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Title {1a} Pavlik harness treatment versus active surveillance for the treatment of Developmental Dysplasia of the Hip (DDH) in babies diagnosed with Graf type 2 hips: Mixed Methods research protocol

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Study protocol

Keywords: Hip Dislocation, Congenital

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Title {1a} Pavlik harness treatment versus active surveillance for the treatment of Developmental Dysplasia of the Hip (DDH) in babies diagnosed with Graf type 2 hips: Mixed Methods research protocol

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Abstract
Background: Brace treatment is the cornerstone of managing developmental dysplasia of the hip (DDH), yet there is a lack of consensus around evidence-based treatment protocols for stable immature hips, which results in wide variations in practice locally in the United Kingdom, as well as globally. Emerging evidence from other countries demonstrates that bracing may not be necessary in Type 2 hip dysplasia. This mixed methods study to evaluate whether similar results are obtained in the United Kingdom and bracing may not be required for type 2B and 2C hip dysplasia.

Methods: This study evaluates whether Pavlik harness treatment is required for Type 2b and 2c hip dysplasia (using the Graf method of diagnosis on ultrasound). Babies under 16 weeks of age will be recruited and randomised to either a Pavlik Harness group or a surveillance group. The babies in the Pavlik harness group will have a harness applied on diagnosis and will be scanned using ultrasound every 3 weeks until their hips mature and they achieve an alpha angle of ≥60 degrees. The babies in the surveillance group will not have any brace applied, and will be scanned every 3 weeks until their hips mature and they achieve an alpha angle of ≥ 60 degrees. They will be placed in a Pavlik harness if the results of two consecutive scans do not demonstrate an improvement in alpha angle. A questionnaire evaluating parenting stress (The Parenting stress Index Short Form) will be administered to caregivers at the 3 week post-baseline visit. Both groups of babies will have a hip x ray at 9 months and 15 months, and the acetabular index will be measured. Focus groups to obtain qualitative data from parents around their experiences of a diagnosis of DDH as well as experiences of Pavlik Harness Treatment or surveillance will be conducted.

Discussion: This study is the first in the United Kingdom to evaluate whether Type 2b and 2b hip dysplasia may not require treatment by Pavlik Harness. The concurrent use of focus groups will also help to determine parent/caregiver experience of bracing versus monitoring.

Trial registration: Trial registration number: NCT07111858. Registration date 2025/08/01
https://clinicaltrials.gov/study/NCT07111858?cond=DDH&intr=monitoring&viewType=Card&rank=2

Keywords
Hip Dislocation, Congenital
Infant
Orthotic Devices
Ultrasonography

Structured summary {1b}

Item	Description
Primary Registry and Trial Identifying Number {4}	Clinicaltrials.gov NCT07111858
Secondary Identifying Numbers	

Source(s) of Monetary or Material Support	*Association of Chartered Paediatric Physiotherapists*
Primary Sponsor and contact information {3b}	Maidstone & Tunbridge Wells NHS Trust mtw-tr.researchgovernance@nhs.net
Role of sponsor and funder {3c}	Sponsor role: governance Funder: financial research bursary
Contact for Public Queries	Nicole.hilburn@canterbury.ac.uk
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Public Title	Pavlik harness treatment versus active surveillance for the treatment of Developmental Dysplasia of the Hip (DDH) in babies diagnosed with Graf type 2 hips: Mixed Methods research protocol
Scientific title	Pavlik harness treatment versus active surveillance for the treatment of Developmental Dysplasia of the Hip (DDH) in babies diagnosed with Graf type 2 hips: Mixed Methods research protocol
Countries of Recruitment	United Kingdom
Health Condition(s) or Problem(s) Studied	Developmental Hip Dysplasia
Intervention(s)	Active surveillance
Key Inclusion and Exclusion Criteria	Inclusion criteria • 2b or 2c hip dysplasia – ultrasound findings confirmed by consultant and ultrasonographer using the Graf method • Age: birth to 16 weeks (2c) and 12 weeks to 16 weeks (2b) • Informed written consent given by parent Exclusion criteria • Babies with associated neuromuscular, genetic or neurological conditions which may complicate the course of treatment • babies who have unstable hips on clinical examination • over 12 weeks of age at initial diagnosis
Study Type	Mixed methods: Randomised controlled trial (parallel group design); and focus groups to obtain qualitative data
Date of First Enrolment (planned)	February 2023
Sample Size	The a priori hypothesis in the study protocol was that there is no difference in treatment effect between the two groups. A Two One-sided T- test (TOTS) of Equivalence showed that 50 hips were needed in each group to reach a power of 90% with a significance of 5% (two-sided) and average alpha angle of 58 degrees in both groups (SD 8.2). The mean group difference ranging between −5 and + 5 degrees led to a conclusion of equivalence.
Primary outcome(s)	Acetabular maturity as evidenced by an alpha angle of ≥60 using the Graf method of analysis
Key Secondary outcome(s)	Parenting stress as evidenced by the Parenting Stress Index Short form (26) Long term acetabular maturity: x rays at 9 and 15 months of age, measuring Acetabular Index Qualitative data on caregiver experiences of harness and non-harness treatment (focus groups)
Ethics Review	Ethical approval has been obtained from the Health Research Authority (22/EM/0149).
Individual Trial Participant Data sharing statement	Deidentified individual participant data (IPD) for all primary and secondary outcomes, together with the study protocol

