Sheffield Children's NHS
NHS Foundation Trust

# Pilot study of the effect physiotherapy led prehabilitation has on hip function and strength following peri-acetabular osteotomy for the management of idiopathic adolescent hip dysplasia.

## Effect of prehabilitation in adolescents undergoing peri-acetabular osteotomy.

**STUDY NUMBER** 317048

**10th APR 2025 Version 1.1**

**For The Sheffield Children's Hospital Charity funding calls**

Each section of the application form has a designated word count shown at the end of each section header. **It is imperative that you stay within these word limits.** During the application validation process the research team will remove any additional text that exceeds section word limits and this text will not be seen by reviewers of the application.

Sponsor's Representative …….. Dated ……..

Chief Investigator …… Dated ……..

**LAY SUMMARY**

This study is designed to investigate the impact of a patient specific physiotherapy prehabilitation programme on the outcomes of patients presenting with symptomatic hip dysplasia.

Prehabilitation for peri-acetabular osteotomy (PAO) surgery has not previously been investigated and we do not know the effect it would have on the post-surgical outcomes.

A clinical study is required to investigate the impact formal prehabilitation has on patients undergoing PAO. We will carry out a pilot project to ensure we have the right study design with appropriate outcomes, and that children and families will consent to taking part.

The pilot project will be funded by The Children's Hospital Charity (TCHC). Once successfully completed, we will apply for funding for a large scale, multicentre trial.

Following completion of our research project we will be able to advise patients on the expected effect of prehabilitation on the outcomes of this surgery.

We hypothesise that patients who have a period of prehabilitation prior to surgery will have better physical outcome measures and hip outcome scores compared to those who do not have prehabilitation.

## GENERAL INFORMATION

| **Sponsor:** | **Sponsor's Representative/Contact:** |
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## GLOSSARY

| **Abbreviation** | **Term** |
|---|---|
| PAO | Peri-acetabular osteotomy |
| NAHS | Non arthritic hip score |
| HOOS | The hip disability and osteoarthritis outcome score |
| iHOT-12 | International hip outcome score (12 items) |
| EQ5D | EuroQol 5 Dimension (quality of life outcome measure) |
| SCH | Sheffield Children's Hospital |
| ROM | Range of movement |
| eDMS | Online notes and patient management system |
| Idiopathic hip dysplasia | Dysplasia of the hip joint which occurs without any known cause |
| Prehabilitation | Exercise programme commenced prior to a planned surgical procedure |
| STS5 | Sit to stand 5 times |
| TSA | Timed stairs assent |

## 1.0 BACKGROUND

Prehabilitation in paediatric lower limb surgery is a top priority for the James Lind Alliance. It has become an area of increasing research although this is predominately within adult populations and involves a wide range of types of surgery (Santa Mina et al., 2014). Adult research has generally show positive outcomes when prehabilitation is added into a surgical pathway with increased patient outcomes, reduced length of stay and reduced costs (Banugo and Amoako, 2017). Quality research is, however, limited and studies cover a wide population of patients. Confident application of research findings to a paediatric, orthopaedic cohort of patients is therefore limited.

Peri-acetabular osteotomy (PAO) is an orthopaedic surgery involving the hip. Following surgery, the patient will have a period of reduced mobility and they will be unable to weight bear through the operated limb. A period of time non-weight bearing is known to have a negative effect on the musculoskeletal systems in terms of muscle atrophy (Yoshiko et al., 2018) and reduced bone mineral density (Loud and Gordon, 2006). It could be proposed that patients entering into a surgical procedure with a higher level of strength and function will return to an improved physical state post-operatively quicker than those with lower physical function (Ditmyer et al., 2002) and will help limit the effects of the enforced inactivity immediately post-operatively (Punnoose et al., 2019).

Within a paediatric setting simple prehabilitation in terms of crutch provision and education around the post-operative rehabilitation has been shown to reduce length of stay in paediatric patients (Brady et al., 2021). Reduced length of stay increased post-operative outcomes and a quicker return to full function and sport are all desirable outcomes for this patient group and their families.

The proposed project aims to establish if there are signals of meaningful improvement in patient outcomes when a course of prehabilitation is undertaken prior to PAO. We also will establish if the proposed study design is suitable, the outcome measures chosen are appropriate and patients/families are happy to be involved in a project like this. This will allow us to investigate the feasibility of a future multi-centre study to investigate the impact of prehabilitation prior to PAO.

We hypothesise that patients will have improved hip strength and function when they enter into surgery at an increased level of physical function following a period of prehabilitation. This project will enable us to plan and implement a multicentre study to investigate this.

## 2.0 STUDY OBJECTIVES AND PURPOSE

The purpose of this pilot study is to evaluate the feasibility of a clinical trial investigating the impact of a physiotherapist led prehabilitation programme on hip strength and function following PAO surgery.

