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Feasibility of a RCT of techniques for managing an impacted fetal head during emergency caesarean section: the MIDAS scoping study

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Group (January 2021 to March 2022), HTA Funding Committee Policy Group (formerly Clinical Studies Group) (2021 to present), HTA Commissioning Committee (2021 to present) and HTA Programme Oversight Committee (2021 to present). Jim G Thornton reports membership of the NIHR HTA and Efficacy and Mechanism Evaluation (EME) Editorial Board (2016–21).

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This report

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Abstract

Feasibility of a RCT of techniques for managing an impacted fetal head during emergency caesarean section: the MIDAS scoping study

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Background: Second-stage caesarean sections, of which there are around 34,000 per year in the United Kingdom, have greater maternal and perinatal morbidity than those in the first stage. The fetal head is often deeply impacted in the maternal pelvis, and extraction can be difficult. Numerous techniques are reported, but the superiority of one over another is contentious and there is no national guidance.

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

Design: A scoping study with five work packages: (1) national surveys to determine current practice and acceptability of research in this area, and a qualitative study to determine acceptability to women who have experienced a second-stage caesarean; (2) a national prospective observational study to determine incidence and rate of complications; (3) a Delphi survey and consensus meeting on choice of techniques and outcomes for a trial; (4) the design of a trial; and (5) a national survey and qualitative study to determine acceptability of the proposed trial.

Setting: Secondary care.

Participants: Health-care professionals, pregnant women, women who have had a second-stage caesarean, and parents.

Results: Most (244/279, 87%) health-care professionals believe that a trial in this area would help guide their practice, and 90% (252/279) would be willing to participate in such a trial. Thirty-eight per cent (98/259) of parents reported that they would take part. Women varied in which technique they thought was most acceptable. Our observational study found that impacted head is common (occurring in 16% of second-stage caesareans) and leads to both maternal (41%) and neonatal (3.5%) complications. It is most often treated by an assistant pushing the head up vaginally. We designed a randomised clinical trial comparing the fetal pillow with the vaginal push technique. The vast majority of health-care professionals, 83% of midwives and 88% of obstetricians, would be willing to participate in the trial proposed, and 37% of parents reported that they would take part. Our qualitative study found that most participants thought the trial would be feasible and acceptable.

Limitations: Our survey is subject to the limitation that, although responses refer to contemporaneous real cases, they are self-reported by the surgeon and collected after the event. Willingness to participate in a hypothetical trial may not translate into recruitment to a real trial.

Conclusions: We proposed a trial to compare a new device, the fetal pillow, with a long-established procedure, the vaginal push technique. Such a trial would be widely supported by health-care professionals. We recommend that it be powered to test an effect on important short term maternal and baby outcomes which would require 754 participants per group. Despite the well-known difference between intent and action, this would be feasible within the United Kingdom.

Future work: We recommend a randomised controlled trial of two techniques for managing an impacted fetal head with an in-built internal pilot phase and alongside economic and qualitative substudies.

Study registration: This study is registered as Research Registry 4942.

Funding: This project was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 27, No. 6. See the NIHR Journals Library website for further project information.

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Report Supplementary Material 5 Visual aid for interviews with women in the qualitative study in 6B

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/KUYP6832).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

COMET	Core Outcome Measures in Effectiveness Trials	NCTU	Nottingham Clinical Trials Unit
CS	caesarean section	PICO	population, intervention, comparison, outcome
GP	general practitioner	PPH	post-partum haemorrhage
GTN	glyceryl trinitrate	PPI	patient and public involvement
IFH	impacted fetal head	RCT	randomised controlled trial
IMD	Index of Multiple Deprivation	SD	standard deviation
IQR	interquartile range	ST	specialty trainee
MIDAS	Management of the Impacted head At caesarean Section	UKOSS	UK Obstetric Surveillance System

Plain language summary

One-quarter of United Kingdom pregnant women have a caesarean section. Most of these procedures are straightforward, but in a small number of cases unexpected complications can make the birth difficult.

One complication, an impacted fetal head, may happen when caesarean sections are done in the second 'pushing' stage of labour. If the baby's head is low and wedged in the woman's pelvis, lifting it can be difficult, which can result in damage to the mother's womb and vagina, and to her baby. Occasionally, babies die.

There are different techniques doctors and midwives can use to make these births easier, but there is uncertainty around which is best. To plan a trial to test these techniques, we needed to know how often impacted head happens, what techniques are used to manage it and whether or not research is acceptable to parents and health-care professionals.

We surveyed doctors and midwives to find out which techniques they use and what training they need. We surveyed parents and pregnant women and interviewed women who had experienced a second-stage caesarean. We collected information from UK hospitals to find out how common this is and the impact on women and babies.

We found out the following:

- Around 7% of caesareans take place in second stage, and impacted fetal head occurs in 16% of these births.
- One-third of women would consent to take part in a trial, if the complication happened to them.
- Nearly all midwives and doctors thought that this research was important and would be willing to take part.

Using all of the information we collected, we designed a clinical trial. We wanted to compare two techniques for managing an impacted fetal head. The first is the vaginal push technique, where the doctor or midwife puts their hand into the mother's vagina to push her baby's head up, and the second is the fetal pillow, a device inserted into the mother's vagina before the operation starts to dislodge the baby's head upwards.

Scientific summary

Background

Emergency caesarean section (CS) performed in the second stage of labour, which occurs in 34,000 births per annum in the United Kingdom (UK), has greater perinatal and maternal morbidity than CS performed in the first stage.

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 CSs. Complications include longer delivery times, uterine tears, injury to the baby and even, albeit rarely, death.

Numerous techniques to assist in delivery of an impacted fetal head (IFH) are reported. The superiority of one technique over another is contentious. At present, there is no national guidance on what techniques to employ.

Research questions

What are the current practice, level of experience and training requirements for managing an IFH during emergency CS among UK obstetricians, obstetric anaesthetists and midwives?