	and statistical analysis plan (SAP), will be made available to qualified researchers upon reasonable request. These materials will be accessible starting 6 months after publication of the main trial results and will remain available for 5 years thereafter

Protocol version {2}
Version 9 19/8/2025
Introduction

Background and rationale {9a}
Developmental dysplasia of the hip (DDH) is a common cause of childhood disability, and diagnosis after 3 months may lead to the need for more complex treatment (1). The incidence in the United Kingdom (UK) before ultrasound (US) screening became available was 1–2 per 1000 babies (2). Since the advent of selective US screening, estimates in incidence in the UK range from 5-30 per 1000 (2). In terms of criteria for screening, there is consensus that a family history of DDH, female gender, breech presentation, primiparity and oligohydramnios increase the risk of DDH, although screening criteria vary amongst UK centres (3). There is a lack of evidence to support birth weight, prematurity, multiple pregnancy, mode of delivery or the presence of foot deformity as increased risk-factors for DDH (4, 5, 6).
Radiographic depiction of the hip is difficult in the first few months of life, due to the absence of the ossific nucleus. The advent of ultrasound (US) has significantly impacted these challenges, and this method has become popular since the first paper describing it by Graf in 1980 (7). The Graf method has been accepted as the Gold Standard in Ultrasound analysis in the UK (8). The method involves an ultrasound examination to measure two angles, alpha and beta, formed by three lines on the hip joint image: the bony roof, the baseline, and the cartilage roof. Based on these angle measurements, the hip is classified into types I through IV. An alpha angle greater than 60°, representing a normal hip, is classified as Type I. An alpha angle between 50° and 59°, representing immature hips, is type IIa/IIb. Alpha angles less than 50°, representing advanced dysplasia, are classified as type IIc/D (7)

It is unclear in well-centred, stable hip dysplasia (Type 2), whether treatment alters the natural history of the development of the hip. Randomised trials of abduction treatment of dysplastic hips according to the existing classification systems have failed to show a difference between the treatment and non-treatment groups between six weeks and three months, and between three months and six months (9,10,11).

While low risk, the Pavlik harness is not entirely benign. The rate of avascular necrosis (AVN) varies widely according to application (12, 13), and has been associated with a longer duration of treatment, as well as late presentation. Rates of around 9,6% have been associated with later diagnosis (14, 15, 16). While other complications from a harness which has been correctly applied are rare, it may cause skin crease dermatitis and femoral nerve palsy (which has been linked with treatment complication) (17, 18, 19). The incidence of femoral nerve palsy has been reported be between 2.5 to 11% (20, 21) It is therefore beneficial to keep time spent in a harness to a minimum, and initiate treatment only when necessary.

