Imperial College Healthcare NHS Trust

Imperial College London

The Sono-VE Study: Assessing the acceptability and feasibility of transperineal ultrasound and developing an ultrasound based predictive model for labour outcome.

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Sponsor

Imperial College London is the main research sponsor for this study.

For further information regarding the sponsorship conditions, please contact the Joint Research Compliance Office at:
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Funding

The British Medical Association through the Helen Lawson Grant has partly provided funding for the clinical fellow. The ultrasound machines provided are already available within the unit. There may be additional loaned ultrasound machines.

This protocol describes the study and provides information about procedures

for entry. Queries 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.

Table of Contents

1. STUDY SUMMARY

TITLE

The Sono-VE Study: Assessing the acceptability and feasibility of transperineal ultrasound and developing an ultrasound based predictive model for labour outcome.

DESIGN

This is a prospective observational study of transperineal ultrasound between 24-42 weeks gestation and a prospective longitudinal observational study in all term (37-42 weeks) labouring women.

AIMS

This study aims to **firstly** assess the effectiveness and acceptability of transperineal ultrasound in women presenting between 24 and 42 weeks gestation in comparison with digital vaginal examination (VE). **Secondly,** in all term (37-42 weeks) labouring women, we aim to create an ultrasound based labour record, “a sonopartogram” and from this develop a predictive model for the outcome of labour.

NULL HYPOTHESIS

That transperineal ultrasound

1) is not an acceptable or feasible technique in comparison with digital VE between 24 and 42 weeks gestation
2) cannot be used to predict labour outcome in term (37-42 weeks) labouring women.

OUTCOME MEASURES

Primary measures:

1. **Assessing feasibility of ultrasound by comparison with digital vaginal examinations:**

   - *Digital vaginal examination:* cervical dilatation, head station, caput, moulding, head position

   - *Ultrasound:*
     - *Transabdominal Ultrasound:* Fetal head position
     - *Transperineal Ultrasound:* Cervical dilatation**,** head-perineum distance, caput and moulding

2. **Acceptability** of Transperineal Ultrasound to patients

3. **Dataset** for predictive model of outcome of labour of Caesarean section due to failure to progress and/or fetal distress
   - Time to delivery
   - Mode of delivery
   - Primary indication for delivery
     - failure to progress
     - suspected fetal compromise

Secondary measures:

1. **Neonatal outcome**

   - Gender
   - Birth-weight
   - Apgar Scores at 1 and 5 minutes
   - Cord Gases
     - Fetal acidosis defined as arterial pH <7.10 and base excess >12.0mmol/l
   - Neonatal unit admission within 24 hours
   - Neonatal morbidity

ELIGIBILITY

All pregnant women booked at Imperial College Healthcare NHS Trust between the ages of 18 and 44 able to give consent

DURATION

The duration of the study is 3 years.

Keywords
Preterm, PPROM, labour, intrapartum, vaginismus, placenta praevia, transperineal ultrasound.

2. Introduction

2.1 Background

Introduction

Currently, all women admitted to St Marys Hospital (SMH) and Queen Charlotte's and Chelsea Hospital (QCCH) in common with delivery units throughout the world, undergo internal digital vaginal examination (digital VE) when they are thought to be in labour or where a diagnosis of labour needs to be discounted. Where labour is established, these digital VEs are characteristically performed every 4 hours or more frequently should concerns arise. The digital VE provides information about the descent through the birth canal of the presenting fetal part (usually the head), its position (which way around the baby's presenting part is) and the dilatation of the cervix.

The digital VE is an age-honoured practice however multiple examinations have been linked to ascending infection to the fetus[1], chorioamnionitis and endometritis as well as reduced time to delivery in preterm labour[1]. It may also be an uncomfortable experience for the labouring woman[2].

It is contraindicated in some circumstances, such as Placenta Praevia or Preterm Prelabour Rupture Of Membranes (PPROM). For some women with a fear of childbirth, previous sexual trauma or vaginismus, digital VEs are especially traumatic and for these women special arrangements are usually made to avoid digital VE except where absolutely necessary. Irrespective of these concerns, digital VE is a notoriously subjective technique and agreement between observers is frequently poor.[3,4] There is no way of objectively recording the findings as these are denoted purely by 'feel' and recorded in the notes as such, in relation to anatomical landmarks in the maternal pelvis and fetus. The findings are classically recorded on a 'partogram', a graphical representation of the progress of labour[5].

It has recently become possible to make assessments more objectively using ultrasound[6,7]. The favoured technique is transperineal ultrasound, where an ultrasound transducer encased in a clean cover is placed on the mother's perineum

but not in the vagina[8-11] and assessments of the descent of the presenting part of the baby[12,13], its position and cervical dilatation[14] can be made within 1-2 minutes and without exerting undue pressure (Figures 1-2). These measurements can be saved as ultrasound images and compared or assessed offline and plotted graphically as an ultrasound partogram, a sonopartogram[15](Figure 3). This would indicate Caesarean sections due to failure to progress.

