SHINE-2: Screening the Hips in Newborns

The Use of an Acoustic Device to Identify Developmental Hip Dysplasia in Babies

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Study Team

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Research Co-ordinator:	Mr Richard Kirk	*The University of Liverpool*

Clinical Queries

Clinical queries should be directed to Mr Daniel Perry who will direct the query to the appropriate person.

Sponsor

The University of Liverpool is the research Sponsor for this Study. For further information regarding the sponsorship conditions, please contact:

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Funder

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STUDY SUMMARY

This protocol describes the SHINE2 study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Executive Summary

Developmental dysplasia of the hip (DDH) is a spectrum of disease. One per 1000 babies have a frankly dislocated hip, and 2-3% are diagnosed with some degree of hip dysplasia(1). DDH is associated with premature osteoarthritis and is the reason for 10% of all hip replacements, and is the most commonly identified cause of hip osteoarthritis in those under 60 years old(2). Early diagnosis is crucial to determine whether surgery is required in childhood, and to maximise outcomes in adulthood. If DDH is identified early in infancy, it can usually be rectified with a removable splint, worn for just a few weeks.

The UK uses a nationwide selective ultrasound screening programme for DDH(3). Clinical examination is universal and if abnormal, is followed by ultrasound screening. Clinical examination involves several screening manoeuvres, which the National Screening Committee (NSC) acknowledges are poor tests, as they are difficult to teach, difficult to monitor or assess competence, and have high variability amongst clinicians. The NSC estimates that around two in three hip dislocations are missed on screening(4).

The alternative approach is universal ultrasound screening, which is practiced in some parts of mainland Europe. A Cochrane review has highlighted the costly nature of the alternative and high levels of false positives that this would generate(5). The NSC therefore does not recommend universal ultrasound screening, opting for the current selective screening model acknowledging the flaws. A new screening tool is needed, which that better fulfils the Wilson and Jungner criteria for screening(6), i.e. the test needs to be simple, safe, precise, validated and cost-effective – and one that ideally is reproducible even with minimal training.

Through a prior study (SHINE), we have demonstrated sound transmission to be an effective tool to identify infant hips that are dislocated. SHINE2 will develop the techniques to refine the screening tool, to progress the technology to Technology Readiness Level (TRL) 4. Alongside this, we will demonstrate the market opportunities for such a device and develop a health economic model to demonstrate the potential value of the tool to society. We will also engage with industry, whilst protecting any IP generated. It is anticipated that SHINE2 will bring the device to the point that the technology is finalised, and a commercial product can be conceived.

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GLOSSARY OF ABBREVIATIONS

DDH	Developmental Dysplasia of the Hip
EATC	Experimental Arthritis Treatment Centre
HRA	Health Research Authority
NIPE	New-born and Infant Physical Examination
NSC	National Screening Committee
REC	Research Ethics Committee

KEYWORDS

Hip Dysplasia, Dislocated Hip, Screening, Osteoarthritis

Title	SHINE-2: Screening the Hips in Newborns. The Use of an Acoustic Device to Identify Developmental Hip Dysplasia in Babies
Secondary trial ID	REC reference: XXXXXX
Chief investigator	Prof Daniel Perry Liverpool Orthopaedic and Trauma Trials Group danperry@liverpool.ac.uk
Funder	Consortium of University of Liverpool, Liverpool John Moores University and Alder Hey Hospital.
Sponsor	University of Liverpool Research Governance, Ethics and Assurance Team sponsor@liverpool.ac.uk
Clinical Study Group	Liverpool Orthopaedic and Trauma Trials Group Institute in the Park. University of Liverpool. L12 2AP
Brief title (acronym)	SHINE 2
Central contact	Lucy Cooper/Richard Kirk Liverpool Orthopaedic and Trauma Trials Group Institute in the Park. University of Liverpool. L12 2AP
Countries of recruitment	UK
Focus of study	To develop a novel device to enhance the detection of developmental dysplasia of the hip (DDH) in babies through specific audible tones and/or the transmission of vibration across the hip joint.
Health condition	Developmental Dysplasia of the Hip (DDH)
Interventions	The assessment will involve an additional examination during routine ultrasound, which is being undertaken as part of the national selective screening program. In addition to the ultrasound examination, the child will have the prototype device applied (i.e. an external excitatory acoustic signal will be generated from an acoustic device that is placed on the knee. An external microphone will 'listen' and interpret the transmission of the acoustic signal across the hip, and any echoed back to the knee