What are the views of pregnant women and their partners on research in this area?

How acceptable is a randomised trial in this area to women who have experienced a second-stage caesarean birth, and what are their views on the different proposed techniques for managing an IFH?

What is the incidence of IFH and maternal and neonatal complications arising from IFH in the UK?

What techniques and outcomes do health-care professionals and parents think should be included in a randomised trial in IFH?

What should the design be for a randomised trial in IFH?

How acceptable is the randomised trial we have designed to health-care professionals, women who have experienced a second-stage caesarean birth and pregnant women?

Methods

We undertook a national survey of obstetricians, trainee obstetricians, obstetric anaesthetists and midwives to determine current practice, level of experience and training requirements for managing IFH during emergency CS. We also undertook a national survey of parents to determine their views on this topic.

Individual face-to-face interviews with women who have experienced a second-stage CS were carried out to determine the acceptability of a randomised trial in this area and their views on the different proposed techniques for managing IFH.

A national, prospective UK Obstetric Surveillance System (UKOSS) surveillance study was undertaken to determine the incidence and consequences of IFH in the UK.

Based on the findings of previous work packages, we conducted a Delphi survey followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in any trial and which outcomes should be included.

A randomised trial of different techniques for managing IFH during emergency CS was designed.

We undertook a national survey of lead obstetricians, pregnant women and midwives to determine the feasibility and acceptability of the randomised trial designed.

Three sets of individual telephone or video interviews were carried out with 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.

Results

The majority (89%) of health-care professionals stated that a clinical trial in this area would help to guide their clinical practice, and 87% would be willing to participate in such a trial. In addition, 37% of parents reported that they would be either likely or very likely to take part, or neutral.

Women varied in which technique they thought was most acceptable, and their trust in medical expertise and prioritising the safety of the baby were important moderators of acceptability.

Our national prospective observational study found that impacted head is common, occurring in 16% of second-stage caesarean births in the UK, and leads to both maternal and neonatal complications. Overall, 230 (41%) women and 20 babies (3.5%) experienced complications. Thirteen babies (2%) died or sustained severe injury. Seven suffered bony fracture, two brachial plexus injury and one facial palsy. Three had moderate or severe hypoxic ischaemic encephalopathy, and seven were cooled. Four babies died: one prior to the caesarean, one with multiple abnormalities and two as a direct result of complications caused by IFH. IFH is currently most often treated by an assistant pushing the head up vaginally during the CS.

Data from earlier work packages were used throughout the project, culminating in the design of a randomised clinical trial. Our proposed trial would compare a new device, the fetal pillow, with a procedure used for many years, the vaginal push technique, for preventing IFH. Most doctors and midwives believed that such a trial would be important and were willing to recruit participants to one. About one in three women said that they would be willing to join such a trial.

The only interventions that were more popular with patients were tocolysis and the head-down technique. Both of these are adjunct techniques used by all obstetricians and, therefore, are not suitable for evaluation in a trial.

The required sample size of such a trial depends on whether it is powered to show a difference in severe maternal morbidity (control event rate 2.3%, 4698 participants per group), a difference in fetal short-term morbidity (control event rate 13.7%, 754 participants per group) or only a difference in less severe maternal events, including haemorrhage over 1000 ml (control event rate 27%, 322 participants per group).

We believe that it is not feasible to conduct the trial powered on severe maternal morbidity. However, parents and doctors believe that a trial to test the effect of different procedures on meaningful baby outcomes is important. We therefore recommend that the required sample size would be 754 per group.

The vast majority of midwives (83%) and obstetricians (88%) would be willing to participate in the clinical trial proposed. In addition, 37% of parents reported that they would be either likely or very likely to take part, or neutral. Our qualitative study found that most participants thought that the trial would be feasible and acceptable.

Conclusions

We recommend that a randomised trial with an internal pilot phase comparing a new device, the fetal pillow, with a procedure used for many years, the vaginal push technique, for managing IFH be conducted.

This trial is widely supported by health-care professionals.

We recommend that the definitive trial be powered to test an effect on important short-term maternal and baby outcomes, which would require 754 participants per group. A sufficient number of women would be willing to be join such a trial to make it likely to be feasible in the UK.

Study registration

This study is registered as Research Registry 4942.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 27, No. 6. See the NIHR Journals Library website for further project information.

Chapter 1 Background and aim

Background

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

Emergency CSs 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 CSs.[4] Complications include longer delivery times, uterine tears and 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 with UK practice.

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 shown in *Figure 1* and include:

- Vaginal push technique – the head is flexed and pushed upwards through the vagina by an assistant.
- Reverse breech extraction (pull) technique – the fetus is delivered feet first.
- Patwardhan method – the fetal shoulders are delivered first.[5]
- Fetal pillow – a balloon device is inserted into the vagina before the CS is started, which inflates in an upwards direction when filled with saline, displacing the head upwards.
- Head-down tilt of the operating table.
- Administration of tocolytic agents to the mother to counteract uterine contractions that may contribute to the mechanical impediment during delivery.
- Tydeman tube[6] – a sterile hollow silicone tube with a rounded cup at one end; the cup is designed to elevate the fetal head and to easily allow the surgeon's fingers to pass between the cup and the fetal head to achieve delivery, and the hollow tube can allow air to enter vaginally and release any potential vacuum.

For management of an impacted fetal head (IFH) during CS, there is at present 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 are pivotal to any future randomised trial in this area.

Aim

To determine the feasibility of a randomised trial of different techniques for managing IFH during emergency CS.