Westacott and Perry (2020) (22) conducted a consensus study of British Society for Children's Orthopaedic Surgery members in which 35% of respondents stated that they treat a stable dysplastic hip in an infant of less than six weeks of age with a flexion/abduction orthosis. Fifty three percent had a treatment threshold (the mildest form of hip pathology deemed to require treatment) of dysplasia at above six weeks of age, and for 11%, the threshold was an unstable or dislocatable hip. There was near universal agreement that subluxed or dislocated but reducible hips require treatment at any age. Forty three percent would attempt to treat a dislocated but irreducible hip with a harness. There were no identifiable trends among those who treat dysplasia under six weeks of age.

Past research has demonstrated that DDH orthotics present an emotional and physical barrier to cuddling and are perceived to hinder the quality of attachment between parent and child (17,19, 23). It is therefore crucial to consider and evaluate parent experiences of treatment, and ensure that treatment is provided only when necessary. National programmes such as the United Kingdom's 'Getting It Right First Time' promotes standardisation of care by healthcare providers (24), and the committee of the Newborn and Infant Physical Examination Programme (25) has indicated that standardisation of diagnosis and treatment pathways would be a prerequisite for establishing a national universal ultrasound screening programme in the United Kingdom. The Steps charity has called for consensus in order to manage parental angst in discussion forums, as variation in screening and treatment protocols may lead to increased anxiety.

There is unnecessary variation in the treatment of infantile DDH. This variation is preventing the United Kingdom national screening programme adopting standards for reporting within their NIPE-Smart system as the correct treatment pathway is uncertain. Furthermore, the uncertainty may contribute to the apparent failure of screening within the UK compared to other healthcare systems. Due to the fact that treatment consensus is lacking particularly in the group with well-centred, stable dysplastic hips, this study aims to investigate Pavlik harness treatment versus active surveillance in acetabular development in these babies. If successful, this research will lead to an adequately powered randomised control trial to inform policy, contribute to the development of treatment consensus, and provide evidence for best practice for this group of patients.

Explanation for the choice of comparator {9b}
Pavlik Harness treatment was selected as the comparator as bracing is the cornerstone of management of Developmental Hip Dysplasia globally.

Objectives {10}
Primary objective:

- Through active surveillance, to show whether Graf Type 2b and 2c hips mature with no intervention, compared with Pavlik Harness treatment

Secondary objectives

- To demonstrate the natural history of Type 2b and 2c hip dysplasia through active surveillance
- To compare active surveillance versus treatment in this group in order to determine whether harnessing is necessary
- To compare parent stress between the group under surveillance and the treated group
- To compare radiographic outcomes between both groups at 9 and 15 months
- To conduct parent/caregiver focus groups to obtain qualitative data on parent/caregiver experiences around the diagnosis of DDH, as well as within the treatment or monitoring group

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}
Caregivers of babies diagnosed with DDH were consulted during a 6-month period before the protocol was finalised and submitted for ethical review. This allowed the investigators to ensure that caregiver views and input were considered. The input gained from the caregivers confirmed that they would value the surveillance treatment option if it was shown to be effective and safe, and that they would feel safe with the study design. Caregivers were also consulted around the scanning protocol and number of visits required for the study, and to assess the burden of participation in the study.

Trial design {12}
This study uses mixed methods, and constitutes a single-centre, parallel-group, randomised controlled trial (RCT) to evaluate whether Pavlik Harness Treatment is necessary in Type 2B hip dysplasia, as well as using focus groups to obtain qualitative data from parents and caregivers of babies in the study on their experiences of treatment versus active surveillance.

Methods: Participants, interventions and outcomes
Trial setting {13}
The research will be conducted at Maidstone and Tunbridge Wells NHS trust (hospital) in Kent, United Kingdom. This is a hospital setting, with specialist paediatric orthopaedic provision.