Recently, research has shown that fetal Doppler examination demonstrating cerebral distribution (low cerebro-umbilical [C/U: MCA/PI] ratio) in advance of labour may be able to predict emergency Caesarean sections[16]. This challenges previously thought to be protective effect of cerebral redistribution[17] to perfuse the brain secondary to hypoxic insult and may help us to develop a model for Caesarean sections for presumed fetal distress.

2.2 Study Rationale and Hypothesis

Several studies have assessed the accuracy of transabdominal ultrasound in comparison with digital VE in determining fetal head position[18-21.] These have concluded that digital VE fails to identify the correct fetal head position in the majority of cases, especially at cervical dilatation ≤3-4cm. Although transperineal ultrasound has been used pre-labour to predict the likelihood of PPROM patients going into labour[22], its feasibility has not yet been assessed in the investigation and management of women either presenting with or established in labour. Initial studies have assessed head descent[12] and rotation[23] and angle of progression in labour[13,24] to assess the second stage of labour to predict the likelihood of spontaneous vaginal delivery, instrumental delivery or Caesarean section. However, there have not been any studies directly assessing the feasibility of transperineal ultrasound scans.

We hypothesise that transperineal ultrasound will be a feasible and acceptable technique in comparison with digital vaginal examinations for 24-42 weeks gestation.

Using the data gathered in term patients, we will develop a model to predict pregnancy outcomes. This may aid in delivery of care to pregnant women by providing a real-time online calculation tool for the likelihood of vaginal delivery and length of labour based on repeat ultrasound measurements. This will allow a more

accurate prediction of the mode of delivery and reduce the number of vaginal examinations. This will improve the information available to women and their birth partners about the progress of their labour.

We anticipate improvements to women's health with additional information allowing better decision-making during labour enhancing the accurate recording of labour to a recordable skill. Universally, it may reduce the frequency of intrusive internal examinations and associated infection and will also be potentially useful in allowing the assessment of women in whom digital VE is traumatic or contra-indicated.

Overall, it may create a paradigm shift on delivery units in an area where the standard assessments have not changed in over one hundred years allowing better provision of resources.

3. Study Objectives

Primary objectives:

1. Feasibility of transperineal ultrasound scanning
2. Acceptability of transperineal ultrasound scanning
3. Creation of a "Sonopartogram" (Figure 3); an ultrasound based labour record
4. Prediction model of time to delivery and mode of delivery at term
    - Caesarean section due to failure to progress and/or fetal distress

Secondary objectives:

1. Creation of a digital representation of the progress of labour (Figure 4).

4. Methodology and Design

4.1 Study Centre

The study will be conducted at Queen Charlotte's and Chelsea Hospital (Primary centre of the study) and St Marys Hospital at Imperial College Healthcare NHS Trust.

There will be:

- A named individual (Clinical Research Fellow) in the relevant Study centre responsible for co-ordinating the project locally, and reporting directly to the chief investigators known as the project manager
- Regular inspection by the project manager, under the supervision of the chief investigator, will be carried out ensuring that both the service (literature, communication, documentation, supervision and logistics) and facilities (Ultrasound, equipment and space) are of high standards.
- All those who contribute are experienced in ultrasound. Suitably trained doctors and midwives (including research midwives) may contribute data to study where this is agreed in advance with the Principal Investigator.
- This study will form part of a PhD thesis and/or other higher degrees.

4.2 Design

This is a prospective observational study of transperineal ultrasound between 24-42 weeks gestation and a prospective longitudinal observational study in all term (37-42 weeks) labouring women.

4.3 Duration

The duration of the study is 3 years.

4.4 Inclusion Criteria

- Gestation 24-42 completed weeks at study entry
- Aged 18-44
- Cephalic
- Singleton pregnancies
- Nulliparous
- Multiparous (excluded for the term predictive model group)
- Multiple pregnancies (excluded for the term predictive model group)
- Established (Active) phase of labour (included for the term predictive model group)

- Clinician opinion that patient is in the established phase of labour according to the current NICE guidelines[25]

4.5 Exclusion Criteria

- Younger than 18 years.
- Imminent iatrogenic intention to deliver
- Life threatening maternal or fetal compromise needing immediate medical attention and/or delivery
- Women who in the opinion of the researcher by virtue of language or learning impairment would be unable to give fully informed consent to the study.
- Miscarriage
- Intra-uterine death
- Previous cervical surgery eg. cone biopsy, cervical cerclage. Note- Single LLETZ is not excluded.
- Non-cephalic presentations
- Multiple pregnancies (for the term predictive model group)
- Multiparous patients (for the term predictive model group)
- Not in established labour (for the term predictive model group)

4.6 Withdrawal Criteria

Patients may be withdrawn from the study at any stage and all data captured in relation to their participation may be destroyed if they so request.

