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Prehabilitation for children having planned lower limb surgery: can preparation before surgery improve recovery?

Submission date 11/06/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/06/2026	**Overall study status** Ongoing	
Last Edited 30/10/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Waiting times for children needing bone and joint surgery are increasing, which can be difficult for children and their families. In adults, rehabilitation programmes before surgery (known as prehabilitation) can help improve recovery and reduce length of hospital stay, and there is some evidence to suggest it's more cost-effective for the NHS. However, we don't know if this works the same way for children. Before starting PREPARE KIDS, we carried out a smaller study. The results suggested that prehabilitation could reduce the time children spend in hospital after surgery. The programme involved children learning how to use walking aids, practising exercises similar to those they may do after surgery, and understanding what to expect during recovery. We are now carrying out a larger study. The aim of the PREPARE KIDS study is to find out whether this prehabilitation programme can improve recovery in children undergoing planned lower limb surgery. The main measure of recovery will be children's functional mobility at two weeks after surgery, assessed using the PROMIS questionnaire.

Who can participate?
Children aged 5 to 14 years old (i.e., from their 5th birthday up to, but not including, their 15th birthday) who are awaiting planned (non-emergency) hip, leg or foot surgery.

What does the study involve?
Once participants agree to take part, they will complete questionnaires before surgery. Children will then be randomly assigned to one of two groups. One group will receive a prehabilitation ('Get-Ready') session alongside usual care before surgery. This session includes learning how to use mobility aids if needed, practising exercises similar to those used after surgery, and discussing what to expect during recovery. The other group will receive usual NHS care alone. Usual care refers to the standard care children normally receive before surgery. This may vary slightly between hospitals but can include discussing the procedure with doctors, a clinical examination, and any necessary tests before surgery.
The child's surgery and postoperative care will take place as planned, regardless of which group they are assigned to.
Participants will be asked to complete follow-up questionnaires 2, 6, and 12 weeks after surgery.

What are the possible benefits and risks of participating?
Participation will help researchers understand whether preparing children for surgery can improve recovery. The findings may help improve care for children undergoing planned lower limb surgery in the future. The study team will also aim to make participation a positive experience and provide support and reassurance for children and their families throughout surgery and recovery.
Taking part in this study is considered safe; however, the following should be noted:
Exercises: Children allocated to the prehabilitation group will be asked to complete exercises before surgery. These exercises require additional time and may cause temporary muscle tiredness or mild discomfort.
Mobility aid training: Some children may receive training in the use of mobility aids, such as crutches or walking frames. As with normal use of these aids, there is a small risk of slipping or minor injury. Training will be provided by a qualified clinician to ensure safe use.

Where is the study run from?
The study is sponsored by the University of Oxford. It is coordinated and managed by the Surgical Intervention Trials Unit (SITU), part of the Oxford Clinical Trials Research Unit (OCTRU) at the University of Oxford. The study will take place at participating NHS hospitals across the United Kingdom.

When is the study starting and how long is it expected to run for?
August 2026 to October 2028

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
366508

Central Portfolio Management System (CPMS)
74449

National Institute for Health and Care Research (NIHR)
167724

Study information

Scientific Title
Pre-operative rehabilitation (prehabilitation) in elective lower limb paediatric orthopaedic surgery

Acronym
PREPARE KIDS

Study objectives
To assess clinical and cost-effectiveness of prehabilitation compared to usual care for children undergoing elective lower limb orthopaedic surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/07/2026, London - Fulham Research Ethics Committee (Health Research Authority 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8021; fulham.rec@hra.nhs.uk), ref: 26/LO/0452

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Elective lower limb paediatric orthopaedic surgery

Interventions
The PREPARE KIDS study is a research study to find out whether giving children a prehabilitation session before planned lower limb surgery, alongside their usual NHS care (Group 1), helps them recover and move better after their operation compared with children who receive usual NHS care alone (Group 2).

Children may be identified at participating hospitals using different methods, depending on local practice. These may include:
1. Waiting lists
2. Routine clinic appointments
3. Study advertising materials

In all cases, the child's direct clinical team will make the first contact and introduce the study using age-appropriate information, such as a study explainer animation/Participant Information Sheet (PIS).

As part of the initial discussion between families and the direct clinical team, and if agreement is given to share details, the site research team may follow up with families as appropriate.