Characteristics of the people who are needed for the trial

Characteristic	**The people we would expect to see included**
Age	Birth to 16 weeks of age
Sex	Male and female
Gender	Male and female

Race, ethnicity and ancestry	Any race, ethnicity and ancestry
Socioeconomic status	Any status.
Geographic location	Participants will live in the South East of England as their location results in referral to Maidstone and Tunbridge Wells Hospital
Other characteristics relevant to the trial	***n/a***

Eligibility criteria for participants {14a}

Inclusion criteria

- 2b or 2c hip dysplasia – ultrasound findings confirmed by consultant and ultrasonographer using the Graf method
- Age: birth to 16 weeks (2c) and 12 weeks to 16 weeks (2b)
- Informed written consent given by parent

Exclusion criteria

- Babies with associated neuromuscular, genetic or neurological conditions which may complicate the course of treatment
- babies who have unstable hips on clinical examination
- over 12 weeks of age at initial diagnosis

Eligibility criteria for sites and those delivering interventions {14b}

The team managing Developmental Hip Dysplasia at Maidstone and Tunbridge Wells consists of Paediatric Orthopaedic surgeons, and physiotherapists.

Who will take informed consent? {32a}

Those named on the delegation log will obtain informed consent – which is written, and requires a parent/caregiver signature on behalf of the baby.

Additional consent provisions for collection and use of participant data and biological specimens {32b}

n/a

Intervention and comparator

Intervention and comparator description {15a}

A total of 50 hips in each group will be recruited

Reliability in analysing ultrasound scans will be conducted between the ultrasonographers and consultants from whose clinics the babies will be recruited on 5 babies per pair. A kappa coefficient of 0.9 to 1 would be deemed acceptable.

Potentially eligible participants will be identified by the consultant following screening ultrasounds. A thorough history and clinical examination will be performed. This will include a hip examination, general examination to exclude other medical issues such as a sacral dimple, torticollis and any evidence of neurological problems. Informed written consent will be obtained from the parent or caregiver and the baby will then be randomly allocated to the Pavlik harness group or active surveillance at a ratio of 1:1 using the random number generation function in Microsoft Excel.

Pavlik Harness Group

A Pavlik harness will be applied to the babies in the treatment group by an orthopaedic consultant or physiotherapist, and standardised information around harness care and treatment will be given to the parent/caregiver. A contact number is provided should any concerns around the harness arise. The baby's harness is checked at 1 week, 3 weeks, 6 weeks and 9 weeks post diagnosis to ensure that it is fitting correctly,

and a new size is not needed. This is done by the consultant or one of two paediatric physiotherapists. Skin condition, femoral nerve integrity and flexion/abduction position of the hips are checked at these points. At week 3 the PSI-SF (Parenting Stress Index) will be administered which will help to determine stress levels of the parent/caregiver. Ultrasound scans will be performed at 3, 6, 9 and 12 weeks, and will be measured and interpreted by both the ultrasonographer and the consultant. Should the ultrasound results not demonstrate Graf 1 mature hips bilaterally by 12 weeks in a Pavlik harness, the baby will be placed in an abduction splint for night and nap time, until their x ray at 9 months of age (standard care).

Active Surveillance Group
The active surveillance group will receive no harness, but will be scanned using ultrasound at 3 weeks, 6 weeks, 9 weeks and 12 weeks (this will be discontinued when the hips normalise and the ultrasound demonstrates Graf 1 hips bilaterally), and the scans are measured and interpreted by both the ultrasonographer and consultant. The PSI-SF will be administered at 3 weeks which will help to determine stress levels of the parent/caregiver so this can be compared with the treatment group. Should the ultrasound scan at 3 weeks not show any maturation of the hip/s, the baby will be placed in a harness and will be moved into the treatment group. The same emergency number is given to parents in this group for any concerns that may arise between appointments, as well as to provide any support that the parent/guardian needs.
The pathways are shown in Figure 1 below:

Parent/ care focus groups
Two parent/caregiver focus groups (6 - 8 participants in each) will be run during the course of data collection to obtain qualitative data around experiences of having a baby who has a diagnosis of DDH, the information and support received during the treatment period, as well as experiences of being in either the harness group or the surveillance group. One group will consist of parents/caregivers whose babies were in the surveillance group and the second focus group will consist of parents/caregivers whose babies were in the harness group. These groups will be conducted on Microsoft Teams, lasting approximately 1 to 1.5 hours, and will be recorded.
Parents whose babies have completed the initial treatment period (up to 12 weeks) will be eligible to attend. They will be given an information sheet, and they will be invited to have any questions answered before completing a consent form, and being included in the focus group. Parents will be able to withdraw prior to the start of the focus group, but will be informed that data cannot be removed from the discussion on completion of the group.

