't be watching this. But, I don't think I even feel the need to go and watch, or research anything, because I just believe what I see in the booklet." [P0011, patient]

Although it was not directly collected as part of baseline data, one participant disclosed to be dyslexic during their interview and reflected upon their experience of accessing medical information for other conditions in

comparison with the SDM intervention. They explained that the font size used, colour schemes, layout and medium (professionally printed in colour on 250 grams per square meter [gsm] silk card with matte lamination) was effective in communicating medical information that they would have otherwise found overwhelming and difficult to engage with.

Physiotherapists viewed the intervention as more effective than usual care. They reported it to have supported "buy in" from patients, who were perceived to have increased knowledge of their injury and treatment options available to them. They felt the intervention offered a good foundation level of knowledge for patients which supported a more pragmatic appointment that was structured, streamlined and tailored to each individual.

> “patients arrived more informed, which therefore streamlined the appointments and the discussions … It helped me as a clinician with quick and structured and accessible advice, based on their questions. Rather than rambling on you could just summarise nicely and when you’ve not seen an ACL rupture for a while it was useful to have the reference point, for particularly the research side of things.” [P0022, physiotherapist]

This was also mirrored by patients who reported the interventions effectiveness in providing them with access to healthcare language. Patients reflected on their ‘non-medical background’ and explained that the intervention increased their understanding of appropriate terminology, allowing them to have individualised conversations with healthcare professionals and ask important questions relevant to them.

> "As a non-medical person, it gives you an understanding so you can speak to medical people about these things … because I have no clue basically. And then once you … learn a little bit about it you can ask questions about what's going on … it has given me a better foundation to have a conversation … instead of just saying is the knee okay?" [P0011, patient]

In addition, physiotherapists reported the effectiveness of the intervention in empowering patients to be involved in their care. They felt this enabled a greater sense of control and improved patients' motivation as they were perceived to have higher accountability for the treatment and its outcomes.

> "it's empowering a patient … to completely know what to expect from both options. … they should be at the forefront of their continued care." [P0024, physiotherapist]

Physiotherapists reflected on the interventions presentation of information and felt it was fair and balanced towards both treatment options, ensuring it was effective for use with all patients following an ACL rupture. They further described the interventions utility in supporting their skills to deliver evidence-based information and have shared decision-making conversations with patients. This was reflected by clinicians in relation to patients following an ACL rupture, but also on their ability to have SDM conversations with patients with other musculoskeletal/orthopaedic conditions as part of usual practice. They explained to feel more confident to take part in SDM and explore patient views about treatment.

> "taking part in this study has … encouraged [shared decision-making conversations] a little bit more … having more of an open dialogue in

> terms of actually what that patient wishes. What are the options available to that patient and what is it that they're thinking at that time." [P0023, physiotherapist]

Overall, the intervention was viewed to be effective in supporting SDM processes and was felt to add value to the ACL rupture pathway.

> "the tool was greatly done. It's very patient friendly. Feels like good quality, it doesn't feel like any corners have been cut and I think sometimes patients do have an underlying feeling of that sometimes in the NHS. You know, a lot of people say, "But I know you're busy. But I know we're on a wait list. But I know there's no money. I know I've got to wait, I know it's struggling." But actually it feels quite premium really." [P0025, physiotherapist]

5.3.3.3 TOPIC 1, THEME 3: TRIAL PROCEDURES

Both patients and clinicians had a positive attitude towards participating in the trial. Patients reflected on the low burden of engagement with the intervention, completing baseline data collection and PROs electronically in-person or via mobile and email links. Some participants explained they would have liked the opportunity to have been followed up for longer, acknowledging that they may have reflected differently about shared decision-making (using the SWD scale) later in their journey. Use of both paper and online resources was seen to support personalisation of engaging with research and ease of completing the follow-up questionnaires.

Physiotherapists further corroborated the ease of engaging with the trial from completing the training through to filling out the checklist measuring

intervention fidelity. Although they acknowledged the long time period between intervention training and delivery to their first patient, they felt the supporting trial material facilitated their understanding of study procedures. Physiotherapists explained how they used the trial website to remind themselves about relevant processes, local site information packs put together by a self-identified physiotherapist acting as a 'trial champion' at that site and reading the reminder email sent by the lead researcher ahead of the appointment with a trial patient. Physiotherapists also utilised one-to-one discussions with other colleagues in their department who they were aware had treated a patient in the trial before them.

Three areas identified by physiotherapists for future trial refinement included, the potential use of drop-in sessions for training refreshers (although not favoured by all), a QR code to access the clinician resources page on the website (replacing access via a password which was or could be forgotten) and a reminder/checklist of key intervention components to be embedded within a patient's electronic record. Physiotherapists reported the use of a 'trial champion' and availability to email and receive a prompt response from a member of the research team to have been successful during the feasibility study and should be incorporated into a future main trial to support delivery.

Future contamination factors were also explored with physiotherapists. When asked about delivery of usual care in parallel to the SDM intervention (as part of an effectiveness trial), they expressed perceived difficulty with delivering usual care given the new knowledge obtained from the SDM intervention and expressed favouring a design where treatment would be delivered for one intervention arm only. This is an important consideration and reflection given

some physiotherapists had also already begun using the intervention, or elements of it, in their usual practice.

5.3.3.4 TOPIC 2, THEME 1: POTENTIAL

Implementation of the SDM intervention depends upon participants' commitment to operationalise it through individual intention and shared commitment. Both patients and physiotherapists demonstrated individual intention to operationalise the intervention. Patients discussed their beliefs and attitudes towards being involved in decision-making about their care, with some reporting conflict between their personal values and social norms and roles. For example, one patient responded to 'neither agree nor disagree' to the following statement on the SWD scale 'the decision I made was the best decision possible for me'. When explored during interview, they described that despite their motivation to engage in SDM, they were unsure of their potential to do so as they didn't feel involved in the decision.

> "I was still in the frame of mind that the decision perhaps wasn't really in my hands, as such. I guess having a consultant say to you, "You are having surgery," or, "I'm listing you for surgery," you kind of trust their judgement. … I think at the time of filling that out I was probably a little bit more on the fence about whether I was able to make the decisions on my own." [P0015, patient]

They explained that they were continually revisiting the SDM intervention and each time gained a greater understanding of their injury, the treatment options available to them and questions they wished to discuss at upcoming appointments. The intervention subsequently supported them to enact upon

their beliefs and behaviours to be involved in treatment decision-making and challenge the system norms and roles they had previously experienced.

Physiotherapists also displayed individual intention to enact the SDM intervention. They described their beliefs to offer patients informed choice by presenting evidence-based information to support all available treatment options. Physiotherapists recognised the role of the intervention in operationalising this belief (coherence) which also fit with their perception of the role of an initial assessment and the work they deliver, demonstrating congruence within the system. Physiotherapists expressed motivation to enact the SDM intervention with all patients and discussed its utility both within and outside of the trial setting. All physiotherapists discussed their beliefs to tailor a consultation to each individual patient and recognised the intervention as adaptable to achieve this goal (capability).

Physiotherapists further discussed the importance of the language used to communicate treatment options (and convey equipoise) and the impact this had on enacting the SDM intervention. They shared their experiences of treating patients who had been advised an ACLR was necessary and how they found it difficult to consider alternative treatment options that seemed to contradict the surgeon's recommendation, subsequently making it challenging to engage with SDM. Physiotherapists reflected on the need for a shared commitment to provide an appropriate context for the delivery of and for patients to engage with SDM.

> "I think it would be really useful [to use with patients following diagnosis of an ACL rupture]. I think it should be done at first point of access. Whoever's

> giving the diagnosis of ACL rupture … this patient, he's already been told he was having a reconstruction, so it was already too late. I think it would be helpful to do [shared decision-making] at diagnosis … because then you're getting it [the intervention] at the right time and it's an informed choice then, at that point." [P0026, physiotherapist]

Physiotherapists felt the responsibility for creating and sustaining shared commitment was owned by the orthopaedic team. This shared commitment across the pathway builds collective readiness to both enact the SDM intervention and respond to changes brought about by its operationalisation. Where patients reported that they had been advised that they needed an ACLR, and consequently felt as though they had less influence over the decision about treatment, they still reflected on the intervention's utility in supporting improvements in their knowledge; demonstrating individual commitment in different clinical scenarios.

5.3.3.5 TOPIC 2, THEME 2: CAPACITY

Implementation of the SDM intervention depends on the capacity of participants to coordinate their actions. As a result, implementation modifies clinical practice and its possible outcomes and impacts upon the social roles, norms and conventions that govern the conduct of participants.

Both patients and physiotherapists demonstrated intent to deliberately incorporate the intervention within the care pathway. Physiotherapists made investment in building co-operative capacity and discussed deliberate actions to deliver the intervention during their initial appointments. The work required to operationalise the intervention was described as minimal and

physiotherapists recognised the relevance of the information in the intervention and the need for SDM with this patient group. Capacity was supported in five ways: (1) delivery of the trial intervention training, (2) use of the fidelity checklist outlining essential components to be delivered during the consultation (although developed to measure fidelity for completion after the initial appointment, some physiotherapists described its use during the appointment as a 'checklist'), (3) trial summary information received via email and paper copies available in the department, (4) trial website and (5) a responsive contact for a research team member. A culture of cooperation was further developed as physiotherapists communicated with each other about their experiences in the trial, offering peer support to deliver the intervention.

However, a key problem discussed by physiotherapists was certainty of engagement with the intervention during prior consultations in the patient's journey. They discussed dealing with this uncertainty and its impact on their ability to operationalise the intervention and engage in what they viewed as an SDM process.

> "People would be less open to have the discussion, if they've already been told in another consultation that repair is the best option for them. They'll obviously be closed off to what you're trying to say because a consultant with more expertise has said otherwise…. it would be good to have this [the intervention] at every level, so be done at the initial appointment, initial consultation with the surgeon who I guess is the one listing them at that time. Because … there must have been at least one if not two that had been put on the waiting list for the repair. So I guess paid less attention because they'd already made that decision with the

> consultant ... I don't know what discussions were had at that stage, but it would be good to know that a similar level of conversation or education was happening at each level of their journey, I guess, so that you're singing from the same hymn sheet." [P0022, physiotherapist]

Physiotherapists also discussed the role of the intervention in altering the social roles of both themselves and the patients within the ACL rupture pathway. They reflected that, in comparison with treatment of non-trial patients receiving usual practice (no SDM intervention), trial patients were expectant of involvement in an SDM conversation during their consultation. This was also corroborated by patients who responded positively to receiving an intervention intended to support them to make decisions about treatment, widening the resources available to them.

In contrast, one participant appeared to struggle with their involvement in decision-making and the change to their social norms and roles. They explained to have been told to need surgery by their orthopaedic consultant, but after engaging with the SDM intervention felt less confident ACLR was essential. They reflected on their experience in dealing with this uncertainty and difficulty acknowledging their new role in contributing to decision-making about their care. They explained that the intervention offered new resources which supported them to understand their options, digest information away from the clinical consultation and formulate questions to discuss with healthcare professionals. Whilst they reported the intervention helped them to come to a decision, they also stated to be undecided about treatment and so had referred back to the decision made by the surgeon; demonstrating ongoing difficulty with responsibility for treatment decision-making.

> “When I mentioned that I wanted to return to running, he [orthopaedic consultant] just said straight away, knee surgery, and I was told that if I didn't have the knee surgery it would always let me down and possibly do more damage. So he was quite clear, cut and dried … then you came in and was able to give me all the more information [the intervention] and that I found … really helpful because we [patient and their partner] then had time to have a look at it. Unfortunately … the decision wasn't really obvious. … But your leaflet I found really helpful and that's a good thing to give out to people like me because there doesn't seem to be time in the appointments to digest what you've been told and formulate sensible questions. … It sort of helped me to come to a decision. The decision I think has been based on the fact that the surgeon just said, “Oh you need surgery, it's always going to let you down” and he was quite certain about it and I just had to sort of think, well he’s seen a few of these so that's what I'm going to have to go with. You see I'm still not dead sure, it is difficult” [P0009, patient]

Further, one participant expressed a perceived lack of intent from their physiotherapist to enact the SDM intervention. They felt their physiotherapist’s priority was to assess levels of pain, range of movement and provide exercises and due to time pressures, had less availability to focus on the SDM conversation.

> “I do wish the physio showed a little bit more intent, but I understand, you know, how busy they are and how understaffed they are in certain areas and I appreciate that their job’s so difficult … but just maybe a little bit more

> empathy and a little bit more showing of understanding might have been useful.” [P0012, patient]

5.3.3.6 TOPIC 2, THEME 3: CAPABILITY

The potential of participants to operationalise the intervention depends on its workability and integration with usual practice.

The SDM intervention was discussed to support interactional work between patients and physiotherapists who used it to structure conversations, ask and answer questions. Physiotherapists reported the intervention to flow with their usual practice during an initial consultation held in-person or via telephone lasting 30- or 60-minutes.

> “from how I work education is a huge part of that, to make sure a patient understands surgically what’s happened, what they’ve done, or if they’ve had images taken what they show, and explain and make sure they’ve got an understanding of that before you leap into treatment. So this facilitated that and works in a similar way that the patient is then well informed before you then start training, so there’s better buy-in, better engagement. So it aligned quite nicely with how I work.” [P0022, physiotherapist]

Physiotherapists were positive about the workability of the intervention suggesting it to be adaptable to meet patient needs. Integration was supported by use of the intervention fidelity checklist, trial summary emails received ahead of a patient consultation and through use of a paper copy of the intervention during face-to-face appointments. Although all physiotherapists felt able to enact the intervention and agreed it was compatible with their

skillset, one physiotherapist raised concerns about the capability of a more junior physiotherapist's skills, with fewer years of experience, to deliver the intervention.

> "it probably depends on the level of expertise, perhaps. If you're a Band 5 rotational, would you have the confidence to do it *[deliver the SDM intervention]*? Maybe not" [P0026, physiotherapist]

The capability to operationalise the intervention outside of an NHS setting was also demonstrated as participants reported enacting it with friends, family members and other healthcare professionals (namely physiotherapists).

> "So I took the material with me to [the university] physio and they've seen it all. … For me the study was really useful and the physio had a look through it as well and, yes, we both were kind of on the same page". [P0012, patient]

5.3.3.7 TOPIC 2, THEME 4: CONTRIBUTION (COHERENCE)

All physiotherapists participating in the trial demonstrated a clear understanding of the intervention's purpose and recognised the role of the trial training in supporting this. They viewed the intervention as novel and suggested that it was more effective than usual care (discussed above). There was further evidence of patients and physiotherapists working collaboratively to build a shared understanding of the intervention's role and potential benefits of its use. Patients further made sense of the intervention in comparison to other resources and described its distinct differences in: offering greater detail about the injury and treatment options, collating research in one accessible document, using appropriate medical terminology, presenting information with

a mix of text and figures, displaying references clearly, provoking thought to consider relevant questions and offering a platform to welcome discussion about treatment options.

> "the NHS website's fine but this goes into a lot more detail … you always think you know what a certain injury is but actually what does it truly involve? And this document has really helped me just digest it all. [P0015, patient]

5.3.3.8 TOPIC 2, THEME 4: CONTRIBUTION (COGNITIVE PARTICIPATION)

The commitment to enacting the intervention has been discussed above with both patients and clinicians demonstrating individual intention to operationalise it (potential). Physiotherapists suggested the SDM intervention provided a framework for discussion with patients and discussed the interventions utility in supporting SDM conversations (legitimation).

> "I think it just gives a structure, or clarity to patients, which is often needed when we give them a barrage of information and an actual reference point as well for say if we're telling them a lot in the consultation about different options made for treatment, or just lots of information about what is their treatment. What they'll come away with is probably quite limited, whereas having a resource where they can refer back to that is useful, both for us and them. [P0022, physiotherapist]

Commitment to operationalise the intervention was supported by availability of the intervention on paper (utilised by patients and physiotherapists) and paper

resources outlining trial procedures (utilised by physiotherapists). However, some patients reported utility of the online version in supporting use of the intervention at 'unexpected times'; demonstrating ongoing commitment to engage with the material.

One participant reported a reduced commitment from their physiotherapist to drive the SDM intervention within the consultation. As a result, they sought support to operationalise the intervention with another therapist not participating in the trial. Some physiotherapists also reported reduced commitment from some patients where the decision about treatment had already been made with the orthopaedic consultant (discussed above, capacity).

Physiotherapists reported they would engage with the intervention with future patients in varying amounts, from discussing the material and quoting the statistical data to providing patients with the intervention and allowing time before discussing it at a subsequent appointment. One physiotherapist suggested use of a QR code to support engagement in practice and to save paper NHS resource. Another suggested use of a reminder in electronic patient records of the core components to cover as part of the SDM consultation to support clinicians to remain engaged with intervention delivery.

5.3.3.9 TOPIC 2, THEME 4: CONTRIBUTION (COLLECTIVE ACTION)

The work involved in carrying out the intervention was described as non-burdensome by both patients and physiotherapists. Patients described their ability to read and interpret the information and translate this into meaningful knowledge despite their self-assessed lack of prior medical knowledge

(discussed in Topic 1, acceptability and effectiveness). Physiotherapists described the utility of the intervention training session in clearly defining the skills needed to deliver the intervention. There was evidence of physiotherapists altering their approach to consultations supported by the SDM intervention, to tailor language and discussions to individual patient needs and expectations.

5.3.3.10 TOPIC 2, THEME 4: CONTRIBUTION (REFLEXIVE MONITORING)

The translation of knowledge about the intervention's effectiveness to reconfigure action was identified from both a patient and physiotherapists' perspective. Participants acknowledged the positive effects of the SDM intervention on SDM process which appeared to support participants (particularly physiotherapists) to evaluate and consider its future use. This was expressed by patients who reported they would recommend the intervention to future patients following diagnosis of an ACL rupture and by physiotherapists who had utilised the intervention with patients outside the trial. Understanding the impact of the SDM intervention on decision-making and awareness of the final decision made about treatment seemed important to physiotherapists and may impact their continued contribution to operationalise the intervention. Understanding satisfaction with treatment decision-making (and decisional regret) was also highlighted by one patient to support their appraisal of engaging with SDM on outcomes of treatment.

Some patients also described continually revisiting the intervention (discussed above, potential). A positive feedback loop was observed where each time they engaged with it, they had increased knowledge about their injury and

treatment options and gained confidence to consider non-surgical intervention. This subsequently appeared to reconfigure their action to support their engagement with SDM.

Physiotherapists further described professional skill development as a result of participating in the trial and compatibility of the intervention to be reconfigured to meet the demands of each patient. Both factors improved their views on future implementation in usual care.

5.3.3.11 TOPIC 2 OVERVIEW

Topic 2 explored the operationalisation of the intervention in a UK NHS acute hospital setting. An overview of the implementation factors identified through ENPT as barriers and enablers to future normalisation are summarised in Table 5.7.

	Potential	Capacity	Capability	Contribution
Enablers	Individual intention (patient and physiotherapist) to enact the intervention. Translation of beliefs into action.	Intent to incorporate intervention in clinical practice. Timing of intervention delivery allowing for introduction of material, independent & collaborative engagement. Time given between interaction points. Setting expectations and supporting change in social roles and norms around decision-making in healthcare. Trial material (training, website, summary documents and fidelity checklist) facilitated delivery and enactment.	The SDM intervention supports interactional work, offers structure and flows with an initial physiotherapy consultation. Adaptability of the SDM intervention to individual patients. Potentially context independent – demonstration of success outside trial procedures and compatibility with other healthcare settings.	Patients and physiotherapists understand the intervention's purpose, its difference to usual care and other resources (coherence). Paper and online resources supported commitment (cognitive participation). Non-burdensome to patients and physiotherapists with use of accessible language (collective action). Positive feedback loop – ongoing engagement (reflexive monitoring). Supports physiotherapists'

		Culture of cooperation amongst physiotherapists.		professional skill development (reflexive monitoring).
Barriers	Communication of equipoise and context created for intervention delivery crucial to engagement. Shared commitment owned by the orthopaedic team which precedes intervention delivery.	Uncertainty of the culture of cooperation across the pathway. Perceived lack of intent of the other party and their priorities (patient of physiotherapist or vice versa). Uncertainty with decision making and patient motivation to be involved.	Confidence and competence of less experienced physiotherapists to engage with the intervention and SDM (those not static in a musculoskeletal/orthopedic environment).	Lack of understanding of the interventions impact on the final decision about treatment, patient's satisfaction with decision and decisional regret (reflexive monitoring). Varying commitment to operationalise the intervention (cognitive participation).

Table 5.7 – Barriers and enablers to implementation and normalisation mapped to ENPT

5.3.4 SHARED DECISION-MAKING INTERVENTION REFINEMENTS

As a result of participant feedback during interviews, the following refinements were suggested: (1) additional research to be added about the use of braces for non-surgical management of ACL ruptures, (2) a prompt for clinicians to review MRI scan results with patients, (3) greater detail about physiotherapy treatment, (4) signposting for local mental health services and where to purchase braces, (5) additional detail about the surgical procedure and potential additional procedures e.g. tenodesis, (6) adding an arm to the spider diagram to prompt patients to ask 'will I need to stop taking my other medication', (7) addition of statistical data reporting patient satisfaction following surgical or non-surgical treatment. One participant suggested deleting the information about ACL self-healing as there was not enough research to support its inclusion.

These suggestions were discussed at TMG and TSC meetings to support refinement of the intervention and its logic model. It was important that refinements were carefully considered to maintain integrity of the intervention development process. No single suggestion was made by more than one participant and so there appeared to be no overwhelming gap in the interventions content. Further, all participants commented on the conciseness of the information and so caution was needed to avoid adding large amounts of additional text. Despite this, it was agreed that the following components were added as they were deemed to add value to the intervention whilst ensuring it remained concise and maintained the principles and design of the original content. The following amendments were made: (1) a prompt for

signposting to local mental health services was added to the information about psychological factors (option grid, ‘what else can I do?’, page 2), (2) the question ‘will I need to stop taking my medication?’ was added under the question ‘how will treatment impact my life?’ (patient information leaflet, spider diagram, page 8) and (3) satisfaction with treatment data was added (patient information leaflet, page 5). One participant identified a typographical error in the option grid which was also corrected.

The final version of the SDM intervention (component A: patient information leaflet, and B: option grid) is presented in Appendix N, with refinements in green text.

Refinements to the IRLM were also made and agreed upon at TMG and TSC meetings. The updated IRLM is presented in Appendix O, with refinements in green text. These refinements were supported by the implementation factors identified as barriers and enablers to future normalisation, discussed in Topic 2 and presented in Table 5.7 above.

5.4 DISCUSSION

The results of this study confirm that a full trial exploring the effectiveness of the SDM intervention is feasible. The intervention is acceptable to both patients and clinicians and indicators of effectiveness suggest its potential utility in supporting SDM processes for treatment decision-making following an ACL rupture. Exploring implementation through the lens of ENPT has further allowed greater understanding of factors which may support or inhibit normalisation of the intervention in usual practice.

The results are discussed against the topics as described in Chapter 5.3.3.

5.4.1 TOPIC 1: FEASIBILITY

Although recruitment to target was reached ahead of schedule, the number of identified eligible patients was lower than anticipated. With 135 ACL procedures at UHDB each year (estimating 10% to be non-primary ACLRs such as revision ACLR procedures), approximately 10 patients receive surgical intervention each month. It was therefore anticipated that approximately 8-10 ACL rupture diagnoses would be made each month, and a 6-month window would be sufficient to recruit 20 participants into the study.

Although 20 participants were recruited after 5-months, on initial commencement of the trial it was 3-weeks until an eligible patient was identified. Recruitment was active in three soft tissue knee clinics taking place every other week for 10-weeks. Recruitment in two further clinics (one soft tissue knee and one fracture clinic) were added after 10-weeks to support recruitment. Despite a soft tissue knee pathway existing at the trust, clinicians observed ACL rupture patients' presence in other clinics, such as fracture clinics, where administrative errors resulted in appointments elsewhere. Of the two identification methods, in-person recruitment in clinic was the most successful. However, a pragmatic decision was made that physical presence of the lead researcher and clinician (HC) was not realistic across all lower limb orthopaedic clinics in the trust. Identification of eligible patients may have been greater with more staff involved in the identification process.

It was further observed that recruitment increased as the number of eligible patients identified increased during spring and summer months. This is

perhaps because of increased participation in outdoor physical activity (and thus, higher risk sports) during warmer weather. These are important consideration for recruitment ahead of a future main trial.

Follow-up outcome measure completion was 100% with acceptability of online methods via text and email links. Participants received a £20 voucher of their choice on receipt of questionnaire responses which may have contributed to the high response rate. During patient interviews, participants stated that the questionnaires were non-burdensome, were relevant and easy to complete following the hyperlinks sent via text or email. Only one patient failed to attend their pre-booked physiotherapy appointment, however, did not withdraw from the trial and proceeded to complete the follow-up questionnaires. They were invited to interview to explore this further however did not respond. During qualitative interviews with other participants, some suggested the face-to-face interaction may not be necessary for all, as they felt the SDM intervention covered sufficient information to support decision making about treatment (supplemented by discussions with the orthopaedic clinical team).