4.7 Recruitment methods

All groups will be identified by the project manager and emphasis will be placed on recruiting patients antenatally as much as possible. The project manager is a member of the participants care team. The project manager will organise the recruitment and written consent, which can be obtained by any one of the research team members that will have been trained (expected to be up to 8 doctors and midwives on the delivery units of both QCCH and SMH although primarily it will be at QCCH). These doctors and midwives will undergo induction and then maintenance training in the study protocol, transperineal ultrasound and data entry/governance

including GCP training. Where a midwife performs the ultrasound examination, it will not be the same midwife responsible for the ongoing care and digital VEs of that woman: another midwife or doctor should perform the examination. Where a doctor performs the ultrasound examination, that doctor will not make the decision for a course of action, it will normally be made by the next most senior doctor. Ultrasound examinations should not be the basis for a course of action unless a clinically unexpected and important situation that would change clinical management is not disclosed through digital VE but is through ultrasound.

Ahead of recruitment, a press release on the Imperial College Healthcare NHS Trust and Imperial College website will display recruitment posters. We will advertise on other relevant websites and display recruitment posters at other sites.

Recruitment areas

- Patient's attending the Early Pregnancy Unit (≤20 weeks gestation)
- Antenatal Clinic (all trimesters)
- Parent Craft classes (second and third trimester)
- Fetal Medicine Unit (all trimesters)
- Day Assessment Unit, Maternity Triage and Labour Ward (≥20 weeks gestation).

The project manager will organise a formal meeting with the charge nurses from all areas to inform them of the study upon ethics approval.

4.8 Consent and Information leaflet

(see supporting documents)

All participating patients will be consented prior to enrolment, and will receive a full explanatory information leaflet. All recruiters will be GCP trained.

4.9 Method of study

For each of the two individual studies, a separate information leaflet detailing the purpose will be provided to all potential recruits (see supporting documents and flow chart- **figure 7**). If a patient is willing to participate, written consent will be obtained.

The patients will then take part in a researcher led Reproductive Health interview which includes routine demographic data and information regarding previous obstetric, medical and gynaecological history, as well as questions regarding psycho-sexual health history. Where possible, the demographic and sensitive information relating to participants such as the ethnicity, obstetric and mental health history will be obtained by the researcher from the participants notes. All information will be entered into a secure study database. Patients will be identified by study number only.

During the ultrasound examination, women will be in the supine position with flexed hips and knees and the bladder empty as previously described. Healthcare professionals will be blinded to the ultrasound findings and these findings will also not be disclosed to the parents. Another doctor or midwife will perform all the ultrasound examinations.

Fetal position will be assessed with a transabdominal scan and recorded with half hourly divisions[7]. Thereafter, the transducer will be placed transperineally at the level of the posterior fourchette in a transverse position (Figure 1), and cervical dilatation[14] and head-perineum distance (HPD) measured as previously described[22]. Caput succedaneum will be measured in a sagittal transperineal scan[9,15] (Figure 1). Moulding will be assessed as either present or not[12].

The healthcare professional will perform digital vaginal examination assessing cervical dilatation, fetal head descent and position. The descent will be categorised using the WHO classification of fetal head station with the ischial spines as reference point 0, -5cm at the pelvic inlet and +5cm at the pelvic outlet[27].

Acceptability and Feasibility:

In this group, patients will also be asked to complete two additional researcher-led questionnaires (modified from a previously validated questionnaire -see supporting documents). This will be in the form of a “pre-study” and a “post-study” questionnaire which will focus on the patient’s views regarding vaginal examinations and the transperineal scanning method to assess the acceptability of the technique.

Transperineal ultrasound will then be carried out between gestations 24-42 weeks when a vaginal or speculum examination is otherwise also required to assess acceptability and feasibility. This scan will be done either immediately before or after the digital vaginal examination and the timing in relation the digital vaginal examination will be recorded.

Predictive Model:

In the predictive model group, there are no additional questionnaires. An admission ultrasound scan will be performed when the patient is deemed to be in established labour by the attending clinician. Subsequent scans will be performed as required at the time of routine clinical examinations typically between 2-4 hours apart.

The admission ultrasound scan will include if feasible fetal Doppler assessment of the umbilical artery, the cerebro-umbilical ratio (C/U: MCA/PI)[16]. Amniotic fluid index will also be measured. Fetal position will be assessed with a transabdominal scan and recorded as described above.

Dataset

Fixed variables

Maternal
Gestation
BMI, Age[28], Parity, Height, Ethnicity
Contraindication to vaginal examinations
Reason for avoidance of vaginal examinations

Fetal
EFW if known
Singleton
Multiple

Intrapartum
Non-USS:
Rupture of Membranes Yes/No: If Yes: Time
Spontaneous onset of labour Yes/No: If Yes: Time
Induction of Labour with prostaglandins Yes/No: If Yes: Time at insertion of prostaglandin

Syntocinon Yes/No: If Yes: Time
Epidural analgesia Yes/No: If Yes: Time

Modifiable parameters

USS Parameters: modified as labour progresses
-head position (TA ultrasound scan)
-cervical dilatation
-head-perineum distance
-caput
-moulding

Prolonged first stage of labour will be diagnosed according to national guidelines set in the UK by the National Institute of Health and Clinical Excellence (NICE) guidelines (cervical dilatation of < 2 cm in 4 hours)[25].