Criteria for discontinuing or modifying allocated intervention/comparator {15b}
Babies in the active surveillance group will be placed in a Pavlik Harness and into the treatment group if two consecutive ultrasound scans do not demonstrate improvement in alpha angle using the Graf method of analysis.

Outcomes {16}

Ultrasound using Graf classification system
The primary outcome measure for this study is ultrasound using the Graf classification system. This is a widely accepted system used in Developmental Dysplasia of the Hip
The Graf classification system is one of the most widely used systems for classification of Developmental Hip Dysplasia based on ultrasound scanning. Once an *α angle of 60 degrees or more is achieved, the hip is classified as Graf 1 mature, and no further ultrasound scans are required.*

X-rays
These will be performed at 9 and 15 months of age as per standard protocol within the trust. The Acetabular index will be measured and classified according to the normal values of the hip joint described by Tonnis (27).

Parenting Stress Index Short form
The PSI-SF (26) is a 36-item version of the full length PSI developed for use in clinical and research settings requiring a valid yet brief (i.e., administration time less than 10 min) measure of parenting stress. Parental distress, parent-child dysfunctional interaction, and difficult child serve as the three subscales of the PSI-SF, which together combine to form a Total Parenting Stress Scale. The PSI-SF has excellent internal consistency, content and construct validity, as well as treatment sensitivity (26). This will be collected at the 3 week visit post-baseline in both groups.

Qualitative outcomes
Parent experience will be captured through the focus groups conducted by a member of the research team. The focus groups will be audio recorded and transcribed. The focus groups will be run before participant recruitment is completed.

Harms {17}
Safety reporting for each participant will begin from the first point of administration of the intervention or surveillance and will end when the participant has reached their final main follow up time point, at 15 months post-randomisation. This is a low risk, pragmatic trial where both of the trial interventions are underpinned by literature. In light of this, we do not anticipate many serious adverse events (SAEs) associated with either group.

Any adverse skin condition/deterioration due to harness application, and femoral nerve palsy due to position in harness. This will be dealt with by removal of the harness in the case of femoral nerve palsy and re-application once the nerve function has returned. Skin conditions will be dealt with by placing padding under straps, advice on cleaning and use of emollients.

Non-resolution of hip maturity in the surveillance group will be dealt with by placing the baby in a harness and adding the baby to the treatment group.

Abduction splinting at night/naps may be necessary following Pavlik harness for 12 weeks should the hip not have completely matured – this is in line with usual clinical protocol.

Participant timeline {18}
Figure 1: Treatment pathways for the Harness and Surveillance groups