Further, some patients participating in the trial had received physiotherapy treatment elsewhere and reported to have used the SDM tools with their non-trial-trained therapist. Despite not being trained in trial procedures, they reported positive responses to the SDM intervention and suggested it to have helped rapport building and communication during consultations. Some patient participants valued the one-to-one consultation with the physiotherapist and felt the opportunity to ask personalised questions arising from reading the SDM intervention was important. Physiotherapists reported success of the intervention in supporting conversations with patients, allowing for a structured

and tailored consultation. It was deemed non-burdensome by both patients and clinicians, and this is likely to support future engagement with the intervention in clinical practice. Ensuring the one-to-one support patients receive alongside the SDM intervention is tailored to individual needs, would be an important element of a future trial and may offer a more pragmatic approach to engaging with SDM.

Fidelity to intervention delivery was 100% for all 11 physiotherapists involved in the trial. The maximum number of patient participants treated by a single therapist was four. Ahead of a participant's appointment, the physiotherapist was sent an email reminder of key trial procedures, likely contributing to high fidelity to the intervention. This was also explored in qualitative interviews. Physiotherapists reported the intervention training to be informative, however identified the long gap between the training session and intervention delivery to contribute to forgetting some trial processes. All physiotherapists valued the reminder email and the ability to ask someone they viewed as informed in trial procedures (either face-to-face or via email). Some also reported use of the 'clinician resources' page on the trial website where they were able to find all relevant trial information. Physiotherapists viewed the intervention to be low risk and so were able to use professional judgement and existing clinical skills to resolve any uncertainties about its delivery that could not be answered prior to intervention use with a participant. Skillset compatibility is an important part of successful future implementation and sustainment of the intervention in practice. This feasibility trial suggests that physiotherapists have the appropriate skills to deliver the intervention and with the support of training, are able to incorporate it as required within their practice.

Potential contamination factors were also explored. Physiotherapists reported to have already begun using the intervention, to varying extents, with patients as part of usual practice. They suggested it may be difficult to deliver usual care alongside the SDM intervention. In addition, physiotherapists and patients identified the importance of a shared commitment to delivery and engagement with the intervention and so a trial design that considers these factors is necessary. For example, a cluster design (by site) may be more effective to support delivery and implementation whilst minimising contamination.

5.4.2 TOPIC 1: INDICATORS OF EFFECTIVENESS

Although it was not the focus of the feasibility study to determine effectiveness (nor was it powered to do so), the SWD scale was used to explore indicators of the intervention's effect on decision-making processes. The average SWD score was 24.85 (95% CI 23.06-26.64, SD 3.82). Only one participant disagreed with one statement, 'that they were adequately informed', all other responses were recorded as 'neither agree nor disagree', 'agree' or 'strongly agree'. This could not be explored further as the participant did not respond to the invitation to interview. Interviews with another participant, who indicated to 'neither agree nor disagree' with the same statement suggested the reason for this to be because they felt there was not enough information available (in the literature) to be adequately informed about the non-operative treatment pathway. This could be one reason for the participant disagreeing with the statement. Another could be that the intervention was not effective in improving knowledge for patients to consider that they were adequately informed. There was however evidence from patient and physiotherapy interviews that the

intervention was useful in supporting improvements in knowledge. As this study was with a small number of participants, this will be an important avenue to consider in a future larger trial to understand potential unmet needs. Another consideration is that the follow-up questionnaire was completed too soon after interaction with the intervention and patients may have needed greater time to consider its impact.

Socioeconomic background is an important determinant of healthcare outcomes and experiences (Braveman and Gottlieb, 2014; McMaughan et al., 2020). Cultural, social and economic factors have also been identified to influence engagement in SDM (Grenfell and Soundy, 2022; Hawley and Morris, 2017; Krist et al., 2017). In this study, there were minimal differences between mean acceptability and SWD scores for patients living among the 50% most deprived neighbourhoods (IMD ≤5), at risk of poor health literacy (REALM-R ≤6) or with a level of education at 3 or below. A 2016 stepped wedge trial exploring use of an option grid to support decision-making about treatment of knee osteoarthritis reported similar findings (Elwyn et al., 2016). Neither levels of deprivation nor health literacy had an impact on observed levels of shared decision-making during consultations (using the Observer OPTION score, a 12-item 5-point scale measuring the magnitude of skill towards each item, or competency, observed or recorded during a consultation, (Elwyn et al., 2005)). Use of the option grid was reported to increase patient knowledge, readiness to decide on treatment and extent of observed SDM. In this feasibility study, there was 90-100% agreement for statements on the acceptability questionnaire reporting the impact of the SDM intervention on patients' understanding of their condition and treatment

options. Qualitative data also corroborated this finding with reports from both patients and physiotherapists about increases in patient knowledge and the effectiveness of the intervention supporting SDM processes. As discussed in Chapter 4, the use of both the pre-encounter tool (patient information leaflet) and encounter tool (option grid) combined to form the SDM intervention was in aim of improving knowledge and supporting patients to consider and express their treatment preferences subsequently improving informed decision-making and SDM processes. Observation of clinical consultations in a future trial would offer further exploration to understand SDM and interactions during one-to-one consultations, adding depth to the self-reported data collected in this study.

Patients further reflected on the intervention's utility in providing them with access to healthcare language and the subsequent ability to ask questions deemed relevant to them. NHS England outline current literacy levels in the UK as a crisis impacting upon people's health (NHS England, n.d.). In England, a 2018 survey revealed 16.4% of the population to have poor literacy skills, defined as reading at or below the level of a 9-year-old (OECD, 2019). A further 43% are thought to not understand written health information, with this rising to 60% when numbers and statistics are included (Gursul, 2022; NHS England, n.d.). The inclusion of statistical data was viewed favourably by both patients and clinicians and there was no significant difference in outcomes between those identified to be at risk of poor health literacy and those who were not. Assessing participants' health literacy is therefore an important element of a future trial to further understand the utility of the intervention in those with lower levels of education and at risk of or deemed to have poor health literacy skills.

There was some evidence of uncertainty with decision-making about treatment. One participant reported difficulty with the lack of clarity offered by the statistical data included in the intervention and discussed the challenge of making an informed decision. Uncertainty with decision-making in usual care was evidenced during interviews with patients in Phase 1 of this mixed-methods study (Chapter 3). Uncertainty with the non-operative treatment pathway has also previously been reported in an individual interview study with Scandinavian patients experiencing rehabilitation as primary treatment following ACL rupture (Piussi et al., 2023). It is unknown how the participant in this feasibility study would have experienced the usual care pathway and whether the intervention had no effect on or added to existing uncertainty or whether it may have introduced it. Evidence from other patients suggested that the intervention did not introduce doubt, but instead offered transparency to the treatment pathway which they reflected positively on. A longer timeframe for follow-up may add greater understanding to this phenomenon in a future trial. Although previous research has identified most patients value the opportunity to be involved in decision-making, some may require more support and greater time for this process than others (Edwards et al., 2001; Salzburg Global Seminar, 2011). The patient demonstrating uncertainty with decision-making in this trial, identified that they were likely to have responded differently (and more positively) to the follow-up questionnaires (acceptability and SWD) had they have been given more time to engage with the intervention before appraising it. Participation in decision-making has been associated with improved health outcomes and overall greater satisfaction with the consultation process (Connor et al., 2009; Hack et al., 2006). Understanding

change in SWD scores over time and in relation to specific points of interaction on the patient pathway may therefore be an important component of a future trial.

In addition, most participants expected the outcomes of ACLR to be higher than that reported in the intervention. This expectation has previously been reported in an Australian cohort study, where only 24% of patients had returned to their pre-injury level of sport at 1-year despite 91% expecting to when asked preoperatively (Webster and Feller, 2019a). Patients' preoperative expectations of ACLR have also been linked to motivation to engage in rehabilitation and overall treatment satisfaction (Jain et al., 2017; Smith and Choma, 2017; Sonesson et al., 2017). A predictors review completed in 2023, identified patients' positive estimation of their ability to return as a predictor of a successful return to physical activity (Carter et al., 2023b). However, it was highlighted that clinicians should take caution to ensure patients' expectations are not enhanced above levels that are realistic. This is an important role of the SDM intervention, with evidence from this study that engagement with it, offered a pragmatic view of treatment outcomes (predominantly a return to physical activity) that would have otherwise been assumed to be higher.

Elwyn et al's (2016) study also reported an average time of 5 minutes and 20 seconds to cover the content in the option grid. Despite this, overall encounter time was no different when using an option grid compared to consultations where option grids were not used. Whilst time taken to discuss the SDM intervention was not recorded, reports from both patients and clinicians confirmed low burden and no perceived negative effects to consultation time.

One therapist with experience of a 30- and 60-minute consultation acknowledged that whilst 60-minutes was preferred, delivery was achievable within 30 minutes. This suggests that the intervention is appropriate for use during usual clinical practice within a physiotherapy consultation. Clinician time constraints have previously been identified as a major barrier to implementing SDM (Waddell et al., 2021). This was reported by one patient participant who felt SDM was not prioritised by the physiotherapist due to time. Exploration in a future full trial would confirm the interventions effectiveness in supporting SDM processes, how it is prioritised by clinicians and its impact on consultation length.

5.4.3 TOPIC 2: IMPLEMENTATION

There were several factors (summarised in Table 5.7) identified in this study to support understanding of future implementation and normalisation of the intervention in clinical practice. These are discussed in greater detail below.

Firstly, physiotherapists viewed the initial appointment in orthopaedics as the most beneficial time for patients to first interact with the SDM intervention. They reflected that this would maximise the potential of normalisation in the pathway and align with social roles and norms within the healthcare system. This was mirrored by patients who perceived provision of the material at this appointment to offer greatest benefit in engaging with SDM. There were three key interaction points to delivery of the SDM intervention: (1) provision of the material, (2) independent engagement, (3) discussion with the physiotherapist. All three interaction points supported engagement and operationalisation of the intervention in practice with individual intent displayed by patients and

physiotherapists. Both patients and physiotherapists identified the intervention as novel and reflected positively on the gap it filled within the current care pathway. It has previously been acknowledged that SDM is more likely, if decision support tools have been developed for use in face-to-face encounters as those designed for use in isolation by the patient outside of clinical practice may not directly influence SDM (Stiggelbout et al., 2012). Participants in this study praised the intervention for its utility in informing and empowering patients following independent engagement. It's adaptability with supporting SDM during face-to-face and telephone consultations was also reflected upon positively. The combination of both components supporting independent and collaborative engagement is therefore likely to support future implementation and sustainment within practice.

Physiotherapists identified the responsibility for creating and sustaining shared commitment to be owned by the orthopaedic team. This shared commitment across the pathway constructs collective readiness and provides context for the delivery of and engagement with the SDM intervention, the ability to enact it and respond to changes brought about by its operationalisation. Whilst physiotherapists sensed patients expected them to engage with the SDM intervention and be involved in the decision-making process (with expectations set by the intervention), they also self-identified that it was within their role to do so.

There was evidence that the intervention altered the social roles and norms of participants within the pathway. Decision-making can be viewed as a spectrum from informed choice (where the decision is patient led) to paternalism (where the decision is clinician led), with SDM sitting in-between (responsibility for

deciding on treatment is shared between the clinician and patient) (Charles et al., 1999). The intervention appeared to challenge patients' perception of social norms and roles and whilst uncertainty was experienced by some, others reflected positively on the intervention enabling them to take a pragmatic approach to decision-making; supporting them to understand outcomes in relation to the current literature, weigh up the pros and cons of treatment and confirm or consider challenging the recommendation offered by the surgeon to proceed with ACLR.

A key component of SDM is the context in which it is presented. It has previously been highlighted that many patients do not expect to be involved in decision-making (Stiggelbout et al., 2012). Some, for example, may have views of healthcare decision-making in line with a paternalistic approach (identified in this study with patients referring to the surgeon's decision as final, trusting their judgement as the expert) and some may already align with the SDM model or welcome an intervention supporting this. Previous research has demonstrated that patients who are initially hesitant to participate in decision-making often change their mind after presentation of their options (van Tol-Geerdink et al., 2006). To support successful implementation in future practice, evidence from this study highlights the importance of clinicians understanding a patient's motivation to be involved in decision-making (to what extent and how this may change), their expectations of clinicians and what support they may require to enact their preferences and beliefs. Understanding congruency of the SDM intervention with patients pre-conceived ideas of decision-making in healthcare and subsequently how these may change following engagement with the intervention is an important element to consider in a future trial.

A shared commitment to operationalising the intervention across the pathway is another important reflection from this study which is likely to impact future normalisation of the intervention. It is also important to acknowledge that SDM practices may be governed by wider contextual factors that may not have been identified in this study. For example, organisational and system-level factors, such as organisational priorities and financial incentives/allocations of service funding. This may also be an important element to consider in a future trial to support a greater understanding of the intervention's implementation and translation to effective SDM processes.

Patients' views of decision-making in the management of ACL ruptures are currently unknown. Whilst the utility of an SDM intervention is explored in this study, understanding who the intervention may not be appropriate for, may also warrant future exploration as this is likely to support or inhibit sustainment of the intervention in practice and ensure it is enacted with all those who stand to benefit from it. Physiotherapists identified that in cases where patients had been listed for surgery, this may not allow for full engagement with SDM (as it is perceived a decision has already been made). Therefore, delaying formally listing a patient for ACLR may be necessary to provide greater opportunity for patients to accept their role in decision-making and thus engage with the SDM intervention. However, this may not be appropriate for all and not listing may cause unnecessary delay in treatment delivery. Further, the communication of equipoise around treatment options and cooperation with the intervention was questioned by some physiotherapists who described the importance of a consistent message across the pathway. A lack of equipoise in both patients and clinicians was highlighted in the recruitment of ACL SNNAP (UK pragmatic

RCT comparing surgery and rehabilitation following ACL rupture) with 57% declining to participate in the trial due to a preference for surgery and 24% due to a preference for rehabilitation (Beard et al., 2022). Creating an awareness of equipoise has previously been described as the first and most important step in SDM (Elwyn et al., 2000; Towle et al., 2006) This culture of cooperation, or lack of, is therefore an important consideration. Future research utilising the Quintet Recruitment Intervention may support understanding of cooperation with the intervention at the point of its provision in orthopaedics.

Physiotherapists also identified a lack of follow-up to identify the final decision made by participants as a potential barrier to sustainment in practice, as without this, clinicians are unaware of the intervention's utility on decision-making. Patients further identified the desire to understand other patients' satisfaction with treatment and decisional regret to support their appraisal of the intervention. Patient satisfaction data varies. A previous systematic review, completed in 2016 highlighted the paucity of high-quality evidence reporting patient satisfaction with ACL treatment (Kahlenberg et al., 2016). It was further identified that reporting of this outcome had significantly declined in the decade preceding the study. A 2016 cross-sectional study explored the relationship between patient reported outcomes and satisfaction with knee function at a minimum of 12-months post-ACLR in 177 patients receiving treatment at two orthopaedic units in Southeastern Sweden (Ardern et al., 2016b). Only 19% reported to be 'happy' in response to the question "If you were to spend the rest of your life with your knee function just the way it has been in the last week, would you feel…". A further 25% reported to be 'satisfied' and so these scores were combined to determine that 44% of patients were satisfied at an average

3-years following surgery (range 1-7 years). In contrast, a much higher rate of satisfaction following ACLR (with hamstring graft) was reported in Denmark at 82% (Koc et al., 2022). This online survey was completed with 183 patients at a median of 3.6 years (IQR 1.5) post-ACLR. A 2017 study of 232 active patients receiving treatment in a USA institution, reported similarly high satisfaction rates at 85.4% at a mean of 3.7 years (SD 12.5 years) following ACLR with 98.1% stating that they would have surgery again (Nwachukwu et al., 2017). Finally, patient satisfaction with treatment was reported at 18-months in ACL SNNAP by asking patients to reflect on the nature of their problems in comparison with pre-treatment and if they would choose the same treatment should they be able to go back in time (Beard et al., 2022). 83% of participants in the surgical group reported their knee to be better than pre-treatment with 80% stating they would choose surgical treatment again. In comparison with the non-surgical treatment group where 68% reported their knee to be better than pre-treatment and 61% would opt for the same treatment. 18% stated they would not choose rehabilitation as a treatment again, compared to 5% in the surgical group. Providing greater detail on patient satisfaction and decision regret may drive future operationalisation of the intervention in practice as patients appraise the impact of SDM on outcomes of treatment.

A 2012 systematic review explored effectiveness of SDM interventions on the adoption of SDM in clinical practice, assessed from the patients' perspective using a self-administered questionnaire (Légaré et al., 2012). A total of 21 studies were included in the review, utilising a variety of interventions that were categorised as: (1) single interventions compared with usual care, (2) single

intervention compared with other single interventions, (3) multifaceted interventions compared with usual care, (4) multifaceted interventions compared with single interventions and (5) multifaceted interventions compared with other multifaceted interventions. Overall, 35 comparisons were made and only three studies demonstrated positive impact on the outcome of interest. In all three studies the intervention combined training of clinicians responsible for SDM with use of a patient-mediated intervention (such as a patient decision aid) (Bieber et al., 2006; Krones et al., 2008; Loh et al., 2007). Whilst the physiotherapists' training in this feasibility study was not considered part of the intervention, this may be an important component for future sustainment of the intervention and translation of its use into effective SDM practices. Physiotherapists involved in the study identified the lack of prior formal training in SDM and recognised the role of participating in this study in their skill development (discussed in relation to delivery of SDM with ACL patients and wider concepts of SDM utilised with patients with other MSK/orthopaedic conditions). Physiotherapists reflected on the intervention's utility in supporting them to deliver SDM practices which is likely to support sustainment of the intervention within usual care. Lack of clinician training has previously been identified as a barrier to implementing SDM and is therefore an important element which may influence normalisation of the intervention in usual practice (Waddell et al., 2021).

5.4.4 STRENGTHS, LIMITATIONS AND REFLEXIVE CONSIDERATIONS

Data were collected on participants' ethnicity, which has not previously been an included demographic in the UK NLR or in the three largest ACL RCTs comparing surgical and non-surgical interventions. Capturing ethnicity data is recognised in the 2022 (most recent) UK NLR report as a future priority to support understanding of the epidemiology and outcomes following ACL injury (National Ligament Registry, 2022). Whilst it is acknowledged that the present study included only 20 participants in one area of the UK, capturing this data may support future understanding of the demographics of those with ACL ruptures. Without consistent reporting of ethnic background in the literature, it is unclear whether the participants in this study are representative of the ACL rupture population in the UK.

Participants' level of deprivation, level of education and health literacy were also recorded to support understanding of the SDMs interventions utility in those at risk of poorer healthcare experiences and outcomes. Whilst no significant differences were detected between groups, this only offers an indication of the intervention's utility in SDM process as the study was not powered to detect effectiveness. It is well documented in the literature that those from more deprived areas have worse healthcare access, experiences and outcomes. There was no evidence that this novel SDM intervention was any more or less acceptable and effective in those from more deprived backgrounds. This is an important area of exploration in a future trial to ensure individuals from lower socioeconomic backgrounds are not at risk of marginalisation from SDM processes. In addition, during individual interviews one participant described their positive experiencing of engaging with the

intervention as a person with dyslexia. This was a demographic that hadn't been considered during trial planning and may be an important metric to determine in a future trial to understand the interventions effectiveness in those with (and without) dyslexia or other learning disorders.

The population further included those from a wide age range, with varying levels of pre-injury and current physical activity, who sustained their ACL rupture via contact and non-contact mechanisms. Although this was only a small number of participants, these demographics would suggest that the study captured an appropriate sample encompassing a range of characteristics representative of the reported adult ACL population in the current literature.

Both quantitative and qualitative data were captured and supported a comprehensive analysis of the results and refinements to the intervention. Analysis of interview data utilised ENPT to support understanding of implementation which allowed for deeper exploration of factors that may support or inhibit routine operationalisation of the intervention in usual practice. The IRLM was used to support planning of study procedures and data from this study has been used to refine the IRLM, considering strategies of action not previously identified to support implementation in a future trial/clinical practice. Three refinements were made to the intervention based on feedback explored during qualitative interviews. Although these amendments and refinements to the IRLM were discussed at TMG and TSC meetings, this would have been strengthened if reviewed by the NGT consensus participants from Phase 2 (Chapter 4). However, consent was not gained from participants at the time of enrolment into the consensus study. This is an important

consideration for a future trial and whether an ongoing committee may be needed to support scheduled reviews and refinements of the intervention to ensure it contains up-to-date evidence-based information and remains clinically relevant.

Although there were provisions in place to recruit non-English speaking participants, none were identified as eligible for the trial. Future consideration to understand how the material may translate into other languages and its utility with non-English speaking participants may therefore be needed. All participants identified to be at risk of poor health literacy declined to be contacted to share their experiences in a qualitative interview. This study may therefore not have captured a full range of perceptions and experiences, particularly of those at risk of poor health literacy.

Further, the qualitative interviews were carried out by the lead researcher who also identifies as a clinician at one of the physiotherapy departments running the study (FNCH) and who has previously practiced at the second department (QHB). The lead researcher has been a member of the clinical team for several years and currently holds a leadership position practicing at a higher band than some of the physiotherapists who were interviewed. This may therefore have limited the discussions with physiotherapists who may not have felt comfortable accounting negative experiences to a clinical colleague in a senior role.

5.5 CONCLUSION AND CONSIDERATIONS FOR FUTURE RESEARCH

This study has demonstrated that implementation of an SDM intervention in the ACL rupture pathway is acceptable to both patients and clinicians. Indicators of effectiveness have been identified and reflect on the intervention's utility in improving patient knowledge, supporting patients to understand medical terminology to formulate clinically relevant questions, facilitating SDM conversations, empowering patients to be involved in decision-making about their treatment and providing up-to-date clinically relevant information for both patients and clinicians. Implementation factors, explored through the lens of ENPT, have supported understanding of future normalisation of the intervention in current practice and areas of focus ahead of a future trial.

The aims and objectives of the feasibility study have been met and considerations for future research, combing results from all three phases of this mixed-methods study are presented in Chapter 6.

CHAPTER 6 DISCUSSION AND CONCLUSION

Summary

This chapter presents the final discussion and overall project conclusions. Firstly, an overview of each phase is presented aligning to the project objectives outlined in Chapter 1. Secondly, a summary of the main findings are discussed, converging results from all three phases. Subsequently, recommendations are made for clinical practice and future research derived from this thesis. Strengths, limitations and reflexive considerations of the research are discussed with final conclusions presented.

6.1 AIMS AND OBJECTIVES

The primary aims of this research were to:

- Develop an intervention for use with patients post-injury to support decision-making around ACLR
- Understand the interventions acceptability and tolerability among patients and clinicians
- Explore indicators of the intervention's effectiveness and implementation factors in clinical practice

The research took a three-phased approach, using mixed methods, to address the above aims. Each phase had a primary objective, these are discussed below and related to the primary aims of the overall research.

6.1.1 OBJECTIVE 1 (PHASE 1)

Objective 1: To understand patients' lived experiences of the treatment pathway following a diagnosis of an ACL rupture and planned surgical management (Phase 1).

This was achieved through individual semi-structured interviews with patients at three key time-points on the ACL surgical pathway: (1) up to three months pre-operation, (2) three months post-operation and (3) 12 months post-operation. 18 interviews were completed; 10 were at the preoperative time-point, six were interviewed at three-months and two at 12-months post-ACLR. Reflexive thematic analysis led to the development of five themes:

Theme 1	Injury experience, impact and support
Theme 2	Navigating the treatment pathway
Theme 3	Sense making in the preoperative period
Theme 4	Uncertainty, expectations and reality of the post-surgical period
Theme 5	Balancing resources, advice and opinions

The study's findings contributed novel insight to the ACL evidence base of the lived experiences of patients prior to and after ACLR. Key challenges faced by patients were highlighted and included difficulty with: (1) obtaining appropriate and timely referrals to support diagnosis and injury management, (2) coping independently in the preoperative period, (3) communicating with HCPs, navigating the NHS system and managing conflicting sources of healthcare

advice, (4) making decisions about injury management and (5) receiving patient-centred, personalised care.

These findings contributed to intervention development in Phase 2.

6.1.2 OBJECTIVE 2 (PHASE 2)

Objective 2: To work with patients and stakeholders to develop a novel intervention (Phase 2) to address the patients' unmet needs identified in Phase 1.

This was achieved through an online nominal group consensus study with patients and key stakeholders including NHS healthcare professionals (physiotherapists, an orthopaedic surgeon and occupational therapist) and an NHS therapy manager.

Two consensus meetings took place with eight voting participants and five non-voting facilitators. Relevant up-to-date literature and the unpublished results from Phase 1 were distributed to participants in addition to completion of pre-meeting voting to support discussions at the first meeting. Meeting 1 identified the need for an SDM intervention and clinical recommendations for use with patients following an ACL rupture. Consensus on core components was gained for the intervention and recommendations. Draft documents were shared ahead of the second meeting in addition to a second pre-meeting voting form to stimulate further discussion points. Meeting 2 supported finalisation of the SDM intervention and recommendations by gaining consensus on specific elements of each component.