If recruited to the study, all patients will undergo normal clinical management with digital VEs or speculum examination performed as planned and in addition, ultrasound examinations before the digital VE/speculum by trained professionals. These ultrasound examinations will be blinded to the normal caregivers (midwives or doctors) so that they do not influence clinical management, though for practical reasons it will not be possible to blind the ultrasound operator to the clinical findings.

In women where **digital** vaginal examinations are contraindicated, we will compare ultrasound observations to those obtained by speculum. In all other women, ultrasound measurements will be compared to the corresponding digital vaginal examinations. In women who decline **digital** vaginal examinations for psychological reasons, this will be noted.

There are no additional visits outside the normal care pathway for the patient.
The length of years of obstetric experience of the healthcare professional carrying out the digital vaginal examinations, speculums, ultrasound scan and the delivery will be recorded.

Study Timeline

The study will run according to the following timeline:

- **Months 0-3:** Ethics completion, staff training, and setting up web based study screens
- **Months 3-27:** Active study recruitment
- **Months 27-36:** Analyses and write up of an ultrasound based labour record (the sonopartogram) and development of a predictive model.

4.10 Study Closure

Data will be collected over the 24 months data collection period.

4.11 Documentation

Recruitment of patients will be noted in the NHS notes. Where photographs of the ultrasound images were obtained, these will be saved securely onto an NHS computer and/or printed in hard copy, which will be filed in a locked secure area. Data will be stored for a minimum of 10 years after completion of study, including the follow up period.

4.12 Patient Engagement

Patients were involved in the creation of the initial study[15] through the Cambridge Maternity Services Liaison Committee, and their feedback from the participation helped shape this research proposal. We have received outline support for the project from the RCOG Intrapartum Care Clinical Study Group led by Dr Sara Kenyon in 2012 and lay representatives, though this latest iteration of the project design has not yet been submitted to the group. Patient views are important in designing this study to maximise recruitment and we have previously consulted the RCOG to invite lay members to steering committees of a similar previous study (Transvaginal Ultrasound Scanning – Hazard and Clinical Practice, awarded CCF Grant, 2012). We will arrange Parent Focus Group Meetings alongside their hospital Parent Craft classes so they do not have to devote extra time to this and explore how they feel this research should be conducted. As well as active recruitment, they will also be allowed to self-volunteer to take part in the study with leaflets in various clinical areas. The Imperial Trust website also fosters public interest by including

links to the Clinical Research Network Coordinating Centre, Women's Health Research Centre and to the ongoing various projects.

4.13 Dissemination to participants

Participants, if consented, will be emailed the results of the study in the form of anonymised published posters and papers.

4.14 External peer review

An earlier version of this protocol has been subject to external peer review by the British Medical Association leading to external funding (Helen Lawson Grant, awarded July 2014)

5. Study Outcome Measures

5.1 Primary measures:

1. **Assessing feasibility of ultrasound by comparison with digital vaginal examinations:**

    - *Digital vaginal examination:* cervical dilatation, head station, caput, moulding, head position

    - *Ultrasound:*
        - *Transabdominal Ultrasound:* Fetal head position
        - *Transperineal Ultrasound:* Cervical dilatation**,** head-perineum distance, caput and moulding

2. **Acceptability** of Transperineal Ultrasound to patients

3. **Dataset** for predictive model of outcome of labour of Caesarean section due to failure to progress and/or fetal distress
    - Time to delivery

- Mode of delivery
- Primary indication for delivery
    - failure to progress
    - suspected fetal compromise

5.2 Secondary measures:

1. **Neonatal outcome**

    - Gender
    - Birth-weight
    - Apgar Scores at 1 and 5 minutes
    - Cord Gases
        - Fetal acidosis defined as arterial pH <7.10 and base excess >12.0mmol/l
    - Neonatal unit admission within 24 hours
    - Neonatal morbidity

6. Adverse events and reporting procedure

RISK ASSESSMENT - This study will not involve any risk to the participants. There are no predicted risks associated with the additional transabdominal and transperineal ultrasound scan. The scans will be used at the same settings and duration as routine ultrasound. We will be using probe covers and disinfection spray to clean the probe between patients.

The patient will be managed accordingly in concordance with local guidance and follow up arrangements will be made. The patient will still be followed up for the purposes of the study.

6.1 Definitions

Adverse Event (AE): Any untoward medical occurrence in a patient or clinical study

subject.

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**

6.2 Adverse events

There are no risks to the patients or the fetus from this study. There is also no evidence to suggest any harm to the mother or the pregnancy associated with the use of ultrasound. Patients may experience slight discomfort when the probe is placed, though this is usually considered less than the discomfort experienced with vaginal examinations. We will be using probe covers and disinfection spray to clean the probe between patients. Medical judgement will 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, will also be considered serious.

6.3 Reporting procedures

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the Chief Investigator in the first instance.