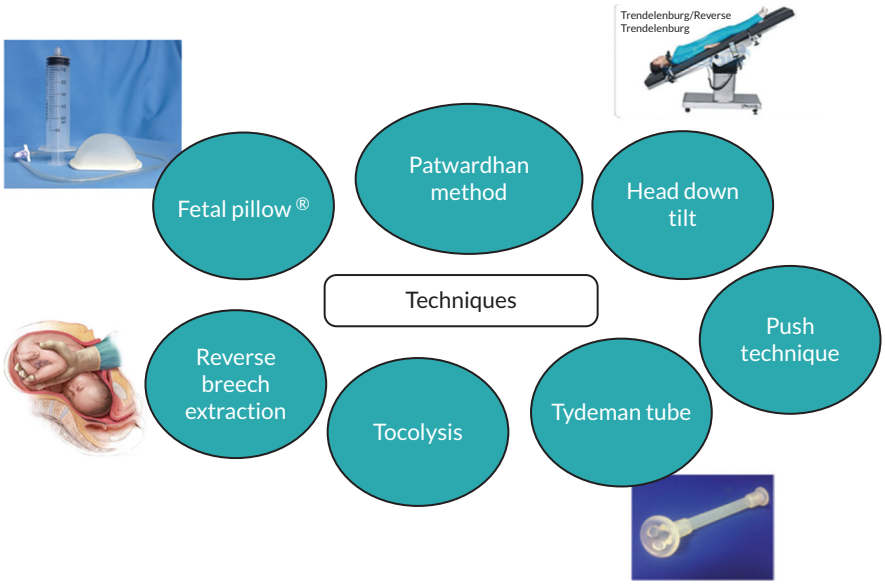

FIGURE 1 Techniques to manage an IFH at caesarean birth.

Study design

Chapter 2 Determining current practice and acceptability of research in this area

We undertook a national survey of obstetricians, trainee obstetricians, obstetric anaesthetists and midwives to determine current practice, level of experience and training requirements for managing IFH during emergency CS. We also undertook a national survey of parents to determine their views on this topic.

Individual face-to-face interviews with women who have experienced a second-stage CS were carried out to determine the acceptability of a randomised trial in this area and their views on the different proposed techniques.

Chapter 3 Determining incidence and consequences of impacted fetal head

A UK Obstetric Surveillance System (UKOSS) survey was conducted to determine the incidence and consequences of IFH in the UK.

Chapter 4 Reaching consensus on techniques and outcomes for the trial

Based on the findings of the previous two work packages, we conducted a Delphi survey followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in any trial.

Chapter 5 Designing a randomised trial

Using data from previous work packages, a randomised trial of different techniques for managing an IFH during emergency CS was designed.

Chapter 6 Determining the acceptability of our proposed randomised trial

We undertook a national survey of lead obstetricians, pregnant women and midwives to determine the feasibility and acceptability of the randomised trial designed in *Chapter 5*.

Three sets of one-to-one telephone or video interviews were carried out with 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.

Chapter 2 Determining current practice and acceptability of research in this area

Objectives

- To determine current practice, training requirements and the acceptability of research in this area for health-care professionals.
- To determine the acceptability of research in this area to parents.

Aims

National surveys

- To understand current practice, level of expertise and training requirements for managing IFH during emergency CS among consultant obstetricians, senior trainee obstetricians, obstetric anaesthetists and midwives.
- To understand parents' opinions of various techniques and their willingness to participate in a clinical trial in this area.

Qualitative study

- To qualitatively examine women's views on the acceptability of different techniques for managing IFH during emergency CS, and the feasibility and acceptability of conducting a randomised controlled trial (RCT) in this area.

Methods

National surveys

Four online surveys (aimed at obstetricians, obstetric anaesthetists, midwives and parents, respectively) were designed using Jisc online surveys© and user-tested by members of the multidisciplinary research team prior to distribution (see *Appendix 1*). The parents' survey was co-designed by the team's parent and public involvement co-investigator. Most questions were created as an 'optional response' with response rates to each question calculated as a percentage of the total number of submitted surveys. To reduce burden on participants, unnecessary questions were eliminated through adaptive questioning and skip logic techniques. The time taken to complete the pilot test surveys was recorded and questions were modified to ensure that all surveys could be completed in a reasonable length of time (approximately 10 minutes). To reduce the number of questions and complexity of some questions, follow-up questions appeared depending on the answer(s) provided previously. Participants were not required to provide an answer to all questions to proceed with the survey, although they did have to complete the survey in one sitting and were unable to return to complete it later. All participants were asked to provide an e-mail address if they wished to be contacted about future research but were reminded that answers to the survey would remain anonymous. Informed consent was assumed by completion of the survey.

The surveys were voluntary and open. The study population was a convenience sample from individuals who could be reached through e-mails sent to members of relevant organisations and through social media. Anonymous survey links were distributed via several networks: British Intrapartum Care Society (BICS) and UK Audit and Research Collaborative in Obstetrics and Gynaecology (UKARCOG) (consultant and trainee obstetricians); Obstetric Anaesthetists Association (OAA) (obstetric anaesthetists); Royal College of Midwives (midwives); and National Childbirth Trust (NCT) (parents). All surveys were publicised via social media, and personal contacts of study co-applicants were also utilised (for obstetric anaesthetists only). Surveys were distributed in July 2019, with at least two reminders sent, and were initially open for 8 weeks. As a result of a poor response rate, the midwives' survey was reopened in September 2019 and reminders were sent.

Data were stored within Jisc online surveys with access only given to individuals within the research team. Once anonymous survey data were downloaded for analysis, they were stored on a secure server and accessible only to the research team.

The study was sponsored by the University of Nottingham and ethically approved by the Research Ethics Committee and Health Research Authority (19/WM/0118).

Analysis

Jisc online surveys only collects and analyses full responses, and no completion checks were built-in; therefore, partially completed surveys were automatically removed from the final analysis. Prior to analysis, all data were de-identified by removing any e-mail addresses provided for contact regarding future studies.

Descriptive statistics of survey data were generated using Stata version 16 (StataCorp LP, College Station, TX, USA). Data were presented as *n* (% of total responses) and, where appropriate, the mean ± 1 SD, median [interquartile range (IQR)], and minimum and maximum data were reported.