Key eligibility criteria **Inclusion Criteria:** **Exclusion Criteria:**	 Male and females under 3 months old meeting the criteria for hip screening as part of the national screening program. Children with joint contractures preventing normal body positioning during the routine neonatal examination (i.e. knee dislocation, arthrogryposis etc).
Study design	Study type: Basic Science involving procedures with human participants Design: Development Cohort. Primary purpose: Develop a beta prototype device (TRL4) which is fine-tuned to enhance the detection of developmental dysplasia of the hip (DDH) in using the transmission of vibration across the joint
Target sample size	150 children, of which at least 25 children have a hip that is decentered on ultrasound.
Planned trial period	24 months
Primary outcome	The sensitivity and specificity of the acoustic tool in the detection of DDH of the hip. This will be amongst children who are already undergoing routine ultrasound examination as part of the national selective screening program [i.e. current gold standard].
Secondary outcomes	Usability Acceptability to families
Conflict of Interest statement:	The following conflicts of interest have been declared by the protocol authors/contributors: Daniel Perry is National Clinical Advisor for hip screening to the Department of Health and Social Care.
Confidentiality Statement:	In accordance with the NIHR Open Access policy, the protocol will and results be published and made freely and openly accessible to all. Elements which may subsequently become commercially important, will be withheld until adequate protection of any intellectual claims is ensured.

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1. INTRODUCTION

1.1 BACKGROUND

Developmental Dysplasia of the Hip (DDH) is a spectrum of disease. 1 in 1000 new-borns have a completely dislocated hip, and 2-3% of new-borns are diagnosed with some degree of hip dysplasia(1). DDH is associated with premature osteoarthritis and is the cause of 10% of all hip replacements, and a third of replacements in those under 60 years old(2). In the UK around 1,200 total hip replacements per year occur as a result of DDH, which is more than that for all inflammatory arthropathies combined.

Early diagnosis is crucial to minimise the need for surgery in childhood and maximise long-term outcomes. In the early infant period DDH can usually be treated with a removable splint (Pavlik harness) which is worn for a period of a few weeks, and generally results in a hip which is structurally and functionally normal. Hips that are diagnosed in children older than 6 months of age usually require a spica cast (plaster trousers) for a period of up to six months. In addition to the spica cast, infants diagnosed after one year of age require surgery to divide tendons and surgically relocate the hip. Those diagnosed at later times require increasingly complex surgery to divide tendons, surgically relocate the hip and to reposition the bones around the hip, to aid the development of the socket. Despite more complex surgery, hips diagnosed at later time periods have poorer functional outcomes with more long-term disability due to early degenerative joint disease. Diagnosis and treatment early in the life of the infant appears key.

The UK uses a nationwide selective ultrasound screening programme for DDH(3). Screening is carried out as part of the statutory Newborn and Infant Physical Examination (NIPE) screening procedure. All babies are screened within 72 hours of life, and again at 6-8 weeks. Screening is usually carried out by midwives, paediatricians and general practitioners. Hip screening involves a series of questions to identify risk factors for disease (i.e. third trimester breech position in-utero, first degree relative affected). Additionally a mandatory clinical examination is performed on all babies, which includes an examination of hip abduction, limb length and special tests known as the Ortolani and Barlow manoeuvres. If any aspects of the screening examination are abnormal, or if the child has significant risk factors, then they are referred for ultrasound screening.

Clinical examination of the hips requires skill and experience to perform(7,8). Ortolani and Barlow manoeuvres involve moving the child's legs into predefined positions, and the examiner feeling the hip to identify the hip dislocating and 'clunking' back into position. The experience of any single examiner in identifying abnormalities of the hips is low, as the diagnosis of DDH is rare. The National Screening Committee have identified that it is very difficult to adequately train individuals, or to monitor standards relating to these tests. Overall, the national screening committee estimated that the current screening regimen misses up to two thirds of cases of DDH(4).