Non serious AEs

All such events, whether expected or not, will be recorded.

Serious AEs

An SAE form will be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs will be reported to the Chief Investigator who will determine if the event was:

- **Related-** resulted from the administration of any of the research procedures; and
- **Unexpected-** an event that is not listed in the protocol as an expected occurrence
- **Unrelated-** an event that is not related to the study

Reports of related and unexpected SAEs will be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator will also notify the Sponsor of all SAEs.

Local investigators will report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting adverse events:

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7. Study Population and Sample size

Recruitment will start upon approval of the study. The infrastructure, research fellow, ultrasound machines, and the database are already in place, which ensure that the study can start promptly upon approval, without affecting or compromising routine clinical service provision.

We aim to recruit minimum number in the groups according to the following calculations[29]:

Primary outcome:

Acceptability

In studies thus far, acceptability of transperineal ultrasound (with no or minimal pain) varies from 68%[30] to 95%[31] compared with 20% for vaginal examinations[30]. Using the lowest percentage of acceptability at 68%, with an alpha of 0.05 and a power of 90%, the minimum sample size required is 42 patients. However, given that this area has been poorly researched before and the power calculation is purely indicative, we would expect to collect at least 100 questionnaires.

Feasibility

A recent study by our group has shown that 95%[15] of transperineal ultrasound parameters can be obtained compared to 82% of digital vaginal examination parameters[15]. With an alpha of 0.05 and a power of 90%, the minimum sample size required is 250 patients.

Labour prediction model

For the labour prediction model, there are approximately 15 variables with 10 patients needed per variable[32-34] and an approximate 25% Caesarean section rate[28,35,36] (the primary outcome) in the UK currently. This equates to 600 patients needed for the study.

Calculation:
15 x 10 x (100/25) = 600 patients

As already discussed above, for statistical power and significance, a minimum of 42 and 250 patients is required for acceptability and feasibility respectively (24-42 weeks). For the predictive modelling, 600 patients are required (37-42 weeks).

The majority of the patients for the acceptability and feasibility samples will be recruited from the predictive modelling group (gestation 37-42 weeks). However, to allow sufficient data collection for feasibility, acceptability and development of the model, at least 700 patients will be required. As the trust has an annual delivery rate of 9000 annually, over a 24-month data collection period with a delivery rate of 18,000 across the trust, 700 patients (4%) sample size is achievable.

7.1 Statistical and Data Analysis

In both groups, data will be collected prospectively and compared with vaginal examinations. In the second group, there will also be additional longitudinal measurements.

We will use a p value of <0.05 to indicate significance.

All measurements will be entered online at the time of examination to a secure database on the Imperial College Healthcare NHS Trust shared server where the patient will be identified by study number only. The database entry page will be accessible to investigators on their login, though they cannot interrogate data already entered. The data rules will follow closely to those performed through the recently completed multicentre European TRUFFLE study of fetal growth restriction where ultrasound measurements were captured at the time of examination[37].

For 24-42 weeks assessment of acceptability and feasibility:

Acceptability and preference will be tested using a questionnaire with Likert scale for discomfort, adapted from the W-DEQ Score[38]

Feasibility of the ultrasound technique will be compared to digital VE for (a) total number of observations missing (head descent, position and cervical dilatation) during an admission on the delivery unit and (b) number of ultrasound examinations or digital VEs that could not be carried out for whatever reason where there was an intention to carry out a digital VE.

As a part of feasibility, *Reproducibility* between the *ultrasound and digital VE techniques* will be assessed both as a correlation (r) and agreement (using the Bland Altman method) between the ultrasound method and digital VE for head descent and cervical dilatation, and the Kappa statistic for head position.

Term predictive model:

The predictive value of intrapartum ultrasound parameters will be investigated using linear and logistic regression analyses. We will calculate the Receiver Operating Characteristic (ROC) curve with the Area Under the Curve (AUC) and associated positive and negative predictive values for delivery outcomes in the evaluation of transperineal ultrasound as a diagnostic tool.

8. Study supervision and Monitoring

Central and local supervision: the chief principal investigator at Imperial College London will be responsible for the protocol, quality control, interim analyses of the data, advice on progress and final analysis and reporting of the study. The Imperial Joint Research Compliance Office may audit the study as part of routine research governance.

9. Regulatory Issues

9.1 Ethical approval

The Study Coordination Centre will obtain ethics approval from the XXX Research Ethics Committee. The study also has been submitted for Site Specific Assessment (SSA) at Imperial College Healthcare Trust for local Trust Research and Development approval.

9.2 Consent

Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The patients GP will be informed of participation if the patient agrees. The right of the participant to refuse to participate without giving reasons will be respected.

After the participant has entered the study the clinician will be expected to manage the patient in exactly the same way that would have been expected had the participant not entered the study. The clinician will be blind to the information obtained from ultrasound assessment. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

9.3 Data Collection and Confidentiality

A study identification number anonymising all patient data will be used to collect and store data on an NHS computer software programme or database. The data may be transferred to a Third Party within the European Union but this will be an anonymised way with the use of study identification number only. This may be by an online website with secure access only. The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

9.4 Data Storage and Archiving

All data will be stored for 10 years in accordance with the Imperial College data archiving policy.