The NGT study led to the co-development of two key outputs:

Output 1 A shared decision-making intervention, comprised of two components: (A) patient information leaflet and key questions diagram, (B) option grid.

Output 2 Evidence-based recommendations for the treatment of patients following ACL rupture in the post-injury or pre-surgical period.

ENPT was used to inform intervention development and supported mapping of implementation strategies to the IRLM. The IPDAS criteria, option grid development guidelines and NICE framework for the development of decision aids were also used (as discussed in Chapter 4.2.6). The novel SDM intervention was therefore evidence-based and theoretically informed, ready for testing in Phase 3.

The recommendations were developed in full and summary format. Priorities were identified to support delivery of personalised care and pragmatic communication to clinicians, providing a resource to support standardisation of UK clinical practice. Co-production ensured the recommendations were clinically relevant and patient focused.

6.1.3 OBJECTIVE 3 (PHASE 3)

Objective 3: To understand feasibility, acceptability and tolerability of the intervention with respect to participants and clinicians in an NHS setting (Phase 3).

This was achieved through a non-randomised feasibility study with embedded qualitative interviews with patients and physiotherapists.

Firstly, the intervention developed in Phase 2 was implemented in clinical practice at one acute NHS trust in orthopaedic and physiotherapy departments at three hospital sites. Twenty participants were recruited, and purposive sampling identified patients and physiotherapists involved in delivery of the intervention to take part in individual semi-structured qualitative interviews. Feasibility data were collected on recruitment rate, acceptability, fidelity and follow-up questionnaire completion. 94%-100% was achieved across all four feasibility outcomes. Framework analysis of qualitative data using ENPT allowed for greater insight into the quantitative data collected. Qualitative data were subsequently mapped to two topics to support understanding in relation to two key questions:

Question 1 What was the outcome of delivering the intervention?

Question 2 How was the intervention operationalised?

Topic 1 addressed Question 1 and encompassed three themes: (1) acceptability, (2) effectiveness and (3) trial procedures. Topic 2 addressed Question 2 and described data under four themes mapped to each construct of ENPT: (1) potential, (2) capacity, (3) capability and (4) contribution.

Convergence of quantitative and qualitative data further supported refinements to the intervention and its logic model ready for future implementation and evaluation.

6.2 SUMMARY OF MAIN FINDINGS

The results of this mixed methods programme of work conclude that it is feasible and acceptable to deliver an SDM intervention in a UK NHS ACL

rupture pathway spanning orthopaedic and physiotherapy services. A future trial was also deemed to be feasible. Comprehensive analysis of data collected across the three phases present key findings which are discussed in turn below.

Several challenges faced by patients when navigating the ACL treatment pathway were highlighted in Phase 1. Five of these were identified to be actioned by the intervention in Phase 3, shown in Table 6.1 below.

Problem identified in Phase 1	Evidence of action in Phase 3
Theme 2 Communication with HCPs was challenging, participants reported struggling to gain rapport with clinicians with limited ability to ask questions about their injury and treatment. *"I had to wait a long time so that made my anxiety worse as well. But then actually getting into the room, she could see I was quite distressed, but she just had no kind of emotion at all." [P10]*	The intervention supported increases in knowledge allowing patients to ask relevant questions. *"As a non-medical person, it gives you an understanding so you can speak to medical people about these things … because I have no clue basically" [P0011, patient]* There was evidence of the intervention's compatibility outside of an NHS setting, supporting patients to gain rapport with clinicians and align on treatment. *"So I took the material with me to [the university] Physio and they've seen it all. … For me the study was really useful and the physio had a look through it as well and, yes, we both were kind of on the same page". [P0012, patient]*
Theme 2 There was limited evidence of SDM for ACL injury treatment. Patients reported feelings of helplessness and decision paralysis as a result of limited SDM practices.	There was evidence of the interventions effectiveness in supporting patients to be involved in decision-making about their care.

"As a non-medical background person, I got the information from the internet and I am unable to make the decision. So, from my point of view, I was not able to make the decisions because I don't know the severeness of the problem that I have." [P14]	*"If I wasn't given this leaflet, I think I would be quite clueless at to what's happening… I feel like I'm in a position where I can make a decision" [P0015, patient]*
Theme 2 The ACL treatment pathway was viewed as a passive process with limited engagement from patients. *"you're just going through the motions" [P3]*	The intervention supported increased engagement of patients in their treatment. *"my physio was like really good … I went away from the first time seeing him like I opened the book of knowledge … anything I asked him, he just explained in depth and made me understand" [P0011, patient]* Physiotherapists reflected on improved communication with patients as a result of operationalising the intervention and its perceived utility in empowering patients to be involved in their care. *"these are a lot of the questions that patients ask you. We should have been able to answer before, but this gave clarity and data to those conversations, which was useful for patients." [P0022, physiotherapist]* *"it's empowering a patient … to completely know what to expect from both options." [P0024, physiotherapist]*
Theme 3 Following ACL injury (and whilst awaiting surgical intervention) patients had several concerns and unanswered questions and reported	The intervention offered patients sufficient information about their injury, addressing common concerns and questions.

uncertainty about where to gain support and look for answers. *'Who can I contact for support?'* *'What surgery am I having?'* *'What additional damage could I do whilst I'm waiting?'* *Examples taken from Chapter 3, Figure 3.4.*	*"I don't think I even feel the need to go and watch, or research anything, because I just believe what I see in the booklet."* *[P0011, patient]* *"It's got some really good statistics in as well that are helping me see. It's not a one-size-fits-all approach."* *[P0015, patient]* Patients discussed increased knowledge of medical terminology as a result of engaging with the intervention. This supported their ability to ask questions and engage in relevant conversations with HCPs further improving understanding of their injury. *"it has given me a better foundation to have a conversation … instead of just saying is the knee okay?"* *[P0011, patient]*
Theme 5 Resources offering information about ACL injuries and their management were difficult to navigate and untrustworthy. Patients reported a lack of information to support understanding of their injury and the treatment pathway resulting in poor awareness of upcoming appointments and expected timelines for treatment. *"You know what Google is like, you look at knee surgeries and it turns out you are dying of something with the lungs, you know, don't trust the internet." [P7]*	The intervention offers evidence-based information about an ACL injury, its management, treatment pathways and timelines. Patients reported, and physiotherapists perceived patients to have, increased knowledge as a result of engaging with the intervention. *"the NHS website's fine but this goes into a lot more detail … you always think you know what a certain injury is but actually what does it truly involve? And this document has really helped me just digest it all."* *[P0015, patient]* Patients further explained needing to do little (or no) additional internet research as the intervention was

	reported to be comprehensive, trustworthy and offered transparency of upcoming treatment. *"there's no smoke and mirrors"* *[P0012, patient]* *"I don't think I even feel the need to go and watch, or research anything, because I just believe what I see in the booklet."* *[P0011, patient]*

Table 6.1 – Problems identified in Phase 1 and evidence of action as a result of operationalisation of the intervention in Phase 3

Whilst the study was not powered to determine effectiveness, these findings are encouraging to consider the interventions utility in addressing issues identified by patients to be challenging when navigating the ACL pathway. As the intervention was co-produced with key stakeholders, further input from patients, clinicians and therapy managers in Phase 2 confirmed that the issues identified in Phase 1 were a priority to be addressed. The qualitative study in Phase 1 was, to the lead researcher's knowledge, the first published study exploring patient experiences of the ACLR pathway relevant to the UK NHS context. These uncertainties present new knowledge to the ACL evidence base, and the subsequently developed intervention addresses contemporary issues.

SDM practices appear to be valued by patients and physiotherapists. Key contextual factors highlighted to be important in operationalising the SDM intervention included: (1) providing an appropriate context for SDM, (2) creating and adopting a shared commitment and culture of cooperation across the pathway and (3) conveying equipoise of treatment options. The

combination of both the pre-encounter and encounter tool to form the SDM intervention appeared beneficial in supporting improvements in knowledge, enactment of SDM and providing capacity to vary support and tailor consultations to individual needs. NICE and NHS England describe SDM as a key component of good healthcare, with a commitment to embedding it across the NHS outlined in the NHS Long Term Plan (as discussed in Chapter 1.4.1) (Carmona et al., 2021; National Health Service, 2019; National Institute for Health and Care Excellence, 2021; NHS England and NHS Improvement, 2019a, 2019b). The developed SDM intervention therefore combines the vision of NICE and NHS England and supports operationalisation of the SDM element in the NHS Long Term Plan.

In addition to development of the SDM intervention, consensus recommendations were co-produced to support delivery of standardised care. The recommendations outlined components considered to be 'very important' and 'important' to allow tailoring of care to meet individual needs. This addresses another key finding from Phase 1, as patients identified the disparity in provision of preoperative care and its prescriptive non-personalised nature. As discussed in Chapter 1.10, the underlying theoretical basis for the intervention, based on work completed prior to the PhD, was a biopsychosocial rehabilitation intervention addressing both physical and psychosocial factors to support preparation for pending surgery. However, in response to key uncertainties identified during individual interviews with patients in Phase 1, the decision to proceed with surgery was the most pressing problem identified. Whilst an SDM intervention was co-developed to address this need, the consensus recommendations were agreed upon by NGT participants as it was

felt that currently, no recommendations exist to support the delivery of care following an ACL injury relevant to the NHS context. Whilst the recommendations developed in Phase 2 do not outline an efficacious intervention, they may provide a basis for future research to consider an optimal treatment package for patients proceeding with non-surgical management and/or prior to ACLR. The change in preconceived ideas about the intervention demonstrates rigor of the research methodology and its relevance to contemporary clinical issues. In addition to reflecting the beliefs and values of patients identified during PPIE work.

Patient and public involvement and engagement was an important thread crosscutting all three phases of this research. Workshops and one-to-one meetings supported design of the study, including its aims and objectives, priorities for inquiry, methods and data analysis (as outlined in Chapters 3, 4 and 5). Stakeholder engagement in between Meetings 1 and 2 during Phase 2 provided oversight that the decisions made during group meetings were relevant and addressed key areas felt to be important by SDM tool developers, expert academics, patients and clinicians. This supported discussions at Meeting 2 ensuring several areas were considered for inclusion in the intervention and recommendations. Patient representatives attending TSC meetings further facilitated research delivery and ensured the research remained clinically relevant with patient care at the forefront of pragmatic decision-making. Patient representatives also supported communication of the research offering oversight of the public facing trial website (www.pop-aclr.co.uk).

6.3 THEORETICAL UNDERPINNING

ENPT was used as the supporting theory throughout this thesis. The qualitative evidence synthesis exploring NPT in orthopaedic and/or musculoskeletal interventional research (discussed in Chapter 2.5) supported the researcher with deeper insight into the theory's use specific to the clinical field of this research.

In Phase 2, ENPT was used to underpin intervention development with key concepts related to the theory's four constructs discussed amongst the group. This ensured implementation factors were considered and embedded in the design of the intervention and its logic model. In Phase 3, ENPT supported in-depth analysis of the qualitative data to consider barriers and enablers to implementation and future normalisation of the intervention in practice.

The decision to utilise ENPT (over NPT) was made following completion of the qualitative evidence synthesis. The lead researcher felt use of only the original four constructs, captured under 'contribution' in the extended iteration of the theory, could miss implementation factors addressed in further detail in ENPT. Whilst NPT does not necessarily exclude considerations of context, a recommendation from the review was 'to consider the additional constructs offered by ENPT to support greater exploration of contextual factors'. The lead researcher therefore felt ENPT would offer greater consideration for wider factors involved in implementation and normalisation. The decision also aligns to the vision of ENPT's developers, and their support of pragmatic use of the theory as an adaptable tool for use by researchers suited to the problem at hand.

The use of theory is also suggested in the MRC and O'Cathain guidance for intervention development (O'Cathain et al., 2019a; Skivington et al., 2021). Using theory has ensured the research was rigorously conducted and aligned with the evidence-base. The IPDAS criteria, option grid development guidelines and NICE framework for development of decision aids were also used to support SDM intervention development (Coulter et al., 2013; Elwyn et al., 2006; Marrin et al., 2013; National Institute for Health and Care Excellence, 2021). The IRLM was used to consider implementation and evaluation of the intervention in the feasibility study presented in Chapter 5.

Sparsity of author reflexivity about the use of ENPT during intervention development, implementation and refinement was highlighted in the qualitative evidence synthesis. Reflexive practices of the lead research have led to the following considerations of ENPT's use.

Firstly, ENPT served as a tool to support data analysis in Phase 3. The lead researcher (HC) reflected on challenges with its use as at times it felt restrictive as they attempted to make data 'fit' within a construct or struggled to select a single construct to represent the data. One author in the ENPT review similarly reflected on the overlap between constructs and resultant uncertainty as to whether data were coded correctly (Drew et al., 2015).

In Phase 3, the data were analysed in two stages. The lead researcher coded each manuscript inductively before mapping codes to ENPT constructs. Data were then subsequently organised into two topics aligning to two key questions. Authors of three manuscripts included in the qualitative evidence synthesis also described using this approach at fear of missing important

themes related to implementation. Another finding from the review was that an initial inductive step may not be necessary as ENPT was able to account for all implementation issues identified in each respective study. Whilst the lead author reflects on ENPT's ability to reflect on several implementation issues, use of the constructs to consider acceptability, feasibility and effectiveness data felt restrictive and complex. The researcher was concerned that this complexity may affect the communication of research findings to the reader, particularly clinical audiences who are likely to have limited exposure to the theory. This was the second reflection of ENPT's use and reason for presenting the data against the two questions where implementation data were mapped to ENPT (question 2) and acceptability, feasibility and effectiveness data (question 1) were not.

The lead researcher adopted several strategies to mitigate the challenges identified with utilising ENPT. Firstly, reflections with their supervisor supported acknowledgment of the pragmatic utility of ENPT to be flexibly applied to the research. Thus, instead of mapping all qualitative data in Phase 3 to the ENPT framework, the results were separated into two topics. This was felt to be a more comprehensive narrative to describe and present the data. Secondly, maintaining a reflexive journal and making short commentary notes capturing each ENPT concept supported iterative data analysis and allowed for ease of theory use with quick reminders of each construct. Finally, analysis over several sessions allowed for an ongoing understanding of the data moving between the codebook and writing the results and discussion as opposed to viewing and working through the data in a linear manner. Although this back-and-forth movement with the data, until the discussion was complete, was

difficult at times, reflecting on the Braun and Clarke guidance and working through the data during supervision supported analytical processes (Braun and Clarke, 2021).

6.3.1 HOW ENPT WAS USED IN THIS RESEARCH, A WORKED EXAMPLE

During intervention development, discussed in Chapter 4, implementation factors were considered with mechanisms of action identified (supplemented by use of the IRLM) that were incorporated into the design and protocol of the feasibility study discussed in Chapter 5. For example, it was discussed amongst participants involved in the NGT consensus study that there was a need for 'built in system support' to ensure a seamless experience for both participants receiving, and clinicians delivering the intervention in the trial. This was actioned in Phase 3 by: (1) asking the administrative team to highlight patients involved in the trial in the physiotherapists daily caseload, (2) providing a summary of trial procedures via email to physiotherapists prior to a consultation with a patient participating in the study, (3) producing summary documents of trial procedures that could be printed off or accessed virtually in a shared clinical folder, (4) providing in person and email support via the lead researcher or an identified physiotherapist who had experience of participating in the trial and (5) developing a dedicated resources page on the trial website for patients and clinicians to allow access to study material at any time. Discussions during NGT meetings further supported development of key training components to deliver to physiotherapists involved in the trial. Success of these actions and consideration for future refinements was further explored

in qualitative interviews with questions added to the topic guide to prompt exploration of capacity within the system, workability and integration of the intervention in clinical practice. Physiotherapists reflected on the success of the above actions as all reported the training to be sufficient, equipping them to deliver the intervention as part of the study. Exploring implementation factors using ENPT supported identification of barriers and enablers to future implementation and normalisation.

6.4 RECOMMENDATIONS FOR CLINICAL PRACTICE

This feasibility study was not powered to determine effectiveness, and so definitive conclusions to change clinical practice cannot be inferred. However new knowledge generated has several important considerations for clinical practice.

1. Patients find navigating the NHS system challenging, interacting with several healthcare professionals and service interfaces that often do not communicate with each other. Treatment pathways could therefore be evaluated and subsequently summarised for communication with patients. This would inform patient expectations and provide an interlink of communication between services, which was also identified by patients to be problematic.
2. Patients are often provided with and seek several sources of healthcare information and struggle to manage conflicting advice independently. Clinicians should signpost patients to reliable information sources, seek to understand patients' needs for healthcare information and consider appropriate methods of communication, tailored to patient needs.

3. Treatment decision-making following an ACL rupture can be challenging. Use of the co-produced SDM intervention may improve SDM practices and support patients to make personalised decisions about treatment and translate beliefs into action.
4. Patients have various motivations to be involved in decision-making and require different levels of support. Clinicians should seek to understand patients' views and motivations to be involved in SDM and tailor their approach accordingly to support involvement. This may include provision of material, such as the SDM intervention, considering digital and paper-based options to suit patient preferences.
5. The culture for adoption of SDM appears important, with perceived intent for its delivery identified as a key barrier to the intervention's operationalisation. There may also be interaction from prior consultations with HCPs and inequity in the communication of equipoise, impacting on engagement with SDM. Clinicians should consider the collaborative commitment to SDM across the pathway in addition to its timing and delivery.
6. In absence of efficacy data supporting the SDM intervention's use, clinicians should consider utilising the SDM principles, determined through consensus, outlined in the treatment recommendations to support SDM conversations during consultations.
7. An evaluation of individual practice and service provision against the treatment recommendations could be considered with the aim of achieving consistency in care for patients following an ACL rupture. The

recommendations contribute to future practice and are a first step towards standardising care in the UK NHS setting.

8. Use of the SDM intervention appears to support physiotherapists' skill development relevant to patients with an ACL rupture and other MSK/orthopaedic conditions. Physiotherapists also indicated that the intervention was compatible with an initial consultation and offered greater structure than usual care practices. Clinicians can therefore consider operationalisation of the intervention without concern of additional burden.

6.5 RECOMMENDATIONS FOR FUTURE RESEARCH

Knowledge generated from this study offering areas for exploration in future research are discussed below.

1. A multi-site feasibility study could be considered to understand feasibility and acceptability of the SDM intervention at other sites, in other healthcare settings and with potentially at-risk groups (such as those from more deprived socioeconomic backgrounds).
2. A multi-centred randomised controlled trial to explore clinical and cost effectiveness of the SDM intervention. To maximize success, it is important to use methodology that considers the implementation factors identified in the feasibility study (Phase 3), such as the importance of shared commitment across the treatment pathway. This could be achieved through a cluster trial design, which may promote shared commitment, or more commonly a design where physiotherapists are assigned (at one site) exclusively to deliver treatment in either the

intervention or usual care group. In the latter case, additional steps may be needed to foster shared commitment, ensuring that those delivering the intervention provide and receive mutual support, for example through regular team meetings.

3. Observation of the SDM intervention, using the observer OPTION tool (Elwyn et al., 2005), may support greater understanding of its use and effects on clinical consultations. The Quintet Recruitment Intervention may also be beneficial to support understanding of cooperation with the intervention at the point of its provision following diagnosis of an ACL rupture in the orthopaedic service. Considering utility of the intervention with participants from a range of socioeconomic and cultural backgrounds to understand effects on existing health inequalities such as levels of health literacy, education levels and language limitations is also an important avenue to explore through observation and quantitative data collection.
4. Exploration of optimal approaches for digital delivery of the SDM intervention appear warranted. Although the paper version (professionally printed in colour on 250gsm silk card with matte lamination) seemed to be preferred in this study (Phase 3), it was also acknowledged to have cost implications that may not be sustainable in the NHS where information is typically printed in monochrome on 80gsm recycled paper. The digital format may include use of a mobile app, a web-based site with interactive elements or downloadable pdf copies of the paper intervention (as used in Phase 3).

5. Understanding patients' perceptions of SDM in ACL injury management in different healthcare contexts may be beneficial. This would support understanding of common issues across different cultures and healthcare models (e.g private and government funded), offering greater insight into implementation strategies and/or targets for SDM interventions.
6. Exploration of patient views on SDM and their congruency with the SDM intervention, in addition to examining system- and organisation-level factors impacting upon SDM processes and the operationalisation of the intervention.
7. Investigation of clinician equipoise in the management of ACL ruptures appears warranted. Evidence from this study demonstrated that orthopaedic colleagues were less likely to communicate equipoise for ACL injury treatment (as reported by patients). Exploring the wider landscape and different clinicians' perspectives may support further understanding of the context for SDM with patients following an ACL rupture. Exploring clinician equipoise may also identify clinician training needs and targets for future implementation strategies and/or interventions.
8. Understanding long-term outcomes (greater than 4-weeks) of engagement with the SDM intervention such as decisional regret post-treatment. This may support further necessary refinements to the intervention and adoption in clinical practice as patients and clinicians evaluate the interventions effects.

9. Capturing patient demographics in addition to age and sex to support greater understanding of the landscape of UK ACL injuries should be considered. This was also recognised as a priority in the UK NLR, to collect ethnicity data of patients entered onto the registry. Whilst this would be an important step to further understanding of demographic data, not all surgeons/orthopaedic departments are enrolled onto the UK NLR. Strategies to increase uptake by other orthopaedic teams may also need to be considered. This would support analysis of the representation of patients within clinical trials and how research results may, or may not, be translated to the ACL rupture patient population.
10. Exploring long-term follow-up of non-surgically treated ACL ruptures, e.g. return to work, may offer greater insight into this treatment pathway. The lack of evidence-based data supporting non-surgical management was highlighted as a concern by patients in Phase 3 and contributed to feelings of uncertainty. Understanding longer-term outcomes could therefore support patients to make decisions about proceeding along this treatment pathway.
11. Exploring optimum non-surgical management for patients following an ACL rupture may be warranted as at present, treatment varies (reported in Phase 1 and 3) and failure of non-surgical (rehabilitation) treatment is high with 41-51% crossover to surgical management reported in the three RCTs comparing surgery with rehabilitation.
12. Determining optimum pre-surgical rehabilitation (prehabilitation) utilising the clinical recommendations may be another avenue for future research. Understanding effectiveness of prehabilitation on post-

operative outcomes such as function, return to work and physical activity would be important to evaluate.

13. Consideration of adapting the SDM intervention to other contexts such as the private healthcare setting may be necessary to support patients seeking treatment outside of a UK NHS setting.
14. Determining regular review and update periods for the SDM intervention, with an appropriate oversight committee, to ensure it remains up-to-date and clinically relevant. This will be particularly important as subsequent treatment options are currently being explored in the UK and Australia (cross-bracing protocol and ACL repair).

6.6 STRENGTHS, LIMITATIONS AND REFLEXIVE CONSIDERATIONS

Strengths and limitations have been discussed in relation to each phase in Chapters 3-5. Section 6.6 summarises key strengths, limitations and reflexive considerations from the project as a whole.

Firstly, PPIE was a central element of this research supporting the design, conduct, interpretation of results and research communication. Two patient representatives, supporting the research since development of the doctoral funding application, were present at TSC meetings and facilitated consensus meetings in Phase 2. They supported development of the protocol for all three phases and were co-authors of the protocol article published in BMJ Open for Phase 3 and are co-authoring the manuscripts for the final feasibility and implementation results. Scheduled one-to-one meetings and workshops were held throughout the PhD to gain feedback from patients about emerging results

and future research plans. An example of this was discussed in Chapter 5, where consultations were held with patients, SDM intervention developers, expert academics and clinicians between Meetings 1 and 2 to discuss the core components of the SDM intervention and clinical recommendations. Feedback was subsequently presented at the second meeting and discussed amongst the consensus group to incorporate into the final design of the intervention and recommendations. Maintaining engagement from patients in PPIE activity is acknowledged to be challenging in this typically young, active group who often disengage from healthcare following return to physical activity and discharge from hospital services (as discussed in Chapter 3). Continual involvement from two patient representatives from pre-PhD to completion and write up of the final study within this research demonstrates success and rigor of the PPIE strategy. However, capturing the views of marginalised groups, under-served communities and socioeconomically deprived backgrounds is a weakness of the PPIE component of this study. Although the NIHR include guidance and toolkit was used to support the PPIE strategy (National Institute for Health Research, 2020), future research may need to consider more innovative methods to capture a wider patient perspective.

Secondly, the lead researcher sought supervision from relevant academic (and clinical academic) experts for support with the chosen methodology of this research and to ensure relevance to the wider clinical and academic landscape. This supported methodological rigour and focus of the research to contemporary issues reflected in the literature and clinical practice. The intervention development and evaluation approach was further supported by the MRC guidance for complex interventions, recommendations by O'Cathain

et al., (2019a), IPDAS criteria, option grid development guidelines, NICE framework and IRLM and was also underpinned by ENPT.