Qualitative study

Sample and recruitment

A systematic sample of women was recruited through one large teaching hospital in England. Women were eligible if they had experienced a second-stage CS in the 24 months prior to recruitment, were aged ≥ 16 years, had adequate spoken English and were able to give informed consent. There were no exclusion criteria. All women who were eligible over a 24-month period (n = 140) were identified from medical records. Of these, 80 were invited to participate: 50 who lived in deprived areas [i.e. an Index of Multiple Deprivation (IMD) decile of 1 or 2] and 30 who lived in less deprived areas (i.e. an IMD decile of 3–10). Women who were interested in taking part returned a response letter in a pre-paid envelope to the research team providing contact details and a signed consent form. Postal responses were returned by 19 women interested in taking part: 17 consented and two expressed interest but did not return the consent form. Of the women who consented, nine (53%) were available to be interviewed.

Women were offered an initial telephone call with a research psychologist so that they could ask questions and state their preference to take part in a one-to-one interview or a focus group. Nearly all women preferred one-to-one interviews. Interviews were conducted at the university campus by two practitioners: a psychologist experienced in qualitative research with vulnerable groups, and our parent and public involvement co-investigator, who has extensive experience in explaining birth-related information in an accessible way, via antenatal teaching. Women were able to bring their baby to the interview and were reimbursed for travel and childcare costs.

Before the interview, participants provided sociodemographic information and were given some brief information about the study and the different techniques used for IFH. During the presentation, participants were shown photographs and physical prototypes of the fetal pillow and Tydeman tube instruments. Using a topic guide, a 45-minute semistructured interview was then conducted to explore

participants' experiences and views on the acceptability of different techniques and a RCT of techniques. This interview guide was developed for this study and is provided as *Report Supplementary Material 1*. Not all women were aware of whether or not they had experienced an impacted head. Women were shown photographs and diagrams to illustrate the different techniques and, where appropriate, were shown a real-life version (fetal pillow and Tydeman Tube) that they could handle themselves. A model pelvis and baby were also used to explain the different techniques.

If women required additional information about their birth and/or referral to an obstetrician, they were encouraged to contact their general practitioner (GP). The participant information sheet provided recommendations of whom they could contact. The number of interviews conducted was dependent on the women's availability. All interviews were audio-recorded and transcribed using an external transcription agency.

Data analysis

Audio recordings were transcribed verbatim and analysed using systematic thematic analysis.[8] A combined inductive and deductive approach was used with the following steps. First, all transcripts were read so that researchers could become familiar with the data. The transcripts were then re-read, and initial codes were identified and coded. When no further codes emerged (i.e. data saturation was reached), all of the codes were examined by two researchers (GR and SA), who agreed which were most frequent or could be combined into key themes. Themes were cross-checked against coded quotations to ensure reliability of coding and that main themes were represented. Analysis was conducted using NVivo 12 (QSR International, Warrington, UK).[9]

Results

National surveys

A total of 206 obstetricians, 38 obstetric anaesthetists, 45 midwives and 259 parents completed their surveys. Ten of those responding to the midwives' survey did not practise as midwives, so they were removed from the final analysis. There were no partially completed surveys. During the 8-week recruitment period, interest in participating was closely aligned with release of social media posts and e-mails. A lower response rate was observed during the periods between the scheduled release of social media posts, e-mails and follow-up advertisements.

Obstetricians, midwives and obstetric anaesthetists

Recall of previous incidences of IFH is reported in *Table 1*. The majority of health-care professionals had encountered IFH during emergency CS [*n* = 190 (92%) obstetricians; *n* = 30 (86%) midwives; *n* = 38 (100%) obstetric anaesthetists]. Among those with previous experience, obstetricians had observed a mean of 24.0 (range 2–300) cases, midwives had observed a mean of 6.1 (range 1–50) cases, and obstetric anaesthetists had observed a mean of 12.0 (range 1–70) cases.
Information on the current use of various techniques to manage IFH in health-care professionals is shown in *Table 2*. The vaginal push technique (84%) and operating table tilted down (80%) were most commonly used by obstetricians; 89% of obstetric anaesthetists had previously administered a tocolytic agent to the mother, and 69% of midwives had previously used the vaginal push technique.

All groups were asked to comment on their willingness to participate in a clinical trial and offer opinions on the acceptability of the various techniques for inclusion in a RCT aimed at managing IFH during an emergency CS (see *Table 3*). For obstetricians, the most accepted techniques for inclusion in a clinical trial were, in order of preference, the insertion of fetal pillow [*n* = 178 (86%)], the vaginal push technique [*n* = 107 (52%)] and the 'pull technique' [*n* = 107 (52%)]. Among those who reported 'other', responses included 'pushing the head up myself before starting the caesarean'; 'using my non-dominant hand to deliver the head with the table tilted down'; 'standing on a step'; and 'patience and waiting

TABLE 1 Previous incidents of IFH in obstetricians, midwives and obstetric anaesthetists

Experience of IFH	Obstetricians (*n* = 206)	Midwives (*n* = 35)	Obstetric anaesthetists (*n* = 38)
CS in past 3 months, *n* (%)			
0	–	13 (37)	0 (0)
1–5	–	14 (40)	2 (5.3)
5–10	–	8 (23)	1 (2.9)
>10	–	0 (0)	35 (92)
Recall of incidents of IFH, *n* (%)			
Yes	190 (92)	30 (86)	38 (100)
No	15 (7)	5 (14)	0 (0)
Unsure	1 (0.5)	0 (0)	0 (0)
Incidents of IFH, mean (SD)			
During career	24.0 (49)	6 (9)	12.0 (14)
During last year	–	0.97 (1.6)	1.8 (2.2)

SD, standard deviation.