Each site will complete screening forms to record basic information and any reasons why a child does not take part.

Consent, assent and baseline information:
If a family is interested, the site team will check whether the child is eligible to take part. If

eligible:
1. Parents/guardians will be asked to give consent.
2. Children will be invited to give assent.

Electronic consent and assent may take place either remotely or during a clinic visit. Families will have time to read the study information and ask questions before deciding whether to take part.

Where electronic consent is not possible, written consent/assent may be obtained by post or in clinic.

After consent/assent has been obtained, participants and families will complete a baseline questionnaire about the child's health, pain and mobility. This must be completed before the child is randomised.

Parent(s)/guardian(s), together with their child, will complete the questionnaires.

Children aged 8 years and over will be invited to complete some questions about their own health and wellbeing (EQ-5D-Y-3L) and mobility (PROMIS Mobility Score for Children) if they are willing and able. If they choose not to, or if the child is under 8 years of age, this questionnaire will be completed by the parent/guardian with input from the child. This will be agreed at the start of the study (before group allocation).

Some questions will be for parents/guardians only, such as those about their own health and wellbeing (EQ-HWB-9). After consent has been obtained and the baseline questionnaire completed, children will be randomly assigned to one of two groups. Each child has an equal chance of being in either group:
Group 1: Prehabilitation programme plus usual NHS care
Group 2: Usual NHS care only

Group 1: Prehabilitation programme plus usual care:
Children in this group will attend a prehabilitation session, lasting about 45 minutes, usually around 6 weeks before surgery. Where possible, this will take place on the same day as the child' s preoperative clinic.

The prehabilitation session includes three key components:
1. An individually tailored exercise programme (the treating clinician will give the child exercises to practise before the surgery).
2. Training on how to use mobility aids (focused on practising how to move around safely using mobility aids like crutches or a frame).
3. A pre-agreed discharge plan (this includes how long they are expected to stay and how their pain and movement will be managed).
The 'Get-Ready' session aims to help children prepare for recovery after surgery by practising exercises and, if needed, using mobility aids so they know what to expect.
Children in this group will also receive all of their usual NHS care.

Group 2: Usual NHS care only:
The exact details may vary depending on each hospital's usual practice. This may include consent for surgery, physical examinations, any required tests and other routine discussions such as checks to ensure a safe journey home, hospital contact details, wound care and guidance on anticipated time off school.

Surgery and follow-up:
All children will have their surgery as planned. After surgery, children and their parents /guardians will be asked to complete follow-up questionnaires at 2 weeks, 6 weeks and 12 weeks after surgery.
Questionnaires are completed remotely electronically, with postal completion available if electronic completion is not feasible as back-up only. The questionnaires used in this study are widely used and quick to complete.
Hospital records will also be reviewed to collect information such as length of hospital stay, use of healthcare services, and any complications related to surgery, from the time of surgery up to 12 weeks afterwards.

Pilot phase and additional study components:
The study includes an internal pilot phase (10 months) to make sure recruitment, study procedures, and data collection work as planned. This helps identify and fix any problems early, before the main study continues.

Process evaluation:
Led by the University of Warwick, this will involve remote (online or telephone) interviews with children, parents, clinicians, and researchers during both the internal pilot and main stages of the trial. The purpose is to maximise recruitment, reduce variation in how the intervention is delivered, and gain a better understanding of participants' experiences, trial processes, and how closely the intervention is delivered as intended during the main trial. Participants who are interested will be provided with information leaflets and will give their consent to take part.

Health economics:
This part of the study will help us understand whether the prehabilitation approach is cost-effective and what impact it could have on NHS resources.

Justification for principal research question:
The main outcome looks at how well children can move two weeks after surgery, as discussions with clinicians and patients/families have told us that early recovery of movement and strength are important for overall recovery. The timing for this (2 weeks postoperatively) allows the study to capture early benefits that might be missed if recovery was only measured later.

The main outcome (PROMIS questionnaire) will be completed by parents/carers, with input from the child where appropriate. This approach is used because younger children are not recommended to complete it on their own, and the child and parent versions are not directly comparable.

Young people, parents, and clinicians have helped shape this study. Their feedback has directly influenced the study design and the patient-facing materials used in the study.

