Management of an impacted fetal head during emergency caesarean section

Final Version 4.0
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Title:	A Study to determine the feasibility of a randomised trial of different techniques for Managing an Impacted fetal heaD At emergency caesarean Section
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SYNOPSIS

Title	A study to determine the feasibility of a randomised trial of different techniques for **M**anaging an **I**mpacted fetal hea**D** **A**t emergency caesarean **S**ection.
Acronym	MIDAS
Short title	Management of an impacted fetal head during emergency caesarean section
Chief Investigator	Dr Kate Walker
Objectives	To determine the feasibility of a randomised trial of different techniques for managing an impacted fetal head during emergency caesarean section.
Study Configuration	Scoping study, which includes 5 work packages
Setting	Secondary care for focus groups
Sample size estimate	Sample size calculations only relate to work packages 1 (focus groups only) and 5 and will be guided by data saturation but is expected to be approximately 20 women (WP1) and approximately 20 women and 10 obstetricians/senior trainee obstetrician (WP5).
Number of participants	As above
Eligibility criteria	**Inclusion criteria** **WP1** <u>Women</u> Women who have experienced a second stage caesarean section in the twenty four months preceding the date of the focus group Aged 16 years or older Women must speak adequate English Ability to give informed consent <u>NHS staff</u> Aged 16 years or older Must speak adequate English Ability to give informed consent <u>Parents</u> Who have had a baby born in the last five years **WP3** Delphi Survey

	Consultant obstetricians or senior obstetric trainees Neonatologists **WP5** <u>Survey</u> Pregnant women Aged 16 years and older NHS staff working as either the lead obstetric consultant on an obstetric unit or a midwife <u>Focus group</u> Pregnant primiparous women or women who have experienced a second stage caesarean section in the eighteen months preceding the date of the focus group Aged 16 years or older Women must speak adequate English Ability to give informed consent <u>NHS staff</u> Aged 16 years or older Ability to give informed consent Exclusion criteria: None
Description of interventions	Work package 1 a) National survey of obstetricians, trainee obstetricians, obstetric anaesthetists and midwives to determine current practice, level of experience and training requirements for managing an impacted fetal head during emergency caesarean section. b) Focus group of women who have experienced second stage caesarean section to determine the acceptability of a randomised trial in this area and their views on the different proposed techniques. c) National survey of parents to determine their views on this topic. Work package 2 a) To conduct a United Kingdom Obstetric Surveillance System (UKOSS) surveillance study to determine the incidence and consequences of impacted fetal head in the UK. Work package 3 a) Based on the findings of 1-2, to conduct a Delphi survey followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in any trial. Work package 4

	a) On the basis of findings of 1-3, to design a randomised trial of different techniques for managing an impacted fetal head during emergency caesarean section Work package 5 a) National survey of lead obstetricians (via UK labour ward leads group), pregnant women (via National Childbirth Trust) and midwives (via Royal College of Midwives) to determine the feasibility and acceptability of the randomised trial designed in 4. b) Three sets of individual telephone or video interviews: lead obstetricians/senior obstetric trainees; women who have experienced a second stage CS and primiparous women to determine the acceptability and feasibility of the planned trial.
Duration of study	24 months
Methods of analysis	For the focus groups: framework analysis

ABBREVIATIONS

CI Chief Investigator overall

CS Caesarean Section

CRF Case Report Form

GCP Good Clinical Practice

NHS National Health Service

NIHR CRN National Institute for Health Research Clinical Research Network

PIS Parent Information Sheet

PI Principal Investigator at a local centre

PIS Participant Information Sheet

PMG Project Management Group

RCT Randomised controlled trial

REC Research Ethics Committee

R&D Research and Development department

UKOSS UK Obstetric Surveillance System

UoN University of Nottingham

WP Work Package

VERSION CONTROL TABLE

Version Number	Author	Purpose/Change	Date
1.0	K Walker	Draft for ethical approval	30.01.19
2.0	K Walker	Final changes following review	30.04.19
3.0	K Walker	COVID-19 changes	17.08.20
4.0	K Walker	Study amendments prior to WP5	25.08.20

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STUDY BACKGROUND INFORMATION AND RATIONALE

Caesarean section (CS) accounts for 26% of all deliveries in the UK (1) of which at least 5% are done at full dilatation (in the second stage of labour), (34,000 deliveries per annum) (2).

Emergency caesarean sections performed in the second stage of labour have greater perinatal and maternal morbidity than those performed in the first stage (3).