9.5 Indemnity

Imperial College London holds negligent harm and non-negligent harm insurance policies, which apply to this study.

9.6 Sponsor

Imperial College London will act as the main sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

9.7 Audits and Inspections

The study may be subject to inspection and audit by Imperial College London 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). Direct access to source data/documents as requested will be permitted.

10. Study Management

The day-to-day management of the trial will be co-ordinated through the Centre for Fetal Care at Queen Charlotte's and Chelsea Hospital by Dr Sana Usman, the Project Manager. The week-by-week supervision will be by the Chief Investigator and the other collaborators who will form the study management group.

11. Publication Policy

All publications and presentations relating to the study will be authorised by the Study Management Group. The investigators will therefore be responsible for publication of the data. As such they are co-authors in all resulting clinically relevant papers, to which they made significant contributions. Co-authors will be included according to their contribution in the study and depending on the journals publication guidelines.

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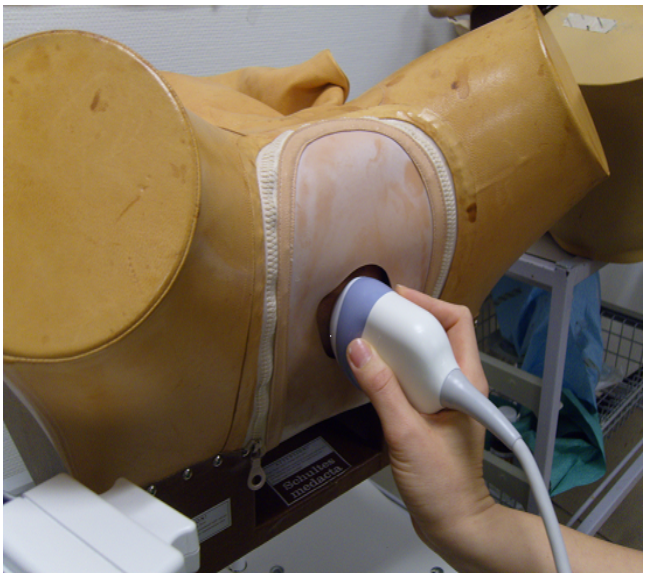
12. Appendix

Sagittal Scan:



Transverse scan:

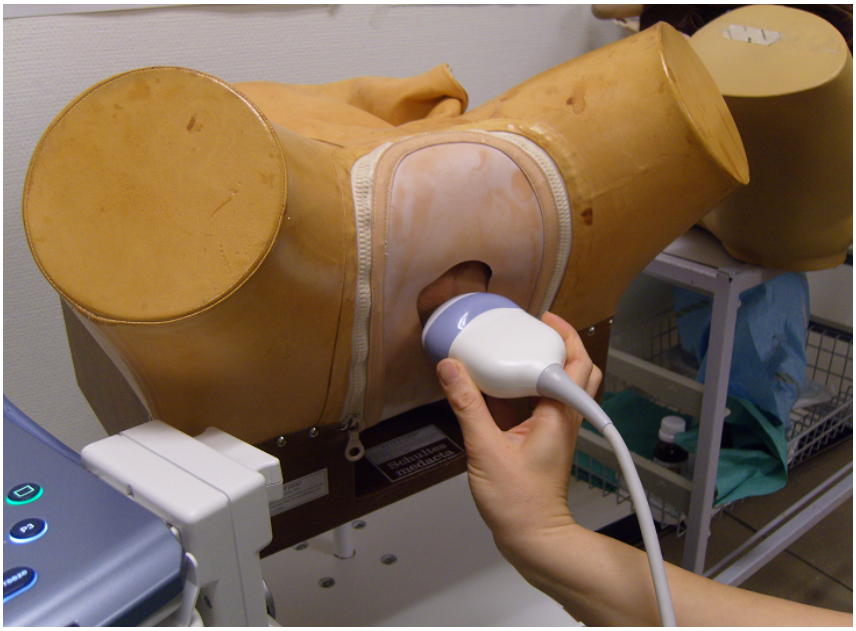


Figure 1 Transperineal Sagittal and Transverse application of 2D transducer. The sagittal scan is used to obtain views of the maternal symphysis pubis and fetal skull. The transducer may be rotated 180 degrees (transverse application) in order to visualise the cervix and head-perineum distance[14].