The mixed methods approach to this research enabled the aims and objectives to be addressed through comprehensive exploration utilising both quantitative and qualitative data. The findings from each phase contributed to the design, conduct and analysis of the next with convergence of results on completion of the final phase. This optimised development of the intervention and ensured it addressed contemporary issues relevant to the context of implementation and considered factors to support the feasibility study in Phase 3. The results were reported with transparency to allow for production of high-quality key findings from all three projects with clear underpinning research, rather than analysis of each project in isolation.

A potential limitation of this research is to consider that the results, particularly the qualitative components, were interpreted by the lead researcher who brings their own pre-conceptions and biases of and about the research. The results could therefore be interpreted differently if analysed by another researcher using an alternative method to the reflexive thematic analysis approach. A pragmatic philosophy helped with decision-making and analytical approaches throughout the research, with examples presented throughout this thesis. There were several measures in place supporting the decisions made throughout this research including maintenance of reflexive journals and regular presentation and discussion of findings at TMG and TSC meetings. The lead researcher also had access to regular supervisory support with ad-hoc meetings organised as required throughout the PhD.

Another limitation was the inadequate diversity in the study samples. As discussed previously, the ethnic and socioeconomic diversity of ACL patients in the UK is unknown and so it is unclear how representative the samples are of the wider population. All participants in Phase 1 were recruited and treated within the Midlands and all participants in Phase 3 were recruited from one hospital trust. Although Phase 1 was advertised at a national conference with interest from clinicians across the UK, no participant was recruited from outside the Midlands. Other study advertisement methods, to capture a more diverse sample, may have resulted in the inclusion of participants with different characteristics and therefore additional or alternative conclusions may have been made. This issue could have also been addressed in Phase 3, with delivery of the feasibility study at other NHS hospital sites. The SDM intervention and clinical recommendations were developed relevant to the UK, NHS context. Clinicians, academics and a therapy manager were involved in co-production, however the inclusion of policy makers may have offered a wider perspective. In addition, refinements to the intervention and IRLM were decided upon at TMG and TSC meetings following Phase 3 data analysis. When enrolling participants into the NGT study in Phase 2, gaining consent to contact them after the feasibility trial to gain consensus on suggested recommendations was not considered. This may have strengthened the changes made and offered a robust consensus approach to the refinements in line with the development process.

This thesis demonstrates that developing both clinical recommendations and an SDM intervention and exploring its feasibility, acceptability, indicators of effectiveness and implementation factors, using a rigorous approach

underpinned by theory is achievable in a three-year doctoral project. A similar approach could be used to develop SDM interventions for other orthopaedic/MSK conditions. Whilst the research from this project is applicable to a UK NHS healthcare setting, the results could help inform development of new or refinements to this intervention for use in other contexts.

6.7 CONCLUSION AND THESIS SUMMARY

This thesis reports the findings of a mixed methods study which aimed to develop an intervention for use with patients following an ACL injury and understand its feasibility, acceptability, indicators of effectiveness and implementation factors in a UK NHS setting. Each study aim was met via completion of key objectives in each phase. An SDM intervention was developed using an evidence- and theory- based approach.

The continual strand of PPIE running throughout the study ensured the research remained clinically relevant and prioritised contemporary issues identified as important by patients and stakeholders. Key outputs include an SDM intervention that has been demonstrated to be feasible to deliver and acceptable to patients and clinicians with potential benefits highlighted. Implementation factors were explored to support translation of knowledge into practice with consideration of future normalisation. These factors may also be used in a future trial to ensure an optimised approach to implementation, and in practice to consider elements which may support or inhibit integration in existing clinical pathways. Recommendations for clinical practice were also co-produced which offer a starting point to standardising practice for care following an ACL rupture in the UK.

Original contributions to the literature arising from this research include:

- Understanding of patients' experiences on the ACLR pathway (both prior to and after surgical intervention) in a UK NHS context. This highlighted key gaps in the delivery of care and supported development of the SDM intervention in a subsequent phase.
- A co-produced SDM intervention supporting treatment decision-making following an ACL rupture.
- Barriers and enablers to implementation of an SDM intervention within an ACL rupture pathway spanning orthopaedic and physiotherapy services at three sites within one NHS trust.
- Evidence-based clinical recommendations outlining key components of treatment for patients following ACL injury rupture in the post-injury or pre-surgical period, ready for adoption and evaluation in clinical practice.
- Understanding of the use of ENPT in the development, implementation and refinement of interventions targeting orthopaedic/MSK conditions.

The next step is to conduct a fully powered multi-centred randomised controlled trial to explore the cost and clinical effectiveness of the intervention. A study within a trial (SWAT) may also be considered to evaluate use of the intervention within a larger trial investigating a different clinical question about ACL injury management. For example, in a trial exploring effectiveness of surgical techniques for the treatment of ACL rupture (such as ACLR versus ACL repair), the SDM intervention could be embedded within the recruitment process. This would ensure all those consenting to participate have engaged

in a shared decision about surgical versus non-surgical management prior to proceeding with a surgery only intervention.

This thesis has presented several findings arising from all three phases of research. Recommendation for clinical practice and future research have also been made. Strengths, limitations and reflexive considerations of the research have also been discussed. Finally, an overview of original contributions to the literature resulting from this thesis have been presented.

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APPENDICES

APPENDIX A: INTERVIEW TOPIC GUIDE

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Interview Topic Guide – Preoperative / 3 Month / 1 Year

Postoperative Interview

(delete as appropriate for interview time point)

Version 1.0 – 31/05/2022

Introduction and Background

- Thank you for agreeing to take part in the study to discuss you experiences
- Tell me about your journey so far

Possible prompts:

- Timeline of injury and initial management
- Waiting times to surgery and support given in that time
- Knowledge of [include as appropriate – planned] surgery and postoperative rehabilitation

Topic 1: Expectations of treatment and returning to physical activity

Possible prompts:

- Expectations of treatment, returning to physical activity and work after surgery
- Who have expectations been set/influenced by
- Have they changed since diagnosis
- Expectation versus reality of current ability

Topic 2: Views and involvement in prehabilitation

Possible prompts:

- Engagement in physical activity [delete as appropriate - since injury / prior to surgery]
- Specific referral for prehabilitation
- Description of rehabilitation intervention e.g. advice, exercise
- Views of prehabilitation and what it should/should not involve
- [Delete as appropriate - Engagement in postoperative rehabilitation]

Topic 3: Healthcare advice

Possible prompts:

- What advice has been given
- Who has given the advice e.g. healthcare professional, friend/family member, internet
- Conflicting advice

Close

- Is there anything you feel could have been managed differently by your healthcare providers e.g. surgeon, GP, physio
- Anything further you would like to mention/discuss
- Thank you for taking the time to discuss your experience

APPENDIX B: CODEBOOK

Theme 1: Injury experience, impact and support	**Theme 2**: Navigating the treatment pathway	**Theme 3**: Sense making in the preoperative period	**Theme 4**: Uncertainty, expectations and reality of the post-surgical period	**Theme 5**: Balancing resources, advice & opinions

No	Code	Definition	Coding Coverage	Exemplar Quote
Theme 1: Injury experience, impact and support				
1.01	Impact of ACL injury	Descriptions of the impact of the ACL injury to the participant	57 references across 14 interviews	*"I have struggled really, really sort of deeply to the point where I didn't want to go to work, didn't want to get out of bed. Obviously you are young and when you are so used to having a certain lifestyle"*
1.02	Blame for injury	Descriptions of blame for sustaining the ACL injury	7 references across 6 interviews	*"I was stationary at a set of traffic lights when a car doing nearly forty miles an hour crashed into the back of me. It was an elderly gentleman who had just come from the hospital, so he was still under medication when he sort of, he bumped me ... I had been playing football for years and never really hurt myself so maybe it was something that was due to come."*

1.03	Actions of the patient re mental health	Actions taken by the participant regarding their mental health	15 references across 11 interviews	*"Being honest I went and got a dog. I went and got a greyhound which needs walking. So I take him out for walks so he can pull me a little bit and I take the children out for walks and stuff. So I have been a little bit more family devoted in respect that I don't really spend that much time on my own anymore, it's always me with somebody else. But I think that was a comfort thing for myself because when I was able to take the dog and take my son out, or take my dog and take my kids out, or just me and my partner and my dog would go for a walk, it was like a de-stress. It was like shifting my focus onto something different"*
1.04	Patient thoughts re mental health support	Descriptions of the participants thoughts regarding the mental health support available	19 references across 7 interviews	*"I think the support would have been definitely helpful and it might have made some changes really to how I felt but that's just how it is I suppose"*
1.05	Support from those with similar experience	Descriptions of support received or wanted by the participant from those with similar experiences e.g. an ACL injury	10 references across 5 interviews	*"I think you can only get so much information from doctors, nurses, and physios and stuff, if they have actually gone through it themselves. You can get a very different picture from someone who has had the surgery and gone through all of the rehab process and how they found it and the setbacks and things like that."*

1.06	Opportunities to seek help	Descriptions of the opportunities for the participant to seek help	6 references across 6 interviews	*"unfortunately I haven't really had a chance to speak to anyone with regards to any questions I have got"*
1.07	Knowledge of injury	Descriptions of the participants knowledge of their injury	14 references across 9 interviews	*"All I have heard from the doctors is that kind of throw away comment of oh that's quite a bad ACL tear isn't it?"*
1.08	Knowledge of ortho interactions pre surgery	Descriptions of the participants knowledge of orthopaedic interactions e.g. appointments prior to surgery	4 references across 3 interviews	*"I just don't know what to expect from now, what kind of like procedure there is or progression there is from now. I am just kind of waiting to hear anything"*
1.09	Knowledge of surgery & postoperative rehabilitation	Descriptions of the participants knowledge of surgery and postoperative rehabilitation	54 references across 14 interviews	*"'ve definitely got surgery in six weeks, I run a company, I've got staff members. I know I'm going to have to be at home. Do I know how long I can't drive for? Do I know how long I'll be in a leg brace? You know how long on crutches for? I know absolutely nothing"*

1.10	Thoughts about recovery from ACL tear	Descriptions of the participants thoughts about recovery following an ACL tear	27 references across 15 interviews	*"Not able to swim and not able to muck about with the kids … I don't think I'll get to that point until I've had a repair"*
1.11	Thoughts about how other's might have dealt with their situation	Accounts and reflections of how the participant feels other may deal/cope in their situation	1 reference across 1 interview	*"other people they do struggle don't they? ... it would be hard and some people wouldn't just accept it because they feel like a victim and probably rightly so but that's the, depends how you see things don't it? Everyone's different"*
1.12	Reactions to negative stories of ACLR	Participants reactions to hearing negative stories of others treatment of ACLR	11 references across 9 interviews	*"any stories of people becoming worse off after the surgery kind of I dismissed"*
1.13	Outlook on life	Participants reflections/descriptions of their outlook on life	9 references across 7 interviews	*"I worked in sales for seven years of me life. It's dead cut throat etc, etc. I set up me own company at 26, got people working for me. If you're not like, you can't beat around the bush so that's my outlook on life. You get in what you get out. Put in what you get out of it"*
1.14	Ability to cope	Descriptions of the participants thoughts about their ability to cope with adversity/their ACL injury	6 references across 3 interviews	*"I just prefer not to know and go in with an open mind, do everything they have asked me to do. If I get through it I get through it. If I don't then that will be something I have to reconsider with regards to my mental health"*

1.15	Importance of physical activity	Descriptions of the important of physical activity to the participant	11 references across 8 interviews	*"looking at the importance of football to myself I think it was like I use it as kind of like a way out psychologically as well as keeping fit so and I've played since I was quite young so around seven so it's quite engrained in me"*
1.16	Actions after initial injury	Descriptions of the participants actions after sustaining their initial knee injury	24 references across 17 interviews	*"I didn't go to the- Because we were out with friends, and I was out with my daughter and you sort of try and hobble along and cope. And then we went for dinner and I stayed out and then when I tried to get up after the meal I was like, I literally can't walk, really, very well. So then it was like, I think maybe I do need to go to A&E"*
1.17	Actions whilst awaiting/pre-diagnosis	Descriptions of the participants actions prior to diagnosis of an ACL rupture	10 references across 7 interviews	*"In the meantime [whilst awaiting a diagnosis] I did start kind of going to the gym and trying to strengthen my leg and get back to normal kind of walking as much as I was able to"*
1.18	Thoughts about the initial injury pre-diagnosis	Participants thoughts about their initial injury prior to diagnosis of an ACL rupture	25 references across 15 interviews	*"I've just gone down to the floor and I knew what I'd done because there was that sound and pain and loose leg, and it just started pumping up quite quickly"*
1.19	Thoughts about the injury post-diagnosis	Participants thoughts about their injury post diagnosis	17 references across 9 interviews	*"I was panicking, I was just assuming that my life is gone, trust me. I've gone to that level because I don't know what is the implication of ACL. So, you are physically fit and you are a normal person and all of a sudden, someone is saying you have got an ACL problem"*

1.20	Experiences of diagnosis	Descriptions of the participants experience of their ACL rupture diagnosis	44 references across 17 interviews	*"So it was just oh we have done the X-ray yes, no there is nothing wrong with you, you have just got a bit of swelling. No there is something definitely wrong with me. Oh what we will do is we will do an ultrasound, oh yes look listen there is still definitely nothing wrong with you. I am telling you there is. I know my knee. I know my body, something is not right. Okay, well we have done everything I just think it's the after effects of the accident. Okay, so what I will do is I will go to the doctor then every time I feel pain, which is obviously quite regular and then this is what happens.* *They referred me. The specialist chased it up and then I got the correct diagnosis."*
1.21	Experiences of (potentially) missed diagnosis	Descriptions of the participants experience of encounters with healthcare after their knee injury where an ACL rupture diagnosis was not made	22 references across 9 interviews	*"I was annoyed that it was missed but then again honestly, it's just - Well I went to A and E and they - Well they did the test for the ACL but I guess my knee was swollen at that point so they couldn't really see it. But I was annoyed when it was missed because after that I thought it was all fine that I could do what I want and then when it collapsed on me in the snow, I was in a lot of pain it took what from that point a month and 1/2 until I got diagnosed with it"*

1.22	Second injury	Descriptions of a second knee injury	12 references across 7 interviews	*"I left it and went back to playing football. In January, I think it was January the 6th or 7th, probably no further distance from about a metre away, someone just passed me the ball, I opened up my leg, or my foot to a right angle again and it just popped and exploded and within about a minute, it was the size of a football. And at that point, I knew that I had actually done something quite bad to it"*
1.23	Actions of the patient after reinjury	Descriptions of a the participants actions after their second knee injury	24 references across 17 interviews	*"I was throwing snow balls at my sister and then it just completely gave way and that's when I got in touch with my GP and they referred me for an MRI"*
1.24	Comparing previous experiences of ACL injury/surgery with current experience	Descriptions/reflections of previous ACL injury experiences and ACLR	9 references across 1 interview	*"This time I'm a bit surprised how long it takes me to build myself up, but now, it makes sense, because the last time, I had that pre-surgery physio and that could be the reason, exactly that's the reason why. Last time, it didn't take as long as I'm doing it now, even though it is a very similar surgery that has been done"*

Theme 2: Navigating the treatment pathway

2.01	Making decisions	Descriptions of the patients decision making processes and thoughts about decision making	54 references across 16 interviews	"I want absolving of any responsibility. I just need to, because I've never really had to have any surgery before, either. So it's, you know, I don't want it if I don't have to have it, but if I do need to have it, then I will have it. Do you know what I mean, so I want somebody to tell me whether I need to have it."

2.02	Factors involved affecting the participant/their choices	Descriptions of factors considered by participants that affected them/their choices	52 references across 14 interviews	"Probably a slight influence would be family, because my father went through the exact same injury"
2.03	Suggestions or references for pathway improvements	Suggestions from participants on improvements that could be made to the ACLR pathway	84 references across 14 interviews	"[I would have liked] having a bit of physiotherapy input before the surgery as well, just to help prepare myself for what would happen afterwards, but also just to improve my level of function beforehand as well."
2.04	Experiences/thoughts of the pathway	Participants descriptions of their experiences and thoughts of the ACLR pathway	33 references across 12 interviews	"I was frustrated that when I went to A&E to get it checked they just, I don't want to say palmed me off as such but they just said, "Oh it's bruised. It will heal within a few weeks." That kind of annoyed me when later on I found out that I've got a stability issue three months down the line and then the GP had to get involved to send me for an MRI."
2.05	Elements valued by participants	Participants descriptions of elements/factors they valued across their care	53 references across 11 interviews	"the surgeon was fantastic. It was quite a younger gentleman, I think he was like mid-thirties. He was quite a sporty person himself so he was dead relatable, he was very friendly. And he was basically saying look I can't sort of say to yourself to go for something or not, but what I am saying to you is if you did want to go and play sports again that this would be your option. However, please note that there is a risk that it will not work and that you could consider not still playing sports like you do now. So he was honest but like I said he was very friendly and understanding"

2.06	Interdisciplinary communication	Descriptions of participants perceptions/experiences of communication between healthcare professionals e.g. orthopaedics and physiotherapy	17 references across 7 interviews	"I will call up my GP and be like hey what's going on with this? And they will be like contact the orthopaedics and they will be like contact your GP and, you know, you are just going round in circles."
2.07	Communication between the participant and healthcare professionals	Descriptions of participants experiences of communicating with healthcare professionals	54 references across 15 interviews	"No they give you the pamphlet but they basically they don't go through it with you they just go here's some documents. You get handed it at the end of the thing and then you walk out. Do you know what I mean they don't run through it with you so it's just this is that, it's all just very here's some documents you might find useful, see you in a bit basically"
2.08	Communication during inpatient stay	Descriptions of participants inpatient experience	3 references across 3 interviews	"I think while you're on the ward as an inpatient it is in and out so you're being seen by the nurse, they pop out, the consultant out, physio out. So I don't think from a patient point of view it doesn't seem very connected in terms of how everyone is collaborating for yourself on the ward"
2.09	Participants' role in communication	Descriptions of the participants role in communication with healthcare professionals	14 references across 9 interviews	"I couldn't remember who I had to ring, so, I just left it to them to get in touch with me."

2.10	Points of contact	Participants descriptions of people they contacted/knew where available to contact for support	8 references across 5 interviews	"Like who do you go to? Do you go the surgeon, do I speak to the receptionist? Do you go to the physio who you have not seen in the last year? Do you go to the GP who you are not going to get seen because GPs are difficult to get hold of at the best of times, never mind if it's not an urgent case where you aren't going to drop dead the next day? So it's like where do you go? You are not being given any information. Do you go back to A&E? A&E is absolutely rammed at the minute with patients left, right and centre"
2.11	Advice/actions sought from GP	Descriptions of advice sought from or actions of the participants GP	25 references across 10 interviews	"I don't like to go to the hospital because I know there is a lot of people that need it more than myself, so I don't like to feel I am wasting any time. So I booked the earliest appointment at the doctors on Monday morning and then they sent me to the hospital"
2.12	Experience of GP interactions	Participants experiences of interactions with the GP	10 references across 6 interviews	"my previous GP unfortunately ... had never passed me on or they had not passed on the right information ... then I moved house, got a new doctors, a new GP earlier this year, which I then said right what's going on? I spoke to my new GP and they basically said I have no idea why you have not been contacted yet regarding this ... my new GP basically got the wheels in motion"
2.13	ED actions	Descriptions of actions taken by the emergency department after participants visited with their knee injury	21 references across 13 interviews	"I went to A&E, I think it was that evening. I think I went straight there pretty much and just explained what had happened and how the injury had taken part. They literally thought it was a meniscus tear because of where the pain was and they said come back in six weeks' time if you still have any pain, any difficulty with walking etcetera"

2.14	Experiences of orthopaedic interactions	Participants descriptions of interacting with orthopaedics	43 references across 14 interviews	"I first saw a consultant and he kind of didn't listen to my problems as much, so I decided to get a second opinion about it and then I felt I was listened to a bit more"
2.15	Thoughts about seeking private treatment/paying for healthcare	Participants thoughts about seeking private healthcare and/or paying for investigations and treatment	18 references across 6 interviews	"We did look at having it done privately but then that was like eight thousand pound. And then I have got a wedding to save for and it's like I don't think the wife is going to be too happy if I take eight grand out of the wedding budget"
2.16	Thoughts about the NHS	Participants thoughts about and reflections of the National Health Service	14 references across 8 interviews	"it's just a case of getting through with the NHS, getting through to the right person that you need to"
2.17	Thoughts about virtual interactions	Participants thoughts about virtual interactions/consultations/appointments	4 references across 2 interviews	"I'd have thought you would need to see somebody in person to see what was up with them"

2.18	Impact of COVID	Participants reflections of the impact of COVID on their ACL injury assessment, management and treatment/hospital care and procedures	26 references across 11 interviews	"because of Covid all the operations and everything got put on hold for like two years. So I had to wait two years from when I found out it was an ACL rupture to trying to get surgery basically"

Theme 3: Sense making in the preoperative period

3.01	Descriptions of preoperative physiotherapy	Participants descriptions of preoperative physiotherapy treatment	30 references across 13 interviews	"gave me an exercise and told me to practice them at home, they showed me how to do them there and just said practice these when you go home"
3.02	Experience of rehabilitation/physio therapy first	Participants accounts of their experiences of undergoing rehabilitation, as recommended by their clinician, for the management of their ACL injury prior to being listed for surgery	3 references across 1 interview	"I waited for six months then after six months, I went to the physio rehabilitation centre, I did all my physios, and then they put me back to an orthopaedic specialist"

3.03	Experiences of preoperative physiotherapy	Participants descriptions of their experiences of undergoing preoperative physiotherapy	37 references across 11 interviews	"So I have been home with exercises and I never really got a follow up or anything like that. And still to this day I didn't hear anything from them until I started chasing it up again at the start of 2020"
3.04	Participants thoughts about engaging in physical activity pre-surgery	Participants thoughts about engaging physical activity with their ACL rupture, prior to ACLR	11 references across 7 interviews	"I thought I can't exercise anymore because anything I do will cause me pain or swollenness again, I will do more damage to it"
3.05	Participants thoughts about preoperative physiotherapy/prehabilitation	Participants thoughts about preoperative physiotherapy/prehabilitation +/- how it may have helped	77 references across 15 interviews	"For me, personally, doing the prehab has helped me continue with daily activities, so if I didn't do it, I probably would be a lot worse and I'm now in a better position to have surgery because my tissue's healing well and stuff."
3.06	Participants thoughts about what prehabilitation should contain	Participants thoughts as to what they think prehabilitation should include to support surgical intervention	18 references across 8 interviews	"probably early stage it's just focus on getting the swelling down, working on more stretching, just to gain that range of movement back, being patient with it, because you can't rush rehab, and then gradually just strengthening"

3.07	Justification for stopping preoperative physiotherapy advice/exercises	Descriptions of particpants reasoning/justification for discontinuing or going against advice and/or exercises given during the preoperative period	5 references across 4 interviews	"in the end I will be honest I left them [the exercises] because again I felt like I was getting no benefit and it was a bit, it was a bit tedious to be honest"
3.08	Other treatment/adjuncts	Descriptions of treatments and adjuncts other than exercise used by the participants during the preoperative period	9 references across 5 interviews	"I went and got a knee brace"
3.09	Participants expectations of the wait for surgery	Descriptions of the participants expectations of the wait for ACLR	10 references across 9 interviews	"obviously with Covid he did say to me that the wait was going to be quite a long time because of the situation, so I was prepared for that at the time"
3.10	Participant experiences of waiting for surgery	Descriptions of the participants experiences whilst awaiting ACLR	42 references across 14 interviews	"Maybe it's not that bad, maybe I'll wait, maybe it's not that long, maybe they'll call me how long will it be? You just sort of blindly expect the best"
3.11	Descriptions of thoughts/feelings pre surgery	Descriptions of the participants thoughts and feelings leading up to ACLR	36 references across 9 interviews	"I feel like I've just been on a pendulum - I want it done, no I don't want it done, I want it done, no I don't want it done, I want it done - and I'm still a little bit like that, and a bit apprehensive"

3.12	Actions of the participant whilst awaiting surgery	Descriptions of actions of the participants whilst awaiting ACLR	17 references across 8 interviews	"over time I was like, look I've had enough. I'm going for my walks in the Peak District and at that point I kind of assessed it myself. I was like, oh I can walk okay but I just have to be a bit careful not to do sudden movements. I just have to be mindful that my leg is not 100%."
3.13	Function during the preoperative period	Descriptions of the participants functional ability during the preoperative period	23 references across 10 interviews	"I can't do that—I can go swimming and that still but it hurts afterwards. And if I'm walking down the road, I used to do quite a bit of walking, if I took the dog for a walk, I wouldn't be able to walk the next day."
3.14	Description of current state - preop	Participants description of their current state during the preoperative period	26 references across 8 interviews	"'ve been tempted to try and play some sport, but it's not been great with it, so I've just left it and focused on more general rehab physical activity"
3.15	Thoughts about surgery	Participants thoughts about surgery	49 references across 18 interviews	"I don't really want to have surgery, but I don't want to be living my life saying, "No." To the kids."
3.16	Participants questions about surgery	Participants questions about surgery	9 references across 6 interviews	"it made me a bit nervous, to be fair, because I don't know what to expect, and I don't know what's going to happen, I'm a bit nervous. I've never had an operation before, never, so, I don't even know what to expect"
3.17	Thoughts during preoperative period	Participants thoughts during the preoperative period (not about surgery)	23 references across 10 interviews	"What's going on and what's happening? ... It's been ages since I've seen anybody. Since I went to the hospital, it must be over a year and a half"

3.18	Things missing from preoperative period	Descriptions of things participants felt were missing from the preoperative period	24 references across 13 interviews	"Well to explain what the surgery entailed and what your recovery's going to look like … I don't know, just a bit of reassurance really, you know. "

Theme 4: Uncertainty, expectations and reality of the post-surgical period

4.01	Experiences of surgery	Descriptions of participants personal experience of surgery	5 references across 3 interviews	"So I had a spinal block and I was actually watching it. It looked like fluffy clouds to me but the fluffy clouds was my ligament basically"
4.02	Experiences as an inpatient	Descriptions of participants experiences during their inpatient stay	14 references across 5 interviews	"I was here at 7 o'clock because I had to be, I couldn't eat, couldn't drink, and I didn't go into surgery until half 4 ... I did stay overnight as well, which I wasn't meant to, I was meant to come and wake up and go. I had to stay overnight, which wasn't ideal, and then I didn't get let out until I think about 5 o'clock the next day. So, in terms of how I was set up for how it would affect me moving forward, it was almost a bit of—You can't drive, use your crutches, we'll be in contact about physio and that was it and I thought, okay, see you later."
4.03	Experiences in the early postoperative period	Descriptions of participants experiences in the first few weeks post-surgery	23 references across 5 interviews	"I found it really, really difficult and frustrating just being in bed for that first week or so, and particularly the pain, I just wasn't expecting that that was quite difficult. Definitely, at certain points in those first couple of weeks, I questioned whether I should have had the surgery or not."