Second stage CS may be complicated by the fetal head being deeply impacted in the maternal pelvis which occurs in 1.5% of all emergency CS (4). Complications include: longer delivery times, uterine tears, injury to the baby.

Numerous techniques to assist in delivery of a deeply impacted head with the aim of trying to reduce the risk of both fetal and maternal complications are reported. The superiority of one technique over another is contentious. Evidence is derived from studies in lower resource settings where there may be significant delays in performing a second stage CS in comparison to UK practice.

For management of an impacted fetal head at CS at present there is no national guidance on what techniques to employ, no embedded training for midwives or obstetricians when faced with this scenario and no consensus on best practice.

The results of this study will be the driving force behind any future randomised trial in this area. It will increase our understanding of the prevalence of an impacted fetal head at caesarean section and the frequency of complications for the mother and baby arising from it. It will increase awareness of the problem amongst health care professionals and parents. It will highlight training deficiencies in this area.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

To determine the feasibility of a randomised trial of different techniques for managing an impacted fetal head during emergency caesarean section.

PRIMARY OBJECTIVES

1. **Work package 1:** To conduct a national survey of obstetricians and trainee obstetricians to determine current practice, level of experience and training requirements for managing an impacted fetal head during emergency CS. To conduct a national survey of midwives on their experience of providing pressure to the fetal head vaginally and training requirements. To conduct a national survey of obstetric anaesthetists to determine their experience of assisting with management of an impacted fetal head e.g. administration of tocolytics. To conduct a focus group of women who have experienced second stage CS to determine the acceptability of a randomised trial in this area, and their views on the different proposed techniques. To conduct a national survey of parents to determine their views on this topic.
2. **Work package 2:** To conduct a UKOSS surveillance study to determine the incidence and consequences of impacted fetal head in the UK. Approval for this aspect will be by substantial amendment to the UKOSS study (REC reference: 10/H0717/20) sponsored by the University of Oxford and therefore does not form part of this protocol.

3. **Work package 3:** Based on the findings of work packages 1-2, a Delphi survey will be conducted followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in an RCT.
4. **Work package 4:** On the basis of findings of work packages 1-3, a randomised trial of different techniques for managing an impacted fetal head during emergency sections will be designed, accounting for the level of experience of the clinician, blinding or how potential bias could be managed; randomisation and consent; and training implications for conducting such a trial.
5. **Work package 5:** To conduct a national survey followed by three sets of individual telephone or video interviews: of obstetricians/senior trainee obstetricians; women who have experienced a second stage CS and primiparous women to determine the acceptability and feasibility of the planned RCT.

STUDY DESIGN

STUDY CONFIGURATION

Our scoping study will determine the feasibility of a randomised trial of different techniques for managing an impacted fetal head during emergency CS. Work packages 1-3 aim to determine what the best techniques are to test in an RCT and parents' views of these techniques. Work packages 4-5 will be the design of a potential RCT and determine its acceptability to women and health care professionals.
Our study is a mixed-methods study and is broken down as follows:

WP1:
Questionnaire study of several groups (health care professionals and parents) via online questionnaires.
Qualitative study taking place in secondary care involving focus groups of women who have experienced a second stage CS.

WP2:
National audit of current practice, taking place in secondary care via UKOSS.

WP3
Conduct a Delphi survey followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in any trial.

WP5:
Qualitative study taking place in secondary care involving focus groups of women who have experienced a second stage CS; obstetricians and senior trainee obstetricians and primiparous pregnant women.

STUDY MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

A Project Management Group (PMG) will be responsible for day-to-day management of the project. Membership of this group will include the Chief Investigator (Walker), Assistant Professor (Mitchell) and Associate Professor (Jones) and study coordinator, with other members of the project team invited to attend as necessary. This group will meet monthly for

the duration of the project. Day-to-day management of individual work packages will be the responsibility of work package lead/co-leads, supported by the PMG.

Oversight will be by a Study Steering Committee consisting of the co-applicants, who are also projects leads and co-leads for the individual work packages and independent members approved by the funding body. This Steering Committee will meet (in person) prior to commencement of the project and then at a minimum of once yearly (to be decided by the Committee according to NIHR guidelines and outlined in the Charter), to ensure maximum integration of the work, problem solving of any issues, and timely delivery of outputs. The PMG will report to the Steering Committee.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: 24 months

Participant Duration: Participants will be included in a single focus group in WP1. They may also participate in the interviews as part of WP5. NHS staff will be included in interviews as part of WP5. WP1 will involve national surveys of several groups of NHS staff and parents.