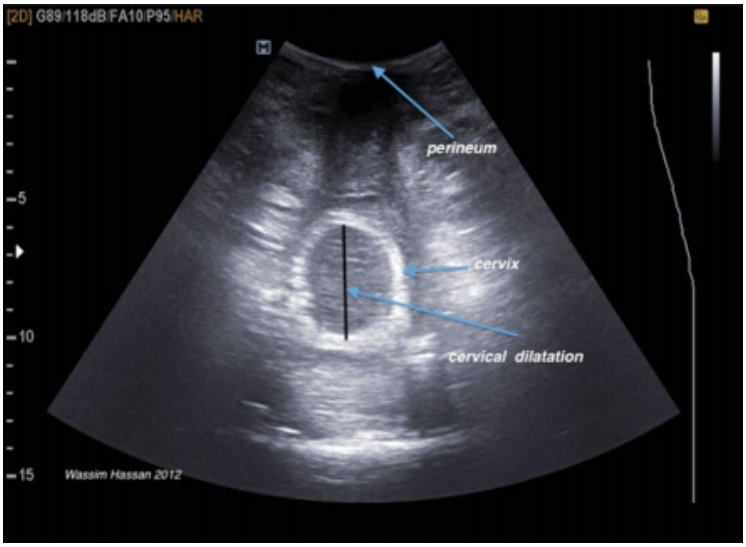


Figure 2 Cervical dilatation assessed by 2D transperineal ultrasound during labour. The cervical dilatation is clearly visible at the centre with vaginal wall hyperechogenic laterally to the cervix. At the top of the picture is the perineum where the transperineal probe is placed[14]

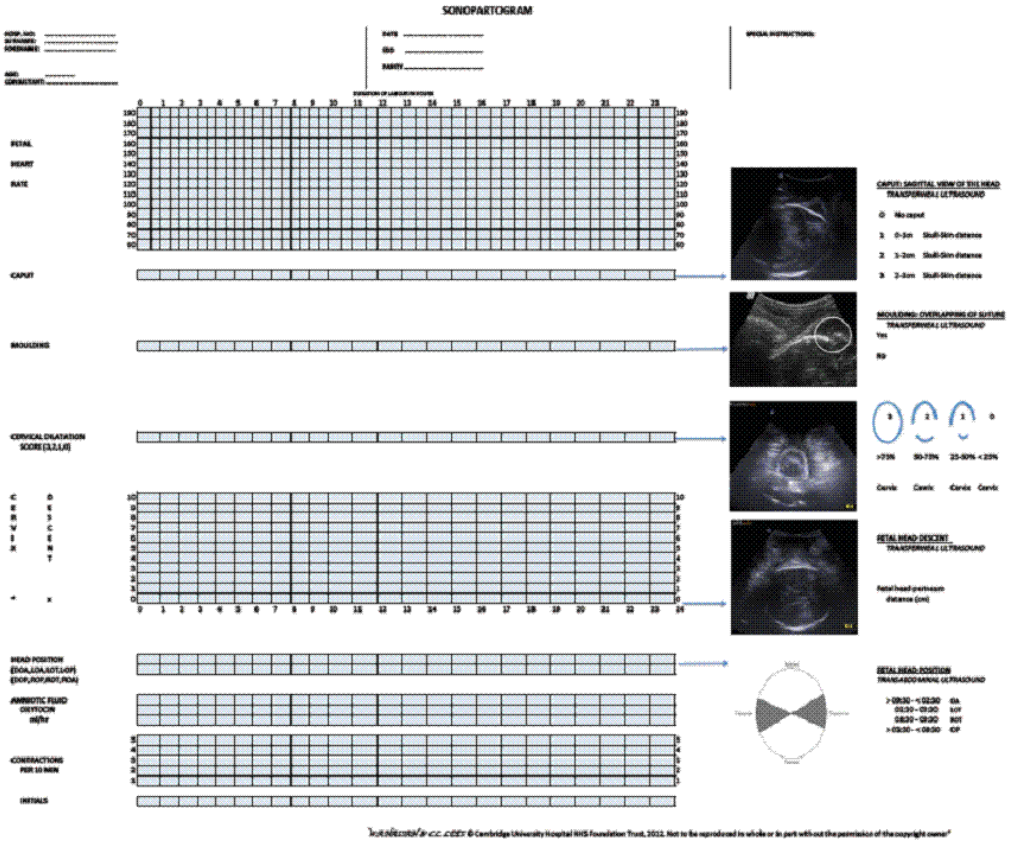


Figure 3 The sonopartogram[15].