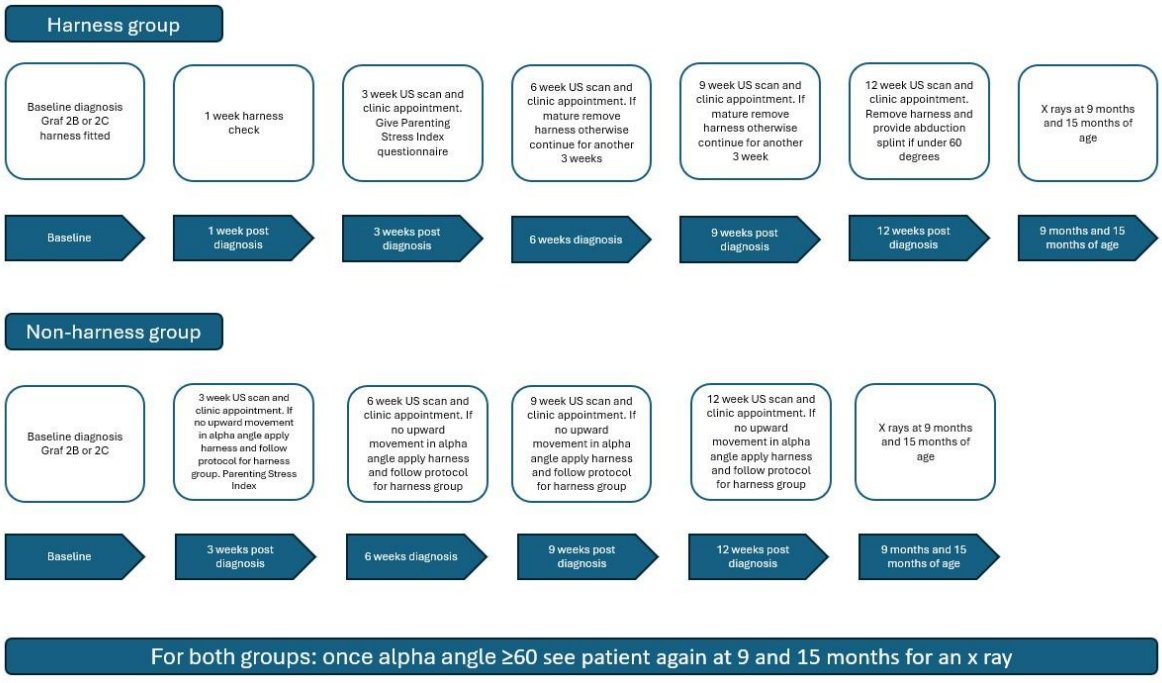


Figure 2: Spirit Figure

		TRIAL PERIOD						
	Enrollment		Post-randomization					Close-out
TIMEPOINT		**Baseline**	***3 weeks***	***6 weeks***	***9 weeks***	***12 weeks***	***9 months of age of baby***	***15 months of age of baby***
ENROLLMENT:		x						
Eligibility screen		X						
Informed consent		X						
Clinical assessment for stable hips		X						
Randomisation		X						
INTERVENTION/ COMPARATOR:								
Intervention: Pavlik Harness		X	x	x	x	x		X
Comparator: Active surveillance		X	x	x	X	X		
ASSESSMENTS:								
Ultrasound	X	X	X	X	X	X		
Clinical assessment			X	X	X	X	x	X
Parenting Stress Index			X					
X-rays							x	X

Sample size {19}
The a priori hypothesis in the study protocol was that there is no difference in treatment effect between the two groups. A Two One-sided T- test (TOTS) of Equivalence showed that 50 hips were needed in each group to reach a power of 90% with a significance of 5% (two-sided) and average alpha angle of 58 degrees in both groups (SD 8.2). The mean group difference ranging between −5 and + 5 degrees led to a conclusion of equivalence.

Recruitment {20}
Potentially eligible participants will be identified by the paediatric orthopaedic consultant following screening ultrasounds which are routinely performed for those babies referred to the clinic for Developmental Hip Dysplasia. A thorough history and clinical examination will be performed. This will include a hip examination, general examination to exclude other medical issues such as a sacral dimple, torticollis and any evidence of neurological problems. Informed written consent will be obtained from the parent or caregiver. Recruitment will continue until the sample size has been achieved

Assignment of interventions: randomisation

Sequence generation: who will generate the sequence {21a}
Before the trial starts, the Pavlik harness group or active surveillance group will be generated at a ratio of 1:1 using the random number generation function in Microsoft Excel.

Implementation {23}

Those who enrol participants do not have access to the random allocation sequence. The principal investigator who is not involved in enrolment is called after consent is given, and reveals the group according to the generated sequence.

Assignment of interventions: blinding

Who will be blinded {24a}
Blinding is not possible in this study due to the use of the Pavlik harness in the non-surveillance group.

Data collection and management

Plans for assessment and collection of outcomes {25a}
Reliability in analysing ultrasound scans will be conducted between the ultrasonographers and consultants from whose clinics the babies will be recruited on 5 babies per pair. A kappa coefficient of 0.9 to 1 would be deemed acceptable.

Ultrasound scan data will be collected for each participant using Alpha Angle. The sonographer and consultant will measure the scan independently and if different values are obtained, a second consultant will measure the scan as well.

The parenting stress index score will be calculated from the standardised assessment tool. X rays will be measured by the consultant, and using Bonefinder to ensure reliability. Focus group qualitative data will be analysed by the principal investigator using NVivo. Data can be obtained by contacting the principal investigator.