End of the Study

When all data for WP1-5 is collected.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Recruitment of health care professionals and parents for the national surveys in WP1 and WP5, the Delphi survey (WP3) and the interviews of trainee obstetricians and obstetricians (WP5) will be conducted in the following ways:

Trainee obstetricians
The UK Audit and Research Collaborative in Obstetrics and Gynaecology (UKARCOG) committee represents a network of obstetric trainees throughout the UK. UKARCOG will promote the study to their regional leads who are located within the geographic areas classified by Health Education England ('Deanery') plus leads in the devolved nations, who will then cascade the survey to trainees within their regions. We will also ask this group of their willingness to participate in the Delphi survey (WP3) and the interviews (WP5).

Consultant obstetricians

We will conduct an identical survey of consultant obstetricians via the UK Labour Ward Leads Group. We will also ask this group of their willingness to participate in the Delphi survey (WP3) and the interviews (WP5).

Midwives

The Royal College of Midwives have confirmed that they will publicise the study on social media (Facebook and Twitter) to their membership through Louise Silverton, Director of Midwifery at the RCM. The survey will be available to all the approximately 3000 members of the RCM to participate. The reach and response to the survey will be maximised by repetition of the publicity. We will ask this group of their willingness to participate in the Delphi survey (WP3).

Consultant obstetric anaesthetists

We will conduct a national survey of consultant obstetric anaesthetists via the Obstetric Anaesthetists Association (http://www.oaa-anaes.ac.uk). We will ask this group of their willingness to participate in the Delphi survey (WP3).

Parents
Women and their partners

The National Childbirth Trust (NCT) have an extensive network of social and mainstream media connections and parent education classes. They will ensure widespread dissemination of the survey by sharing a survey link on their social media feeds and the results will be shared with parents and practitioners through NCT mailings and CPD events.

The acceptability of such an RCT to women and their partners will be explored in detail using one focus group of women who have experienced a second stage CS in WP1 and interviews: with primiparous pregnant women and women who have experienced a second stage CS, in WP5.

The NIHR CRN will facilitate recruitment of potential women for WP1 and WP5. This will involve one NHS hospital (Nottingham University Hospitals NHS Trust) acting as a Participant Identification Centres (PIC) for this study. Pregnant primiparous women or women who had a second stage CS in the prior twenty four months will be identified from hospital records by a member of their treating care team. Both urgency of CS (emergency versus elective) and indication for CS (failed instrumental delivery) are mandatory reporting fields on the Maternity dataset enabling women to be identified. To ensure diversity amongst the women who participate systematic sampling will be used based on ethnicity and postcode indices of deprivation (http://imd-by-postcode.opendatacommunities.org/). Women will be identified through hospital records and sent a letter of invitation and participant information sheet (PIS). If they are interested in taking part they will return a pre-paid postal card to the research team indicating their interest and providing contact details. Those who agree to participate will be invited to attend a focus group in Nottingham for WP1. Participants' travel and childcare costs will be reimbursed. For WP5, all interviews will be conducted via telephone or video conferencing.

To increase the generalisability of the results of the WP5 interviews, primiparous women and women who have had a second stage CS in the prior twenty four months will also be invited to take part via social media. Due to the interviews being conducted exclusively by telephone or video, recruitment will not be restricted to Nottingham only.

Purposive sampling will be used to ensure specific groups are represented where there is evidence the characteristics of these groups might influence the acceptability of different intrapartum tests or techniques and where groups are typically under-represented in perinatal research. In WP1 we will sample women who have experienced a second stage CS. Postcode indices of deprivation will be used when sending out invitations to ensure samples of women are diverse and representative. There is also evidence that ethnicity may affect the acceptability of intrapartum tests (5). Women must speak adequate English but will not be excluded for reasons of literacy as the researcher will read information to women who need this. Sample size will be guided by data saturation but is expected to be approximately 20 women in WP1 and 20 women in WP5.

Women who participate in the focus group in WP1 will also be able to participate in WP5 if they wish.

Purposive sampling will be used to ensure a range of views and experiences are represented and when approaching women the importance of this will be emphasised. Recruitment information for these groups will emphasise that we want to hear about all experiences (good and bad), and how staff actions' helped parents cope with the experience. Our PPI group will review recruitment materials and consider how best to phrase things and get productive discussion going.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Eligibility criteria is for women and NHS staff invited to participate in focus groups, interviews and surveys in WP1, WP3 and WP5.