**Primary Objective:**

To evaluate the physical outcome measures between participants who receive prehabilitation physiotherapy before surgery and children who receive only postoperative physiotherapy.

**Secondary Objective:**

To evaluate patient reported outcome measures.

Cost effectiveness of providing prehabilitation to children.

The objectives of this pilot study are to investigate

- Suitability of the chosen outcome measures
- If there are signals of positive outcomes within the prehabilitation group.
- Recruitment strategy, rate and retention
- Data collection and management
- Establish the cost of running this project to enable calculations of the cost of a larger project.

## 3.0 STUDY DESIGN

This study is a prospective, randomised feasibility study evaluating the effectiveness of providing children with idiopathic hip dysplasia prehabilitation physiotherapy before PAO surgery. The study team will identify, and recruit patients diagnosed with idiopathic hip dysplasia and due to be listed for PAO surgery at Sheffield Children's Hospital. In total 12 patients will be recruited for this pilot study.

Eligible patients will be approached and recruited by delegated members of the research team in their standard of care clinic visits. All recruited participants will then attend a baseline visit with the study physiotherapist; they will assess each patient for a series of physical outcome measures:

- Hip flexion, abduction and adduction muscle power using a handheld dynamometer.
- Sit to stand 5 times.
- Timed stairs assent
- Hip Outcome scores (iHOT NAHS, HOOS, EQ5D)

Then the study physiotherapist will randomise each patient, using a sealed envelope method, into a treatment arm involving prehabilitation (Group 1) and one treatment arm which follows standard of care procedures (Group 2).

Group 1 will attend SCH for a prehabilitation programme whilst they await surgery. Prehabilitation programmes will involve strengthening exercises for hip flexors, abductors, adductors, trunk strengthening and lower limb control work. The exercise programme will be tailored to the participants age and current ability. The participant will be reviewed by the physiotherapist and the exercises will be progressed/adapted as needed throughout the process. Advice and education will be given about the post-operative rehabilitation process and use of crutches will be taught prior to surgery.

Group 2 will be issued with an information leaflet about exercising before surgery.

All patients will have their physical outcome measures assessed again by a member of the research team, immediately prior to surgery and 6 months post operation. The results will be collated, and pseudo anonymised by a member of the study team.

All outcome measure and hip outcome scores will be compared between groups.

The length of time the patients will be involved will be variable depending on the waiting list for surgery. The study will finish at 6 months post-operative.

The primary end point of the study will be the comparison of change in function outcome (STS5 and TSA), between patients having undergone prehabilitation, and those who have not, following PAO surgery.

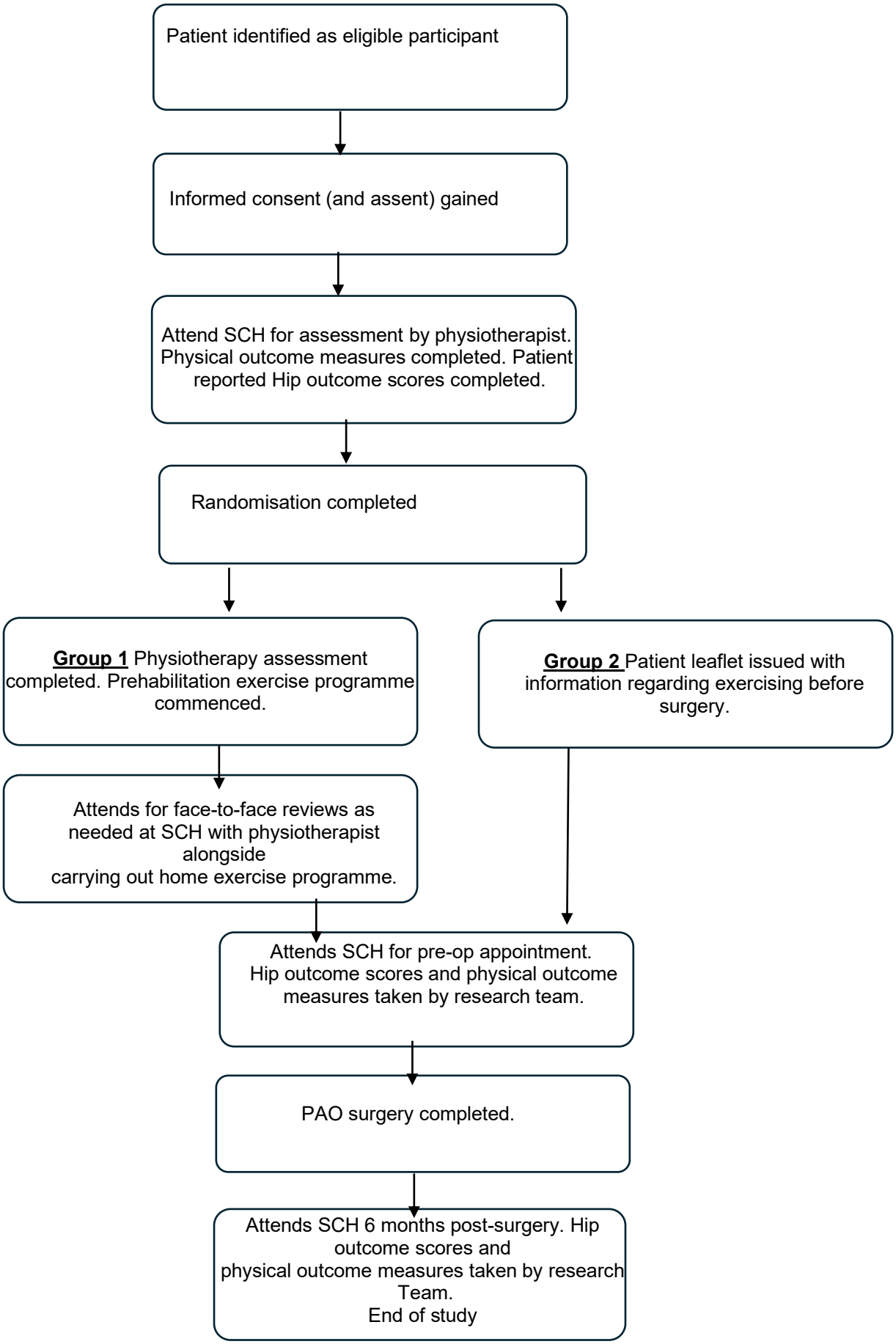
The secondary end points of the study, include the change in non arthritic hip score pre-operatively, following a period of prehabilitation, and the change in functional physical assessment pre-operatively, following a period of prehabilitation.