4.04	Experiences postoperatively	Descriptions of participants experiences following surgery	24 references across 5 interviews	"I think initially, it didn't feel too hard but then I think you get to a certain point where it does feel quite intense and trying to fit that around university and work and things like that is quite difficult as well"
4.05	Participants thoughts postoperatively	Descriptions of participants thoughts following surgery	6 references across 3 interviews	"I've got different feelings, a lot of feelings in my leg, so, that makes you think a lot like, why are these muscles not building back; why is it taking so long, is everything alright? So, you start to overthink everything now, I'm at that point now. Did they do a good surgery, do I need another, because I know there are so many unsuccessful ones and you do have to—Is that right? So, yes, overthinking definitely by this point."
4.06	Thoughts about postoperative progress	Descriptions of participants thoughts about their progression following surgery	11 references across 6 interviews	"As I said, it's frustrating now because we're talking—June, July, August, September, October, so, it is three months and I still can't bend fully without pain"
4.07	Thoughts about postoperative rehab	Descriptions of participants thoughts about postoperative rehabilitation	35 references across 12 interviews	"I feel like the stuff I have been given post-surgery has been more detailed and more explanation as to why we are doing this."
4.08	Expectations postoperation	Descriptions of participants expectations of the postoperative period	14 references across 10 interviews	"once I've had the surgery and the recovery process is complete, don't get me wrong there will still be that lingering doubt but it will be a lot less and then over time it will just be eliminated because you will establish confidence in your knee"

4.09	Expectations of RTW post surgery	Descriptions of participants expectations about returning to work following surgery	9 references across 8 interviews	"I expect to go back to work probably six weeks"
4.10	Expectations and thoughts about return to preinjury sport/physical activity	Accounts of participants expectations and thoughts about returning to their preinjury levels of sport or physical activity	49 references across 16 interviews	"I am between a rock and a hard place. I am thirty-five years old and I don't know, should I play rugby being a police officer? I would like to, to be honest, I never want to stop. But I also need to take into consideration the probability of injury"
4.11	Expectations vs reality	Participants descriptions and reflections of the reality of their situation versus their prior expectations	8 references across 3 interviews	"You don't necessarily think about the setbacks that you might have and how difficult you might find that. You just have this idea that you'll have the surgery, you might have a bit of pain for a few days and then gradually, you'll just keep making progress. Whereas in reality, you might have setbacks or your progress might level off for a while and you might not see much improvement and dealing with that is quite difficult"
4.12	Experiences of RTW postoperatively	Descriptions of participants experiences of returning to work following surgery	3 references across 3 interviews	"I was working the day after my surgery. Because I was working from home and I was like well I am just going to be sat here anyway."

4.13	Experience of return to impact	Descriptions of participants experiences of returning to impact activities following surgery	3 references across 1 interviews	"It felt very weird the first few times I did it, I remember when I started to jog, it was like I had completely forgotten how to do it and I was overthinking everything. And it's quite scary as well, the first time you start hopping and jumping and things like that because you've always got that worry in the back of your mind that your knee is going to give way or you're going to re-injure yourself."
4.14	Thoughts about rehab progression and return to preinjury sport/level	Descriptions of participants thoughts about their rehabilitation progression and how this related to returning to their preinjury levels of sport or physical activity	14 references across 6 interviews	"Not yet, I feel like I'm just about ready to although since I've started work I probably have not been doing as much physio as I'd like to be doing normally. So, I think I'm probably at the stage where I could get back into it, it's more just fitting it around my work commitments and everything."
4.15	RTS following previous ACLR (contralateral leg)	Descriptions of returning to sport following previous ACLR on the contralateral side	2 references across 1 interviews	"I was doing it but physically, it wasn't too bad but mentally to get over it, was a lot harder so I didn't push myself too much. I was starting it but I didn't go to that competitiveness zone, I would say, where I was before the surgery. I would say it took me around a year, it did take me a year."

Theme 5: Balancing resources, advice & opinions

5.01	Advice and treatment outside the UK	Descriptions of advice given and treatment received outside of a UK healthcare setting	7 references across 2 interviews	"The first thing, in India, they told me; they said the same advice in terms of it's not a life-saving problem, so, it's not something that needs to be operated on, but however, what they told me was, at your age, we recommend you to get operated, but it is left to your choice."
5.02	Advice given re engaging in physical activity pre surgery	Descriptions of advice given about engaging in physical activity prior to surgery	18 references across 11 interviews	"Doctor Z said I shouldn't run on the road or and just run on the treadmill when I am fit enough"
5.03	Advice given regarding surgery	Descriptions of advice given regarding surgery	47 references across 16 interviews	"There was a lot of mixed messages, and then the knee fellow had said, 'Oh you're not doing a high-level sport, so you probably won't need to.' And then I saw Mr A, and you know when you're going like this to that to this to that in your head as to what's going to happen, I thought I'd just be guided by Mr A and he sort of said, 'If I was you, then I'd be having that repaired'"
5.04	Advice given regarding postoperative rehabilitation	Descriptions of advice given regarding postoperative rehabilitation	8 references across 6 interviews	"They said to me, you have to do all the rehabilitation or the operation won't work, they have said that but they ain't actually said what it is or nothing ... Yes, they said that is the most important bit, the rehabilitation really, that's what I got off him because they can do the surgery and if I do that then it's a waste of time doing the surgery, so, I think that is the more important bit, so, he said

5.05	Advice/information given re RTS	Descriptions of advice given regarding returning to sport	7 references across 6 interviews	"So the aim is to be fighting fit for April next year, so that's about nine months on from the surgery and he [the physio] knows that. And, you know, we have sort of said nine months is a push to get you there for nine months but it has been done"
5.06	Consistency of advice	Descriptions and accounts of the consistency of advice participants received	29 references across 14 interviews	"I think the only thing probably was that I had spoken to Doctor X about obviously netball and said, you know, can I still play netball and he said absolutely not. And then I think when I went to see the physio she said I would still probably be able to play as long as I wasn't twisting and turning as much. And then I kind of said to my mum like what do you think and she was like absolutely not, I don't think that's the best thing to do. So I haven't played at all.
5.07	Resources used (preoperatively)	Descriptions and accounts resources used by participants prior to surgery	27 references across 15 interviews	"I didn't really know what your ACL was to be honest with you, so obviously they showed it to me on the scan. And then I did go home and obviously just had a little look at it and I watched some videos of like people after they had had surgery"
5.08	Thoughts on information/resources available	Participants thoughts about information and resources available	36 references across 11 interviews	"I think online, it does say what ACL means, there is no doubt about it, but what I was expecting, as the indirect resource, the information is everywhere, I don't know which one I should believe and which one I shouldn't believe."

5.09	Consequences of lack of information	Descriptions of the consequences of the lack of information given regarding their condition and treatment	32 references across 9 interviews	"I don't know what I am expecting next because I have kind of been in the dark a bit with it. And I don't know whether I am going to get a call next to just say hey your surgery is on this date or whether I am going to have a consultation with a surgical consultant regarding what's going to happen. Still to this day I don't know whether the plan is kind of keyhole or something more extreme than that. I don't know ... I work as an outdoor pursuits instructor, so the last thing I want if I was to get a call tomorrow saying hey we have got you in for surgery in two weeks' time, it's going to be a six month recovery. I can't do that. After two years of waiting for potentially something to happen with my knee, I would have to turn that down because, you know, I have got a child and I have got a mortgage and I can't just turn down work. I can't just stop working like that"
5.10	Influence and advice of/given by friends and family	Descriptions of the influence of opinions from friends and family in addition to advice given by them	32 references across 14 interviews	"before the surgery my Mum was kind of simply saying don't get it done because it's obviously a surgery it's an invasive kind of procedure. You don't know what the outcome is going to be afterwards. So if it, if I didn't have a physio background, if it was just what other people were telling me and my family I probably would have thought, second thoughts about it."
5.11	Influence of the media	Descriptions of the influence of the media	3 references across 2 interviews	"I am a Liverpool fan. I have seen Van Dyke it took him a year to get back to playing football and he's got the best physio's and best coaches around him in the world, so I am not expecting to be kicking a football any time soon"

5.12	Information / Knowledge = power	Accounts of information and knowledge equating to power	28 references across 11 interviews	"And unfortunately you and I both know, NHS don't give enough information on rehab on the injuries. So yes if I was in a situation where I didn't know what I was doing I would have liked more information on how to do it and with my health as well, access to gyms and stuff like that ... I think knowledge is power"
5.13	Concerns	Descriptions of participants concerns	3 references across 2 interviews	"Yes, you worry, obviously, outcomes was mentioned as well, that I should think about—I was surprised about how many things were mentioned, in the future, what I should expect because of the surgery, because of this injury that I had, that knee replacement itself, I have to expect; I should think of within 30 years or whatever."

APPENDIX C: FIGURE 3.4 SUPPORTING QUOTES

Concerns and questions raised during the preoperative period	Supporting Quote(s)
What surgery am I having?	"I don't know what surgery I am expecting" [P7] "All I knew is that I was going to get two procedures" [P17]
How long until I can drive after surgery?	"Do I know how long I can't drive for? … I know absolutely nothing" [P3]
How long will I need a brace/crutches for?	"Do I know how long I'll be in a leg brace? You know how long on crutches for? I know absolutely nothing" [P3]
How long will the recovery period be?	"Well to explain what the surgery entailed and what your recovery's going to look like" [P4] "it depends what surgery I am expecting depends on what Google is telling me and I don't know what surgery I am expecting. I don't know if it's, as I said Google is telling me how long recovery is for like a small keyhole surgery and what the length of the surgery will be and this and that. But then it's telling me something completely different for a different style of knee surgery to repair it a different way and I don't know which one I am having." [P7] "Because the questions that I was asking the nurse, she could sort of give me an idea but couldn't confirm it, so like things like how long the recovery period would take and things like that." [P8] "I don't even know how long it will take me to heal up, nobody has said ought" [P13]
I shouldn't exercise, it's risky	"I don't like it, well it's more that confidence thing I probably could exercise but it's just the mental blocks like what happens if I fall off, what happens if I do further damage to it and that's a risk I don't want to take" [P5] "I didn't really have the confidence to go and run for example. So I have not really done any running for at least two years. A bit of a confidence thing because my knee has given way pre-surgery a couple of times and it's not a nice feeling, but I also know that it's not stable at all so I haven't even risked it really." [P8]

	“there is not enough information for people and the probability of reoccurrence injury is much higher than I would like it to be because people will rush back to exercise, especially football, rugby or any sport where they have torn their ACL… Avoid things that are going to damage it even more” [P9]
Who can I contact for support?	“Like who do you go to? Do you go the surgeon, do I speak to the receptionist? Do you go to the physio who you have not seen in the last year? Do you go to the GP who you are not going to get seen because GPs are difficult to get hold of at the best of times, never mind if it’s not an urgent case where you aren’t going to drop dead the next day? So it’s like where do you go? You are not being given any information. Do you go back to A&E? A&E is absolutely rammed at the minute with patients left, right and centre” [P8] “knowing that someone could be on the end of a phone would have been great.” [P16]
What additional damage could I cause whilst waiting?	“he says, ‘Oh, you’re at a much higher risk of doing further damage if it’s not repaired.’ And then they leave you for all that big, long period of time to do that further damage, that then he infers might make repair definitely more difficult, or impossible. Do you know what I mean, so I think that you feel a bit adrift for that.” [P4] “I probably could exercise but it's just the mental blocks like what happens if I fall off, what happens if I do further damage to it and that's a risk I don’t want to take” [P5] “I have kept myself active. I have kept myself moving, I have kept myself really healthy despite my injury but how much extra damage has that done? Has it done extra damage? I don’t know.” [P7]
What about re-rupture?	“The only thing I’m worried about is well when I was reading up on the surgery side of things if it snaps again because if you have surgery a second time it’s going to give it less chance to heal or fail. That is the only thing I am worried about; I’ve just got to make sure I take good care of it in the recovery process.” [P5]
What can/can’t I do?	“obviously throughout the year and a half I’ve been waiting I know what my knee is capable of it just that time period, but I suppose a physio could of helped with that don’t do these movements, these movements, these movements, only do these certain movements” [P5]

	“I had no direction for prehab … can I do this, can I do that, whereas I may have just done it ... I want to push myself as much as possible but you need to tell me where that limit is because otherwise I may get nowhere near it.” [P11] “I think it would have been good to have a bit of physiotherapy support, and also, to make sure I was doing the right kind of things to prepare myself for the surgery because I didn’t really have any plan before the surgery.” [P15]

APPENDIX D: CONSENSUS MEETING PRE-READING, HEALTHCARE PROFESSIONALS

POP-ACLR Consensus Meeting Pre-Reading

Information, Decision Making and Treatment

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Research aims

The aim of this research is to develop an evidenced-based intervention to support adults (aged ≥18) after an Anterior Cruciate Ligament (ACL) injury and before surgery. The focus of the intervention is around information, decision making and treatment.

Meeting aims

The consensus meeting(s) aim is to develop the intervention through a preliminary round of voting followed by group discussion(s) to agree the final components.

Purpose of this document

This document outlines some key research to help us consider what the intervention might look like. It should take 15 minutes to read.

Quick Summary

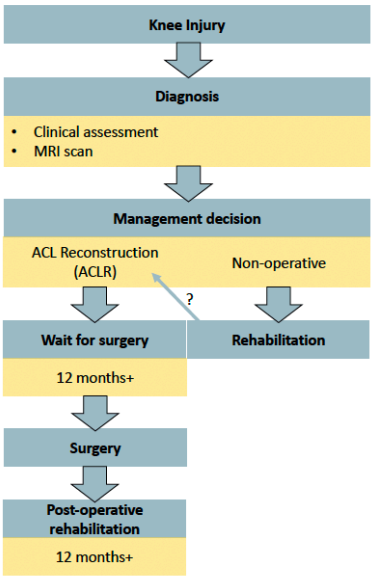
Optimal treatment before ACL surgery is unknown, current practice in the NHS varies.

The preoperative phase of treatment has been highlighted by patients as a period of uncertainty. Patient and public stakeholder events concluded that further research was warranted to determine optimal treatment for this period to improve outcomes and consistency of care.

Patients report the preoperative period to be challenging for a number of reasons. They experience difficulty with:

- Deciding upon injury management
- Navigating the breadth of ACL resources and deciding how generic information applies to them
- Understanding how best to prepare for surgery
- Interacting with and understanding what to expect of the treatment pathway for example, which healthcare professional(s) to contact, who is involved in their care, what realistic expectations of treatment are, how to best prepare for surgery and when they can expect to return to normal activities

Overview of the Anterior Cruciate Ligament (ACL) Treatment Pathway



The above flow chart outlines a typical ACL injury pathway in the UK. Whilst this may vary between hospitals, this overview helps us to consider where the intervention may fit in.

ACL injury management

Currently, there is no gold-standard way to make a decision about the treatment an individual should receive following an ACL rupture. Typically, surgery is recommended for those who wish to return to physical activity that involves cutting, pivoting and changing direction. In the UK, a large proportion of patients go on to have surgery (Anterior Cruciate Ligament Reconstruction, ACLR).

Whilst it is outside the scope of this consensus group to discuss and compare the treatment methods of surgery and non-operative management, it is important to consider this decision. Recent research (qualitative interviews; manuscript under development) has found that making decisions about surgery are difficult for patients, who perhaps need more support than previously thought. It was also found that individuals awaiting surgery were still uncertain whether this was the right treatment for them.

NHS England and the National Institute for Health and Care Excellence (NICE) recognise that shared decision making, between patients and healthcare professionals about treatment is important. For some conditions, such as knee and shoulder pain, decision support tools have been developed to help patients think through decisions about their condition and its management. You can view these here:

1) https://www.versusarthritis.org/about-arthritis/healthcare-professionals/musculoskeletal-decision-support-tools/
2) https://www.england.nhs.uk/personalisedcare/shared-decision-making/decision-support-tools/

What is the current evidence for management?

The most recent, and only, randomised controlled trial (RCT) comparing surgery with rehabilitation in the UK was published in 2022.[1] The study included 315 participants and concluded that (at 18-months) those who received surgery had substantially better outcomes than those in the non-surgical group for:

- Self-reported knee outcomes (KOOS4 – a combination of questions about knee pain, symptoms, sport/recreational activity and knee-related quality of life)
- Quality-of-life (Anterior Cruciate Ligament Quality of Life Questionnaire)
- Activity level (Tegner score)

Of those who received rehabilitation, 41% went on to have surgery. Surgical reconstruction was also reported to be the most cost-effective treatment.

Two RCTs in other countries (Netherlands and Sweden) have also compared surgery against rehabilitation.[2,3] The Swedish study (2010) concluded that surgery was unnecessary for some and that rehabilitation should be trialled first and the Netherlands study (2021) suggested that early reconstruction may offer better results.

What do patients say?

The POP-ACLR patient and public involvement group helped to design the study proposal, highlighting the preoperative phase of ACLR treatment as a period of uncertainty. They felt further research was warranted to explore treatment options for this period and to improve consistency in care.

Phase 1 of the POP-ACLR study

Phase 1 of the POP-ACLR study interviewed ACL patients at three different time-points on the ACLR pathway in aim to understand:

(1) Patient experiences of treatment
(2) Views and involvement in prehabilitation
(3) Sources and consistency of healthcare advice.

The results from this study are currently being written up, please do not share these outside of this group.

Overview

- 18 patients interviewed between August and November 2022
- Age
  - 18 to 45 (median age 29 years)
- Sex
  - 3 female
  - 15 male
- Ethnic origin (as described by the participant)
  - 14 White
  - 2 Indian
  - 1 British Asian
  - 1 Pakistani
- Time point on the pathway
  - 10 awaiting ACLR, 6 3-month post-surgery 2 1-year post-surgery
- Prehabilitation
  - 12 participants stated to have engaged in some sort of prehabilitation prior to surgery
- Activity level
  - 2 participants had returned to their preinjury level of physical activity, both were at the preoperative time-point.

Results

Interview results were grouped into 5 themes. The table below shows these themes and a summary of what these represent. An example quote from interview transcripts has also been included for each theme.

Theme	Summary of Theme Topics	Example Quote
1) Injury experience, impact and support	• Varied experience of diagnosis *e.g. multiple routes to diagnosis (GP, ED, Physio), missed-diagnosis* • Physically and mentally challenging injury • Difficulty with injury acceptance • Burdensome and life-changing injury • Existing support networks and support from those with injury experience is important	*"It's been **absolutely horrific** … there are days where I just lie in bed and I am just absolutely **heartbroken** because I can't do the things that I used to love doing?"* *Pre-operative patient*
2) Navigating the treatment pathway	• Pathway described as 'passive' • Uncertainty around the decision to have surgery • Limited support with decision making for surgery • Lack of personalised care • Communication with healthcare professionals is challenging	*When describing treatment, one patient explained: "you're just **going through the motions**"* *Pre-operative patient*
3) Sense making in the preoperative period	• Many unanswered questions and concerns • Participants described lacking in confidence in a number of areas • Prehabilitation (with physiotherapy) valued, participants suggested that it: ○ Offers advantage to recovery, postoperative rehabilitation and supports a faster return to physical activity ○ Supports psychological wellbeing ○ Provides increased knowledge of the injury and its management ○ Needs to be specific	*"For me, personally, doing the prehab has helped me **continue with daily activities**, so if I didn't do it, I probably would be a lot worse and I'm now in a **better position to have surgery** because my tissue's healing well"* *Pre-operative patient*
4) Uncertainty, expectations and reality of the post-surgical period	• Inpatient environment is overwhelming with delays experienced and interactions limited • The first few weeks following surgery are a particularly challenging time • Mental wellbeing is a reflection of physical progress *e.g. as physical function improves so does mental wellbeing* • Range of expectations regarding return to work and physical activity ○ Limited expectation management	*"it's about **two weeks you don't see anybody about it** … you're expected to crack on with the exercises, in a lot of pain aggravation you can imagine all the thoughts going through your mind should I have the surgery all of these things, and all you're left is really a **booklet** to read so **doesn't really take on our thoughts and feelings** about what is happening there and then."* *3-month postoperative patient*

5) Balancing resources, advice and opinions	• Resources are difficult to navigate and thought to be unreliable • Standardised information is not well received • Absent information on surgery, how to prepare for it and what to expect after it • Information regarding pathway timelines was a common frustration among participants who described to feel "in the dark" • Media influential on treatment expectations • Conflicting advice - physiotherapists, surgeons, friends, family members, colleagues • Cultural influences on treatment expectations and outcomes	*"the information is everywhere, **I don't know which one I should believe** and which one I shouldn't believe"* *Pre-operative patient*

These results represent the challenges patients face when diagnosed with an ACL injury and the difficulties of navigating the NHS treatment pathway.

Summary

Key findings from this study include:

- **Lack of consistent and reliable information** regarding the injury and its treatment

- **Lack of support with decision making** regarding treatment, this resulted in patients feeling helpless. Limited demonstration of shared decision making:
  - Some explained to have not been involved in the decision to have surgery
  - Some did not want to feel responsible for the decision regarding surgery due to fear of making a 'wrong' decision
  - Some felt they were presented with no choice but to have surgery as if they didn't, this would limit lifelong engagement in physical activity
  - Patients wanted a recommendation from their healthcare professional which was not always offered

- **Guidance on how to manage the condition whilst awaiting surgery was limited.** Participants where unclear which healthcare professional to contact for support, what to expect in the preoperative period and how they could best prepare for surgery

- **Prehabilitation was valued** highly amongst participants, they felt it offered an advantage to:
  - Recovery and postoperative rehabilitation
  - Returning to physical activity/sport faster
  - Psychological/mental wellbeing and increased knowledge of the injury and its management
  - Support decision making for surgery (e.g. exhaust prehabilitation first before deciding to proceed with surgery)

- **Specificity of prehabilitation was important**, standard and generalised exercise prescription was not well received. Where prehabilitation was 'general' this was deemed low value and resulted in reduced engagement from the participant

- **Standardised information** that was not personalised/tailored to the participant was **not well received**

- **Healthcare advice was inconsistent** and received from a range of individuals including healthcare professionals (such as surgeons, physiotherapists, nurses and general practitioners), friends, family members and colleagues

- **Communication with and between healthcare professionals was disjointed**. Participants explained to have little time during consultations at various points on the pathway (e.g. initial diagnosis, appointments with orthopaedics regarding surgery, inpatient ward) which left them feeling rushed and overwhelmed. Patients were also frustrated when healthcare professionals did not liaise with each other regarding their care

Why a preoperative intervention?

The wait for an ACLR in the UK is over 12-months. Optimum treatment prior to surgery is unknown.[4,5] Previous evidence has suggested that treatment should address both physical and mental health but little further is described as to specific treatment approaches.

A 2020 systematic review explored the effectiveness of preoperative rehabilitation programmes (commonly referred to as 'prehabilitation' or 'prehab') on post-operative outcomes.[5] The evidence was limited, with only three RCTs relevant for inclusion. The intervention in all three studies was a rehabilitation programme, however these varied in content, frequency and length. The outcomes used to evaluate the effects of the prehab programme were muscle strength, function, pain and return to sport. Results concluded that prehabilitation offers some benefits to quadriceps strength and single leg hop distance three months after ACLR.