Inclusion criteria

WP1

Focus groups

<u>Women</u>
Women who have experienced a second stage caesarean section in the twenty four months preceding the date of the focus group
Aged 16 years or older (no upper age limit)
Women must speak adequate English
Ability to give informed consent

Survey

<u>NHS staff</u>
Aged 16 years or older (no upper age limit)
Employed as either: trainee obstetrician, consultant obstetrician, midwife or consultant obstetric anaesthetist
Must speak adequate English
Ability to give informed consent

<u>Parents</u>
Had a baby born in the last 5 years

WP3

Delphi Survey
Consultant obstetricians or senior obstetric trainees
Neonatologists

WP5

Survey

Pregnant women
Aged 16 years and older (no upper age limit)

NHS staff working as either the lead obstetric consultant on an obstetric unit or a midwife

One-to-one interviews
Pregnant primiparous women or women who have experienced a second stage caesarean section in the twenty four months preceding the date of the interview
Aged 16 years or older (no upper age limit)
Women must speak adequate English
Ability to give informed consent
NHS staff
Aged 16 years or older (no upper age limit)
Employed as Consultant Obstetrician or Senior Obstetric Trainee
Ability to give informed consent

Exclusion criteria

None

Expected duration of participant participation

Study participants will be participating in the study for Focus groups (WP1) from months 3-6 and for interviews (WP5) from months 17-22.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants who take part in a focus group or interview will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the trial and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation. Survey participants will not provide written informed consent, but submission of the survey will be taken as implied consent.

The process of obtaining written informed consent will be conducted at the beginning of the focus groups (WP1). For participants taking part in a one-to-one telephone or video interview for WP5, written informed consent will be posted or emailed to the Investigator prior to the interview.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

STUDY REGIMEN

Work package 1: National survey of obstetricians, trainee obstetricians, midwives, obstetric anaesthetists, women and their partners

Design:

We will perform four national surveys of relevant stakeholders and conduct a focus group of women who have experienced a second stage CS.

The surveys will be national surveys of parents and health care professionals.

Trainee obstetricians

Trainee doctors perform the majority of second stage CS, with consultant presence in approximately 40% of cases (2, 6). Any trial involving intervention during the second stage of labour will involve engagement with trainee doctors. The UK Audit and research Collaborative in Obstetrics and Gynaecology (UKARCOG) utilises a network of obstetric trainees throughout the UK. UKARCOG will promote the study to their regional leads who are located within the geographic areas classified by Health Education England ('Deanery') plus leads in the devolved nations, who will then cascade the survey to trainees within their regions. We will use this network to survey trainees on their knowledge of techniques currently used for impacted fetal head during second stage CS, their current level of skills and training in the various delivery techniques, and devices described above. We will also ask this group of their willingness to participate in the Delphi survey (work package 3), described in detail below.

Consultant obstetricians

We will conduct an identical survey of consultant obstetricians via the UK Labour Ward Leads Group to determine what techniques they employ in this scenario. We will also ask this group of their willingness to participate in the Delphi survey (work package 3), described in detail below.

Midwives

The Royal College of Midwives have confirmed that they will publicise the study on social media (Facebook and Twitter) to their membership. The survey will be available to all the approximately 3000 members of the RCM to participate. The reach and response to the survey will be maximised by repetition of the publicity.

Consultant obstetric anaesthetists

We will conduct a national survey of consultant obstetric anaesthetists via the Obstetric Anaesthetists Association (http://www.oaa-anaes.ac.uk) to determine their experience of assisting in delivery of an impacted head e.g. use of tocolytics, head-down position of the operating table. We will ask this group of their willingness to participate in the Delphi survey (work package 3), described in detail below.

Women and their partners

We will consult the University of Nottingham "Nottingham Maternity Research Network" (www.nottsmaternity.ac.uk) on the acceptability of techniques employed and a randomised trial in this area and the design of a national survey of women and their partners.

The National Childbirth Trust (NCT) have an extensive network of social and mainstream media connections and parent education classes. They will ensure widespread dissemination of the survey by sharing a survey link on their social media feeds and the results will be shared with parents and practitioners through NCT mailings and CPD events.