TABLE 2 Previous use of various techniques to manage an IFH in obstetricians, midwives and obstetric anaesthetists

Technique	Health-care professional	Yes, used technique before, *n* (%)	No, not used technique before, *n* (%)
Vaginal push technique	Obstetricians (*n* = 190)	160 (84)	30 (16)
	Midwives (*n* = 35)	24 (69)	11 (31)
Pull technique	Obstetricians	90 (47)	100 (53)
Patwardhan method	Obstetricians	12 (6.3)	178 (94)
Insertion of fetal pillow	Obstetricians	100 (53)	90 (47)
	Midwives	4 (11)	31 (89)
Operating table tilted head down	Obstetricians	154 (80)	39 (20)
	Obstetric anaesthetists	25 (66)	13 (34)
Administration of a tocolytic agent to the mother	Obstetricians	140 (74)	50 (26)
	Midwives	4 (11)	31 (89)
	Obstetric anaesthetists	34 (89)	4 (11)
Insertion of a Tydeman tube into the vagina	Obstetricians	1 (0.53)	189 (99)
	Midwives	0 (0)	35 (100)

Note
Only professional groups that use a particular technique were asked about that technique. Obstetricians, *N* = 190; midwives, *N* = 35; obstetric anaesthetists, *N* = 38.

TABLE 3 Willingness to participate, training requirements and appropriate techniques for inclusion in a clinical trial

Input on a potential clinical trial	Obstetricians, *n* (%)	Midwives, *n* (%)	Obstetric anaesthetists, *n* (%)
Would a clinical trial in this area guide your clinical practice?			
Yes	179 (87)	35 (100)	30 (79)
No	27 (13)	0 (0)	8 (21)
Willing to participate?			
Yes	190 (92)	29 (83)	33 (87)
No	16 (7.8)	6 (17)	5 (13)
Further training required?			
Yes	–	28 (80)	18 (47)
No	–	5 (14)	19 (50)
Not interested	–	2 (5.7)	1 (2.6)
Type of training required			
Lecture	–	11 (19)	4 (14)
Online	–	13 (22)	12 (41)
Demonstration	–	22 (38)	8 (28)
Hands-on	–	12 (21)	5 (17)
Other	–	–	0 (0)
Appropriate techniques			
Vaginal push technique	107	26	17
Pull technique	107	2	11
Patwardhan method	61	7	2
Insertion of fetal pillow	178	4	15
Operating table tilted head down	50	20	20
Administration of a tocolytic agent	100	6	24
Insertion of a Tydeman tube	104	1	1
Other	8	–	–
Unable to comment	–	–	11

Note
Regarding type of training required and acceptability of techniques for managing IFH, respondents could select multiple responses (≤4 responses).

for the uterus to relax with steady longitudinal traction'. Other responses included 'using left hand to lift body up then inserting right hand below head' and 'rather than push the baby's head up I request flexion of the head by a senior assistant i.e. not just blind pulling'. Information regarding obstetricians' required training for the delivery of a clinical trial intended to manage IFH is presented in *Table 3*. The vaginal push technique was most accepted by midwives [*n* = 26 (74%)] and the administration of a tocolytic agent to the mother was most accepted by obstetric anaesthetists [*n* = 24 (63%)].

Parents

A total of 259 parents completed the parent survey: 256 (99%) had given birth in the previous 5 years and three (1%) had a partner who had given birth in that same timeframe. Most respondents (*n* = 113, 44%) were aged 30–34 years. Of the respondents, 196 (76%) reported one previous birth, 56 (22%) reported two previous births and seven (2.7%) reported three previous births.

Parents were presented with a scenario (*Box 1*) and asked to report their views on the acceptability of various techniques to deliver a baby with IFH during an emergency CS (see *Table 4*).

Parents were also asked to report, using a Likert scale of 1 (least likely) to 5 (most likely), the likelihood that they would take part in a study during labour to determine the best techniques to deliver a baby with IFH. Ninety-eight (38%) respondents scored 3, 4 or 5, and 161 (62%) respondents scored 1 or 2. Participants who scored 1 or 2 were asked to report the reasons why they would be unlikely to take part in such a study. Of these respondents, 101 (63%) stated that they would prefer the doctor to deliver the baby in the way they felt most comfortable, 33 (20%) stated that they did not like the concept of randomisation and 27 (17%) would not like to have to think about a research study while in labour. Suggestions were made regarding a combined decision tool, specifically a combination of the doctor's

BOX 1 Scenario presented to parents to determine the acceptability of various techniques to deliver a baby with IFH during an emergency CS

> You/your partner are in labour, and you are told you need an emergency caesarean section. You are told that occasionally the doctor can encounter difficulty delivering the baby's head, because the baby has become deeply stuck in the pelvis, which means the doctor needs to take action quickly to avoid complications for the mother and baby.
>
> Due to a lack of research in this difficult area, doctors do not know the best technique to deliver your baby and could choose from a number of different techniques. There is no evidence to suggest which techniques are better than others.

TABLE 4 Parents' acceptability of various techniques to deliver a baby with an IFH

Technique	Acceptable (scored 1 or 2), *n* (%)	Neutral (scored 3), *n* (%)	Unacceptable (scored 4 or 5), *n* (%)
Vaginal push technique	80 (31)	64 (25)	115 (44)
Pull technique	152 (59)	70 (27)	37 (14)
Patwardhan method	125 (48)	78 (30)	56 (22)
Insertion of fetal pillow	132 (51)	80 (31)	47 (18)
Operating table tilted head down	148 (57)	77 (30)	34 (13)
Administration of a tocolytic agent to mother	150 (58)	68 (26)	41 (16)
Insertion of a Tydeman tube into the vagina	94 (36)	84 (33)	81 (31)
Doctor to undertake procedure he/she felt most comfortable with	211 (82)	29 (11)	19 (7.3)
No preference	73 (28)	141 (54)	45 (17)

Note
Parents were asked to select 1 (very acceptable), 2 (somewhat acceptable), 3 (neutral), 4 (somewhat not acceptable) or 5 (not at all acceptable) for each technique.

judgement and the computer-generated result, while also considering the success of such techniques from previous deliveries. One woman also stated that she felt she would not 'make the best decisions whilst in pain and would prefer to be approached with comprehensive information before being in labour'.