An alternative approach to maximise the identification of DDH is universal ultrasound screening of the hips(5). Ultrasound assesses the morphology of the largely cartilaginous hip joint of the new-born, specifically the depth of the acetabulum and the location of the femoral head. Universal ultrasound screening has been adopted in some European countries, however whilst this led to a reduction in surgery for DDH, there was a

marked increase in abduction splinting for DDH to levels 4–7 times higher than expected**.** High levels of splinting are a particular concern because treatment of the hip even in a simple splint is not entirely benign, with a risk that even a normal hip may be affected by avascular necrosis, resulting in destructive changes to the joint(9). A decision analysis to differentiate between different screening models demonstrated that universal ultrasound screening was the most effective method to identify DDH, though was very costly and associated with the greatest risk of iatrogenic complications(10). For this reason, the UK national screening committee advocate the current model of a selective ultrasound programme.

Whilst clinical examination is a poor screening test, the National Screening Committee note "it is so ingrained in the clinical practice of so many people that it would be almost impossible to stop it unless overwhelming evidence of ineffectiveness could be obtained"(4). Ultrasound is a useful test, yet the number of false positives and cost of performing the procedure are too high to apply as a universal screening model. An alternative-screening tool is therefore needed that better fulfils the Wilson and Jungner screening criteria(6), i.e. the tool needs to be simple, safe, precise, validated, cost-effective and reproducible even with minimal training.

1.2 RATIONALE FOR CURRENT STUDY

In 1987 and 1990, studies published in the Lancet demonstrated the utility of an acoustic device to identify DDH (11,12). These studies identified that the transmission of vibration may be used to detect dysplasia. When vibration was passed along the femur bone, transmission of the signal across the hip was different based on whether the hip was dislocated, dysplastic or normal. At the time, limitations in technology prevented the development of this work.

Using developments in sensor technologies, we have experimented with acoustic sensors and sound transmission across joints. Through our previous project SHINE, we worked in the laboratory to develop the concept and refine the optimal means of sound transmission and detection though bone, along with optimal sound frequency (TRL1/2). We then developed a poof-of-concept device that could identify gaps within bone continuity (TRL3). We then worked on this proof-of-concept in the laboratory and in the hospital environment; where we tested in on the hips of 150 babies. Through this, we were able to make refinements to the device, clarify the optimal means of device application and the optimal position of the baby. We were able to demonstrate signals of effectiveness (TRL4/5).

However, the proof-of-concept has challenges to overcome, which include:

- Ensuring the device can be used by a single clinical user.
- Interpreting the signal to a meaningful output for the user.

In addition, the health economic argument for a device is unclear, which therefore means that the market opportunities are poorly defined.

2. STUDY AIMS/ OBJECTIVES

The aim of the study is to:

- Produce a beta prototype device (TRL4) which is fine-tuned to enhance the detection of developmental dysplasia of the hip (DDH) in using the transmission of vibration across the joint.

The secondary objectives are:

- To optimise characteristic acoustic signatures of DDH in response to acoustic excitation.
- To refine the optimal acoustic frequency to be transmitted across the hip for the detection of DDH.
- To optimise the delivery and detection of the acoustic/ ultrasonic source.
- To develop a device that can be used by a single user.
- To develop software that interprets the acoustic signals received and displays them in a meaningful way to enable clinical decisions.
- To understand the market opportunities considering the health economics of screening for DDH.

3. STUDY DESIGN

This project will be split into appropriate Work Packages (WPs) as follows, with deliverables (Ds) listed for each WP. The total duration of the project is 24 months, with a total of 150 children being recruited over a 10-month period during WP 2. Of these 150 children, at least 25 will have a hip that is decentred on ultrasound examination. Participants for this study will be infants who have been referred to secondary care for ultrasound hip screening.