The acceptability of such an RCT to women and their partners will be explored in detail using a focus group of women who have experienced a second stage CS.
Focus groups will be conducted by research psychologists experienced in conducting research with women who have had an adverse outcome such as preterm birth or stillbirth. The research psychologist running focus groups will talk to participants beforehand to determine whether there are circumstances that make smaller groups or interviews preferable. It will also be checked whether participants have any possible distress or sensitivity around the topic. If so, participants will be offered the option of an interview or smaller group with women with similar circumstances.
The number of focus groups we run will be dependent on availability, sensitivities (as above) and data saturation. At the beginning of the group participants will be given the PIS, any questions answered, and full consent will be obtained. Participants will be asked to provide basic sociodemographic information such as age, ethnicity and relationship status. Focus groups will be offered at convenient times and places (e.g. hospital, community centre, university). Each focus group will take approximately 60 minutes. Participants' experiences and views on acceptability of different techniques and the RCT will be explored using a topic guide developed from a theoretical framework of acceptability (7). This includes attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. Focus groups will be conducted by research psychologists experienced in qualitative interviewing. Women will be allowed to bring young infants to the group. At the end of the group women will be reimbursed for any travel and childcare costs.

Work package 2: UKOSS Surveillance study

Surveillance of the frequency of emergency CS during the second stage of labour in the NHS, and an audit of those complicated by an impacted fetal head. UK Obstetric Surveillance System (UKOSS) will conduct a six-month UKOSS study in two stages:

1. Surveillance of the number of cases of emergency CS during the second stage of labour in the NHS over six months
2. An in-depth study of cases identified by this surveillance that were complicated by an impacted fetal head

There will be six months of case reporting period by UKOSS reporters and a further four months for completion of data collection. UKOSS utilises routinely collected anonymised data, collected nationally from UKOSS contributors according to the requirements of the study.

This work package will be Ethically approved by substantial amendment to the UKOSS Study (REC reference: 10/H0717/20), and sponsored by the University of Oxford.

Work package 3: Delphi survey and consensus meeting

Methods

Once the results of the first two work packages are available, the third aspect of the study will utilise all information gathered, and translate this into a recommendation as to what the most feasible study is for managing an impacted fetal head during emergency CS. For this, we will use a Delphi technique.

The principles of the Delphi technique is consensus building amongst a group of experts utilising a succession of questionnaires interspersed by feedback of results from each questionnaire. This is the most appropriate methodology in this circumstance and will convert the opinion of a large and diverse group of individuals into a judgement or recommendation, on the most appropriate technique(s) to be studied within the context of a clinical trial to determine the best technique for managing an impacted fetal head during emergency CS. It will also limit the influence of any dominant individual and peer pressure for conformity (8) and be cost effective as the process can all be completed online.

Compiling the Delphi Survey

Once the results of the first two work packages are available, the information gathered will be used to create an online Delphi survey.

Panel size and membership

As there is no standard method for sample size calculation for Delphi processes, we will use a pragmatic approach based on practicality and time available. The aim will be to recruit the largest panel possible, encouraging individuals from each stakeholder group to participate via email invitations to the online survey. The stakeholder groups will be: obstetricians (ST6/7 trainees and consultants), obstetric anaesthetists and neonatologists (ST6-8 and consultants). The obstetricians will be asked to comment on the techniques used for managing an impacted fetal head during emergency CS and on what they consider the most important maternal and neonatal outcomes for any RCT. The neonatologists will be asked to consider only the neonatal outcomes.

Recruitment of the panel

We will identify obstetricians from the survey performed in work package 1. Other known contacts of the co-applicants will also be utilised. Clinicians who complete the online survey will be asked if they are willing to be approached to participate in a Delphi survey. We have defined an expert for the purpose of a Delphi survey as a clinician with relevant knowledge and experience of managing an impacted fetal head during emergency CS in the second stage of labour. We will therefore limit those included in the Delphi survey to obstetricians who are consultants or senior trainees e.g. ST6/7. The benefit of using this technique for selection of the panel is that it removes selection bias of an acquaintance with the researchers, although the level of experience may be less than that from a handpicked panel. Additionally the individuals that have taken the time to respond to the online survey are those that have demonstrated an interest in the subject and are therefore more likely to respond to the various rounds of questionnaires. We will not limit the number of respondents to the Delphi survey. Anonymity of each expert panellist's response will be maintained throughout the process. Neonatologists will be identified via the British Association of Perinatal Medicine (BAPM) membership and invited to participate.

The Delphi survey

An email invitation to the three round Delphi survey containing a brief explanation of the study, emphasising the importance of completing all three rounds, an estimate of the time needed to complete each round (15 minutes), and a hyperlink to register with the survey will be sent. We will aim to complete each survey round within three weeks. Non-responders will be sent an automated reminder after two weeks. Rounds will be extended by a few days if requested by participants to enable completion.