As there is little guidance in the literature as to what prehabilitation should entail, a 2021 survey explored physiotherapy practice for ACL patients waiting for surgery.[4] Although advice, education and exercise were cited as consistent components of treatment, the types of exercises given, how often exercises should be completed and the length of treatment varied. A range of other interventions were also reported (e.g. manual therapy, electrotherapy, bracing), confirming that prehabilitation varies. A 2022 review confirmed that there this is little consensus on what should be included in ACL rehabilitation (both prior to and after surgery) leading to a variety of protocols used in practice.[6]

It has previously been reported that some preoperative factors can predict post-operative outcomes. A 2023 systematic review (results pending publication, please do not share) aimed to identify modifiable factors from the preoperative period that may influence return to physical activity outcomes after ACLR. The review found four factors to be associated with a return to physical activity after ACLR:

1) Quadriceps strength (higher strength)
2) Psychovitality – a questionnaire designed to assess patients' expectations related to treatment outcome and motivation to resume pre-injury activity levels (score ≥15)
3) Positive estimation of ability to return to preinjury level
4) Quadriceps tendon graft (Bone-Patella Tendon-Bone)

These results can help us to consider what factors may be beneficial to target in ACL patients awaiting surgery.

What is the evidence for preoperative treatment in other orthopaedic surgeries?

NICE guidelines recommend that prehabilitation is offered to patients awaiting total hip and knee replacement surgery.[7] NICE suggest that this should include:

- Exercises
- Lifestyle advice including weight management, diet and smoking cessation
- Support to maximise functional independence and quality of life

A 2023 systematic review and meta-analysis explored the effectiveness of prehabilitation in all orthopaedic surgeries.[8] There were 48 studies included covering total knee replacement, total hip replacement, lumbar spine, ACL and hip impingement surgery (only one study included ACL patients and this study was included in the 2020 review mentioned above). 81% of the prehabilitation programmes used exercise interventions and only 10% had multiple components to the intervention. The table below shows the results of the review and the benefits of prehabilitation in the different patient populations.

		Total Knee Replacement	Total Hip Replacement	Lumbar Spine Surgery	Hip impingement surgery	ACL
Preoperative	Reduced pain	✓	✓	✓		
	Improved function	✓	✓	✓		
	Improved health-related quality of life		✓	✓		
	Improved muscle strength	✓ (inner thigh muscles – adductors)	✓ (front thigh muscles – knee flexors)			
Postoperative	Reduced pain			✓		
	Improved function	✓ 6-weeks & 3-months	✓ 3-months and 12-months	✓ 6-months		
	Improved health-related quality of life	✓ 6-weeks & 3-months				
	Improved muscle strength	✓ (front and back thigh muscles - knee flexors and extensors)				

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POP-ACLR

POP-ACLR Pre-Meeting Voting

Below is a list of components for consideration in the preoperative treatment package/intervention. Please select one answer to indicate how important you think each component is for inclusion.

Component 1

Advice and Education.

1. Preoperative advice and education should include:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Knee anatomy and injury	○	○	○	○	○
Surgical procedure	○	○	○	○	○
Evidence-based information regarding graft choice	○	○	○	○	○
Risks of surgery	○	○	○	○	○
ACL injury management - surgery versus rehabilitation	○	○	○	○	○
Pathway milestones, expected appointments and timeframes e.g. physiotherapy, surgery, orthopaedic follow-up	○	○	○	○	○
Evidence based information on injury outcomes e.g. re-rupture, return to work, return to physical activity	○	○	○	○	○
Expected timeline specific to the patient e.g. considering prognostic factors that may delay a return to physical activity/work	○	○	○	○	○
Evidence-based information regarding outcomes of surgical and non-surgical treatment	○	○	○	○	○
Prehabilitations e.g. purpose, importance, timeframe	○	○	○	○	○
Discussing the postoperative period	○	○	○	○	○
What to expect during the inpatient stay	○	○	○	○	○
Common issues pre- and post-surgery	○	○	○	○	○
Pain management	○	○	○	○	○
Managing work and home preparations e.g. expected absence from work, expectations for return to work, childcare, driving	○	○	○	○	○
Common psychological difficulties associated with ACL injury	○	○	○	○	○
Signposting towards relevant services for mental health support	○	○	○	○	○
Weight management and nutrition	○	○	○	○	○
Smoking cessation	○	○	○	○	○
Goal setting	○	○	○	○	○

2. Free text for any further comments you wish to make with regards to advice and education

Enter your answer

Component 2

Exercise Guidance

3. Exercise guidance in the preoperative period should include:

	Very important	Important	Neither important nor not important	Not important	Not at all important
At least 1 session with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	◯	◯	◯	◯	◯
2-6 sessions with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	◯	◯	◯	◯	◯
More than 6 sessions with a rehabilitation/exercise therapist e.g. physiotherapist, sports rehabilitator	◯	◯	◯	◯	◯
Exercise type(s)	◯	◯	◯	◯	◯
Frequency of exercise completion	◯	◯	◯	◯	◯
Exercise programme length	◯	◯	◯	◯	◯
Time-period to be completed e.g. immediately after injury, 3-months prior to surgery, continuous	◯	◯	◯	◯	◯
Delivery method e.g. virtual, group, individual, guided by a healthcare professional, self-directed	◯	◯	◯	◯	◯
Guidance on exercise/ types of activity to avoid	◯	◯	◯	◯	◯

4. Free text for any further comments you wish to make with regards to exercise guidance or delivery method

Enter your answer

Component 3

Delivery method

5. The preoperative intervention should be delivered via:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Booklet	◯	◯	◯	◯	◯
Website	◯	◯	◯	◯	◯
Face-to-face	◯	◯	◯	◯	◯
Forum	◯	◯	◯	◯	◯
Group	◯	◯	◯	◯	◯
1:1	◯	◯	◯	◯	◯
Peer support	◯	◯	◯	◯	◯
By a single healthcare profession	◯	◯	◯	◯	◯
By a team of healthcare professionals	◯	◯	◯	◯	◯
Combination of face-to-face interactions and printed/ digital resources	◯	◯	◯	◯	◯

6. Free text for any further comments you wish to make with regards to intervention delivery method

Enter your answer

Component 4

Outcome measures

7. Outcome measures to be collected/used as part of the preoperative intervention should include:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Knee-specific outcome score e.g. Knee injury and Osteoarthritis Outcome Score (KOOS)	◯	◯	◯	◯	◯
Psychological measures e.g. anxiety and depression screening	◯	◯	◯	◯	◯
Clinical assessment e.g. knee range of motion, muscle strength	◯	◯	◯	◯	◯
Weight screening	◯	◯	◯	◯	◯
Patient satisfaction	◯	◯	◯	◯	◯
Pre-injury level of activity	◯	◯	◯	◯	◯
Current level of activity	◯	◯	◯	◯	◯
Expectation screening	◯	◯	◯	◯	◯
Patient estimation of ability to return to preinjury activity levels	◯	◯	◯	◯	◯
Occupation	◯	◯	◯	◯	◯

8. Free text for any further comments you wish to make with regards to outcome measures

Enter your answer

Component 5

Decision Making

9. Decision-making support should be:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Primarily for the patient in the form of an information sheet with interactive components for them to bring to consultations e.g. sections to fill in / questions to respond to	◯	◯	◯	◯	◯
For both the healthcare professional and the patient to complete together	◯	◯	◯	◯	◯
In the form of a paper document	◯	◯	◯	◯	◯
In the form of an online tool	◯	◯	◯	◯	◯
Both a paper and online tool	◯	◯	◯	◯	◯
A flow-chart of key questions to help consider treatment options	◯	◯	◯	◯	◯

10. Decision-making support include:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Education on the condition	◯	◯	◯	◯	◯
Treatment options	◯	◯	◯	◯	◯
Patient preference for treatment	◯	◯	◯	◯	◯
Clinician preference / recommendation for treatment	◯	◯	◯	◯	◯
Space for the patient to document/consider what is important to them about the recovery of their knee injury e.g. reduced pain, improved mobility, return to work	◯	◯	◯	◯	◯
Space for the patient to document/consider what is important to them in their treatment	◯	◯	◯	◯	◯
Information about rehabilitation	◯	◯	◯	◯	◯
Information about surgery	◯	◯	◯	◯	◯
Space for the patient to document/consider how they feel about their treatment options	◯	◯	◯	◯	◯
Support to make a decision about treatment	◯	◯	◯	◯	◯
Resource signposting	◯	◯	◯	◯	◯
Up-to-date and evidence-based outcome information e.g. percentage of those who return to physical activity following surgery	◯	◯	◯	◯	◯

11. Free text for any further comments you wish to make with regards to decision making.

Enter your answer

Component 4

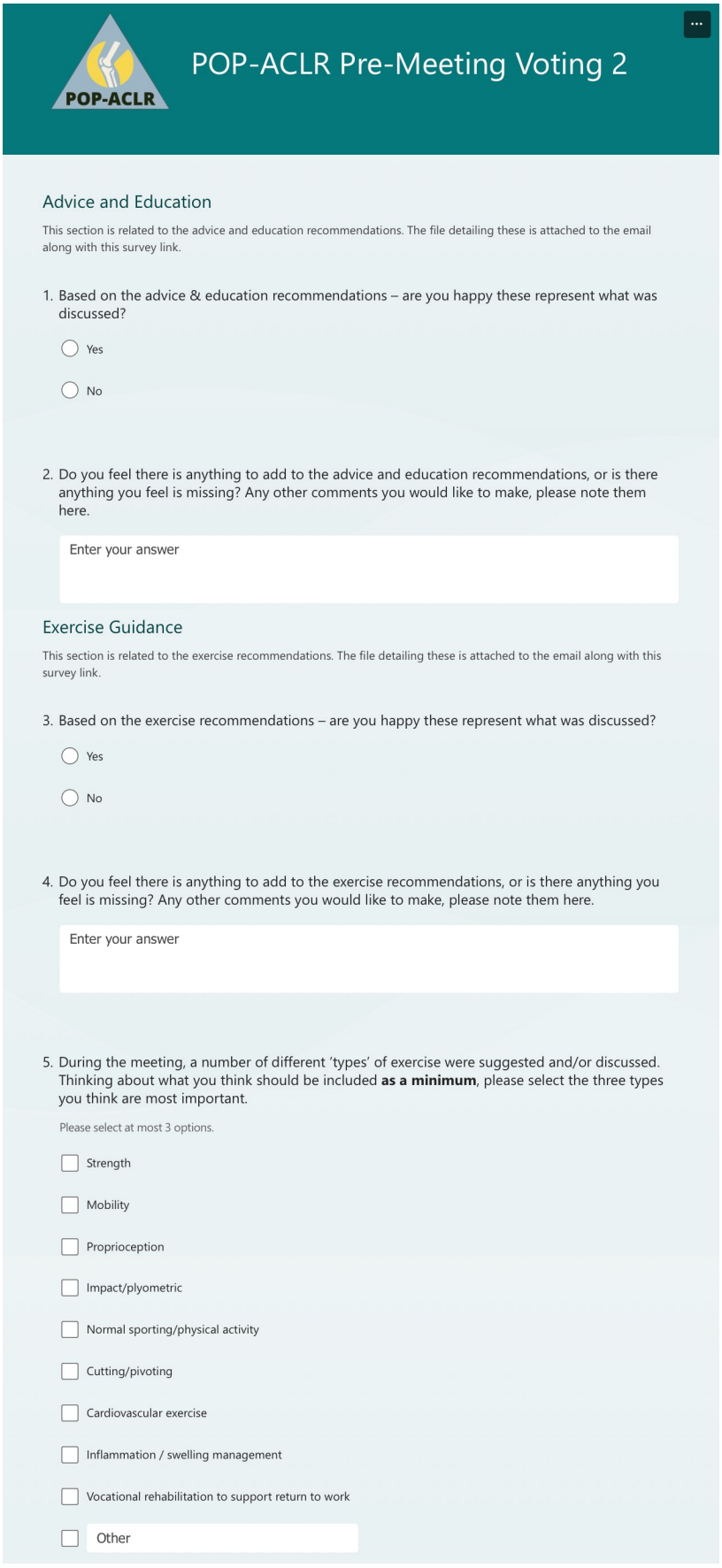
Outcome measures

7. Outcome measures to be collected/used as part of the preoperative intervention should include:

	Very important	Important	Neither important nor not important	Not important	Not at all important
Knee-specific outcome score e.g. Knee injury and Osteoarthritis Outcome Score (KOOS)	◯	◯	◯	◯	◯
Psychological measures e.g. anxiety and depression screening	◯	◯	◯	◯	◯
Clinical assessment e.g. knee range of motion, muscle strength	◯	◯	◯	◯	◯
Weight screening	◯	◯	◯	◯	◯
Patient satisfaction	◯	◯	◯	◯	◯
Pre-injury level of activity	◯	◯	◯	◯	◯
Current level of activity	◯	◯	◯	◯	◯
Expectation screening	◯	◯	◯	◯	◯
Patient estimation of ability to return to preinjury activity levels	◯	◯	◯	◯	◯
Occupation	◯	◯	◯	◯	◯

8. Free text for any further comments you wish to make with regards to outcome measures

Enter your answer



POP-ACLR Pre-Meeting Voting 2

Advice and Education

This section is related to the advice and education recommendations. The file detailing these is attached to the email along with this survey link.

1. Based on the advice & education recommendations – are you happy these represent what was discussed?

- ◯ Yes
- ◯ No

2. Do you feel there is anything to add to the advice and education recommendations, or is there anything you feel is missing? Any other comments you would like to make, please note them here.

Enter your answer

Exercise Guidance

This section is related to the exercise recommendations. The file detailing these is attached to the email along with this survey link.

3. Based on the exercise recommendations – are you happy these represent what was discussed?

- ◯ Yes
- ◯ No

4. Do you feel there is anything to add to the exercise recommendations, or is there anything you feel is missing? Any other comments you would like to make, please note them here.

Enter your answer

5. During the meeting, a number of different 'types' of exercise were suggested and/or discussed. Thinking about what you think should be included **as a minimum**, please select the three types you think are most important.

Please select at most 3 options.

- ☐ Strength
- ☐ Mobility
- ☐ Proprioception
- ☐ Impact/plyometric
- ☐ Normal sporting/physical activity
- ☐ Cutting/pivoting
- ☐ Cardiovascular exercise
- ☐ Inflammation / swelling management
- ☐ Vocational rehabilitation to support return to work
- ☐ Other

6. During the meeting, we voted on & discussed some things we may consider suggesting ACL patients avoid prior to surgery. We eluded to the idea that perhaps nothing should be avoided. Reading the recommendations of Do's and Don'ts - do you agree with this statement?

- [ ] Yes
- [ ] No

7. Anything else you would like to add for 'Do's and Don'ts' or any other comments you would like to make?

Enter your answer

8. Do you think exercise guidance should differ for those who have decided to have surgery versus those who have opted for non-operative management?

- ◯ Yes
- ◯ No

9. If yes to question 8 - why?

Enter your answer

Delivery Method

This section is related to the delivery method recommendations. The file detailing these is attached to the email along with this survey link.

10. Based on the delivery method recommendations – are you happy these represent what was discussed?

- ◯ Yes
- ◯ No

11. Do you feel there is anything to add to the delivery recommendations, or is there anything you feel is missing? Any other comments you would like to make, please note them here.

Enter your answer

Outcome Measures

This section is related to the outcome measure recommendations. The file detailing these is attached to the email along with this survey link.

12. Do you think outcome measures used should differ for those who have decided to have surgery versus those who have opted for non-operative management?

- ◯ Yes
- ◯ No

13. If yes to Question 12, why? What do you think should differ?

Enter your answer

14. Based on the previous voting and discussions, 3 outcome measures were considered very important to be used, at a minimum, with every patient. These included:

1. Knee specific outcome measures
2. Psychological outcome measure
3. Current level of activity including occupation

Are there any specific outcome measures you feel should be included under these categories, for example the Knee injury and Osteoarthritis Outcome Score (KOOS) or Tegner activity level.

Enter your answer

Shared Decision Making

This section is related to the shared decision making recommendations and tool. The file detailing these is attached to the email along with this survey link.

15. Based on the shared decision making recommendations – are you happy these represent what was discussed?

- ◯ Yes
- ◯ No

16. Do you feel there is anything to add to the shared decision making recommendations, or is there anything you feel is missing? Any other comments you would like to make, please note them here.

Enter your answer

17. The shared decision making tool is split into 3 components which we will discuss in more detail at meeting 2. The 3 documents are attached to your email and include:

1. Patient information leaflet
2. 'What should I be thinking about' diagram
3. Option grid

Ahead of the meeting, it would be helpful if you could review these & make any comments in the following text box. For example, is there anything missing? Is it too short/too lengthy? Any suggestions for change?

Enter your answer

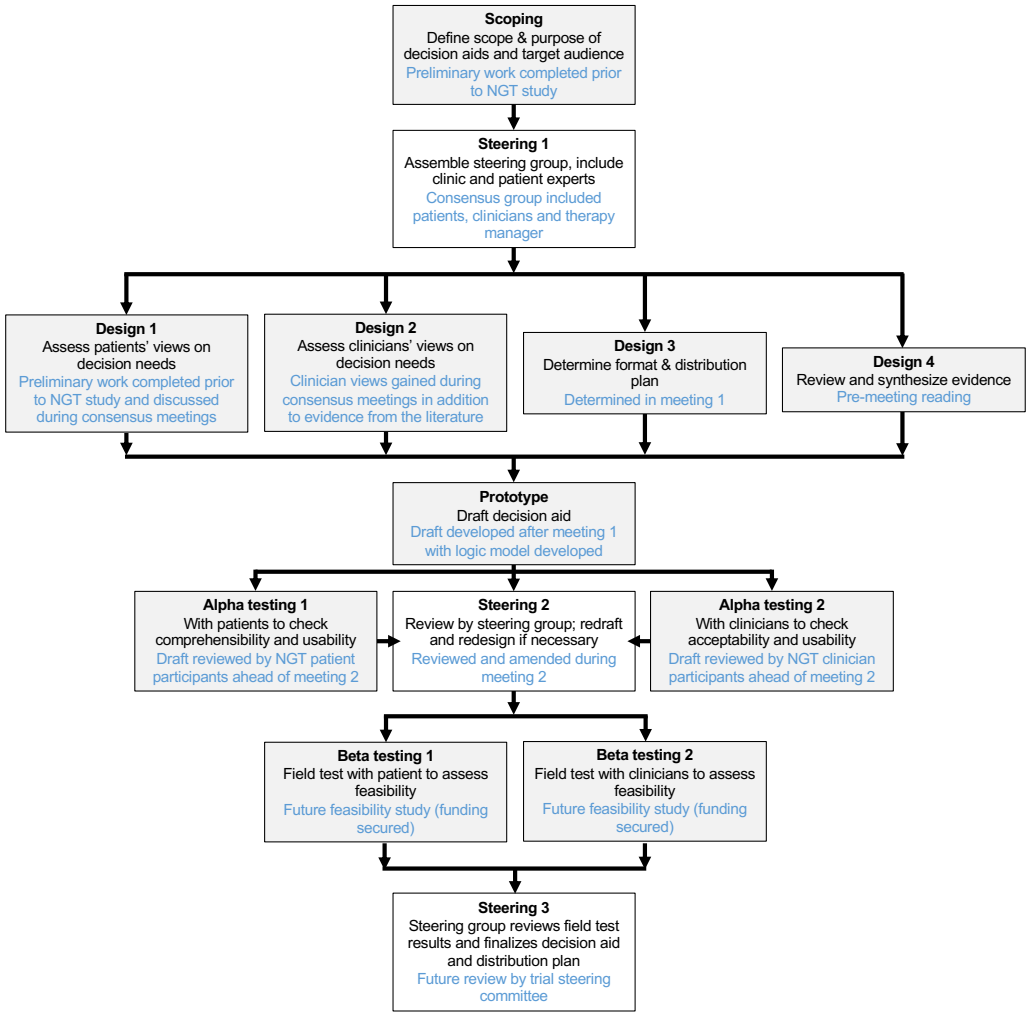
APPENDIX G: USE OF GUIDELINES AND SUPPORTING THEORY

Elwyn G, O'Connor A, Stacey D, *et al.* Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333:417–9

Quality Criterion Framework	Development of the shared decision-making intervention
Systematic development process	Nominal group technique consensus study.
Providing information about options	Included in the patient information leaflet and option grid.
Presenting probabilities	Probabilities included where available for each treatment option, this is presented in both the patient information leaflet and option grid.
Clarifying and expressing values	Section on the option grid included for patient treatment preferences.
Using patient stories	Patient experiences are embedded into the design of the intervention. Specific stories were not included however the section 'What else can I do?' of the option grid was driven by patient feedback of things they felt were important for patients to know.
Guiding or coaching in deliberation and communication	Prompts included in the intervention for both patients and clinicians. The intervention is planned to be delivered with clinicians who will receive training on its use with patients.
Disclosing conflicts of interest	Included on the first page of the patient information leaflet.
Delivering patient decision aids on the internet	During feasibility testing the material will be made available online.
Balancing the presentation of options	Embedded into the design and feedback to be gained from patients during feasibility testing regarding the presentation of the treatment options.
Using plain language	The language used throughout the intervention has been checked with the patient participants in the study. Feedback on readability/language will also be gained during feasibility testing.
Basing information on up to date scientific evidence	Up-to-date evidence used and referenced throughout.
Establishing effectiveness	Funding gained for feasibility testing ahead of testing in a future large main trail.

Model Development Process for Decision Aids, adapted from Coulter A, Stilwell D, Kryworuchko J, *et al.* A systematic development process for patient decision aids. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2. doi: 10.1186/1472-6947-13-S2-S2, under the CC BY 2.0 licence.

Text in black represents guidance from Coulter et al., text in blue demonstrates steps during taken intervention development



Marrin K, Brain K, Cpsychol P, *et al.* Fast and frugal tools for shared decision-making: how to develop Option Grids. *Eur J Pers Cent Healthc*. 2013;1:240–5.

Option Grid Development Process	Development of the shared decision-making intervention (Component B, Option Grid)
Identification of need	Preliminary work completed prior to NGT study
Est. of Editorial Team	NGT participants included patients and key stakeholders
Development of FAQs	Established during meeting 1 and 2
Evidence review	Pre-meeting reading
Population of the Option Grid	Draft composed ahead of meeting 2
Sign-off 1	Signed off by participants after meeting 2
User testing	Future feasibility testing
Review of Option Grid	Review planned following feasibility testing
Sign-off 2	Sign off following feasibility testing
Annual review	To be determined following feasibility and effectiveness testing

National Institute for Health and Care Excellence. Standards framework for shared-decision-making support tools, including patient decision aids | Guidance | NICE. *NICE Corporate Document*. 2021.

Standards framework for shared-decision-making support tools, including patient decision aids

Essential standards



Enhanced standards, additional to essential standards



For further details of the standards, see NICE's standards framework for shared-decision-making support tools, including patient decision aids.

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Published date: June 2021

APPENDIX H: SDM INTERVENTION COMPONENT A - PATIENT INFORMATION LEAFLET

Anterior Cruciate Ligament (ACL) Rupture and Treatment

Patient Information Leaflet

POP-ACLR

The POP-ACLR Study

Authors: Hayley Carter, David Beard, Paul Leighton, Fiona Moffatt, Benjamin Smith, Kate Webster, POP-ACLR consensus group*, Pip Logan.

***Consensus group**: Scott Backler, George Crouchley, Rebecca Cussens, Charlotte Dodsley, Matthew Gane, Sarah Holt, Josh McCallion, Thomas Kurien, Justin Murr and Michelle Slack.

Acknowledgements: This leaflet was produced as part of the POP-ACLR research consensus study. The consensus team contributed to the overall content to be included and we acknowledge their valuable input.

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Introduction

This information leaflet is designed to provide you with essential information about your Anterior Cruciate Ligament (ACL) injury and your treatment options.

This leaflet should be used alongside the **Option Grid**.

What is the ACL?

The ACL is one of two ligaments that cross inside the knee joint. It attaches between your thigh bone (femur) and shin bone (tibia). The ACL's main job is to provide stability to the knee joint. **Figure 1**, shows an ACL in the left knee.

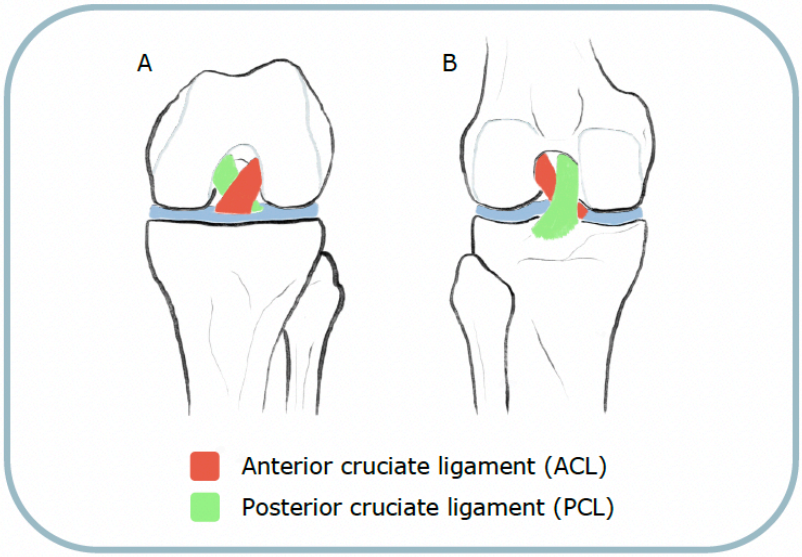


Figure 1 - Left knee joint

A. Front view of the left knee with the knee bent to 90 degrees
B. Back view of the left knee joint with the knee fully straight

ACL ruptures (also referred to as tears) are common. They can cause pain, swelling and difficulty with knee function. A rupture can also cause instability of the knee, which can be more of a problem for some people than others.