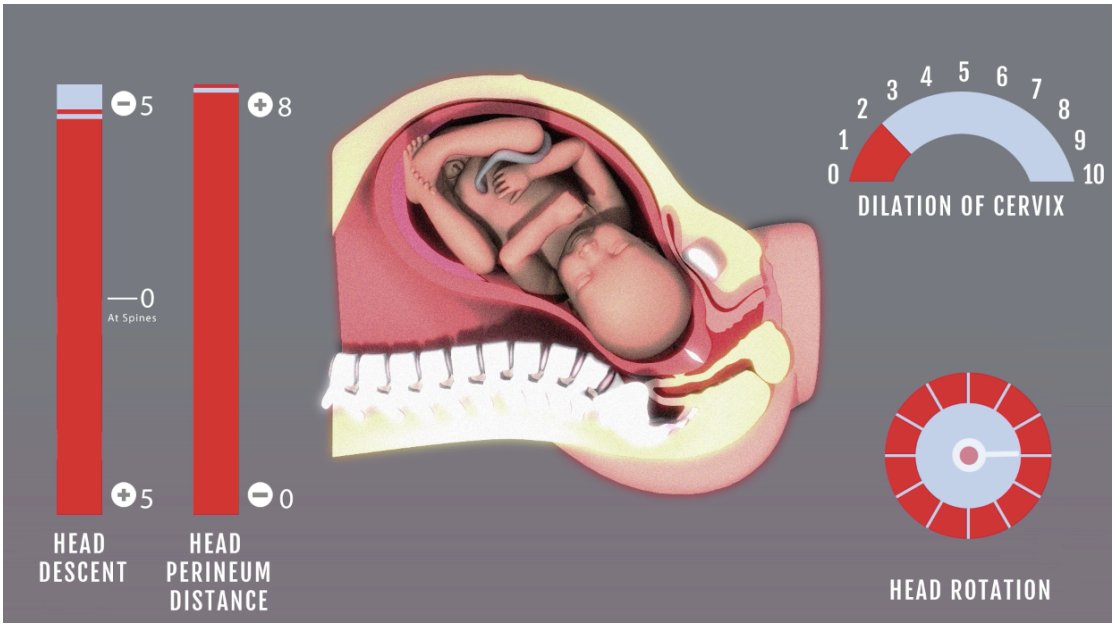


Figure 4 The sonopartogram animation video- note we have only been able to provide a screenshot. (*Courtesy of Mr CC Lees)*.

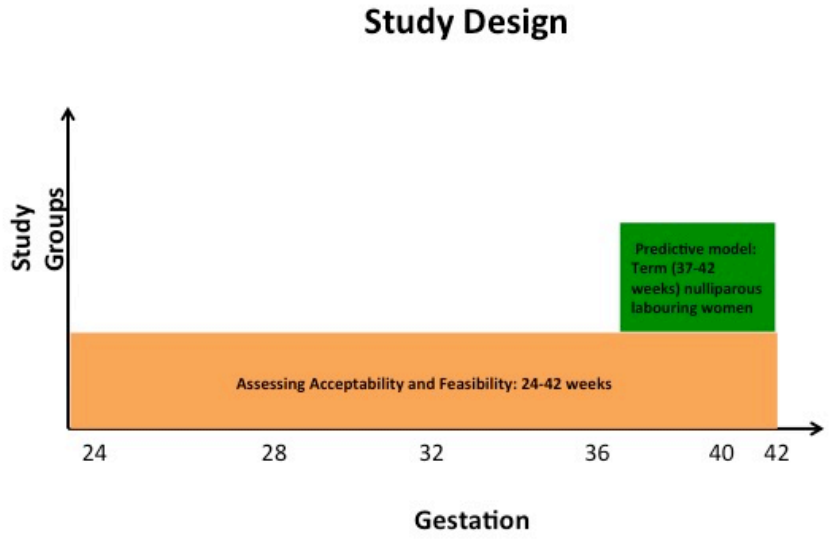


Figure 5- Study Design Overview

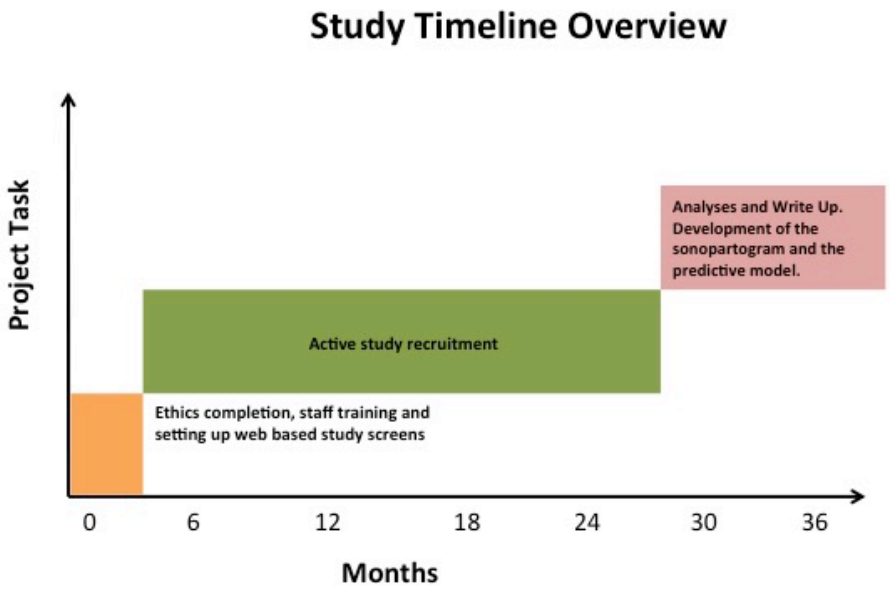


Figure 6- Gantt Chart of Study Timeline

Figure 7: Flowchart of study design