Upon registration, participants will be asked for their name, geographical location, their primary professional role and if applicable their year of training. Participants' names and contact details will be recorded so that personalised reminders to complete the survey can be sent. However, to maintain full anonymity following online registration, the software will assign a unique study identifier to each participant, which will be linked to their survey responses but cannot be traced to individual names.

Rounds one-three

Participants will be asked to score each of the techniques for managing an impacted fetal head according to the importance of including it in a future randomised trial. The Grading of

Recommendations Assessment Development and Evaluation (GRADE) scale will be used, which suggests a Likert 9-point scale (1 to 9) to rank importance (9). Scores of 7 to 9 denote techniques of 'critical' importance, scores of 4 to 6 are 'important but not critical', and scores of 1 to 3 are deemed 'not important'. An 'unable to score' option (score 10) and a space to provide optional feedback on reasons for allocating particular scores were included. Participants can nominate additional techniques in round one to be included in round two. New techniques will be added to the list for round two if two or more participants suggested its inclusion, and it was not deemed to duplicate or overlap significantly with any other technique already included (10).

Respondents will be considered as a single panel. All round one techniques will be carried forward to subsequent rounds. In rounds two and three, each participant will be presented with the distribution of scores from all participants in the previous round alongside their own score for each technique. Participants will be asked to consider the responses from the other participants and review their score, either confirming or changing it. A space will be provided for participants to explain their reasons for changing an individual score. Invitation to participate in rounds two and three was contingent upon completing the preceding round as participants were always presented with their own scores from the previous round.

To investigate potential attrition bias, we will compare round one item mean scores and percentage of respondents scoring each metric as 'critical' for participants who only completed round one with those of participants who went on to complete round two. We similarly compared round two data for participants who only completed rounds one and two with those participants who went on to complete round three.

Consensus

We will use the definitions of consensus described in Table 1. Inclusion of an item in the subset to be discussed at the consensus meeting will require agreement by the majority of survey participants regarding the critical importance of the metric, with only a minority considering it unimportant.

Table 1: Definition of consensus (11).

Consensus Classification	Description	Definition
Consensus in	Consensus that the technique should be included	≥70% participants scoring 7 to 9 AND <15% participants scoring 1 to 3
Consensus out	Consensus that the technique should not be included	≥70% participants scoring 1 to 3 AND <15% of participants scoring 7 to 9
No consensus	Uncertainty about importance of the technique	Anything else

Consensus meeting

Finally, a collaborators workshop of relevant stakeholders, importantly including parents, will be convened virtually to discuss the most feasible study to put forward for a future trial. The workshop will discuss all the information gathered throughout the project and gain consensus.

Work package 4: Design of a randomised controlled trial

We will use information from all preceding work packages to plan the main components of a RCT of one or more techniques for the management of an impacted fetal head at CS. Key

elements of potential numbers of eligible women and the training implications will come from work undertaken with trainee doctors/obstetricians and UKOSS.

Co-applicants with expertise in the design and conduct of clinical trials will design the trial in collaboration with clinicians and PPI members.

Work package 5: Study to determine the acceptability and feasibility of such an RCT

The feasibility of such an RCT will be determined through a survey of whether consultant obstetric units would be willing to participate in a clinical trial in this area and what training would be required in advance of this trial. This survey will be sent to the lead obstetrician consultant at each maternity unit throughout the UK through the UK labour ward leads group, to pregnant women through NCT and to midwives via the RCM.

The acceptability of such an RCT to women and clinicians will be explored in detail using three sets of one-to-one interviews: one with obstetricians and trainee obstetricians; one with primiparous pregnant women; and one with women who have experienced a second stage CS.
The NIHR CRN will facilitate recruitment of potential women for the interviews as detailed in WP1. Women will also be recruited via social media.
The survey questions and interview schedule for the interviews developed for WP5 following the prior phase of the research will be submitted to the REC as a substantial amendment for approval before use.
Obstetricians and senior trainee obstetricians e.g. ST6/7 to take part in the interviews will be identified via the survey conducted in work package 1. Obstetricians and senior trainee obstetricians will be sampled to ensure a range of experience.

Compliance

For this project, compliance is not applicable

Criteria for terminating the study

Not applicable

ANALYSES

Methods

WP1

Data Analysis: Focus groups will be audio-recorded, transcribed and fully anonymised before analysis. Framework analysis will be used, which is suitable for research with different groups and can be used with focus group or interview data. A combined inductive-deductive approach will be used which enables specific research questions to be addressed as well as identifying unexpected or new themes related to acceptability of techniques and the RCT. It also enables examination of themes within and across different groups. Coding will be done by one researcher and a selection checked for reliability. Data will be analysed using NVivo software. Credibility will be ensured by regular meetings of the research team where problematic issues are documented, discussed and resolved.