What are the treatment options?

In the UK, there are two main treatment options:

1. **Surgery**
2. **Non-surgery** (also referred to as rehabilitation)

Three research trials have compared ACL reconstruction surgery (ACLR) with rehabilitation (non-surgery). Only one of these was in a UK, NHS setting.

The oldest trial, from 2010, found no difference between surgery and rehabilitation.[1] The researchers suggested that surgery may be unnecessary for some. They recommended that rehabilitation should be trialled first. The second trial, from 2021, compared early ACLR to rehabilitation with delayed ACLR. The researchers of this trial reported early surgery to be better.[2] The final trial, completed in the UK in 2022, reported outcomes for those having surgery to be better.[3]

These results show that there isn't a one-size fits all approach when it comes to ACL injury management. This is why making a decision that is right for you is important. Patients involved in developing this leaflet felt it was important to know that ACL treatment (surgery and non-surgery) is both physically and mentally challenging. Both treatment options require time and effort. It is important you are aware what both treatments involve. The following information provides some more detail about each option.

1. Surgery

Surgery involves **reconstructing the torn ligament with a graft.** This graft is usually taken from another part of your body. The graft most used in the UK is a piece of tendon (part of the muscle) from your hamstring. However, a graft can also be taken from the tendon in your knee or from a donor.

If you decide to have surgery, you will have a conversation with your surgeon about which graft is best for you.

After your ACL reconstruction you will need to undergo a progressive rehabilitation programme with a physiotherapist. This will take at least 6-months and depending on your goal (e.g. if you wish to return to competitive sports), may take longer than 12-months.

2. Non-surgery

Non-surgery involves **rehabilitation with a therapist**, such as a physiotherapist or sports rehabilitator. This will involve exercises that aim to improve your walking, knee range of movement, strength and stability. Although there is some similarity with everyone's rehabilitation, your rehabilitation will be specific to you and depend upon your symptoms and ability.

Other options

There has been some early evidence that the ACL may be able to heal itself, without surgery. This research, from 2022, showed that 32 patients had evidence of some ACL healing on an MRI scan after 2 years.[4] At this stage we cannot say that your ACL would heal itself without surgery. The evidence is not yet strong enough.

What are the outcomes of each treatment option?

Most patients want to know when they can return to work, physical activity, sport and driving. **Table 1** shows some statistics take from research studies to answer these questions.

Further information is discussed below the table.

	Surgery	**Rehabilitation**
Return to preinjury activity level	28% by 18-months	24% by 18-months
Return to sport	55% returned by 40 months	No research available
Work	2.5 months (average, job dependent)	No research available but job dependent
Driving	Typically 6-weeks	No set restriction

Table 1 - Treatment outcomes

Return to preinjury activity level

Returning to your preinjury activity level means going back to your activities 'as normal'. For example, returning to the same level football league as you were playing in before your injury. The percentages in the table are from a 2022 UK trial.[3] Other research trials have shown that for those having surgery:

- **24%** have returned to their preinjury levels of activity **after 1-year**
- Less than **45%** have returned at **2-years**.[5,6]

Return to sport

Return to sport means that you have gone back to your sport but may not be competing at the same level.

There is no research reporting the number of people who return to sport after rehabilitation. A 2014 study (that also included people having revision ACL surgery) reported **55%** returned to competitive sport **40 months after surgery**.[7]

Return to work

Return to work hasn't been reported as frequently in the research as return to sport. It also varies depending on how physically active/labour intense your job is. A 2017 study completed in the Netherlands reported that on average, patients had returned to work by **78 days after surgery**.[8] Returning after 78 days was most likely for those in more labour-intensive jobs or those who needed crutches for longer after surgery.

There is no data to suggest when you can return to work if you choose not to have surgery. If you're currently off work and choose not to have surgery, your clinician (e.g. physiotherapist or occupational therapist) will support you in returning when it is right for you.

Return to driving

There is no data to suggest when people return to driving after surgery or rehabilitation.

Typically, you can return to driving 6-weeks after your operation. Although there are no set limitations, you can return when you feel safe and are able to carry out all emergency procedures. Your car insurance company may have set limitations for when you can return, so it is worth checking with them too.

If you choose not to have surgery, your clinician will support you to return to driving.

Other

As the research around ACL self-healing is new, there are no statistics to draw upon in the research to answer any of the above questions.

What are the risks?

There are some risks associated with having surgery which include:

Re-rupture

There is a chance the graft could **re-rupture** after surgery. A 2022 study reported 7.8% of patients underwent revision surgery within 9 years of their first surgery due to a re-rupture.[9]

Complications of surgery

Some patients may develop a '**cyclops lesion**' (a ball of excess graft tissue at the front of the ACL graft). The chance of this occurring is approximately 21-35% and is more common in women.[10] Cyclops lesions can require further surgery to be removed. Once removed, patients typically make a full recovery.

There are also risks associated with having surgery such as **infection** (less than 2%) and a **blood clot** (less than 1%).[11]

Donor site pain/discomfort

You may experience some **pain/discomfort** where your donor graft has been taken from (e.g. hamstring).

Osteoarthritis and further injury

It is a common thought that surgery protects against the development of **osteoarthritis**. However, a 2022 study found no difference in the rate of osteoarthritis between those who did or did not have surgery.[12] Whether you go on to have surgery or not, you are at an increased risk of developing osteoarthritis because of your ACL injury.

It is also thought that without surgery, you are at risk of a **meniscal (cartilage) injury**. The evidence about this is unclear. We cannot say for sure that surgery prevents further meniscal injury.[13]

Instability

If you choose not to have surgery, there is a chance you **may not regain stability** in your knee. This might mean you are unable to return to the activities you want to. Where this is the case, you will need to discuss the option of surgery with your clinician. In research studies comparing rehabilitation with surgery, approximately 50% of patients who had rehabilitation first, went on to have surgery later.[1–3]

Your clinician will discuss these risks with you.

What to expect

The typical patient journey for surgery and rehabilitation is outlined in **Figure 2**.

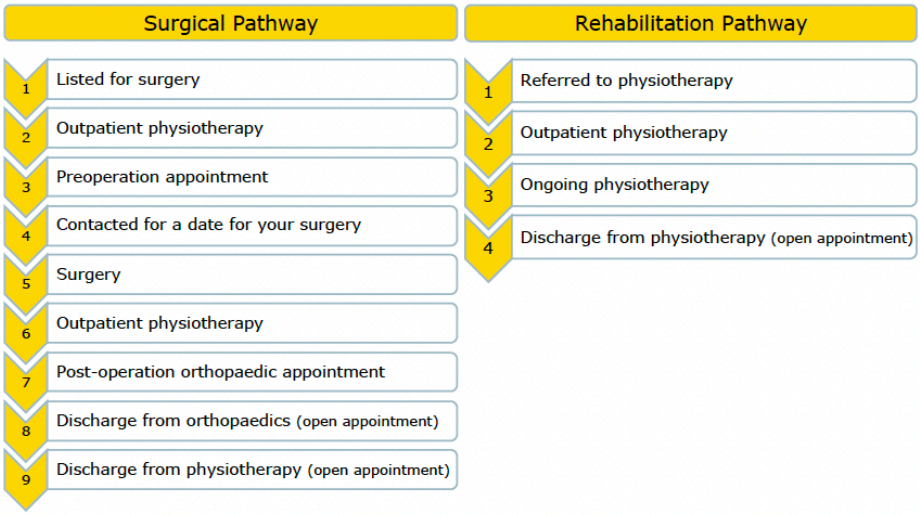
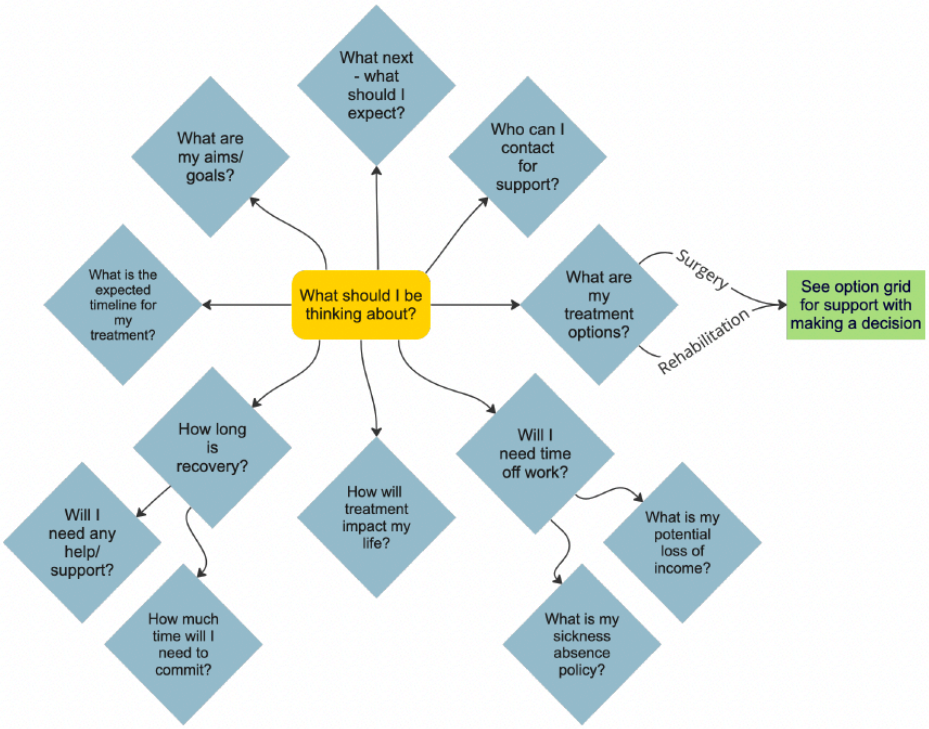


Figure 2 - Expected journey

We recommend discussing expected timeframes for each step with your clinician.

What to think about

The 'what should I be thinking about' diagram (next page) outlines some key questions to think about. You should discuss these with your clinician. These will help you to make a decision about what treatment is best for you.



What next?

You will need to make a decision about what treatment is best for you. At present, the evidence isn't strong enough for us to conclude that surgery is necessary for everyone or that rehabilitation is the best option.

This information leaflet aims to provide you with the necessary information to help you understand your options.

The **Option Grid** should be used with your clinician(s) to help you decide on the treatment that is right for you.

Other information

There is a lot of information about ACL injuries and treatment available online. Some of this information is more accurate than others. If you read anything online that doesn't fit with what your healthcare professional is telling you or that you have read here, you should ask them about it.

References

Below are links to the research studies mentioned in this leaflet. The number next to the sentence in the leaflet represents the research the finding was taken from.

1 Frobell RB, Roos EM, Roos HP, Ranstam J, Lohmander LS. A Randomized Trial of Treatment for Acute Anterior Cruciate Ligament Tears. *New England Journal of Medicine* 2010; **363**: 331–42.

2 Reijman M, Eggerding V, Van Es E, *et al.* Early surgical reconstruction versus rehabilitation with elective delayed reconstruction for patients with anterior cruciate ligament rupture: COMPARE randomised controlled trial. *The BMJ* 2021; **372**. DOI:10.1136/bmj.n375.

3 Beard DJ, Davies L, Cook JA, *et al.* Rehabilitation versus surgical reconstruction for non-acute anterior cruciate ligament injury (ACL SNNAP): a pragmatic randomised controlled trial. *The Lancet* 2022; **400**: 605–15.

4 Filbay SR, Roemer FW, Lohmander LS, *et al.* Evidence of ACL healing on MRI following ACL rupture treated with rehabilitation alone may be associated with better patient-reported outcomes: a secondary analysis from the KANON trial. *Br J Sports Med* 2022; **0**: 1–9.

5 Dunn WR, Spindler KP. Predictors of activity level 2 years after anterior cruciate ligament reconstruction (ACLR): A multicenter orthopaedic outcomes network (MOON) ACLR cohort study. *American Journal of Sports Medicine* 2010; **38**: 2040–50.

6 Ardern CL, Taylor NF, Feller JA, Whitehead TS, Webster KE. Sports participation 2 years after anterior cruciate ligament reconstruction in athletes who had not returned to sport at 1 year: A prospective follow-up of physical function and psychological factors in 122 athletes. *American Journal of Sports Medicine* 2015; **43**: 848–56.

7 Ardern CL, Taylor NF, Feller JA, Webster KE. Fifty-five per cent return to competitive sport following anterior cruciate ligament reconstruction surgery: An updated systematic review and meta-analysis including aspects of physical functioning and contextual factors. *Br J Sports Med* 2014; **48**: 1543–52.

8 Groot JAM, Jonkers FJ, Kievit AJ, Kuijer PPFM, Hoozemans MJM. Beneficial and limiting factors for return to work following anterior cruciate ligament reconstruction: a retrospective cohort study. *Arch Orthop Trauma Surg* 2017; **137**: 155.

9 Gupta R, Singhal A, Malhotra A, Soni A, Masih GD, Raghav M. Predictors for Anterior Cruciate Ligament (ACL) Re-injury after Successful Primary ACL Reconstruction (ACLR). *Malays Orthop J* 2020; **14**: 50.

10 Kambhampati SBS, Gollamudi S, Shanmugasundaram S, Josyula VVS. Cyclops Lesions of the Knee: A Narrative Review of the Literature. *Orthop J Sports Med* 2020; **8**: 2325967120945671.

11 Ding DY, Tucker LY, Rugg CM. Comparison of Anterior Cruciate Ligament Tears Treated Nonoperatively Versus With Reconstruction: Risk of Subsequent Surgery. *American Journal of Sports Medicine* 2022; **50**: 652–61.

12 Webster KE, Hewett TE. Anterior Cruciate Ligament Injury and Knee Osteoarthritis: An Umbrella Systematic Review and Meta-analysis. Clinical Journal of Sport Medicine. 2022; **32**: 145–52.

13 Filbay SR. Early ACL reconstruction is required to prevent additional knee injury: a misconception not supported by high-quality evidence. *Br J Sports Med* 2019; **53**. DOI:10.1136/bjsports-2018-099842.

Notes

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APPENDIX I: SDM INTERVENTION COMPONENT B – OPTION GRID

Making a Decision about Anterior Cruciate Ligament Injury Treatment

This option grid presents evidence-based information about treatment for an anterior cruciate ligament (ACL) rupture. You should use this with your healthcare professional to help you make the right decision for you.

	Surgery **(ACL reconstruction)**	**Rehabilitation** **(non-operative management)**
What are my options?	Surgery involves reconstructing your torn ACL with a graft taken from another part of your body (typically a tendon from your hamstring or knee). Sometimes a donor graft may be used.	Rehabilitation involves working with a therapist. The areas targeted during treatment are specific to you and your injury but typically aim to improve your overall fitness, knee function, strength and stability.
What do I need to know about this treatment?	Surgery involves a keyhole operation to reconstruct your torn ACL with a graft. This takes approximately 1 hour and will require you to be under local or general anesthetic. You may need to wear a brace after surgery and use elbow crutches.	Rehabilitation requires you to commit time to a regular exercise programme. This may be in a one-to-one or group setting. Your therapy sessions are unlikely to be supervised for the duration of your treatment and you will need to complete your exercises independently at home or in a gym.
What does the research say about this treatment option?	A trial completed in the UK (2022) reported surgery to be better than rehabilitation for patients with an ACL tear older than 4-months. In this trial, it was concluded that those who had surgery had better scores 18-months after surgery for knee outcomes, quality of life and activity level. However, 2 previous trials have concluded that: ▪ surgery may be unnecessary for some and rehabilitation should be trialed first ▪ early reconstruction may be better than delayed reconstruction Both trials were completed outside the UK in different healthcare settings.	The UK 2022 trial reported that 41% of patients went on to have surgery after a period of rehabilitation. There has previously been no consensus on the best rehabilitation to offer to patients. Because of this treatment has varied across the UK and in research studies. In 2023 a group of patients and clinicians agreed some recommendations for rehabilitation to help improve and standardise treatment. We know that some patients manage well without surgery. At present (2023) it is unclear who is an ideal candidate for surgery and who may manage without it.
What are the outcomes of this treatment?	**Preinjury activity level** - 20% of patients return to their preinjury levels of activity 1-year after surgery, 28% return at 18-months and less than 45% return at 2-years. **Work** – The average time to return to work after ACL reconstruction is approximately 2 and a half months. This may be shorter for desk-based jobs and longer for more labour-intensive roles. **Driving** – Typically you can return to driving 6-weeks after your operation.	**Preinjury activity level** - 24% of patients return to their preinjury activity level 18-months after surgery. **Work** – no research to date has collected information on the time to return to work following ACL injury for patients who chose non-operative treatment. **Driving** – there is no set restriction on returning to driving after an ACL rupture. This should be decided by you and your clinician.
If I choose this treatment, what happens next?	If you decide to have surgery, you will be placed on the waiting list. Your clinician should be able to give you an estimated waiting time. Your surgeon will also discuss your graft choice with you. You should also be referred to physiotherapy for support whilst you wait for surgery.	You will be referred to physiotherapy, your clinician should be able to give you an estimated waiting time. You will work with your physiotherapist to develop some goals to work towards. You should start thinking about these now, ready to discuss at your first appointment.

What are the risks?	The risks associated with surgery include: ▪ Re-rupture (7.8%) ▪ Cyclops lesion (21-35%) ▪ Infection (less than 2%) ▪ Blood clot (less than 1%) ▪ Donor site pain/discomfort ▪ Numbness around the knee There is no increased risk of osteoarthritis should you decide to have surgery.	The risks associated with rehabilitation include: ▪ Ongoing, symptomatic instability ▪ Potential for further injury (unclear risk) It is a common thought that, without surgery, you are at risk of a meniscal (cartilage) injury. There is evidence to suggest this may or may not be true. As of 2023, the evidence is unclear. There is no increased risk of osteoarthritis should you decide not to have surgery.
Will I need to have more treatment?	After your ACL reconstruction you will need to undergo a progressive rehabilitation programme with a physiotherapist. This will take at least 6-months and depending on your goal (e.g. if you wish to return to competitive sports), may take longer than 12-months. If complications arise, further surgery may be needed. Otherwise, the graft remains in place and does not need to be replaced in the future unless you have a second injury.	If you do not return to your desired functional level, you can discuss the option of surgery with your clinician.
Are there any other options?	**Repair** There is limited evidence that ACL repair is a successful surgical option to treat an ACL rupture. ACL repair is a technique that does not use a graft and instead repairs the torn ligament with stitches. Research in this area is limited and so at present (2023), we do not have enough evidence to suggest the success of this treatment.	**Self-healing** New evidence was published in 2022 showing the ACL to have healed (to some extent) without surgery. This has been reported in a small number of patients and the long-term effects are mostly unknown. Research in this area is limited and so at present (2023), we do not have enough evidence to suggest the success of this treatment.
What else can I do?	It is important that you consider the following: ▪ **Fitness management** – your clinician may discuss your overall health and fitness with you. This may include your cardiovascular health and weight management to support you in the recovery of your ACL rupture and/or help you prepare for surgery. ▪ **Psychological factors** – research suggests that psychological barriers, such as fear of reinjury, are the most common reason for patients failing to return to their preinjury level of activity. There is also research to suggest that some psychological factors, measured before surgery, can predict your return to preinjury levels after surgery. If you are concerned about your mental wellbeing and feel you would like further support, talk to your clinician. They can support you to access further help if needed. ▪ Optimising your **sleep and diet/nutrition** may also be important to help your recovery, if you would like further support, talk to your clinician. ▪ Take time to think about what your **end goal** is, this will help you to think about whether surgery or rehabilitation is the best option for you.	
What does my clinician recommend?	You may wish to gain a recommendation from more than one clinician. (e.g. surgeon 1, physiotherapist, surgeon 2)	
What is my treatment preference?	It is important to think about what treatment you think you would like to have. Write this here to discuss with your clinician.	

Post-injury/pre-operative recommendations for patients following anterior cruciate ligament (ACL) rupture

This document provides recommendations for patients following an ACL rupture who may be awaiting surgery or proceeding with non-surgical management. The recommendations include:

- Advice and education
- Exercise guidance
- Delivery method
- Outcome measure use
- Shared decision making

The recommendations were developed using the nominal group technique (NGT) approach involving a group of patients and professionals in the UK. The group consisted of the lead researcher, expert facilitators (patients, clinical and academic experts) and research participants including:

- 2 patients
- 4 therapists [physiotherapists and occupational therapist]
- 1 surgeon
- 1 MSK outpatient therapy manager

A 70% threshold was used to determine consensus on component items. Items were voted and discussed to be considered as 'very important', 'important', 'neither important nor not important', 'not important' or 'not at all important'. Our recommendations are based on those that were considered to be '**very important**' and '**important**' amongst the group.

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Advice and Education Recommendations

5 advice and education items were considered to be **very important**. We recommend these items as the **minimum elements** to cover when delivering advice and education to patients following diagnosis of an ACL rupture. As a minimum, post-injury/pre-operative ACL advice and education **should include**:

1. Advice on injury management
   e.g., surgery or rehabilitation
2. Evidence based information on injury outcomes
   e.g., information about re-rupture, return-to-work, return to physical activity/sport
3. Expected timeline, specific to the patient, from present to return to patients end goal e.g. return to sport
   e.g., return to sport
4. Information about pathway milestones including expected appointments and timeframes
5. Evidence based info on outcomes of treatment

We recommend the following **16 items**, considered to be **important**, to be included at the discretion of the clinician, to tailor advice/education to each individual patient. Topics **to be considered** include:

- Knee anatomy and injury
- Surgical procedure
- Risks of surgery
- Prehabilitation
- Goal setting
- Smoking cessation
- Common issues pre- and post-operation
- Pain management
- Weight management & nutrition
- Evidence based information regarding graft choice
- What to expect during the inpatient stay
- Postoperative period
- Common psychological difficulties associated with ACL injury
- Signposting to relevant services for mental health support
- Managing work and home preparations
- Information regarding spontaneous ACL healing

Advice and Education Recommendations

Whilst signposting to relevant services for mental health support is not included as a very important item, the group emphasise that this should be considered by clinicians for all patients following ACL injury. The extent to which this is discussed, and the amount of support offered however, must be **tailored to each individual patient**.

We recommend advice and education to be delivered **at the point of injury diagnosis** (or shortly after) **before a definitive decision about treatment** is made.

It is further essential to ensure the advice and education delivered is **consistent** throughout the patients care. Although we did not feel it was important to distinguish who (i.e. which profession) should deliver the advice/education, we recommend that it is delivered in a **one-to-one consultation**.

In summary, advice and education **should be delivered**:

- In a **one-to-one** session
- By **any clinician** with expertise and knowledge to do so
- **Consistently** by the healthcare team across the patients care

Exercise Recommendations

A range of components were discussed in relation to exercise guidance including:

1. Number of sessions
2. Exercise type
3. Exercise programme length and frequency
4. Risks and considerations

1. Number of sessions

It was considered to be **very important** that, as a minimum:

> **At least one-session** to be offered with a rehabilitation / exercise therapist, **within 3-months** of ACL injury diagnosis

We recommend that clinicians determine individual patients' need and offer further sessions, where it is deemed appropriate considering **specific patient goals and waiting times** for surgery. Where more than 6 sessions are offered, goals need to be revisited and rehabilitation progressed to support patient motivation and engagement.

2. Exercise type

We recommend that clinicians **consider the appropriateness** of the following types of exercise in a programme for patients following ACL injury:

- Strength
- Mobility
- Proprioception
- Vocational rehabilitation
- Impact and plyometric
- Normal sporting activities
- Inflammation and swelling management

Selection needs to be **specific** to each patient and based on their **goals**.

Exercise Recommendations

3. Exercise programme

It was considered **very important** that, as a **minimum**, exercise programme's:

- Include a variety of exercise types (including the 3 very important types)
- Be completed **2-3 times a week**
- Be completed **continuously** by the patient for the duration of the preoperative period (not to be supervised for the entirety of the preoperative period)

4. Risks and considerations

It was considered **very important** that:

The **risks** of engaging in physical activity are discussed with each patient.

This discussion should include a balanced presentation of the evidence considering potential **risks and benefits**.

We recommend that exercise is guided by the appropriate professional and should be **within the limits of the individual**. Whilst it is acknowledged that activities that provoke knee swelling and instability and and cause intolerable amounts of pain may need to be **limited**, we recommend **progressive and graded exposure** to activities, working towards the patient's individual goals.

The risk benefit discussion should be based on the patients' goals to allow them to make educated decisions about engaging in physical activity after their ACL injury. The group discussed the importance of this discussion in **empowering patients** to engage in physical activity within the **scope of risk deemed acceptable to** them and their treating clinician(s).