WP1: Prototype Development *(Months 1 - 9)*

A design house, Medtechtomarket Ltd., will build upon the proof-of-concept developed by LJMU to establish a specification for the sensor technology in terms of technical (i.e. device specifications), appearance (e.g., size) and performance (e.g., repeatability) characteristics. They will then develop the acoustic sensor system (i.e. acoustic sensor head and driving electronics) to meet these specification requirements. The system design and development must take into account particularly the patient size, ease of use (i.e., to minimise training requirements) in addition to elimination of background noise from environments in which testing is conducted. Cost will also be a consideration, although the team will aim to make the device largely reusable with the possible exception of the acoustic sensors adhered to the patient.

The device involves an external excitatory acoustic signal generated from an acoustic device, with an external microphone 'listening' and interpreting the transmission of the acoustic signal across the hip, and any echoed sound. A sound generator will be used to apply an external excitatory acoustic signal to determine the optimal frequency and intensity to determine a characteristic acoustic threshold. Based upon a well-considered specification, a prototype system suitable for use with human subjects will be realised. The sensor concept has already been demonstrated as a concept (TRL2/3) and therefore the prototype will be at TRL4 (i.e., constructed

and tested in laboratory conditions, but requiring testing (as per WP2) and validation (WP4).

It is expected at the end of this phase the following will be achieved;

D1.1 *Sensor specification and design to suit test environment on infant patients, and*
D1.2 *Prototype sensor system constructed.*

WP2: Sensor Testing *(Months 6 - 18)*
This WP will encompass aspects necessary as preparatory actions for testing (e.g., regulatory approvals and protocol development) in addition to the physical testing conducted primarily by staff at Alder Hey. A period of time has been included within this phase to allow for overlapping of tasks with sensor development, to mitigate risk of delays or questions arising from the application.

As the sensor development progresses, it will be important to establish a testing protocol that can be followed by clinical staff at Alder Hey during the course of their normal roles. This protocol will be developed jointly between the partners, and in part may inform the development activities of WP1. Once development is complete (Delivered D1.2) testing may commence for a 10 month period, in which it is anticipated that at least 150 patients (based on recruiting one per clinic for the first 5 months, and 2 per clinic in the subsequent 5 months (12 babies are treated per baby hip ultrasound clinic at Alder Hey, of which there are three clinics per week)). Initial recruitment will be lower to enable the device to be readily refined on an iterative basis. Purposive sampling will ensure that a broad spectrum of the pathology is included. At no point will the device be used to inform clinical decisions, and data from the device will be collected only to inform WP3. Testing of this device will be conducted in cases where ultrasound screening has been performed as part of routine clinical practice.

It is expected at the end of this phase the following will be achieved;

D2.1 *Finalisation study documents and begin recruiting,*
D2.2 *Test protocol specification, and*
D2.3 *Catalogue of data collected, with correlating ultrasound diagnosis in respect of hip dislocation.*

WP3: Data Analysis and Validation *(Months 15 - 21)*

A period of consideration and evaluation of the results will be undertaken by the team, to determine the sensor efficacy as a result of the trials in WP2, based upon D2.3. Statistical analysis of data will seek trends of sensor output that correlate with the diagnosis from ultrasound screening; discovered relationships will be tested for statistical significance, thus enabling prediction of the device accuracy and repeatability. At this stage the sensor system is expected to be at TRL4, i.e., at the point at which development of a commercial device can be considered.

It is expected at the end of this phase the following will be achieved;

D3.1 *Report of acoustic device efficacy based on D2.3 data, with full details of analysis process provided.*

WP4: Health Economics (Month 0-24)

A decision analytic model will be developed which is reflective of the diagnosis and management of DDH in the UK. The model will consider immediate and long-term outcomes. Cost-effectiveness will be estimated from the perspective of the UK NHS and Personal Social Services.

A literature review will be conducted to ascertain the distribution of age at diagnosis, the most likely treatment options based on age at diagnosis, and the associated long-term prognosis. Unit costs relating to the immediate treatment of DDH and significant long-term outcomes (e.g. pain management, hip replacement surgery) will be identified based on HRG codes [National tariff].

Utility decrements relating to health states (e.g. osteoarthritis) will be derived from the literature, else based on ICD codes [Sullivan2011], and combined with age related EQ-5D norms [Kind1998].