Qualitative study

Sample characteristics

Nine participants were included; all were 30–40 years of age and white British. Five participants were married, and the rest (*n* = 4) were living with their partner. The majority of women were educated to degree level (*n* = 5) or above (*n* = 1). All participants were in employment across a range of industries, including health care (*n* = 3), retail (*n* = 3), probation (*n* = 1), education (*n* = 1) and catering (*n* = 1).

Main themes

Three main themes were identified: (1) acceptability of different techniques; (2) informed choice in trials; and (3) birth education. Each theme had a number of subthemes, as shown in *Table 5*.

Theme 1: acceptability of different techniques

The acceptability of different techniques varied between women. This is shown in *Table 6*, which summarises the contrasting choices of techniques that women preferred. Variation in acceptability of different techniques appeared to be due to three key subthemes: level of invasiveness, security in practitioner expertise and baby safety.

Level of invasiveness When weighing up the acceptability of one technique over another, women often talked about the extent to which an approach was invasive or intrusive to them or the baby. Women differed in what they perceived as intrusive, be it a clinician's hand, an instrument or a physical approach:

> *. . . you want the least intrusive thing that you can get hold of, really. And they don't seem as bad as some of the alternatives . . . like, the head down tilt thing seems less invasive than some of the ones where you'd be using instruments, and that sort of thing.*
>
> *P5*

Another participant described a sense of safety from the doctor's hand, which is viewed as being more sensitive and functional than a tool or inanimate object:

TABLE 5 Themes and subthemes

Theme	Subtheme	Participants, *n* (%)
Acceptability of different techniques	Level of invasiveness	5 (55)
	Security in practitioner expertise	5 (55)
	Baby safety	4 (44)
Informed choice in trials	Timing of invitation	7 (77)
	Capacity to make an informed choice	5 (55)
	Birth outcome	3 (33)
	Importance of rapport	4 (44)
Birth education	Antenatal education	9 (100)
	Post-partum information	7 (77)

TABLE 6 Summary of women's views on which technique(s) they preferred

Technique	Justification for choice
Head down or the vaginal push technique	*… probably the ones where the pushing and the head down tilt one, feels a bit more natural, I would say… unless I have misunderstood it, it feels like me as the mother who's trying to give birth to my child, I still am trying to give birth to my child with some more assistance. Whereas, these [other techniques] feel completely, the power's more out of my hands a little bit* *P1*
Tydeman tube	*… I prefer the tube because the doctor would be holding on to the bottom … and the air as well, will release a suction, so 'cos that will have a benefit over just using your hand because they'll be able to get rid of the suction with the air … the hand you have better control …* *P2*
Fetal pillow	*I suppose this one [pillow] would be better than that [tube] … this pillow it seems, it looks erm, I don't know about the right word, don't look as hard as the tube … I think to be pushing on a baby's soft skull. I think they've had enough sort of trauma down there already and the head's getting squashed. And then to be coming from that way pushing them up … but maybe the pillow feels like a soft sort of 'fabric'* *P3*
Tydeman tube or the fetal pillow	*Any of those techniques would be preferable to having hands or really physically pulling on a baby … I think sometimes you can feel like you are being manhandled I think and people can be a bit rough* *P4* *Um, possibly the pillow and the tube, maybe. I think the, I don't know how to pronounce it, Patwardhan method, is the furthest method away. That really seems like a very, very, within an emergency, an extra emergency kind of procedure to me* *P5* *… if I had a choice in terms of how, if that technique was gonna be used, I'd rather something like this, it would be slightly more gentle … than the other, like the push technique* *P6*
Health-care professionals' decision	*None of them seem particularly unacceptable or you know, there was nothing that I thought, oh, I really wouldn't want to have that done to me … I would put my hand in the health professional to be choosing the right implement … 'cos you don't really have a choice anyway* *P7*
Any technique	*I suppose I would be happy with whatever you had to use really. I suppose you trust the doctor to make the right decision don't you and whatever you need to do to make sure the baby is safe really* *P8* *I would go with anything. I'm quite trusting of medicine, and if something has to be done then that's what has to be done, you know* *P9*

> *So erm yeah . . . perhaps it's safer to actually have somebody doing that, with their own hand, rather than a plastic implement.*
>
> *P7*

Invasiveness was also understood in terms of potential risk of infection. This participant talks about the importance of hygiene:

> *I suppose I prefer the tube or the pillow rather than the midwife hands I think . . . they just seem a bit more hygienic and a bit cleaner.*
>
> *P8*

Security in practitioner expertise Some women talked about trusting the medical team to use the appropriate technique:

> *I suppose I would be happy with whatever you had to use really. I suppose you trust the doctor to make the right decision don't you and whatever you need to do to make sure the baby is safe really.*
>
> *P8*

A few women mentioned that the technique used was less important than ensuring women feel secure and reassured by the clinical team during the emergency situation:

> *I think it's, that it is really important in terms of making sure mum's emotional well-being is you know at the forefront in terms of . . . 'cos you've got to perform this surgery, it's huge surgery, you need to make sure that she feels secure in your care so that actually when she leaves there she's like OK [laughs] well that's happened.*
>
> *P6*

Baby safety Last, the extent to which a technique may damage or threaten the safety of their baby was mentioned by some women when considering acceptability:

> *The other things . . . Tocolysis, I'm not sure, I would probably put that as more, last resort if, obviously the main thing is to save the baby, so I would do anything if the baby was in trouble.*
>
> *P2*

Another participant emphasised the importance of the baby arriving safely and was less concerned about the baby being injured during the process:

> *Even if it meant to deliver your baby we had to break the baby's leg, it sounds horrific but I personally, would much rather that than not have a baby.*
>
> *P9*

Theme 2: informed choice in trials

Women's views of a trial of different techniques produced the theme 'informed choice in trials', which had four subthemes: timing of the invitation, capacity to make an informed choice, birth outcome and importance of rapport.