There are no additional risks from surgical intervention as this does not differ from our standard practice. There is a risk of increased pain from completing exercises, but any symptoms will be monitored by the physiotherapist and the exercise programme modified as needed. There is risk of injury from the exercises. The patient will be monitored throughout the prehabilitation stage and will have opportunity to feedback to the physiotherapist regularly.

The physiotherapy assessment and intervention will be carried out by Philippa Fenlon (Advanced physiotherapist). Clinical outcome measures will be taken by Miss Caroline Blakey (Consultant orthopaedic surgeon), Philippa Fenlon and Nicola Brown (Advanced nurse practitioner).

The end of the study will be when the final participant’s last protocol-defined assessment has been completed. This will be at the assessment 6 months post-surgery.

**Flow-chart of the study**



## 4.0 SELECTION OF PARTICIPANTS

This study will involve patients based at Sheffield Children's Hospital under the care of Miss Caroline Blakey and Mr Sanjeev Madan. Patients will be recruited from orthopaedic clinic having been considered for periacetabular osteotomy.

Approximately twenty participants would be expected to be eligible per year for inclusion in the study. The target sample of size will be 12 which as this is the minimum sample size recommended for a pilot study (Julious, 2005)

*Inclusion Criteria*

- Idiopathic hip dysplasia listed for PAO surgery
- Able to attend physiotherapy assessment and follow-up at SCH

*Exclusion Criteria*

- Unable to follow instruction and carry out a home exercise programme safely and independently
- PAO surgery not an appropriate treatment option
- Tonnis 2 or greater radiographic changes
- Incongruent hip joint / salvage hip surgery

## 5.0 PARTICIPANT RECRUITMENT

Eligible patients will be identified by their treating clinician at their normal standard of care clinic appointment. Potential participants will be provided with a participant information sheet to take home. If they want to join the study, the participant will be consented at their next appointment at SCH. Consent will be obtained by a GCP trained clinician delegated on the study.

A follow-up appointment will be made to discuss additional results and further discussion of treatment options before listing for surgery. Consent for the study will be obtained at the second clinic review by a GCP trained clinician working on the study. SCH translation services for will be provided for patients and families if required.

Before randomisation to a treatment arm, patients will be assessed by the study physiotherapist for a series of outcome measures (see flowchart in section 2.0). Once complete, the physiotherapist will randomise the patient using a sealed envelope method to either prehabilitation arm (Group 1) or post rehabilitation arm (Group 2). If the patient is randomised to the prehabilitation arm they will be assessed further and provided with a tailored exercise programme before their scheduled PAO surgery.

Participants randomised to Group 1 will be reimbursed their travel expenses for attending the additional research appointments. All other orthopaedic clinic appointments or post operative physiotherapy sessions are standard of care and will not be reimbursed.