Sample size and justification

WP1

For those surveys with a finite membership e.g. Labour Ward Leads Group with 150 members we aim for a response rate of > 60%. For larger groups e.g. NCT we aim to gather responses from 500 parents.

For the focus groups, the sample size will be guided by data saturation but is expected to be approximately 20 women in WP1.

WP5

For the interviews, the sample size will be guided by data saturation but is expected to be approximately 20 women and 10 obstetricians/senior trainee obstetrician in WP5.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and therefore no adverse event data will be collected.
All participants taking part in the focus group will be contacted afterwards to make sure they were satisfied with their experience. Should any emotional discomfort arise as a result of taking part, they will be offered a self-referral to an obstetrician or midwife for further support and debriefing, or we will ask their permission to contact their clinical care team. We will also provide information about other local services that can provide support.

ETHICAL AND REGULATORY ASPECTS

Focus groups (WP1) and interviews (WP5) will be conducted by research psychologists experienced in conducting research with women who have had an adverse outcome such as preterm birth or stillbirth. The research psychologist running focus groups will talk to participants beforehand to determine whether there are circumstances that make smaller groups or interviews preferable. It will also be checked whether participants have any possible distress or sensitivity around the topic. If so, participants will be offered the option of an interview or smaller group with women with similar circumstances. For WP5, only a one-to-one telephone or video conferencing interview will be offered due to restrictions on face-to-face contact due to COVID-19.

If women disclose to the research team that they are upset or distressed by their birth they will be offered referral to the obstetrician or midwife responsible for their care for further support and debriefing. The research team will also sign post women depending on their needs to appropriate support groups, helplines and self-referral pathways such as the Improving Access to Psychological Therapies (IAPT) Pathway. The PPI group will be run by co-applicant Plachcinski who is an experienced NCT facilitator and will be able to offer extra emotional support if necessary.

If women disclose to the research team that they are unhappy with the care they have received during labour or birth at Nottingham University Hospitals NHS Trust, they will be directed to the Patient Advice and Liaison Service (PALS) who provide a confidential service aiming to listen, respond, liaise and resolve complaints.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research

& Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records. A second copy will be filed in the participant's medical notes where appropriate and a signed and dated note made in the notes that informed consent was obtained for the study.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

For surveys performed in WP1 and WP5:

Completion and subsequent return of questionnaires will be taken as informed consent and separate written informed consent will not be sought

RECORDS

Case Report Forms

Each participant of the focus groups and interviews will be assigned a study identity code number, allocated at entry to the study, for use on a brief demographic information collection form, audio recordings, transcriptions and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the focus group participant's name, date of birth, local hospital number or NHS number, and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required. Identifiable information will not be collected from the survey respondents.

CRFs shall be restricted to those personnel approved by the Chief Investigator and recorded on the 'Study Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Audio files and transcripts

Audio from the focus groups/interviews will be recorded with an audio recording device. The audio recorded files will be transferred from the audio recording device to a password protected laptop (property of the Centre for Maternity and Child Health, City University London). The laptop will be stored at the Centre for Maternal and Child Health in a locked cabinet at City University London. Audio files will then be transferred from the laptop to a password protected desktop PC at Centre for Maternity and Child Health, City University London.
Audio files will be labelled with the study identity code number. Audio files will be sent to an external data transcribing organisation 'Essential Secretary' bound by data protection regulations.
Transcripts of the audio files will be labelled with a study identity code number and stored on a desktop PC. Transcript codes will be held on a password protected database which will be shared within the research team only.
Audio files and transcripts will be stored for seven years and then archived at secure archive facilities at the University of Nottingham.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see

above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Surveys in WP1 will be conducted using Online Surveys (onlinesurveys.ac.uk) software. Survey responses will be anonymous except for staff groups who wish to join the Delphi survey in WP3 or the interviews in WP5 as they will be asked to provide an email address to allow ongoing contact. Full details of the data security for Bristol Online Survey are given here: https://www.onlinesurveys.ac.uk/help-support/online-surveys-security/. The Delphi survey will be distributed using COMET Delphi Manager software.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all

entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

The researcher will ensure the participants confidentiality is maintained when using telephone and video call methods by using university encrypted devices. This will include a City University of London Laptop attached to the University network, this device is password protected and encrypted to maintain its security. Video calls will be made using either Skype, Teams or Zoom from this device using the researchers City University of London ID. The participants ID used to contact them via these programmes will be removed from the device after the interview is complete. For telephone interviews, calls will be made using the researcher's university issued mobile device, all contact information (Name, Telephone Number) will be removed from this device once the interview is complete. No one other than the researcher will see this User ID or contact information. There will be no retention of personal data on the devices or platforms used.
As the interviews will be carried out remotely, the researcher will use a private office space at their home where only the researcher is present. This will allow them to maintain confidentiality of any information shared.