Intervention Type
Other

Primary outcome(s)
Functional mobility is measured using the PROMIS Mobility Score for Children (MSC), Parent Proxy Version, at 2 weeks postoperatively

Key secondary outcome(s)

1. Functional mobility is measured using the PROMIS Mobility Score for Children (MSC), Parent Proxy Version, at baseline, 6 weeks, and 12 weeks postoperatively
2. Functional mobility is measured using the PROMIS Mobility Score for Children (MSC), Parent Proxy Version and Self-Reported Version (≥8 years), at baseline, 2 weeks, 6 weeks, and 12 weeks postoperatively
3. Pain is measured using the Wong-Baker FACES Scale (WBS) at baseline, 2 weeks, 6 weeks, and 12 weeks postoperatively
4. Health-related quality of life is measured using the EQ-5D-Y-3L (self-reported for children ≥8 years or parent proxy version for children <8 years) at baseline, 2 weeks, 6 weeks, and 12 weeks postoperatively
5. Carer health and wellbeing is measured using the EQ-HWB-9 at baseline and 12 weeks postoperatively
6. Parental satisfaction is measured using a Parental Satisfaction Questionnaire (Likert scale) at 12 weeks postoperatively
7. School attendance is measured using an Educational Participation Questionnaire at 12 weeks postoperatively
8. Length of hospital stay is measured using the number of postoperative nights spent in hospital at 12 weeks postoperatively
9. Surgical complications are measured using the Modified Clavien–Dindo Classification System at 12 weeks postoperatively
10. Healthcare resource use is measured using a study-specific questionnaire and review of medical records at 12 weeks postoperatively
11. Use of additional childcare services measured using a study-specific questionnaire at 12 weeks postoperatively
12. Use of additional carer time off work measured using a study-specific questionnaire at 12 weeks postoperatively

Completion date
31/10/2028

Eligibility

Key inclusion criteria
Main Study:
1. Aged 5-14 years (i.e., from their 5th birthday up to, but not including, their 15th birthday at the time of consent)
2. Scheduled for elective lower-limb surgery (hips to toes, excluding toenail surgery)

Process Evaluation:
Children:
1. Currently enrolled in the main study
2. Parent/guardian has provided informed consent for the child's participation in the interview study
3. Child is willing and able to participate in the interview

Parent/Guardian:
1. Parent/Guardian of a participant enrolled in the main study
2. Has provided consent to be contacted regarding interview study
3. Willing and able to give informed consent for participation in the interview study

Site Clinical/Research Staff:
1. Clinical and research staff participating in the PREPARE KIDS study
2. Willing and able to give informed consent for participation in the interview study

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
14 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Main Study:
1. The child is currently receiving a physiotherapy programme which replicates the content of PREPARE KIDS
2. The child and/or their parent(s)/guardian(s) are unable to comply with assessment procedures
3. Previous participation in PREPARE KIDS study

Process Evaluation:
Children:
1. Withdrawn from the main study

Parent/Guardian:
1. No longer acting as parent/guardian of a participant enrolled in the main study
2. Child withdrawn from the main study

Site Clinical/Research Staff:
1. No longer involved in the conduct of the main study

Date of first enrolment
10/09/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
England
HA7 4LP

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
England
PE3 9GZ

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
London
England
SW17 0QT

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
England
L12 2AP

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London
England
WC1N 3JH

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
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CF14 4HH

Study participating centre
Robert Jones & Agnes Hunt Orthopaedic Hospital
Gobowen
Oswestry
England
SY10 7AG

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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England
CV2 2DX

Study participating centre
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UB8 3NN

Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. At the end of the trial, the trial statistician will prepare a data-sharing package (including a dataset along with the corresponding metadata description) of de-identified participant data, provided sufficient anonymity of participants can be achieved. This data sharing package will cover the main results of the planned statistical analyses. Other trial data may be available upon reasonable request, provided sufficient safeguards to participant identification can be ensured and subject to agreement of relevant parties. De-identified research data may be shared with other organisations upon request. All requests for data sharing will be handled in accordance with the OCTRU Standard Operating Procedure on Data Sharing and will be considered in accordance with the data sharing policies of OCTRU, the Sponsor and funder(s). De-identified data may also be used for teaching and learning purposes.

IPD sharing plan summary
Available on request