Where parameters are not able to be identified through the literature, formal expert elicitation methods (e.g. Sheffield Elicitation Framework SHELF) will be used in order to estimate the parameter and associated probability distribution. Expert input will be obtained via an e-mail survey using a remote elicitation tool [Morris2014, Grigore2017] and will be combined using mathematical techniques to generate a single distribution [Bojke2017].

Given that early diagnosis improves outcomes, we will simulate a series of hypothetical improved screening programmes and estimate cost-effectiveness expressed as the cost per quality adjusted life year (QALY) gained.

A threshold analysis will also be presented which will estimate the required improvement in screening efficacy required for a screening intervention to be cost-effective, based on a range of potential costs for the new screening programme.

Probabilistic sensitivity analyses will yield the probability of each screening strategy being cost-effective and will be used to conduct a value of information analysis which can be used to inform future research priorities [Wilson2015].

3.1 STUDY OUTCOME MEASURES

The following section details how the study outcomes will be measured.

For the primary outcome, the following measures will be used;

The sensitivity and specificity of the acoustic tool in the detection of DDH of the hip. This will be amongst children who are already undergoing routine ultrasound examination as part of the national selective screening program [i.e. current gold standard].

	Normal Acoustic Signal	Abnormal Acoustic Signal
Normal Hips (Graf 1)		
Mildly Abnormal Hips (Dysplastic)		
Dislocated Hips (Decentered)		

For the secondary outcomes, the following measure will be used;

- Usability -
- Acceptability to families.
-

3.2 STUDY TOOL – SAFETY TESTING

A draft risk assessment has been completed for the device. As it will not be used for diagnosis in this trial, risks associated with Use Errors are considered out of scope. Risks associated with electrical safety and generation of acoustic energy were identified.
As far as possible, the device has been assembled from commercially available units, which have individually been certified by their manufacturers for sale. It comprises a USB-audio interface, an amplifier and associated wiring, running from a 240v mains supply. All the units are housed in a protective case rated to IP67, which provides an extra means of operator protection and prevents access to any of the internal units. The device is controlled by a standard Windows PC connected via USB.
There are two attached parts which come into contact with the patient: the emitter and the detector. Both are housed in plastic enclosures which do not allow contact with internal components. The detector is purely passive. The emitter contains a commercial bone transducer which is powered by the amplifier. The amplifier can supply a maximum of 1.5A/12V. It generates a signal in the audible range 20-20000Hz. Sound level measurements have not been conducted but the audio volume is low in practice. We will carry out in-house electrical safety testing to EN 60601-1 1 “Medical electrical equipment — Part 1: General requirements for basic safety and essential performance”.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

All infants who are eligible to take part in this study (WP2) will have been referred to the baby hip ultrasound screening service as part of the national selective screening program for Developmental Hip Dysplasia.

4.2 INCLUSION CRITERIA

Neonates under 3 months old meeting the criteria for hip screening as part of the national screening program.

4.3 EXCLUSION CRITERIA

Children with joint contractures preventing normal body positioning during the routine neonatal examination of ‘Ortolani and Barlow’ (i.e. knee dislocation, arthrogryposis etc).

4.4 WITHDRAWAL CRITERIA

Parents may decide to withdraw their child from this study at any time. They will be advised that this will not affect the subsequent care their child receives.

5. ASSESSMENT AND FOLLOW-UP

The assessment will involve an additional examination during routine ultrasound, which being is undertaken as part of the national selective screening program. In addition to the ultrasound examination, the child will have the prototype device applied (i.e. an external excitatory acoustic signal will be generated from an acoustic device that is placed on the knee. An external microphone will 'listen' and interpret the transmission of the acoustic signal across the hip, and any echoed back to the knee).

6. STATISTICS AND DATA ANALYSIS

The primary outcomes will be the sensitivity and specificity of the final device after optimising the excitatory acoustic signals, and acoustic detection thresholds. The sample size is pragmatic based on the number of eligible participants that are likely to be identified during the study period.

7. REGULATORY ISSUES

7.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the Health Research Authority (HRA). The study will be submitted to each proposed research site for Confirmation of Capacity and Capability.