Data management {26}
All data collected related to the study will be confidential and anonymous. The participant will be allocated a randomised participant number code, and all data collected will relate to this code. A record of which code belongs to which subject will be stored in a locked cabinet separate from the study data. Only the principle investigator (who will be a member of the participant's direct care team) will have access to this documentation. Data will be kept for up to 5 years after the study is complete.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}
The primary outcomes are:

1. **Rate of improvement in alpha angle** from diagnosis until normalisation

Longitudinal changes in alpha angle will be analysed using a **linear mixed-effects model (LMM)** incorporating all available repeated measurements collected every 3 weeks from diagnosis. The outcome will be alpha angle (continuous)

2. **Time to normalisation**, defined as the first ultrasound at which the alpha angle reaches **≥60°**.

Kaplan–Meier curves will be generated for each treatment group and compared using the log-rank test. A Cox proportional hazards model will be used to estimate the hazard ratio (HR) for normalisation comparing Pavlik to Surveillance, adjusting for baseline alpha angle, Graf type and age at diagnosis. Proportional hazards assumptions will be evaluated using Schoenfeld residuals.For secondary outcome analysis, as part of standard of care, Fisher exact test analysis of the Acetabular Index will be used to show significance, with a p-value of less than 0.05

Focus group analysis

Audio reData will be uploaded to NVivo and analysed using a thematic analysis including: familiarisation of the transcript, identifying themes, indexing the data including highlighting quotes, charting and mapping the quotes according to themes identified and interpretation the data with reference to context, internal consistency, frequency, extensiveness and specificity of comments.

How missing data will be handled in the analysis {27c}
Little's Missing Completely at Random (MCAR) test will be conducted to determine the nature of missing data. If data are classified as MCAR or Missing at Random (MAR), multiple imputation will be applied to estimate and pool plausible values for missing observations while accounting for uncertainty related to the imputation process. If the data appear to be Missing Not at Random (MNAR), more advanced methods, such as Pattern Mixture Models or Selection Models, will be used.

Protocol and statistical analysis plan {5}

By publishing this protocol, it will be accessible.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}

The steering committee consists of the Chief Investigator, Principal Investigator, and Research and Development team from Maidstone and Tunbridge Wells NHS trust. The study does not have an independent data monitoring committee.

Frequency and plans for auditing trial conduct {29}
Weekly meetings will be held with the Chief Investigator, Principal Investigator and members of the team responsible for enrolment. Quarterly meetings will be held with the Steering Committee.

Dissemination policy {8}
Results will be disseminated via publication and presentation at conferences on completion of the study. Participants will be invited to attend a meeting once results have been analysed and collated to receive these and have an opportunity for discussion.

Trial status

Protocol version 9: August 2025. Data collection commenced in February 2023. The last participant was recruited in October 2026 and follow-up for the last participant is expected to complete in July 2027. This protocol was first submitted to the journal in May 2026 before the last participant was recruited.

Declarations

- Acknowledgements

Maidstone and Tunbridge Wells NHS Trust is the Sponsor for this study. mtw-tr.researchgovernance@nhs.net . The sponsor is responsible for the governance of the study, and is involved in steering meetings.

- Authors' contributions

Nicole Hilburn, Joanne Dartnell and Marcos Katchburian conceptualised the study. Nicole Hilburn is responsible for the funding acquisition. Nicole Hilburn, Joanne Dartnell and Marcos Katchburian developed the study protocol and materials. Nicole Hilburn, Joanne Dartnell, Marcos Katchburian, Gemma Green, Greg Firth, Joanna Cripps and Jennie Quilter have been involved in implementing the study, and will be involved in the analysis. All authors have read and approved the final manuscript.

- Funding

Associated of Chartered Paediatric Physiotherapists – Research Bursary

- Availability of data and material

This can be obtained by contacting the principal investigator. The Chief and principal investigators will have access to the final dataset. This will be shared with a statistician for statistical analysis but data is

anonymised.

Ethics approval and consent to participate {30}
Ethical approval has been obtained from the Health Research Authority (22/EM/0149). Written informed consent will be obtained from a parent/caregiver prior to enrolment

Consent for publication
All listed authors have provided consent for publication

Competing interests {7b}
The authors declare that they have no competing interests

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