All interviews will be audio recorded using a City University of London issued audio recording device with encryption software, ensuring this device is GDPR compliant. After the data has been collected it will be transferred from the device onto the researcher's City, University of London laptop and stored on the encrypted University Network Drives. The data will be collected via audio recording only, no screenshots or recording of the video images will take place.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The research findings will be disseminated via a published HTA monograph, research papers published in high-impact peer reviewed journals and presentation at medical and midwifery conferences locally, nationally and internationally. They will also be made available via NCT, alongside plain English summaries.

USER AND PUBLIC INVOLVEMENT

We have included a member of the charity NCT as a co-applicant to this study (Rachel Plachcinski) to ensure that views of women and their partners are included within this application and have consulted the Nottingham Maternity Research Network (www.nottsmaternity.ac.uk) in the development of this application.
The Nottingham Maternity Research Network (NMRN) is a partnership between local people who have used, or are interested in Maternity services in Nottinghamshire and the University of Nottingham maternal health researchers (including co-applicant Pallotti) working to ensure that local women can have significant input into maternity research being undertaken at the University of Nottingham. The network has a core membership of around 100 women, largely consisting of women within the first year of childbirth, meets four times per year, and produces a regular newsletter. The NMRN has reviewed the lay summary for this application and two members (Doubleday and Foulke) have agreed to join our PPI group. The PPI group have assisted in the development of the research protocol.
One of our PPI members has agreed to sit on the Study Oversight Committee.

STUDY FINANCES

Funding source

This study is funded by the NIHR Health Technology Assessment (HTA) Programme.

Participant stipends and payments

Participants will not be paid to participate in the study. We will reimburse focus group participants travel and childcare costs.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

REFERENCES

1. Statistics OoN. NHS Maternity Statistics - England 2013-14 London2015.
2. Unterscheider J, McMenamin M, Cullinane F. Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2011 Aug;157(2):141-4. PubMed PMID: WOS:000293727800004. English.
3. Allen VM, O'Connell CM, Baskett TF. Maternal and perinatal morbidity of caesarean delivery at full cervical dilatation compared with caesarean delivery in the first stage of labour. Bjog-Int J Obstet Gy. 2005 Jul;112(7):986-90. PubMed PMID: WOS:000229704700024. English.
4. Levy R, Chernomoretz T, Appelman Z, Levin D, Or Y, Hagay ZJ. Head pushing versus reverse breech extraction in cases of impacted fetal head during Cesarean section. Eur J Obstet Gyn R B. 2005 Jul 1;121(1):24-6. PubMed PMID: WOS:000230704500004. English.
5. Daniels JP, Gray J, Pattison HM, Gray R, Hills RK, Khan KS. Intrapartum tests for group B streptococcus: accuracy and acceptability of screening. Bjog. 2011 Jan;118(2):257-65. PubMed PMID: 21040389. Epub 2010/11/03. eng.
6. Mitchell N, Rajesh U. Complications of caesarean section at full dilatation, time to review alternatives? Bjog-Int J Obstet Gy. 2015 Apr;122:93-. PubMed PMID: WOS:000356715200254. English.
7. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. Bmc Health Serv Res. 2017 Jan 26;17. PubMed PMID: WOS:000393275600007. English.
8. Hsu CC, Brian S. The Delphi Technique: Making Sense Of Consensus. 2007 [cited 2017 21.11.2017]. Available from: http://pareonline.net/getvn.asp?v=12&n=10.
9. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. Trials. 2017 Jun 20;18. PubMed PMID: WOS:000403845500001. English.
10. Devane D, Begley CM, Clarke M, Horey D, OBoyle C. Evaluating maternity care: A core set of outcome measures. Birth-Iss Perinat C. 2007 Jun;34(2):164-72. PubMed PMID: WOS:000246801400008. English.
11. Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, et al. MOMENT - Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey. Trials. 2013 Mar 12;14. PubMed PMID: WOS:000321926500001. English.