As this is in-house development, without any intention for commercialisation at this point, the UK medical device regulations 2020 (UKMDR202) deems that approval from the Medicines and Healthcare products Regulatory Agency (MHRA) is not required.

7.2 CONSENT

The assessment will involve a single additional examination during routine ultrasound examination as part of the national selective screening program. Prior to the routine clinic episode all parents will have details of the study sent to them as part of the routine clinic information that is offered to these parents. The information will outline the study, and inform parents that they may be invited to participate in this research. Parents will be advised that STEPS UK (the National Charity for Children with Lower Limb Abnormalities) have been instrumental in guiding the study and have advised on many aspects of the study to date, including the original concept, protocol development and consent process.

At the clinic visit, parents will be approached by the clinician and invited to participate in the research. If parents are willing, the research team will be introduced to the parents. The research team will outline the study and answer any questions. If parents are willing to proceed with participation in the study, signed consent will be sought. If parents wish to have more time to consider the research, the contact details of the researchers will be given to parents to enable future contact to make a mutually convenient appointment. If parents do not wish to participate, this will be respected without any detriment to care.

For parents who wish to participate, and complete the consent process, parents and their child will be invited to a clinic room adjacent to the routine room, in which the acoustic tests on the hip will take place. The research does not affect routine care and is an adjunct to routine care that will not influence the treatment offered.

7.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act.

They will ensure that participant's anonymity will be maintained and that their identities are protected from unauthorised parties. Participants will not be identified by their names on any study documentation, but by an identification code. The investigator will keep a separate participant enrolment log showing codes, names and addresses. A confidential research folder for each participant will be kept at the lead site (Alder Hey Children's NHS Foundation Trust) including any documentation that will include the participants details (e.g., consent form, participant contact letters and the assessment feedback report). These will also be stored electronically in a separate database which will be password protected and only accessed by designated members of the core research team.

7.4 INDEMNITY

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

7.5 SPONSOR

The University of Liverpool will act as 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.

7.6 FUNDING

The research is funded by a consortium from Alder Hey Hospital, Liverpool John Moores University and the University of Liverpool.

7.7 AUDITS

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 NHS Research Governance Framework for Health and Social Care (2nd edition).

8. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated through the Children's Orthopaedic and Trauma trials group.

9. END OF STUDY

The end of the study is defined as when all deliverables, as previously set out in the protocol, have been achieved.

10. ARCHIVING

Data and all appropriate documentation should be stored for a minimum of10 years after the completion of the study, including the follow-up period, unless otherwise directed by the funder/sponsor/regulatory bodies.

11. PUBLICATION POLICY

Patients and the Public

Material for dissemination will be developed in conjunction with the *patient panel*, the NIHR CRN: Children 'Young Peoples Advisory Group' and STEPS Worldwide.

STEPS have agreed to communicate the outcomes of the research via their newsletter, website and information packages. For the wider public it is planned that the INVOLVE national advisory group will be an important liaison throughout, with dissemination adhering to the 'make it clear' guidance.

Following the recommendations of the 2013 'GenerationR' report, written feedback will be offered to study participants, which is produced in accordance with the advisory groups (above). This will enable participants to gain appreciation of the contribution they have made to the research, and how this has positively influenced the care of others. Participant e-mail addresses will be collected on consent forms (as an optional field), to enable future dissemination in this manner. The SHINE website will enable the collection of e-mail addresses from other interested individuals to facilitate the final dissemination of results.

Specialists & Generalists:

On completion of the study, results will be formally presented to BSCOS and the British Orthopaedic Association (BOA). Results will be written for high impact journals, to target the both the specialist audience, and the generalist.

Research Bodies & Policy makers:

Cochrane have produced a review of screening for DDH, recommending further high quality research. If successful, this study could attract significant investment from Research Bodies (i.e. ARUK/ NIHR i4i/ EME) to develop the technology and industry to commercialize the project.

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13. APPENDICES

Appendices should be additional information to the protocol. It is not recommended to insert participant information sheets, consent forms, or other study documentation as appendices. Please submit these as individual documents.