Patients can withdraw from the study at any point without giving a reason and this will have no impact on their standard of care treatment. Data from Group 1 participants who are non-compliant will be included in the final statistical analysis.

The study will end when the last participant has reached 6 months post-surgery.

## 6.0 DATA HANDLING AND RECORD KEEPING

All source documentation for patients from their research visits will be stored on eDMS. Each participant will be assigned a study number by a member of the research team. All patient data from this pilot study will be pseudonymised and inputted onto a master excel password protected spreadsheet that will be stored on NHS servers. Data will be collected and retained in accordance with the Data Protection Act 2018.

Trial documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of 5 years following the end of the trial. Where trial related information is documented in the medical records – those records will be retained for 5 years after the last patient last visit.

## 7.0 ACCESS TO SOURCE DATA

The sponsor will permit monitoring and audits by the relevant authorities, including the Health Research Authority and Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents.

## 8.0 STATISTICAL ANALYSIS

The primary and secondary outcome measures used in the study will produce quantitative data. If the data is normally distributed a two-sample t test will be used to analyse the data. Patients who withdraw from the prehabilitation process but continue to have surgery will be included in the analysis.

As this is a pilot study statistical significance will be interpreted with caution as is recommended for pilot studies (Lancaster, Dodd, & Williamson, 2004).

## 9.0 SAFETY ASSESSMENTS

The study is in line with the current practice at Sheffield Children's Hospital and therefore risk assessments have already been carried out for each procedure. Further risk assessment is completed at the physiotherapy assessment and re-done after surgery to reflect any changes in risk.

Serious adverse events in relation to surgical procedure will be reported as per the normal protocol for surgical adverse events and reported to the Sponsor within 24 hours.

The study will be monitored and audited in accordance with the Monitoring Standard Operating Procedures of the Directorate of Research & Innovation at Sheffield Children's NHS Foundation Trust. All study related documents will be made available on request for monitoring and audits by the Sponsor, the Health Research Authority and the relevant Research Ethics Committee.

## 10.0 ETHICAL CONSIDERATIONS

The study will be conducted in compliance with a Research Ethics Committee favourable opinion, Health Research Authority approval and Confirmation of Capacity & Capability at all participating sites.
The study will also be conducted in accordance with the International Conference for Harmonisation of Good Clinical Practice (ICH GCP), and the Research Governance Framework for Health and Social Care (2nd Edition).

## 11.0 FINANCE AND INDEMNITY

Participants will be reimbursed for the travel to prehabilitation appointments and pre-operative assessment by the physiotherapist as these are outside of current standard care. Participants will not be paid for their involvement in the study.

This is an NHS sponsored study. For NHS sponsored research HSG (96) 48 reference no. 2 refers. If there is negligent harm during the study when the NHS body owes a duty of care to the person harmed, NHS Indemnity will cover NHS staff, medical academic staff with honorary contracts and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

## 12.0 JUSTIFICATION OF FINANCE

This application is seeking funding for additional appointments in physiotherapy as required. Current practice would only cover participants aged under 16 at the time of referral to physiotherapy. In addition, funding will allow for reimbursement of travel for participants for all appointments outside of standard care.

Funding is sought for the time of Miss Blakey (Chief Investigator) and Philippa Fenlon (Principal Investigator) outside of their current clinical practice.

## 13.0 JUSTIFICATION OF RESOURCES

The use of a dynamometer is an additional resource not currently used to monitor strength in the physiotherapy sessions. The dynamometer is owned by the Physiotherapy department and available for use as needed with no extra cost.

## 13.0 REPORTING AND DISSEMINATION

Results will be presented through conference presentation and publication in peer reviewed journals. Results of the study will be available to participants via a variety of methods. With support from the trust communications team we will share the project findings via the trust website and social media channels as appropriate.

## 14.0 **IMPACT**

The findings of this study will be used to guide the planning of the management of adolescents presenting with symptomatic hip dysplasia. It will allow the team at SCH to give better, more evidence based, guidance to patients awaiting PAO regarding preparation for surgery. The results of the pilot study will help us in planning and implementing a larger multi-centre trial.

## **15.0 OUTCOMES**

Results will be available if relevant for wider studies.

**TABLES, FIGURES AND REFERENCES**

**APPENDICES**

Appendix 1 – data collection form.

| Patient No: | | Visit No: | | | Date completed: | | |
|---|---|---|---|---|---|---|---|
| Physical Outcome Measure | | Right | | | Left | | |
| | | Attempt 1 | Attempt 2 | Attempt 3 | Attempt 1 | Attempt 2 | Attempt 3 |
| Sit to stand 5 times | | | | | | | |
| Timed stairs assent | | | | | | | |
| Hip flexion strength | | | | | | | |
| Hip abduction strength | | | | | | | |
| Hip adduction strength | | | | | | | |

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