Timing of the invitation Timing of an invitation to take part in a trial was important, as being offered information before the birth would allow women time to understand and reflect on the project:

> *I think it's quite a stressful time anyway, and there is quite a lot going on . . . if you are asked earlier on in the process, then you have got more time to sort of think about it properly, if that makes sense and . . . give a . . . sort of more informed right choice.*
>
> *P8*

Capacity to make an informed choice There was a consistent view from women that consenting to a trial under critical conditions would be challenging. Furthermore, in an emergency situation they might be more compliant and agreeable because they would not be able to consider information carefully:

> *I appreciate all of that and I'd have been more than happy to be part of it, as I am now, but I just think you can't ask people at those times. I just don't know if they have full capacity even . . . I just wasn't even thinking right . . .*
>
> *P3*

Birth outcome Women described a willingness to take part in research once they were confident that their baby was safe and well:

> *After the baby's nicely, safely delivered, so that would be, I'd have said yes to anything when my baby was here safely.*
>
> *P4*

> *After the baby has been . . . yeah that probably will be better, yeah because yeah you are sort of almost . . . you have gone through the process and you are relieved that everything is OK.*
>
> *P8*

Importance of rapport Last, participants described the importance of being approached for research purposes by a clinician they knew; most women identified their midwife as a suitable person:

> *I think maybe more by a midwife than anybody else . . . 'cos you have that, you have more of a relationship with your midwife than anybody else.*
>
> *P4*

Theme 3: birth education and information

Women spontaneously reflected on their own birth experience and what would have been helpful with hindsight. The theme 'birth education' emerged from women reflecting on their experiences of having a second-stage emergency CS and the need for education and knowledge before and after. This had two subthemes of antenatal education and post-partum information.

Antenatal education Antenatal education and knowledge were seen as an opportunity to have some control over the impact of birth events as opposed to being blind to potential adverse events:

> *Going into a situation you know nothing about it takes away a lot of your control I think . . . you wouldn't do this for any other surgery, you wouldn't approach any other situation without the full picture, but you present women who are pregnant with this almost glorified textbook.*
>
> *P4*

Participants reflected on whether or not it is important for women to be informed about all types of birth outcomes, not just positive 'glorified' births. Women said that it was important to reframe narratives around CS at antenatal classes so that this is presented like any other type of birth, which would reduce any sense of failure among women who have a CS:

> *So actually I think there probably is a lot more education that could be available so people . . . don't feel this is a weird way to give birth, but it's still a way to give birth.*
>
> *P4*

Post-partum information Similarly, women said that it was important to be given information post partum so that they could understand the events during birth. Women discussed the value of processing the events of birth afterwards and of knowledge in validating their experiences and alleviating the negative emotional impact:

> *. . . Because I had to stay in hospital for 5 days afterwards. Um, and he just came back and sort of said, 'Do you know what's happened to you?' [laughs]. And I said [high voice], 'Ooh no, I don't think I do.' [laughs]. I was very emotional. And then he explained it all to me, and that actually made me feel 1000 times better, just him taking 5 minutes just to explain that to me.*
>
> *P1*

Chapter 3 UK Obstetric Surveillance System study

Objectives

- To determine the incidence of, and complication rates from, IFH at full dilatation caesarean birth in the UK, and record which techniques are in use.

Methods

UKOSS was set up in 2005[10] to collect population-based information about rare pregnancy events from all 194 consultant-led maternity hospitals in the UK. Over the 6 months between 1 March and 31 August 2019, nominated reporting clinicians notified UKOSS of all pregnant women with a singleton fetus in cephalic presentation who had a CS during the second stage of labour. Further information (see *Report Supplementary Material 2*) was collected if any technique was used to assist delivery of the fetal head (either as a preventative measure when IFH was anticipated or as treatment when IFH was encountered) or where the operating surgeon deemed there to be 'difficulty' in delivering the fetal head. Reporting clinicians were sent regular reminders to return data at weeks 1, 2 and 3 after notification.

The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies.[11] The sample size was not predetermined. Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corporation, Armonk, NY, USA). Data are presented as descriptive statistics (median, IQR), with the Kolmogorov–Smirnov test used to assess the distribution of continuous data. Ethics approval was obtained from the North London Research Ethics Committee 1 (REC1) (10/H0717/20). Further information is available at www.npeu.ox.ac.uk/ukoss/completed-surveillance/ifh (accessed 4 November 2022).

Results

Overall, 159 (82%) of the 194 hospitals with obstetric units in the UK reported 3518 second-stage CSs, which we estimate[12] equates to 7.3% of emergency caesarean births in those hospitals. Among 564 reports of the use of a disimpaction technique or of 'difficulty' delivering the head, two were duplicates and five referred to twins (second twin in four cases and unspecified in one). These were excluded, leaving 557 reports (16% of second-stage caesarean births) in the final analysis.

Characteristics of women who experienced an impacted fetal head

Women and labour characteristics are included in *Table 7*, and operative findings in *Table 8*.