For patients proceeding with surgery, consider the risks of further injury and the subsequent consequences to the planned surgical procedure. **Caution** to return to cutting/pivoting activities **may be greater** with this patient group.

Delivery Method Recommendations

The delivery method for any intervention was discussed amongst the group with the following **6 mediums** considered **important.**

- Booklet
- Website
- Face-to-face
- One-to-one
- Peer support
- Combination of face-to-face and digital or printed resources

We discussed the importance of the delivery method meeting the needs of the individual patient. Clinician's should consider the trade-off between a 1:1 session that offers tailored support and the peer support offered in a group setting.

We recommend an **initial 1:1 session** to ensure specific needs are met. The above methods should be utilised as appropriate for individual patients.

Outcome Measure Recommendations

3 outcome measures were considered to be **very important** for use with patients following ACL injury. As a minimum, we recommend clinicians **should** record:

- Knee specific outcome measure
- Psychological outcome measure
- Current level of activity including occupation

The following **6** measures were considered to be **important** and are advised to be used at the discretion of the clinician, selected as appropriate to each patient. Outcome measures **to be considered** include:

- Patient estimation of ability to return to their preinjury level
- Expectation screening
- Preinjury level of activity
- Patient satisfaction
- Weight screening
- Clinical assessment e.g. knee range-of-motion, leg strength

We discussed the need to alter outcome measure use according to the patients decision to proceed with surgical or non-surgical management. The group agreed that outcome measure use should not differ. We encourage clinicians to consider assessing patients at baseline regardless of their treatment decision as this may help with future treatment planning and progress tracking.

Shared Decision Making Recommendations

6 principles were considered to be **very important** to include in a shared decision making tool / conversation for patients following ACL injury. At a minimum, shared decision making **should** include:

- Up-to-date evidence-based outcome information e.g. percentage of those who return to preinjury levels of surgery
- Education on the condition
- Treatment options
- Risks
- Clinician preference and recommendations
- Patient preferences for treatment

The following 7 principles were considered to be **important** and are advised to be included at the discretion of the clinician/those developing the tool. Shared decision making principles **to be considered** include:

- Space for the patient to document / consider how they feel about their treatment options
- Space for the patient to document/consider what is important to them in their treatment
- Space for the patient to document/consider what is important to them about the recovery of their knee injury
- Support to make a decision about treatment
- Information about rehabilitation
- Information about surgery
- Resource signposting

It was also **considered important** that a shared decision making tool:

- Is for the healthcare professional and patient to complete together
- Is available online and paper
- Includes a flow chart of key questions to help the patient consider their treatment options

Recommendations Summary 1

Advice and education should:

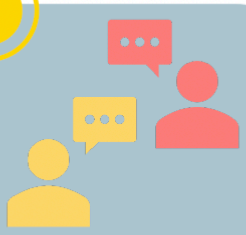
1



Include the 5 **very important** elements

1. Injury management
2. Injury outcomes
3. Treatment outcomes
4. Expected timeline
5. Pathway milestones

2



Be delivered in a **one-to-one** session by a clinician with appropriate **knowledge** and **expertise**

3



Be **consistent** across the patients care

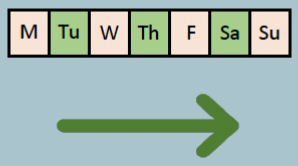
Exercise should:

1



Include at least **1 session** within 3-months of diagnosis

2



Be completed **2-3 times a week** and **continuously** whilst awaiting surgery

3



Be **graded** and **progressive** ensuring a **risk discussion** is had with every patient

Recommendations Summary 2

Intervention delivery:

1



Should include an initial **1:1 session**

2



Could be delivered via several **different mediums**

Outcome measures should include:

1



Knee specific measure

2



Psychological measure

3



Current **activity** level including **occupation**

Recommendations Summary 3

Shared decision making should include:

1. 

Outcome information

2. 

Education on the condition

3. 

Treatment options

4. 

Risks

5. 

Clinician preference & recommendation

6. 

Patient preferences for treatment

The POP-ACLR Study

Acceptability Questionnaire

Please tick whether you **agree or disagree** with the following statements. Think about each statement in relation to the **shared decision making tools** you have used to help you decide on the **treatment of your ACL injury**.

	Agree	Disagree
The information in the shared decision making tools was **helpful**		
The information helped me to **understand my ACL tear**		
The information helped me to **understand my treatment options**		
The diagram on page 8 of the information leaflet was helpful in getting me to **think about key questions** to discuss with my healthcare professional		
The **option grid** helped me to **make a decision**		
I am aware of the **advantages** of each **treatment option** for my ACL injury		
I am aware of the **disadvantages** of each **treatment option** for my ACL injury		
I **understood** all the information in the **shared decision making tools**		
The **length** of the shared decision making tools was '**just right**'		
The **length** of the shared decision making tools was '**too short**'		
The **length** of the shared decision making tools was '**too long**'		
The presentation of information seemed in **favour of having surgery**		
The presentation of information seemed in **favour of not having surgery**		
The presentation of information was '**balanced**' and **fair** towards each treatment option		
I **would recommend** the shared decision making tools to **other patients** in a similar position to me		

The POP-ACLR Study

Satisfaction with Decision (SWD) Scale for ACL injury treatment decision

Please answer the following questions about your decision about treatment for you ACL injury. Please indicate to what extend each statement is true for you **AT THIS TIME** (circle one number for each statement).

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I was adequately informed about the different treatments available for my ACL injury	1	2	3	4	5
The decision I made was the best decision possible for me personally	1	2	3	4	5
My decision was consistent with my personal values	1	2	3	4	5
I expect to successfully carry out(or continue to carry out) the decision I made	1	2	3	4	5
I had as much input as I wanted in the choice of treatment for my ACL injury	1	2	3	4	5
I am satisfied with the decision that was made about treatment for my ACL injury	1	2	3	4	5

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Interview Topic Guide – Participant / Clinician Interview

(delete as appropriate for interviewee)

Version 1.0 – 23/10/2023

Introduction and Background

- Thank you for agreeing to take part in the study to discuss use of the shared decision making tools
- Tell me about your experience of using the tools

Possible prompts:

- Helpfulness of tools
- Length / readability / layout

Topic 1: Acceptability

Possible prompts:

- Acceptability of using the tools
- Thoughts on acceptability of use in practice
- Where they helpful in decision making about treatment
- Format – paper vs online

Topic 2: Implementation Factors

Possible prompts:

- Where the tools burdensome to use?
- For participants only
  - Where you happy using the tools with the physiotherapist? Whose role do you think it should be?
  - Did you feel the tools allowed for a consultation and discussion specific to you and your goals
- For clinicians only
  - Was the education you received in training sufficient to use the tools?
  - How you do envision the tools being used in practice?
  - Were the tools compatible with current practice?
  - Did you feel able to use the tools with every participants e.g were you able to adapt/tailor consultations using them
  - Did you feel like it was your role to deliver the tools?
  - How do you think we should be evaluating the tools?

[Clinicians only] Topic 3: Contamination

Possible prompts:

- Having used the tools – how do you think it's impacted your practice in consultations where you have not used the tools (for ACL patients and other MSK conditions)

Close

- Is there anything you feel could be changed about the SDM tools
- Anything further you would like to mention/discuss
- Thank you for taking the time to discuss your experience

Anterior Cruciate Ligament (ACL) Rupture and Treatment

Patient Information Leaflet

POP-ACLR

The POP-ACLR Study

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Introduction

This information leaflet is designed to provide you with essential information about your Anterior Cruciate Ligament (ACL) injury and your treatment options.

This leaflet should be used alongside the **Option Grid**.

What is the ACL?

The ACL is one of two ligaments that cross inside the knee joint. It attaches between your thigh bone (femur) and shin bone (tibia). The ACL's main job is to provide stability to the knee joint. **Figure 1**, shows an ACL in the left knee.

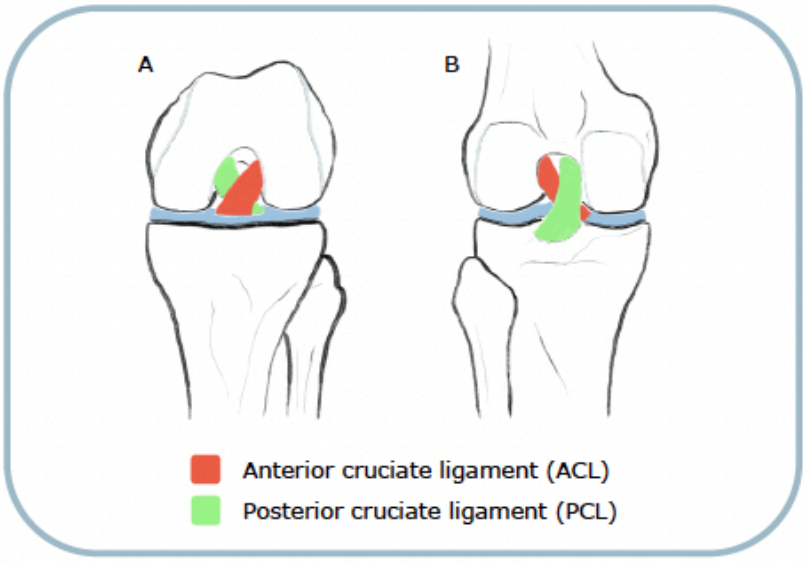


Figure 1 - Left knee joint

A. Front view of the left knee with the knee bent to 90 degrees
B. Back view of the left knee joint with the knee fully straight

ACL ruptures (also referred to as tears) are common. They can cause pain, swelling and difficulty with knee function. A rupture can also cause instability of the knee, which can be more of a problem for some people than others.

What are the treatment options?

In the UK, there are two main treatment options:

1. **Surgery**

2. **Non-surgery** (also referred to as rehabilitation)

Three research trials have compared ACL reconstruction surgery (ACLR) with rehabilitation (non-surgery). Only one of these was in a UK, NHS setting.

The oldest trial, from 2010, found no difference between surgery and rehabilitation.[1] The researchers suggested that surgery may be unnecessary for some. They recommended that rehabilitation should be trialled first. The second trial, from 2021, compared early ACLR to rehabilitation with delayed ACLR. The researchers of this trial reported early surgery to be better.[2] The final trial, completed in the UK in 2022, reported outcomes for those having surgery to be better.[3]

These results show that there isn't a one-size fits all approach when it comes to ACL injury management. This is why making a decision that is right for you is important. Patients involved in developing this leaflet felt it was important to know that ACL treatment (surgery and non-surgery) is both physically and mentally challenging. Both treatment options require time and effort. It is important you are aware what both treatments involve. The following information provides some more detail about each option.

1. Surgery

Surgery involves **reconstructing the torn ligament with a graft.** This graft is usually taken from another part of your body. The graft most used in the UK is a piece of tendon (part of the muscle) from your hamstring. However, a graft can also be taken from the tendon in your knee or from a donor.

If you decide to have surgery, you will have a conversation with your surgeon about which graft is best for you.

After your ACL reconstruction you will need to undergo a progressive rehabilitation programme with a physiotherapist. This will take at least 6-months and depending on your goal (e.g. if you wish to return to competitive sports), may take longer than 12-months.

2. Non-surgery

Non-surgery involves **rehabilitation with a therapist**, such as a physiotherapist or sports rehabilitator. This will involve exercises that aim to improve your walking, knee range of movement, strength and stability. Although there is some similarity with everyone's rehabilitation, your rehabilitation will be specific to you and depend upon your symptoms and ability.

Other options

There has been some early evidence that the ACL may be able to heal itself, without surgery. This research, from 2022, showed that 32 patients had evidence of some ACL healing on an MRI scan after 2 years.[4] At this stage we cannot say that your ACL would heal itself without surgery. The evidence is not yet strong enough.

What are the outcomes of each treatment option?

Most patients want to know when they can return to work, physical activity, sport and driving. **Table 1** shows some statistics taken from research studies to answer these questions.

Further information is discussed below the table.

	Surgery	Rehabilitation
Return to preinjury activity level	28% by 18-months	24% by 18-months
Return to sport	55% returned by 40 months	No research available
Work	2.5 months (average, job dependent)	No research available but job dependent
Driving	Typically 6-weeks	No set restriction
Satisfaction	83% felt their knee was better than before treatment	68% felt their knee was better than before treatment

Table 1 - Treatment outcomes

Return to preinjury activity level

Returning to your preinjury activity level means going back to your activities 'as normal'. For example, returning to the same level football league as you were playing in before your injury. The percentages in the table are from a 2022 UK trial.[3] Other research trials have shown that for those having surgery:

- **24%** have returned to their preinjury levels of activity **after 1-year**
- Less than **45%** have returned at **2-years**.[5,6]

Return to sport

Return to sport means that you have gone back to your sport but may not be competing at the same level.

There is no research reporting the number of people who return to sport after rehabilitation. A 2014 study (that also included people having revision ACL

surgery) reported **55%** returned to competitive sport **40 months after surgery.**[7]

Return to work

Return to work hasn't been reported as frequently in the research as return to sport. It also varies depending on how physically active/labour intense your job is. A 2017 study completed in the Netherlands reported that on average, patients had returned to work by **78 days after surgery.**[8] Returning after 78 days was most likely for those in more labour-intensive jobs or those who needed crutches for longer after surgery.

There is no data to suggest when you can return to work if you choose not to have surgery. If you're currently off work and choose not to have surgery, your clinician (e.g. physiotherapist or occupational therapist) will support you in returning when it is right for you.

Return to driving

There is no data to suggest when people return to driving after surgery or rehabilitation.

Typically, you can return to driving 6-weeks after your operation. Although there are no set limitations, you can return when you feel safe and are able to carry out all emergency procedures. Your car insurance company may have set limitations for when you can return, so it is worth checking with them too.

If you choose not to have surgery, your clinician will support you to return to driving.

Satisfaction

In the 2022 UK trial comparing ACL surgery with rehabilitation, patients were asked about satisfaction of their treatment at an 18-month follow-up.

Surgery

Of those who were treated with surgery:

- 83% said their knee was better than before treatment.
- 80% said they would choose surgery again, 5% said they would not.

Rehabilitation

Of those who were treated with rehabilitation:

- 68% said their knee was better than before treatment.
- 61% said they would choose rehabilitation again, 18% said they would not.

Other

As the research around ACL self-healing is new, there are no statistics to draw upon in the research to answer any of the above questions.

What are the risks?

There are some risks associated with having surgery which include:

Re-rupture

There is a chance the graft could **re-rupture** after surgery. A 2022 study reported 7.2% of patients underwent revision surgery within 9 years of their first surgery due to a re-rupture.[9]

Complications of surgery

Some patients may develop a '**cyclops lesion**' (a ball of excess graft tissue at the front of the ACL graft). The chance of this occurring is approximately 21-35% and is more common in women.[10] Cyclops lesions can require further surgery to be removed. Once removed, patients typically make a full recovery.

There are also risks associated with having surgery such as **infection** (less than 2%) and a **blood clot** (less than 1%).[11]

Donor site pain/discomfort

You may experience some **pain/discomfort** where your donor graft has been taken from (e.g. hamstring).

Osteoarthritis and further injury

It is a common thought that surgery protects against the development of **osteoarthritis**. However, a 2022 study found no difference in the rate of osteoarthritis between those who did or did not have surgery.[12] Whether you go on to have surgery or not, you are at an increased risk of developing osteoarthritis because of your ACL injury.

It is also thought that without surgery, you are at risk of a **meniscal (cartilage) injury**. The evidence about this is unclear. We cannot say for sure that surgery prevents further meniscal injury.[13]

Instability

If you choose not to have surgery, there is a chance you **may not regain stability** in your knee. This might mean you are unable to return to the activities you want to. Where this is the case, you will need to discuss the option of surgery with your clinician. In research studies comparing rehabilitation with surgery, approximately 50% of patients who had rehabilitation first, went on to have surgery later.[1–3]

Your clinician will discuss these risks with you.

What to expect

The typical patient journey for surgery and rehabilitation is outlined in **Figure 2**.

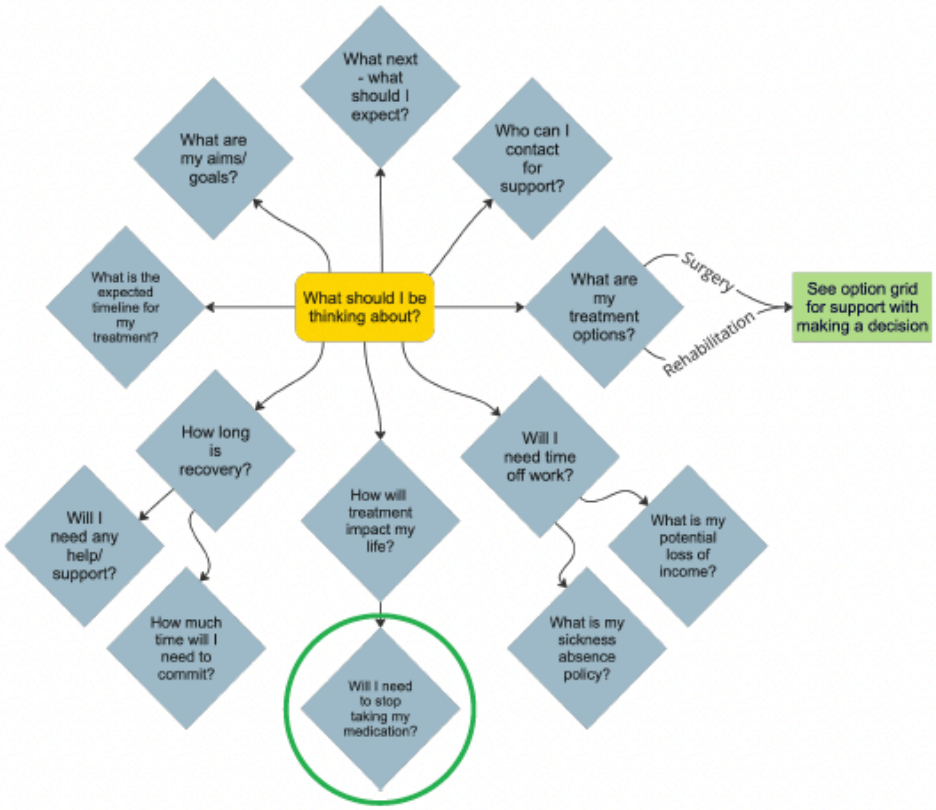


Figure 2 - Expected journey

We recommend discussing expected timeframes for each step with your clinician.

What to think about

The 'what should I be thinking about' diagram (next page) outlines some key questions to think about. You should discuss these with your clinician. These will help you to make a decision about what treatment is best for you.



What next?

You will need to make a decision about what treatment is best for you. At present, the evidence isn't strong enough for us to conclude that surgery is necessary for everyone or that rehabilitation is the best option.

This information leaflet aims to provide you with the necessary information to help you understand your options.

The **Option Grid** should be used with your clinician(s) to help you decide on the treatment that is right for you.

Other information

There is a lot of information about ACL injuries and treatment available online. Some of this information is more accurate than others. If you read anything online that doesn't fit with what your healthcare professional is telling you or that you have read here, you should ask them about it.

References

Below are links to the research studies mentioned in this leaflet. The number next to the sentence in the leaflet represents the research the finding was taken from.

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Notes

Making a Decision about Anterior Cruciate Ligament Injury Treatment

This option grid presents evidence-based information about treatment for an anterior cruciate ligament (ACL) rupture. You should use this with your healthcare professional to help you make the right decision for you.

	Surgery (ACL reconstruction)	Rehabilitation (non-operative management)
What are my options?	Surgery involves reconstructing your torn ACL with a graft taken from another part of your body (typically a tendon from your hamstring or knee). Sometimes a donor graft may be used.	Rehabilitation involves working with a therapist. The areas targeted during treatment are specific to you and your injury but typically aim to improve your overall fitness, knee function, strength and stability.
What do I need to know about this treatment?	Surgery involves a keyhole operation to reconstruct your torn ACL with a graft. This takes approximately 1 hour and will require you to be under local or general anesthetic. You may need to wear a brace after surgery and use elbow crutches.	Rehabilitation requires you to commit time to a regular exercise programme. This may be in a one-to-one or group setting. Your therapy sessions are unlikely to be supervised for the duration of your treatment and you will need to complete your exercises independently at home or in a gym.
What does the research say about this treatment option?	A trial completed in the UK (2022) reported surgery to be better than rehabilitation for patients with an ACL tear older than 4-months. In this trial, it was concluded that those who had surgery had better scores 18-months after surgery for knee outcomes, quality of life and activity level. However, 2 previous trials have concluded that: ▪ surgery may be unnecessary for some and rehabilitation should be trialed first ▪ early reconstruction may be better than delayed reconstruction Both trials were completed outside the UK in different healthcare settings.	The UK 2022 trial reported that 41% of patients went on to have surgery after a period of rehabilitation. There has previously been no consensus on the best rehabilitation to offer to patients. Because of this, treatment has varied across the UK and in research studies. In 2023 a group of patients and clinicians agreed some recommendations for rehabilitation to help improve and standardise treatment. We know that some patients manage well without surgery. At present (2023) it is unclear who is an ideal candidate for surgery and who may manage without it.
What are the outcomes of this treatment?	**Preinjury activity level** - 20% of patients return to their preinjury levels of activity 1-year after surgery, 28% return at 18-months and less than 45% return at 2-years. **Work** – The average time to return to work after ACL reconstruction is approximately 2 and a half months. This may be shorter for desk-based jobs and longer for more labour-intensive roles. **Driving** – Typically you can return to driving 6-weeks after your operation.	**Preinjury activity level** - 24% of patients return to their preinjury activity level 18-months after rehabilitation. **Work** – no research to date has collected information on the time to return to work following ACL injury for patients who chose non-operative treatment. **Driving** – there is no set restriction on returning to driving after an ACL rupture. This should be decided by you and your clinician.
If I choose this treatment, what happens next?	If you decide to have surgery, you will be placed on the waiting list. Your clinician should be able to give you an estimated waiting time. Your surgeon will also discuss your graft choice with you. You should also be referred to physiotherapy for support whilst you wait for surgery.	You will be referred to physiotherapy, your clinician should be able to give you an estimated waiting time. You will work with your physiotherapist to develop some goals to work towards. You should start thinking about these now, ready to discuss at your first appointment.

What are the risks?	The risks associated with surgery include: ▪ Re-rupture (7.2%) ▪ Cyclops lesion (21-35%) ▪ Infection (less than 2%) ▪ Blood clot (less than 1%) ▪ Donor site pain/discomfort ▪ Numbness around the knee There is no increased risk of osteoarthritis should you decide to have surgery.	The risks associated with rehabilitation include: ▪ Ongoing, symptomatic instability ▪ Potential for further injury (unclear risk) It is a common thought that, without surgery, you are at risk of a meniscal (cartilage) injury. There is evidence to suggest this may or may not be true. As of 2023, the evidence is unclear. There is no increased risk of osteoarthritis should you decide not to have surgery.
Will I need to have more treatment?	After your ACL reconstruction you will need to undergo a progressive rehabilitation programme with a physiotherapist. This will take at least 6-months and depending on your goal (e.g. if you wish to return to competitive sports), may take longer than 12-months. If complications arise, further surgery may be needed. Otherwise, the graft remains in place and does not need to be replaced in the future unless you have a second injury.	If you do not return to your desired functional level, you can discuss the option of surgery with your clinician.
Are there any other options?	**Repair** There is limited evidence that ACL repair is a successful surgical option to treat an ACL rupture. ACL repair is a technique that does not use a graft and instead repairs the torn ligament with stitches. Research in this area is limited and so at present (2023), we do not have enough evidence to suggest the success of this treatment.	**Self-healing** New evidence was published in 2022 showing the ACL to have healed (to some extent) without surgery. This has been reported in a small number of patients and the long-term effects are mostly unknown. Research in this area is limited and so at present (2023), we do not have enough evidence to suggest the success of this treatment.
What else can I do?	It is important that you consider the following: ▪ **Fitness management** – your clinician may discuss your overall health and fitness with you. This may include your cardiovascular health and weight management to support you in the recovery of your ACL rupture and/or help you prepare for surgery. ▪ **Psychological factors** – research suggests that psychological barriers, such as fear of reinjury, are the most common reason for patients failing to return to their preinjury level of activity. There is also research to suggest that some psychological factors, measured before surgery, can predict your return to preinjury levels after surgery. If you are concerned about your mental wellbeing and feel you would like further support, talk to your clinician. They can signpost you to local services and support you to access further help if needed. ▪ Optimising your **sleep and diet/nutrition** may also be important to help your recovery, if you would like further support, talk to your clinician. ▪ Take time to think about what your **end goal** is, this will help you to think about whether surgery or rehabilitation is the best option for you.	
What does my clinician recommend?	You may wish to gain a recommendation from more than one clinician. (e.g. surgeon 1, physiotherapist, surgeon 2)	
What is my treatment preference?	It is important to think about what treatment you think you would like to have. Write this here to discuss with your clinician.	

APPENDIX O: REVISED IRLM

