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Using a shared decision-making tool with adults after an anterior cruciate ligament injury

Submission date
22/01/2024

Recruitment status
No longer recruiting

Registration date
23/01/2024

Overall study status
Completed

Last Edited
28/08/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
The anterior cruciate ligament (ACL) is the most commonly injured ligament in the knee. ACL tears can be treated surgically or non-surgically. Patients in previous research have reported difficulty with making decisions about treatment. Shared decision-making tools have been used in other patient groups, such as those with knee osteoarthritis, and have been shown to help patients make decisions about treatment. Shared decision-making tools provide evidence-based information about treatment options such as what treatment entails and the associated benefits and harms. They help patients to consider what matters most to them to help with making a decision.
Research about shared decision-making with ACL patients has not been done before. This remains an important gap in the evidence. This study aims to understand the acceptability and feasibility of using a newly designed shared decision-making tool with patients who have torn their ACL.

Who can participate?
Adults aged 18 years and over who have been diagnosed with an ACL tear, and physiotherapists

What does the study involve?
On agreeing to take part in the study, patients will complete an initial questionnaire which will ask some questions about them and their knee injury. They will be provided with the shared decision-making tool (paper and/or online) and referred to a physiotherapist. The physiotherapist will discuss the shared decision-making tool with the patient to see if they have any questions to discuss about their treatment options. After the physiotherapy appointment, patients will be asked to fill in two questionnaires. Patients may also be asked to take part in an interview to discuss their experiences of being involved in the study. The interviews are optional.

What are the possible benefits and risks of participating?
The main benefit of participating in the study will be the information collected by the researcher. This may help inform future research and treatment for patients with anterior cruciate ligament injuries.
There are no anticipated risks of taking part in this study. The main disadvantages are that patients will need to take time out of their day to complete the questionnaires and look at the

shared decision-making tool. Participation in the interview could make patients feel uncomfortable when discussing their experiences. If this is the case, they will be able to end the discussion at any point and will not be forced to discuss anything they do not wish to.

Where is the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2023 to September 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Hayley Carter, hayley.carter1@nhs.net

Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)
333180

Central Portfolio Management System (CPMS)
59482

Study information

Scientific Title
The PreOperative management of Patients awaiting Anterior Cruciate Ligament Reconstruction (POP-ACLR) feasibility study

Acronym
POP-ACLR

Study objectives
Is it feasible and acceptable to use a shared decision-making (SDM) tool in an NHS outpatient setting with patients following an anterior cruciate ligament injury?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2023, Nottingham 1 Research Ethics Committee (postal address not provided; +44 (0)207 104 8115, +44 (0)207 104 8063, +44 (0)207 104 8089; Nottingham1.rec@hra.nhs.uk), ref: 23/EM/0263

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Treatment, Process of Care, Management of Care, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior cruciate ligament reconstruction

Interventions
Recruitment and procedure
Potential participants will be identified by the orthopaedic team during the patient's clinical appointment where they are diagnosed with an ACL rupture. The recruitment of patients has been discussed with surgeons and their administrative assistants at UHDB. Appropriate patients will be identified during their consultation with a member of the orthopaedic team by clinical staff. Clinical staff will also identify appropriate patients from orthopaedic and physiotherapy clinic/waiting lists. They will confirm eligibility and gain consent for the researcher to make contact to discuss the study. If a participant interested in the study does not read or speak English, relevant study material will be translated into their preferred language and communicated with the facilitation of a translator. This will be arranged following normal procedures of the in-house translation service at UHDB.

Procedure
Participants will engage with the SDM tool as part of a normal clinical consultation with a physiotherapist. Baseline data will be collected via paper or online (participant preference) prior to the consultation and will complete follow-up outcome data after the consultation. No further follow-up is required.

Data Analysis
Descriptive statistics will be presented to summarize the baseline variables of participants. The categorical variables (e.g. sex, ethnicity) will be reported with frequencies and percentages.

Outcome
To understand the feasibility and acceptability of the SDM tool. Feasibility outcomes will be collected to support future main trial planning for stop-go criteria. Feasibility data will be collected on:
1. Recruitment rate
2. Fidelity
3. Acceptability
4. Follow-up questionnaire completion

Nested Qualitative Interviews
Qualitative individual interviews will be completed with patients and clinicians participating in the study. Consent will be gained from patients participating in the feasibility study to be contacted to participate in the interviews. Interviews will be used to support understanding of the acceptability of the SDM tool to patients and clinicians, in addition to understanding contamination and factors associated with implementing the tool in clinical practice. Patient and clinician views on study processes will also be explored to support the refinement of the intervention and trial design ahead of a future main trial. Interviews will last approximately 60 minutes and be completed at the hospital, virtually or at a location preferred by the participant. No further follow-up will be required. Framework analysis will be used to analyse interview data underpinned by the Extended Normalisation Process Theory (ENPT).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Four feasibility outcomes measured at the end of the study:
1. Recruitment rate measured as the number of eligible participants who consent to participate in the study
2. Fidelity measured by reviewing the case report form to establish the content of the clinical consultation against the predefined SDM tool content/guidance delivered during training to physiotherapists
3. Acceptability measured using an acceptability questionnaire completed by participants within 4 weeks of their clinical consultation using the SDM tool
4. Follow-up questionnaire completion measured as the number of questionnaires completed by participants

Key secondary outcome(s)
1. Satisfaction with treatment decision will be measured using the satisfaction with decision (SWD) scale up to 4 weeks following the clinical consultation where the SDM tool is used
2. Implementation factors will also be explored through individual qualitative semi-structured interviews conducted with patient participants and treating clinicians after completion of the clinical consultation

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Feasibility:
1. >=18 years old
2. Confirmed first-time ACL rupture via MRI

Qualitative interviews:
1. Clinician or patient with experience of using the SDM tool

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
Feasibility:
1. Concomitant injuries requiring surgical intervention that will significantly alter usual treatment e.g. fracture
2. Previous knee surgery to the affected limb
3. Pregnancy (as this is likely to affect decision-making regarding surgical treatment)

Date of first enrolment
29/01/2024

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
Uttoxeter Road

Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: NIHR302104

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/08/2025	28/08/2025	Yes	No
Protocol article		07/05/2024	08/05/2024	Yes	No
Participant information sheet	version 1.2	21/12/2023	22/01/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes