The WINDY study

Full study title: The WINDY study- Weaning in INfant hip Dysplasia- a randomised multicentre feasibility study of weaning of brace treatment versus immediate cessation for developmental dysplasia of the hip

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Research Reference Numbers

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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
...../...../.....

Name (please print):

Mrs Karen Jennings-Wilding

Position:

Senior Clinical Research Governance Manager

Chief Investigator:

Signature:

Date:
28/03/2025

Name: (please print):

Daniel Perry

Key Study Contacts

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Sponsor	The University of Liverpool is the research Sponsor for this Study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter. For further information regarding the sponsorship conditions, please contact: Mrs Karen Jennings-Wilding Senior Clinical Research Governance Manager Sponsor@liverpool.ac.uk
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Study Summary

Study Design	Multicentre, parallel, 2 group, feasibility randomised controlled trial	
Study Participants	Infants under 6 months of age with Developmental Dysplasia of the Hip (DDH) who are treated with full-time Pavlik harness wear and have achieved an alpha angle of 60 degrees.	
Intervention	Nighttime wear of the Pavlik harness (minimum of 10 hours per night) for a duration of 4 weeks	
Comparator	Immediate Pavlik harness cessation	
Planned Size of Sample (if applicable)	Aim 60 participants	
Follow up duration (if applicable)	12 weeks	
Planned Study Period	12 months September 2025- September 2026	
Research Question/Aim(s)	Feasibility research question: is it feasible to conduct a definitive multicentre parallel group randomised controlled trial (RCT) of weaning of brace treatment to immediate cessation of brace treatment for infants with developmental dysplasia of the hip (DDH)?	
Feasibility objectives and outcomes	**Objectives**	**Outcome measures**
	Acceptance of the study design	Recruitment rate per month per centre % eligible infants randomised. Reason for exclusion/ declining to participate.
	Parental engagement	Parent reported compliance and availability of parent reported data
	EMBRACE reliability	Floor and ceiling effects (%), test- retest and Cronbach's alpha.
	EMBRACE validity	Correlation between EMBRACEand VAS for impact to family, parent and infant

	EMBRACE acceptability	Time taken to complete survey and missing data (%)
	Accessibility of Smart4NIPE data	Availability of routinely collected data within the Smart4NIPE system for research purposes
	Accuracy and completeness of Smart4NIPE data	Accuracy and completeness of Smart4NIPE data compared trial data recorded within trial database (REDCap) (%)
Exploratory outcomes and objectives	**Objectives**	**Outcome measures**
	Acetabular dysplasia	Assessment of routine imaging
	Reintervention rate	Number of infants who require further bracing or surgery once randomised (excluding the weaning intervention)
	Impact on the family unit	EMBRACE comparison between the groups
	Number of hospital appointments	To compare the total number of DDH related hospital appointments between groups post randomisation
	Adverse advents	Foreseeable adverse events

Funding and Support in Kind

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute for Health Research- doctoral research fellowship (NIHR303304)	Full doctoral research award - £449,965.00

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study Steering Groups

Trial management group

Name	Affiliation	Role/ Responsibilities
Ms Joanna Craven	University of Liverpool	Chair, PhD candidate
Professor Alexander Aarvold	University Hospital Southampton	Professor of Trauma and Orthopaedics, PI
Ms Lucy Llewellyn- Stanton	Oxford University Hospitals	Advanced Physiotherapy Practitioner, PI
Ms Amrita Athwal	University of Oxford	Senior trial manager
Mr Duncan Appelbe	University of Oxford	Senior Information Specialist
Ms Emma Morely	Patient and Public Involvement member	Parent representative
Ms Lucy Cooper	University of Liverpool	Trial manager
Mr Richard Kirk	University of Liverpool	Trial manager
Dr Elizabeth Conroy	University of Oxford	Statistician

Professor Xavier Griffin	Queen Mary University London	Professor of Trauma and Orthopaedics
Professor Daniel Perry	University of Liverpool	Professor of Trauma and Orthopaedics

Trial management group

Joanna Craven oversees the day-to-day operations of the trial, supervised by Daniel Perry (CI). A statistician and data manger will oversee set up of systems for data collection and analysis. Training will be conducted for recruiting sites. The TMG will meet monthly to monitor progress. The TMG will have PPI representation (Emma Morley).

Trial steering committee

This is a low-risk study so no independent data and safety monitoring committee will be formed, independent oversight will be undertaken by the trial steering committee (TSC). The TSC will meet at least once during the recruitment period and will be responsible for monitoring the progress of the trial, review of data and any safety concerns. The chair of the TSC is Mr Dan Westacott.

Patient and Public Involvement (PPI)

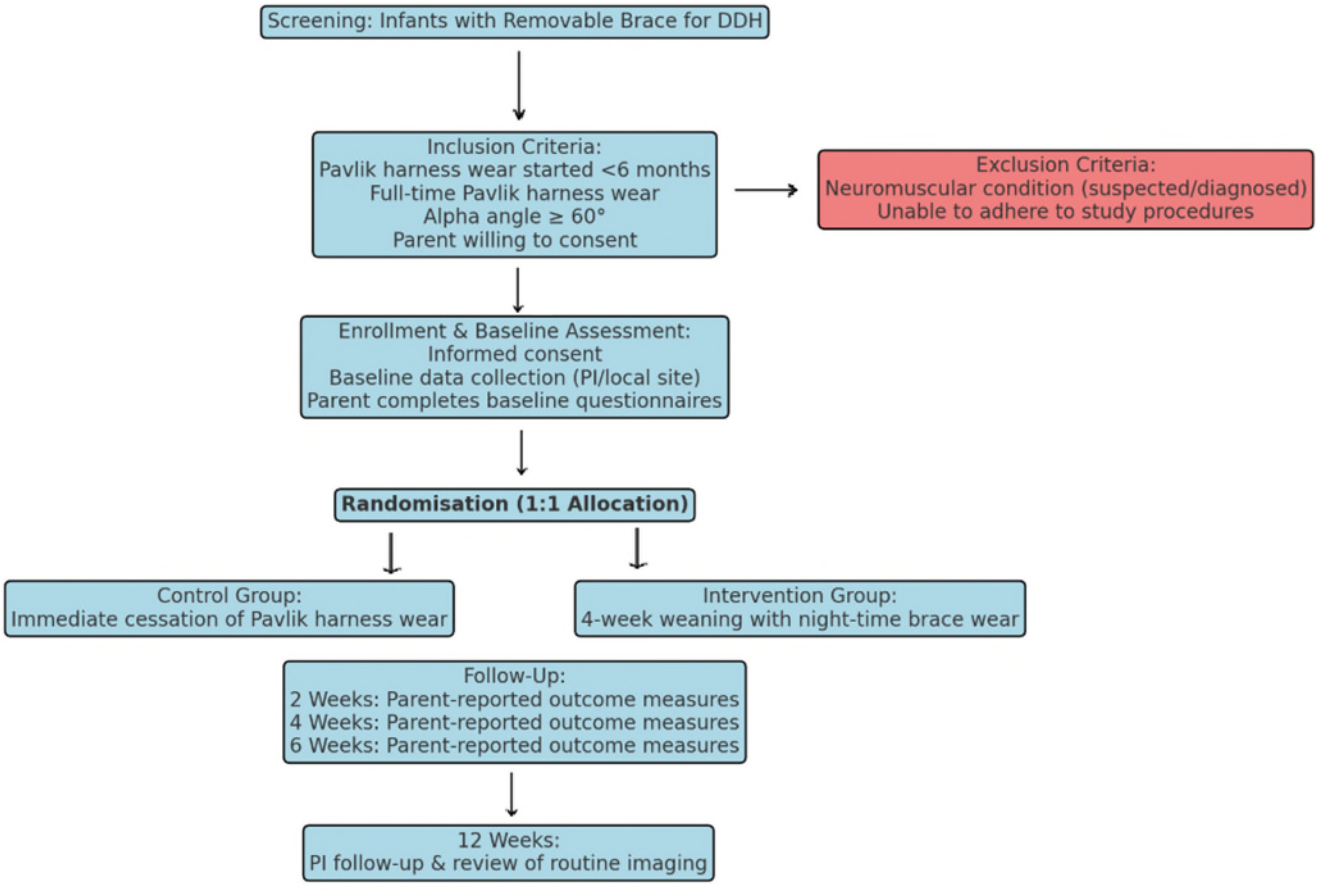
Patient and Public Involvement (PPI) has been integral to the design and execution of the WINDY study from its very inception. Parents played a key role during the acquisition of funding and helped shape the project's overall vision. Notably, Emma Morley, serving as a parent representative, contributed significantly to the trial design, ensuring that the study remains aligned with family needs and perspectives. Broader parent engagement was secured through collaboration with the STEPs charity with surveys and a discrete choice experiment, which not only demonstrated strong support for the trial and the use of the S4N database but also provided critical insights that guided the design of the intervention. Additionally, parents were actively involved in developing the family impact outcome measurement tool (EMBRACE) through a Delphi consensus exercise further embedding the parent voice in the research process. This comprehensive and collaborative approach underscores our commitment to conducting research that is both family-centred and responsive to the real-world needs of families.

Protocol Contributors

Ms Joanna Craven	PhD candidate
Ms Ruth Knight Statistician, University of Liverpool	PhD supervisor and statistician
Professor Xavier Griffin Professor of Trauma and Orthopaedic Surgery, Queen Mary University London	PhD supervisor
Professor Dan Perry Professor of Trauma and Orthopaedic Surgery University of Liverpool	PhD supervisor, Chief Investigator
Emma Morely Parent representative	Parent representative

Key Words: DDH, weaning, brace treatment

Study Flow Chart



Glossary of Abbreviations

AE	Adverse event
BSCOS	British Society of Children's Orthopaedic Surgery
CI	Chief investigator
DDH	Developmental dysplasia of the hip
EMBRACE	Evaluation Measure for BRACe Experience
GCP	Good clinical practise
HRA	Health research authority
ICF	Informed consent form
IP	Intellectual property
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health Research
PH	Pavlik harness
PI	Principle Investigator
RCT	Randomised controlled trial
REC	Research ethics committee
REDCap	Research Electronic Data Capture
RIDAC	Research, Innovation and Development Advisory Committee
S4N	Smart4NIPE
SAE	Serious adverse event
SAP	Statistical analysis plan
SOP	Standard operating procedure
TMG	Trial management group
UK	United Kingdom

Contents

1. INTRODUCTION

This protocol describes The WINDY study and provides information about procedures for entering participants, study procedures, safety reporting and governance requirements. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study following receipt of required approvals.

Queries relating to this Study should be referred, in the first instance, to the Chief Investigator, Daniel Perry.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy as well as any other regulatory requirements as appropriate.

2. LAY SUMMARY

Developmental Dysplasia of the Hip (DDH) is a condition where a baby's hip joint doesn't develop properly. This can mean the hip is a little or a lot out of place. About 1 in 100 babies are affected. To help fix this, doctors most commonly use a brace called the Pavlik harness, which helps hold the baby's hip in the right position.

However, there isn't a clear answer on when or how the brace should come off. Some doctors say the brace should come off all at once, while others suggest gradually reducing how many hours the baby wears the brace, which is called "weaning."

Right now, doctors in the UK have different ideas on how to do this, and we don't know for sure which method works best. To find out, we want to run a big study. But before we do that, we need to test the study design to make sure it works well. This smaller test is called a "feasibility study."

In this study, your baby will be randomly chosen to either keep the brace on at night only for four weeks or to have the brace taken off immediately. We will then ask you to fill out a few short questionnaires to learn more about how you and your baby are doing. These questionnaires will be filled out when you first join the study, then again at 2 weeks, 4 weeks, and 6 weeks. They can be completed online and at home.

The questionnaires will ask about how your baby is doing with the brace and how it's affecting your family. We will also ask how many hours your baby wore the brace. This information will help us understand if the study design works and if the treatment is helpful for baby's with DDH.

You have time to read this information, talk to your family and decide if you want to join the study. You can also leave the study at any time, and it will not affect your baby's care.

This smaller study will help us figure out the best way to treat DDH and make sure the study design works for a larger trial in the future. We hope this research will lead to better care for babies with DDH.

3. BACKGROUND

Introduction

Developmental Dysplasia of the Hip (DDH) is a condition affecting the hip joint. DDH encompasses a spectrum of abnormality ranging from an underdeveloped hip to a dislocated one(1,2). 1% of newborns are affected to some degree and approximately 1 in 1000 infants present with a fully dislocated hip(3). Risk factors include females, firstborns and positive family history(4).

Hip screening is part of the newborn infant physical examination in England, with all screening and treatment data for babies diagnosed with DDH stored in the national Smart4NIPE electronic database (S4N). Early detection and intervention have been shown to improve long-term outcomes(5,6).

Babies with abnormal hip examinations or risk factors are referred for an ultrasound scan. For infants under six months, ultrasound is the preferred imaging modality to diagnose, classify and guide DDH treatment. The British Society of Children's Orthopaedic Surgery (BSCOS) has established a core measurement set that includes essential criteria to be documented for every scan. This set includes whether the hip is centred, the alpha angle (only measured if the hip is centred) and a sonographic dynamic test of stability (7).

For infants under six months with reducible hips, the standard treatment involves a removable abduction brace (8,9).In the UK, 93% of clinicians routinely use a brace called a Pavlik harness as first line (10).

However, there is considerable variation in how the brace is used, including in the approach to its removal(10). While some clinicians advocate for immediate cessation, others favour a gradual removal process, commonly referred to as "weaning".

Current variation in care

In the UK, 65% of clinicians immediately remove the brace, while the remaining 35% wean (10). Whilst weaning is practiced by a minority of clinicians in the UK, it is the predominant practice internationally. Surveys indicate that two-thirds of members of the Paediatric Orthopaedic Society of North America (POSNA) and half of those from the European Paediatric Orthopaedic Society (EPOS) use some form of weaning regimen when treating infants(11).

Consensus exercises have produced mixed results about the necessity for weaning. The International Hip Dysplasia Institute (IHDI) supports weaning with night-time use only (12), whereas BSCOS has not reached a consensus (7).

Current evidence

The current literature is limited and of low quality, with no randomised controlled trials (RCTs) comparing weaning to immediate cessation of brace treatment, leading to clinical equipoise and variation in practice(6). To date, only two comparative studies on weaning versus immediate cessation have been published (13,14).

The first study, conducted across two centres, involved 128 infants—80 who underwent a structured 4-week weaning process (1 hour out of the harness per day during the first week, 2 hours in the second week, 4 hours

in the third week and 8 hours in the final week), and 48 who had immediate brace removal(14). At a minimum follow-up of six months, no statistically significant differences were observed between groups in terms of reintervention rates (repeat harness treatment, closed or open reduction), avascular necrosis or acetabular index. However, there was a trend towards a higher reintervention rate but lower avascular necrosis rate in the immediate removal group, though this was not statistically significant.

The second study followed 53 infants (64 hips) to 12 months of age(13). This study compared immediate brace cessation with a weaning approach, which included two different protocols based on hip stability. In patients with dislocated/reducible hips, weaning consisted of 2 weeks each of 18 hours/day, 12 hours/day, and 6 hours/day in the harness. An accelerated weaning period was used for hips with stable dysplasia, consisting of 4 weeks at 12 hours/ day. However, no significant differences in radiographic outcomes were found at one year.

Taken together, these studies indicate that while various discontinuation strategies are used in clinical practice, there is currently no strong evidence to favour weaning over immediate cessation.

Rationale for a RCT of weaning versus immediate cessation

Standardising treatment pathways in DDH has been identified as a research priority by BSCOS and by a James Lind Alliance Priority Setting Partnership (15,16).

Proponents of weaning advocate for this approach as it is low-risk, minimally invasive and well-tolerated by infants, allowing additional time for hip development. They argue that gradually reducing brace use, rather than stopping abruptly, is more effective in preventing relapse in hip development. This approach may help reduce the risk of residual acetabular dysplasia and, consequently, decrease the likelihood of requiring further bracing or surgical intervention(17–19). Residual acetabular dysplasia is a significant concern, as failed brace treatment can lead to poorer long-term outcomes, increased healthcare costs, and distress for both the child and their family. It is also strongly associated with early-onset arthritis, a painful and debilitating condition that can severely impact quality of life and may necessitate early hip replacement surgery(20,21). Currently, DDH accounts for at least 10% of all hip replacements and one-third of those performed in individuals under the age of 60 years old (21). Therefore, maximising benefit from the brace is crucial.

Opponents argue that continuing brace use after the hip normalises offers no additional benefit (22), instead adding unnecessary burden to families and posing further risk to the infant. While a removable brace is generally accepted to be low-risk, it is not without complications, including AVN, skin crease dermatitis, femoral nerve palsy, inferior hip dislocation, pseudo-paralysis and significant strain on the caregivers(23–27). Parents have highlighted the profound impact brace wearing has on the family unit, which affects parental wellbeing, infant-parent bonding, feeding, clothing, sleep and development (19,24). Therefore, minimising harness use duration may be advantageous. Gradual weaning may result in additional costs for families, including expenses for extra equipment and lost income due to time off work for caregiving and medical appointments. Similarly, health service costs may rise due to increased outpatient visits and additional ultrasonographic examinations. Parental fatigue and anxieties concerning brace fitting may also affect intervention compliance (12).

4. RATIONALE FOR CURRENT STUDY

Rationale for a feasibility study

Before a large definitive randomised controlled study, ensuring the feasibility through iterative changes to the design is important to optimise an efficient and successful delivery. This feasibility study will focus on key aspects such as the acceptability of the trial design, testing the Evaluation Measure for BRACe Experience(EMBRACE) and evaluating whether the Smart4NIPE (S4N) database can be used as a data collection tool for research.

To undertake an RCT, “weaning” as an intervention needs to be defined. Weaning practices vary widely, with clinicians using different approaches, which include gradually reducing hours of brace-wear or nighttime-only wearing. There is no single preferred weaning regimen across the literature. An international survey, including a UK-specific sub-analysis, explored these practices and informed the trial design. The survey found that the most common weaning regimen in the UK was nighttime-only brace-wearing, which continued for between 2 and 6 weeks, and clinicians indicated that this is their preferred intervention for a trial. There is strong support for an RCT, with 72.9% of respondents expressing willingness to participate. However, without a feasibility trial, there remains uncertainty about whether the chosen study intervention will be accepted by clinicians. Parents have shown support for a weaning trial in DDH, particularly given the impact that brace wearing has on the family unit(18,19,24). However, it is unclear whether parents will consent to participation, as families may express a desire to simply to remove the brace when presented with the clinician equipoise.

Our previous research into the impact of brace treatment on families has led to the development of a family-centred core outcome set (COS) for trials involving infants with DDH (**accepted**). The COS includes nine outcomes that capture the effects on both infants and parents, reflecting family priorities. As no suitable parent-reported outcome measure (PROM) existed to address these outcomes, the Evaluation Measure for BRACe Experience (EMBRACE)was developed (appendix 2) (**paper under review**). However, further evaluation of the acceptability, validity and reliability of the EMBRACE is essential before conducting a definitive trial.

The Smart4NIPE (S4N) system collects data on approximately 500,000 infants annually in England, including 5,000 with DDH, as part of routine care. This data includes demographic details, the BSCOS core measurement set from ultrasound scans, and DDH treatment information—critical components for a trial. If this data is accessible, complete and accurate enough for research purposes, it could streamline trial design, reduce duplication in data collection, and lower the burden on both clinicians and participants. The approach of embedding trial elements within routine care is supported by NHS England, 170 families surveyed as part of the trial workup, and the Clinical Trials Transformation Initiative (CTTI), which emphasises the benefits of integrating trial components into clinical practice(28).

5. THEORECTICAL FRAMEWORK

The WINDY study is designed in accordance with established frameworks and regulatory guidelines for feasibility randomised controlled trials (RCTs). The study follows the CONSORT 2010 Statement: Extension to Randomised Pilot and Feasibility Trials, which provides a structured framework for reporting feasibility studies(29).

6. RESEARCH QUESTION/AIM(S)

Feasibility research question: is it feasible to conduct a definitive multicentre parallel group randomised controlled trial (RCT) of weaning of brace treatment to immediate cessation of brace treatment for infants with developmental dysplasia of the hip (DDH)?

6.1. Objectives

The **primary** objective of this feasibility study is to assess the acceptability of the study design. This will be evaluated by monthly recruitment rate per centre and the percentage of eligible infants randomised. Additionally, reasons for exclusion or declining participation will be recorded.

The **secondary** objectives of the study are:
Feasibility objectives:

(i) To assess parental engagement via parent reported compliance and availability of parent reported data.
(ii) To assess the reliability of the EMBRACE through evaluating floor and ceiling effects, test- retest and Cronbach's alpha.
(iii) To assess the validity of the EMBRACE through correlation with a visual analogue scale, assessing the impact to the family unit, parent and infant.
(iv) To assess the acceptability of the EMBRACE using the time taken to complete the survey and the amount of missing data.
(v) To assess the accessibility of routinely collected data within the Smart4NIPE system for research purposes.
(vi) To assess the accuracy and completeness of the routinely collected data within the Smart4NIPE system, compared to data recorded within the trial database (REDCap).

Exploratory objectives:

(i) To assess the rate of acetabular dysplasia between groups.
(ii) To assess the reintervention rate following brace removal between groups.
(iii) To compare the impact on the family unit between groups.
(iv) To compare the total number of hospital appointments between groups.
(v) To report any foreseeable adverse events.

6.2. Outcomes

Feasibility objectives

Feasibility objective 1: acceptability of trial design

The primary outcome is the acceptability of the trial design, including the proposed intervention. This will be assessed as the number of participants recruited per centre per month. This data will inform the definitive trial, including the number of centres needed and the anticipated trial duration.

Detailed screening logs will be kept, recording data to provide the percentage of eligible infants who are approached and subsequently randomised. Reasons for exclusion or declined participation will be recorded.

Feasibility objective 2: parental engagement

Parental engagement will be assessed through self-reported compliance with their allocation and response rates to the **Evaluation Measure for BRACe Experience** (EMBRACE) at baseline, 2, 4, and 6 weeks.

To assess compliance, parents of infants in both trial arms will be contacted at 2 and 4 weeks post-randomisation and asked the following questions:

Parents of the immediate cessation group will be asked: *"During the past two weeks, has your baby worn their brace?"* Response options: Yes or No. If Yes is selected, a free-text box will be provided with the prompt: *"Please describe your baby's brace use over the past two weeks."*

Parents of the weaning group will be asked: *"For how many of the past 14 days (2 weeks) did your baby wear the brace at night for at least 10 hours?"*

Parents will be asked to enter a number between 0 and 14, indicating the number of days the brace was worn as instructed.

Parental engagement will also be measured by the response rate to the EMBRACE survey at baseline, 2, 4 and 6 weeks, recorded as a percentage completion rate for both intervention and control groups.

Feasibility objective 3: reliability of the EMBRACE

Reliability will be assessed using floor and ceiling effects, test-retest reliability (between weeks 2 and 4) and Cronbach's alpha for internal consistency

Floor and Ceiling Effects: These will be reported as the percentage of participants scoring the lowest and highest possible scores on the EMBRACE.

Test-Retest Reliability: Parents will complete the EMBRACE at 2- and 4-weeks post-randomisation, reflecting on the previous 7 days. Their circumstances are expected to remain stable during this period. The Intraclass Correlation Coefficient (ICC) will be calculated to assess the consistency of responses across these time points.

Internal Consistency: The EMBRACE includes sections for both parents/caregivers and infants. The

interrelatedness of items within each section will be evaluated using Cronbach's alpha.

Feasibility objective 4: validity of the EMBRACE

Parents will be asked to complete a visual analogue scale (VAS) ranging from 1 to 10, assessing the "overall impact of DDH care on the family," the "impact of DDH care on the parent/caregiver," and the "impact of DDH care on the infant" at baseline, 2, 4, and 6 weeks. Construct validity will be evaluated by examining the correlation between the EMBRACE and the VAS scores.

Feasibility objective 5: acceptability of the EMBRACE

The feasibility of the EMBRACEwill be determined by:

- The average time taken to complete the measure, recorded via the electronic format.
- The percentage of missing data within completed forms, providing insight into usability and completeness.

Feasibility objective 6: accessibility of routinely collected data within the Smart4NIPE system for research purposes

The Smart4NIPE (S4N) database routinely captures:

- Side of DDH
- Comorbidities
- Risk factors for DDH
- Severity of DDH (Graf classification)
- Sex at birth
- Age on the day of diagnosis
- Ethnicity
- Date of birth
- Date of diagnosis
- Date of initiation of the Pavlik harness (full-time wear)
- Date hip is considered to have centred
- BSCOS core measurement set (including whether the hip is centred, the alpha angle if the hip is centred, and sonographic dynamic test of stability) for routine ultrasounds at diagnosis, randomisation and removal of the brace

There is currently agreement in place to provide anonymised data from the Smart4NIPE database for use in audit. Through the feasibility study we will assess whether or not Smart4NIPE data can be accessed for use in research. Once the feasibility study has ethical approval, a subsequent Research, Innovation and Development Advisory Committee (RIDAC) application will be completed to request access to patient specific S4N data. Consent for this is included on the consent form.

Feasibility objective 7: accuracy and completeness of the routinely collected Smart4NIPE data

The data points needed for the trial which are routinely collected via the Smart4NIPE database will separately be recorded on the trial database via REDCap. If the Smart4NIPE data is available, the completeness and accuracy of the data collected within Smart4NIPE, compared to the trial database, will be assessed and reported as a percentage.

Exploratory outcomes

Exploratory outcome 1: acetabular dysplasia

Acetabular dysplasia is expected to be the primary outcome in a definitive trial, with assessment likely occurring at 1 or 2 years, which is not practical within the scope of this feasibility trial. In this study, the impact on acetabular dysplasia will be assessed at 12 weeks post-randomisation using the most recent routine imaging (acceptable range 4- 12-weeks post-randomisation). No additional imaging will be conducted for the purposes of the trial.

Ultrasound examination is the standard imaging modality for infants under six months and will be assessed using the BSCOS core measurement set, including whether the hip is centred, the alpha angle if the hip is centred and a sonographic dynamic test of stability. Amongst all infants all routinely available imaging will be harvested to assess the acetabular development.

Exploratory outcome 2: reintervention rate

The reintervention rate (need for further bracing or completed/planned surgery) following brace removal will be recorded at 12 weeks. This will be reported as a percentage reintervention rate.

Exploratory outcome 3: impact on the family unit

EMBRACE will be reported at baseline, 2 weeks, 4 weeks and 6 weeks post randomisation.

At baseline, parents will be asked to complete the tool retrospectively to report on their experience prior to randomisation. At 2-, 4- and 6-weeks parents will be asked to report their experience of the preceding 7 days.

Exploratory outcome 4: additional hospital attendance

Given the current clinical equipoise and varied practices, we do not expect this trial to increase the total number of hospital appointments across the group. It is standard practice for infants in a Pavlik harness to have ultrasound scans every 2-4 weeks during treatment and at the time of brace removal. The feasibility study will enable us to assess any unanticipated differences between groups in terms of appointment frequency. The total number of hospital appointments related to DDH, will be recorded for each group from the point of randomisation to 12 weeks.

Exploratory outcome 5: adverse events

All serious adverse events will be reported as detailed in this protocol. These events will be reported by recruitment centres upon becoming aware of them.

Foreseeable adverse events will also be recorded including:

- Skin irritation including skin crease dermatitis or pressure areas (part of family centred COS)
- Avascular necrosis (AVN)
- Femoral nerve palsy
- Inferior hip dislocation
- Brachial plexus injury
- Pseud- paralysis

7. STUDY DESIGN AND METHODS OF DATA COLLECTION

WINDY is a multi- centre, parallel group, feasibility RCT comparing weaning of brace treatment to immediate cessation of brace treatment for infants with DDH. The study will use a 1:1 allocation ratio and randomisation with stratification for site.

Screening and recruitment will take place in at least three NHS hospitals over a six-month period. Infants will be followed up according to standard hospital policies, with no additional scans or appointments required by the study protocol. Infants randomised to the weaning intervention will have a final ultrasound scan and appointment at the end of the intervention, as would occur in usual practice at the point of brace removal.

Infants will be followed up with parent-reported electronic questionnaires at baseline, 2-, 4- and 6 weeks post randomisation. If parents are unable to complete the form electronically, they will be contacted by telephone.

Description of the study intervention, control and study procedures (clinical)

Infants will be randomised to either the weaning intervention or immediate cessation of the brace. Parents will be provided with written instructions outlining the allocation and timings of follow up questionnaires within the welcome letter.

Usual care for infants with DDH treated in a brace

Full-time wear of the Pavlik harness is standard practice during the treatment-phase of harness use. The treatment phase ensues whilst a hip becomes centred and until the alpha angle reaches 60 degrees (30). Following the treatment phase, a clinician decides whether to instigate brace weaning.

Weaning intervention (intervention)

The weaning intervention consists of nighttime wear of the Pavlik harness (minimum of 10 hours per night) for a duration of 4 weeks. This intervention was informed by an international survey, including a UK-specific sub-analysis, which assessed clinical practices and practitioner preferences regarding weaning protocols **(accepted for publication**). The survey identified nighttime-only wear as the most common weaning regimen in the UK, with durations ranging from 2 to 6 weeks, and this approach was subsequently selected as the preferred intervention for the trial. Parents will be provided with written instructions outlining the allocation and timings of follow up questionnaires within the welcome letter. As all infants in the trial will have been previously managed in a Pavlik harness prior to randomisation, the weaning protocol represents a continuation of care,

with modified hours of brace wear.

Immediate cessation (control)

If the infant is randomised to immediate cessation, the Pavlik harness will be immediately removed. Therefore, the infant will go from full time Pavlik harness wear to no wear.

Baseline assessments

Baseline demographic data, comorbidities, risk factors and treatment details including BSCOS core measurement set (whether the hip is centred, the alpha angle (if hip is centred), sonographic dynamic test of stability) for routine ultrasounds at diagnosis and randomisation will be collected by the local study team with usual trust computers.

Parents will be asked to complete EMBRACE (Appendix 2) and VAS scores on their own device.

Follow up

Parents will receive an electronic invite to complete the parent reported questionnaires as detailed below. Reminders will be sent by email. If questionnaires are not completed this will be followed by a phone call from the central team if needed. If any data queries arise from participant-completed questionnaires, the central study team will make efforts to contact the participant via telephone, email or text message to resolve the issue, provided it is not suitable for clarification by the clinical site team.

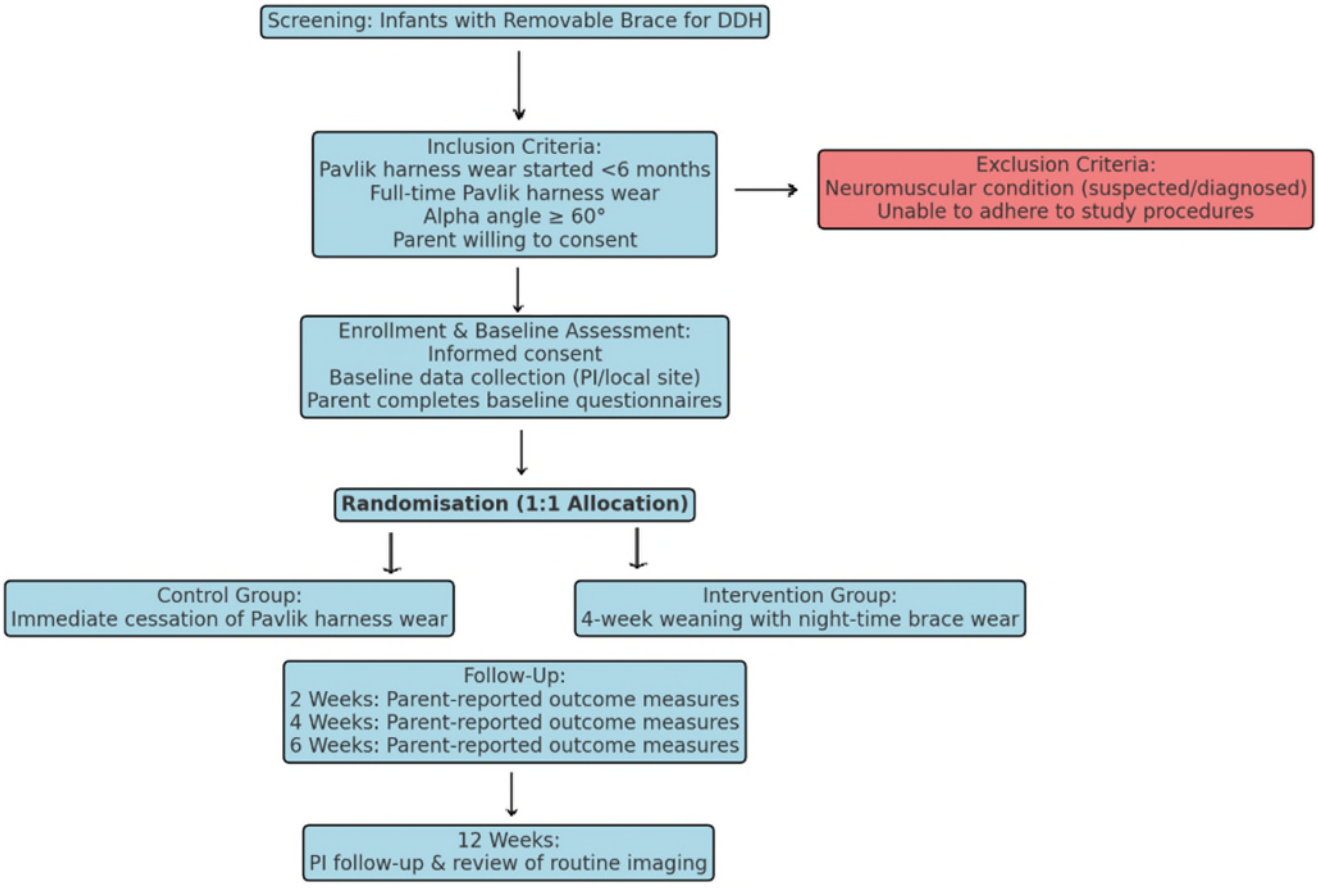
At **2 weeks post-randomisation**, parents will complete EMBRACE (Appendix 2) and VAS scores. Self-reported compliance will be assessed.

At **4 weeks post-randomisation**, parents will again complete the EMBRACE (Appendix 2) and VAS scores. Additionally, the total number of hospital appointments related to DDH post-randomisation will be recorded. Self-reported compliance will be assessed.

At **6 weeks post-randomisation**, participants will complete the EMBRACE (Appendix 2) and VAS scores for the final time.

At **12 weeks post-randomisation** the degree of acetabular dysplasia will be recorded based on the most recent routine imaging available at that point. Reintervention details will also be collected.

Study flow chart



Data collection schedule

	Timepoint				
Outcome measure	**Baseline**	**2 weeks**	**4 weeks**	**6 weeks**	**12 weeks**
Demographic and health data *(clinician reported)*	X				
BSCOS core measurement set *(clinician reported)*	X				
Acetabular dysplasia on routine imaging *(clinician reported)*					X
EMBRACE *(parent reported)*	X	X	X	X	
VAS *(parent reported)*	X	X	X	X	
Self-reported compliance *(parent reported)*		X	X		
Foreseeable complications *(clinician reported)*			X		

8. STUDY SETTING

Screening and recruitment will take place in at least three NHS hospitals over a six-month period. Infants will be followed up according to standard hospital policies, with no additional scans or appointments required by the study protocol. Infants randomised to the weaning intervention are expected to have a final ultrasound scan and appointment at the end of the intervention, as would typically occur at the point of brace removal. This is not considered additional care, given the current variation in standard practice, where many children already follow a weaning regimen that includes a scan and appointment as part of routine care. The BSCOS core measurement set from routine ultrasound scans at diagnosis, randomisation and brace removal will be recorded where present. Total number of hospital attendances (for DDH related contact) post randomisation will be reported.

Infants will be followed up with parent reported electronic questionnaires at 2-, 4- and 6 weeks post randomisation. If parents are unable to complete the form electronically, they will contacted via telephone.

The study will be advertised to potential sites through clinical networks and selected based on their suitability. Each site will receive an invitation pack containing a site feasibility questionnaire (SFQ), which should be completed by an appropriate individual. The Principal Investigator (PI), or an assigned deputy, will confirm participation and submit the SFQ to the chief investigator (CI).

The CI or an assigned deputy will review the SFQ to ensure the site's suitability for delivering the study. Written confirmation of collaboration will then be provided to the PI.

9. SAMPLE AND RECRUITMENT PARTICIPANT ENTRY

9.1 Eligibility Criteria

Study participants: Infants treated in a Pavlik harness for DDH

9.1.1 Inclusion Criteria

- Pavlik harness wear commenced under 6 months old.
- Pavlik harness wear has been full time
- Alpha angle is at least 60 degrees
- Parent* willing and able to provide consent for the infant to participate.

9.1.2 Exclusion Criteria

The infant may not enter the study if ANY of the following apply:

- Infant has (or suspected to have) a neuromuscular condition
- Unable to adhere to the study procedures or complete questionnaires

*For this protocol, “parent” refers to parent or legal guardian for the infant

9.2 Recruitment

A target of 60 participants will be recruited from at least three NHS sites. Recruitment will take place over a six-month period and will close either when 60 participants are enrolled or at the end of the six months, whichever comes first.

The study will be advertised to potential sites through clinical networks and will be selected based on their suitability. Each site will receive an invitation pack containing a site feasibility questionnaire (SFQ), which should be completed by an appropriate individual. The Principal Investigator (PI), or an assigned deputy, will confirm participation and submit the SFQ to the research team.

The CI or an assigned deputy will review the SFQ to ensure the site's suitability for delivering the study. Written confirmation of collaboration will then be provided to the PI.

9.2.1 Sample identification

Eligible patients will be identified by the treating clinical team. Eligibility will be confirmed by the treating clinician and highlighted to the local research team. Local research teams will include research nurses, site PIs and associate PIs. Parents of eligible infants will be provided with a Parent Information Sheet (PIS).

Most infants treated with a Pavlik harness will ultimately meet the eligibility criteria. All infants treated for DDH in a Pavlik harness will be screened. A screening log will be completed by the local team. Online screening logs will capture:

- Side of DDH
- Severity of DDH (Graf classification)
- Sex at birth
- Age on the day of diagnosis
- Ethnicity
- Index of Multiple Deprivation Score
- Whether the participant was eligible
- Reason(s) for ineligibility
- Whether the participant was approached to be enrolled
- Reason participant not approached
- Whether the participant was willing to consent to the study
- Reason for declining consent

9.2.2 Informed Consent

Consent will be provided by the parent or legal guardian. The parent will be provided with a parent information sheet.

A member of the responsible clinical team will introduce the study to the parent and facilitate discussion with a member of the local research team. The local research team will provide a detailed explanation of the trial and address any questions the parent may have. The formal informed consent discussion will take place in

accordance with local site policy. The individual obtaining informed consent must be appropriately qualified and must have been delegated this responsibility by the Principal Investigator.

If the parent agrees to participation, consent will be documented using the latest approved version of the online parent Informed Consent Form (ICF). A copy of the completed consent form will be provided to the parents. The local research team will also store a further copy in the medical notes.

9.2.3 Randomisation

After providing informed consent, infants will be randomly allocated 1:1 to "weaning" or "immediate cessation" of the Pavlik harness by researchers at study sites using REDCap, an encrypted wed- based service provided by the University of Liverpool. Randomisation will be stratified by site and will use permuted blocks of varying sizes.

REDCap is a validated computer randomisation program that operates on an encrypted and secure server

9.2.4 Blinding

Blinding of the intervention to treating clinicians, the local research team or parents is not possible in this study.

10.ADVERSE EVENTS

Safety reporting for each participant will begin from randomisation and will end at 12 weeks post randomisation. This study is regarded as low risk. There is clinical equipoise and variation in current practices, with both the intervention and comparator groups receiving treatment pathways that some clinicians may consider standard. We do not expect serious adverse events (SAE).

10.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject, including unfavourable and unintended signs, including abnormal laboratory results, symptoms or a disease associated with treatment.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the

subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

10.2 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance. All SAEs will be discussed at the next Trial Management Group (TMG) and Trial Steering Committee meetings.

10.2.1 Non-serious Adverse Events (AEs)

Adverse Events (AEs) include any foreseeable complications. All such events, whether expected or not, should be recorded. Adverse Events will be recorded on a Case Report Form (CRF) and in the patient's medical notes.

These complications may include avascular necrosis (AVN), skin irritation including crease dermatitis, femoral nerve palsy, inferior dislocation, brachial plexus injury and pseudo-paralysis

The clinician will manage the complication as they see fit, which may include removing the brace. The infant will remain in the trial, and the complication will be reported accordingly.

10.2.2 Serious Adverse Events (SAEs)

Upon identification of an SAE the Principle Investigator should complete a study specific SAE form and sent to the Chief Investigator within 24 hours.

Contact details for reporting SAEs

Daniel Perry

Please send SAE forms to: danperry@liverpool.ac.uk

All SAEs should be reported to the REC where in the opinion of the Chief Investigator, the event was:

- **'related'**, i.e. resulted from the administration of any of the research procedures; and
- **'unexpected'**, i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event. The Chief Investigator must also notify the Sponsor of all SAEs.

11.STATISTICS AND DATA ANALYSIS

The statistical aspects of the study are detailed here. There will not be a separate statistical analysis plan for this study.

11.1 Sampling

Recruitment will take place over a six-month period and will close either when 60 participants are enrolled or at the end of the six months, whichever comes first. The target sample size is 60 infants, based on the planned

participation of four recruiting sites, each expected to enrol approximately 15 infants over a 6-month recruitment period.

11.2 Data Analysis

A definitive trial will likely use radiographic measures, such as the acetabular index, as a primary outcome for intervention efficacy. However, the feasibility study will not collect this data as it would require a 1 to 2 year follow-up and provide limited added value within the context of this feasibility study. Radiographs at 1 year form part of standard care and do not require acceptability testing. Therefore, efficacy outcome analyses are not planned. Routine imaging during the follow up period will be assessed.

It is anticipated that all analysis will be undertaken using Stata (Stata Statistical Software: Release 16 or later, StataCorp LLC) or other well validated statistical packages. A trial statistician will oversee all the statistical aspects of the study.

Description of the Statistical Methods

The statistical analysis for this study will be conducted using descriptive statistical methods to assess feasibility objectives and exploratory outcomes.

Screening data will be analysed by reporting the total numbers and proportions of screened infants who are eligible, the number and proportion of eligible participants that consent and are randomised. Reasons for exclusion, as well as the number of participants who were not approached or declined participation (with reasons if provided), will also be documented. A CONSORT flow diagram will display enrolment, allocation, follow up and analysis (31). A recruitment graph will display the number of sites open and number of patients recruited over time.

Monthly recruitment rate per centre will be reported.

The number and proportion of study withdrawals will be reported, along with reasons if provided and time to withdrawal.

Baseline characteristics, including sociodemographic data such as age at diagnosis, sex at birth, ethnicity and Index of Multiple Deprivation Score, will be summarised using descriptive statistics. Treatment details, including the duration of full-time Pavlik harness wear, as well as clinical data such as the side of DDH, severity at diagnosis (Graf classification), comorbidities, risk factors for DDH, time taken for the hip to centre, and the BSCOS core measurement set, will be reported for the entire study cohort and separately by trial arm. Continuous variables will be summarised using mean and standard deviation or median and interquartile range if non-normally distributed. Categorical and binary variables will be presented as counts and percentages.

Parental engagement will be assessed through self-reported compliance with the intervention and response rates to the Evaluation Measure for BRACe Experience (EMBRACE)at baseline, 2, 4, and 6 weeks. Compliance will be recorded as a binary measure: compliant or non-compliant. An infant will be considered compliant with the weaning regime if the brace has been worn as instructed for at least 85% of the time, equating to a minimum of 12 out of 14 nights. Compliance for the immediate cessation group is recorded as a binary yes/ no

response by parents. The compliance percentage will be calculated from all participants randomised. The response rates of the EMBRACEwill be reported as the proportion of parents who return all questionnaires and expressed as a percentage for each group.

The reliability of the EMBRACE will be evaluated through floor and ceiling effects, test-retest reliability, and internal consistency. Floor and ceiling effects will be separately reported as the percentage of participants scoring the lowest and highest possible scores. Floor and ceiling effects will be considered present if >20% of parents achieve the worst score/floor effect (8/45) or best score/ceiling effect (40/40) score. Test-retest reliability will be assessed using the Intraclass Correlation Coefficient (ICC) by comparing responses at 2 and 4 weeks post-randomisation, participants' circumstances are assumed to remain stable during this time frame as they are asked to complete the score reflecting upon the previous 7 days.

Internal consistency will be measured using Cronbach's alpha to assess the interrelatedness of items within the parent/caregiver and infant sections. ≥0.7 will be considered acceptable.

The construct validity of the EMBRACE will be assessed by calculating the correlation between VAS scores and the EMBRACE at baseline, 2, 4, and 6 weeks. Specifically, the correlation between the impact on the family unit and the total EMBRACE score, the impact on the parent and the parent EMBRACE section, and the impact on the infant and the infant EMBRACE section will be evaluated. If the PROM scores are normally distributed, Pearson's correlation coefficient will be used. For non-normally distributed scores, Spearman's rank correlation coefficient will be applied. A correlation coefficient of ≥0.50 indicates good construct validity, 0.30–0.49 suggests moderate validity, and a coefficient of <0.30 indicates weak or no correlation.

The feasibility of the EMBRACE will be examined by recording the average time taken to complete the measure using the electronic format and the percentage of missing data within completed forms, which will provide insight into its usability and completeness. The time taken to complete the questionnaire will be recorded for all returned EMBRACEs. The average completion time for the entire group will be calculated and summarised using the mean and standard deviation. Missing data items will be recorded for all returned EMBRACE s and reported as a percentage completion rate (the total number of completed items returned/ the total number of items within returned questionnaires), the percentage completion rate for each statement within the EMBRACE will be reported to identify issues with a specific item.

Provided that the Smart4NIPE data is accessible and approved by RIDAC, the accuracy and completeness of routinely collected Smart4NIPE data will be assessed by comparing recorded data points with those entered into the trial database via REDCap at baseline. REDCap data will be considered the truth in the event of a discrepancy. Variables including the side of DDH, comorbidities, risk factors, severity (Graf classification), sex at birth, age at diagnosis, ethnicity, dates of diagnosis, initiation of Pavlik harness treatment, and hip-centring, as well as the BSCOS core measurement set, will be evaluated. The completeness of these data points will be reported as a percentage. The accuracy of the completed data points will be reported as a percentage.

The impact on acetabular dysplasia will be assessed at 12 weeks post-randomisation using the most recent routine imaging performed by the treating team between 4- and 12-weeks post-randomisation. Ultrasound examination is the standard imaging modality for infants under six months and will be assessed using the BSCOS core measurement set, including whether the hip is centred, the alpha angle if the hip is centred and a

sonographic dynamic test of stability. For infants older than six months, if hip radiographs are taken as part of routine care, these will be evaluated for the acetabular index.

Reintervention rate will be reported as a percentage. Clinicians will be asked whether or not further bracing or surgery is required post brace removal at 12 weeks post randomisation. This will be reported as a percentage.

Exploratory analyses will include assessing the impact on the family unit using the EMBRACE, which will be completed at baseline and at 2, 4 and 6 weeks post-randomisation. At baseline, parents will report retrospectively on their experience prior to randomisation, while at later time points, they will report on the preceding 7 days. Descriptive statistics will be used to summarise and compare scores between treatment arms, providing an initial assessment of the impact on families. The total EMBRACE score, the parent EMBRACE section and infant EMBRACE section will be summarised using mean and standard deviation or median and interquartile range if non-normally distributed. Scores over time will be plotted on a graph for a visual comparison.

The number of additional hospital attendances related to DDH will also be analysed to determine whether weaning leads to any unanticipated differences in appointment frequency. The total number of DDH-related hospital visits will be recorded for each group from randomisation until brace removal. Reported as median and interquartile range if non-normally distributed

All unexpected serious adverse events related to the interventions will be recorded and reported by recruitment centres upon identification. Any SAE will be reported as a lione listing. Additionally, foreseeable adverse events, including skin irritation (a part of the family-centred COS), avascular necrosis (AVN), and femoral nerve palsy, will be tabulated as the number of events and percentage.

No formal statistical hypothesis testing will be conducted, as the study is designed to assess feasibility rather than efficacy. All statistical analyses will be performed using appropriate statistical software, and results will primarily be presented as descriptive statistics to inform the design of a future definitive trial.

All randomised participants will be included in the analysis of the feasibility outcomes. All outcome measures will be reported for the ITT population.

Analysis populations

Infant outcomes will be analysed based on the group to which they were originally assigned, regardless of their actual adherence to the treatment protocol. This approach represents an intention-to-treat (ITT) analysis.

Statistical significance

No formal statistical analysis will be conducted for this feasibility study.

Procedure for accounting for missing data

Reports will include summaries of missing data for each outcome at every time point. The analysis will be based on the data that is available.

Procedure for reporting any deviation(s) from the original statistical plan

Any deviations from the study protocol will be documented and justified either in an amendment to the protocol or in the final report.

12. REGULATORY ISSUES

12.1 Ethics Approval

Before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service for the study protocol, informed consent forms and other relevant documents e.g. advertisements. Health Research Authority (HRA) approval will be obtained.

The study will be submitted to each proposed research site for Confirmation of Capacity and Capability.

12.2 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy.

Participants will be assigned a study number unique to them which will be the sole identifier on all study documentation and databases. Only appropriate members of the study team will be granted access to the data. Data will be stored securely accessible only to authorised personnel, compliant with the UK Data Protection Act (2018).

Data collection forms will be developed by the trial team. All data from clinicians will be collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based platform compliant with Good Clinical Practice (GCP). As standard, parent reported data will be directly entered into REDCap. If parents are unable to complete the form electronically, they will be contacted by telephone. If data is collected via telephone, it will be entered into REDCap by a designated individual, referencing participants by study number only.

REDCap offers built-in data logic to minimise missing data, reduce input errors and ensure completeness. Data entered into REDCap will be encrypted, and access will be restricted to authorised research team members based on their study role. Regular backups of the REDCap database and server will be conducted to ensure data security.

Patient-identifiable data, such as contact details, will be stored securely on a University of Liverpool-hosted server, separate from pseudo anonymised outcome data. Participants will be referenced by a unique trial ID, ensuring confidentiality.

Subject to RIDAC approvals, SMART4NIPE data will be directly accessed by the central trial team. Source data, including hospital notes, Smart4NIPE records, ultrasound reports and parent-reported outcome measures, will be kept secure and confidential. Authorised personnel from the sponsor and host institution may access source data for monitoring, audit or regulatory purposes.

Consent documentation will be stored electronically within REDCap, in medical notes and participants will receive a copy.

A separate data management plan will outline procedures for data storage, and access, ensuring compliance with ethical and regulatory standards.

Data Retention Policy

- **Contact details**: Retained for 12 months post-study completion on the University of Liverpool server.
- **Consent forms**:
    - Medical record copy: As per local policy.
    - Central trial team copy: 12 months post-study completion on the University of Liverpool server.
- **Research data**: Anonymised data used for analysis, including trial outcome measures, participant-reported outcomes, and feasibility assessment data, will be stored securely and deposited in the University of Liverpool Research Data Catalogue for perpetuity after the publication of the primary results.

This structured approach ensures data integrity, confidentiality, and compliance with regulatory requirements, while the use of REDCap as the trial database provides a secure, efficient, and GCP-compliant solution for data management throughout the study.

12.3 Indemnity

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

12.4 Audits and quality assurance procedures

The University of Liverpool will oversee the study, implementing quality control measures and ensuring compliance with GCP, relevant regulations, and standard operating procedures, in accordance with this protocol and UK legislation.

The study may be subject to inspection and audit by the University of Liverpool under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

Study monitoring and oversight

The study will be conducted in accordance with the current approved protocol, relevant regulations and standard operating procedures. The day-to-day management of this study will be the responsibility of the Chief Investigator. The CI or an assigned deputy will submit once a year throughout the study, or on request, an Annual Progress report to the HRA (where required), host organisation, Sponsor and funder. In addition, an End of Study notification and final report will be submitted to the same parties.

Trial management group

Joanna Craven oversees the day-to-day operations of the trial, supervised by Daniel Perry (CI). A statistician and data manger will oversee set up of systems for data collection and analysis. Training will be conducted for

recruiting sites. The TMG will meet monthly to monitor progress. The TMG will have PPI representation (Emma Morley).

Trial steering committee

This is a low-risk study so no independent data and safety monitoring committee will be formed, independent oversight will be undertaken by the trial steering committee (TSC). The TSC will meet at least once during the recruitment period and will be responsible for monitoring the progress of the trial, review of data and any safety concerns.

Protocol deviations

A study-related deviation is any deviation from the approved protocol, related study documents or processes, Good Clinical Practice (GCP), or relevant regulatory standards. All deviations will be documented on a protocol deviation form and archived in the study master file.

Serious breaches

A serious breach is a major deviation from the protocol or GCP that could affect participant safety or the scientific integrity of the research. In such cases, the sponsor must be notified within 24 hours. If necessary, the sponsor and CI or an assigned deputy will report the breach to the REC and NHS host organisation within 5 working days.

13. END OF STUDY

The end of the study is after the last contact with the final participant has been completed and all queries have been resolved.

14. DISSEMINIATION POLICY

14.1 Dissemination policy

The CI or an assigned deputy will submit an end of study notification and final report to the REC, HRA, host organisation, sponsor and funder.

To achieve our desired impact on clinical practise, it is essential to report the study in a high-quality academic journal. The study protocol will also be published.

We will collaborate with networks, such as the British Society of Children's Orthopaedic Surgery, to disseminate findings. Additionally, results will be shared with the DDH community and the public through national charity newsletters and social media platforms.

15.ARCHIVING

Data Retention Policy

- **Contact details**: Retained for 12 months post-study completion on the University of Liverpool server.

- **Consent forms**:
    - Medical record copy: As per local policy.
    - Central trial team copy: 12 months post-study completion on the University of Liverpool server.
- **Research data**: Anonymised data used for analysis, including trial outcome measures, participant-reported outcomes, and feasibility assessment data, will be stored securely and deposited in the University of Liverpool Research Data Catalogue for perpetuity after the publication of the primary results.

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17. APPENDICES

17.1 Appendix 1- Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

17.2 The Evaluation Measure for BRACe Experience (EMBRACE)

The Evaluation Measure for BRACe Experience (EMBRACE)is a simple questionnaire that helps doctors understand how treatment for DDH affects both babies and their parents.

It has 8 short statements, and for each one, parents are asked to say how much they agree, from 1 (strongly disagree) to 5 (strongly agree). It should take **no more than 5 minutes** to complete.

Three of the statements are about how the treatment affects parents or caregivers, and five are about the baby's experience.

The questionnaire should be filled out by the infant's main caregiver(s).

All responses will be **anonymous**, meaning no one will know who gave each answer. You don't have to take part—it's completely up to you. Saying no won't change your care in any way. The results are for **research purposes only** to help understand the impact of treatment. If you are struggling with managing care for yourself or your baby, please reach out to a **medical professional** for support.

Instruction for baseline: *Please think about how brace treatment has affected you and your baby **from the day the Pavlik harness was first applied until today** before answering the following statements.*

Instruction for follow up(2-, 4- and 6- weeks): *Please consider the following statements about your experiences **over the past week**, whether or not your child has worn a Pavlik harness.*

Demographic section

What is your relationship to the child?

Mother

Father

Caregiver other

Caregiver Section

I feel confident and supported in managing my wellbeing while caring for my baby

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

I have suitable access to relevant information and resources to understand my baby's condition and how to manage

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

I am bonding with my baby

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

Infant section

I feel confident keeping my baby clean

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

My baby is sleeping well

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

My baby is comfortable

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

I feel confident feeding my baby

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree

My baby is meeting milestones as expected

1- Strongly disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly agree