Operator characteristics

The grade of the initial operator starting the CS is summarised in *Table 8*. Overall, 210 out of 557 cases were performed by a specialty trainee (ST) 3–5 doctor (trainee obstetrician in year 3–5 of their 7-year specialist training programme). Of those 210 cases, 153 (73%) were supervised by either a ST6–7 (trainee obstetrician in the final 2 years of their 7-year specialist training programme) or a consultant. The highest-grade supervising operator where the initial operator was not a consultant is summarised in *Table 8*. The main initial operator was unsuccessful in delivery in 103 (19%) of cases. Presenting the lack of success by the initial operator as a proportion of deliveries undertaken by each grade of obstetrician,

TABLE 7 Demographic data for women included in the study

Characteristic	*n* (%)	Median (IQR)
Age (*n* = 556) (years)		31 (27–34)
BMI (*n* = 537) (kg/m^2)		26 (23–29)
BMI group (*N* = 537)		
< 20	39 (7)	
20–24.9	194 (36)	
25–29.9	181 (34)	
30–34.9	75 (14)	
≥ 35	48 (9)	
Ethnicity (*N* = 557)		
White	453 (81)	
Asian	67 (12)	
Black	11 (2.0)	
Mixed/any other ethnic group	21 (3.8)	
Unknown	5 (0.9)	
Previous pregnancy > 24 weeks' gestation	114 (20)	
Previous CS	37 (6.6)	
Gestation at delivery (weeks)		40^{+2} (39^{+3}–41^{+1})
Length of first stage (hours)		8.25 (5.00–12.03)
Length of second stage (hours)		2.98 (1.49–3.58)
Onset of labour		
Spontaneous	283 (51)	
Induction of labour	273 (49)	
Indication for induction of labour		
Fetal concerns	90 (33)	
Maternal concerns	56 (21)	
Post dates	59 (22)	
Prolonged rupture of membranes	35 (13)	
Maternal request	3 (1)	
Other/not reported	30 (11)	
Oxytocin (Syntocinon®, Mylan Products Ltd) use	352 (64)	

BMI, body mass index.

grade ST3–5 doctors were unsuccessful in delivery in 61 (29%) cases, in comparison to 23 (14%) for ST6–7 and 8 (10%) for consultants.

The operator undertaking the attempted unsuccessful instrumental delivery is summarised in *Table 8*.

TABLE 8 Indications for CS and grade of operator performing the CS

Characteristic	Findings	*n* (%)
Position of fetal head prior to delivery	Occipito-posterior (OP)	257 (46)
	Occipito-transverse (OT)	160 (29)
	Occipito-anterior (OA)	108 (19)
	Brow	8 (1.4)
	Not reported	24 (4.3)
Station of fetal head	At or below ischial spines	407 (73)
	Above spines	142 (26)
	Not reported	8 (1.4)
Prior unsuccessful attempt at instrumental delivery	Yes	316 (57)
	Ventouse	96 (30)
	Forceps	244 (77)
	Dual instrumentation	24 (7.6)
	Rotation	204 (65)
	Manual	97 (48)
	Rotational forceps	59 (29)
	Rotational ventouse	35 (17)
	Multiple methods	23 (11)
Grade of operator performing unsuccessful instrumental delivery (*N* = 316)	ST3–5 (resident)	91 (29)
	ST6–7 (resident)	110 (35)
	Consultant (attending)	88 (28)
	Other	27 (8.6)
Indication for CS (*N* = 557)	Failed instrumental attempt	242 (43)
	Prolonged second stage	174 (31)
	Fetal compromise	92 (17)
	Malposition	20 (4)
	Maternal compromise/request	8 (1.4)
	Not reported	21 (4)
Grade of operator for CS (*N* = 557)	ST3–5 (resident)	210 (38)
	ST6–7 (resident)	171 (31)
	Consultant (attending)	78 (14)
	SAS doctor	49 (9)
	Other/not reported	49 (9)
Highest grade of operator present for CS (supervising) (*N* = 482)	ST3–5 (resident)	50 (10)
	ST6–7 (resident)	216 (45)
	Consultant (attending)	212 (44)
	Not reported	4 (1)

continued

TABLE 8 Indications for CS and grade of operator performing the CS (*continued*)

Characteristic	Findings	*n* (%)
Category of CS	1 (immediate threat to life of woman or fetus; within 30 minutes)	260 (47)
	2 (no immediate threat to life of woman or fetus; within 75 minutes)	291 (52)
	3 (the fetus needs to be born early but there is no immediate risk to mother or fetus)	6 (1)
Anaesthesia	Regional	506 (91)
Median time from uterine incision to delivery interval (minutes)		3 (IQR 2–5)

ST, specialty trainee.

Note
ST3–5 or a junior registrar is a trainee obstetrician in years 3–5 of their 7-year specialist training programme equivalent to a resident in the US; ST6–7 or a senior registrar is a trainee obstetrician in the final 2 years of their 7-year specialist training programme equivalent to a resident; specialty doctor are non-training posts that include staff grade, associate specialist and specialty doctors with at least 4 years of postgraduate training; and consultant is a doctor who has completed all of their specialist training equivalent to an attending physician.

Techniques, and the order in which they were used

The vaginal push technique was used as treatment on 167 out of 557 (30%) occasions and ranked as the first technique used by the majority of operators (see *Table 9*). It was also used as a preventative measure on 68 further occasions. The fetal pillow was used 142 times as a preventative measure (25%) and 34 times as treatment. Of the 78 (14%) of cases where tocolysis was used, the drug was glyceryl trinitrate (GTN) (Pharmaserve, North West Ltd) in 37 (47%), terbutaline sulphate (Bricanyl Injection, Cambridge, AstraZeneca UK Limited) in 33 (42%), salbutamol (Ventolin, GlaxoSmithKline, Brentford, UK) in three (4%) and a combination of terbutaline and GTN in five (6%).

TABLE 9 Preventative or therapeutic techniques for IFH at the time of CS at full dilatation, and the rank order in which they were used

			Rank					
Technique	Use	*n*	1	2	3	4	5	Not specified
Fetal pillow	Preventative	142	163	10	1			2
	Therapeutic	34						
Vaginal push technique	Preventative	68	186	28	10	1	1	9
	Therapeutic	167						
Reverse breech	Preventative	0	5	12	15	6	7	3
	Therapeutic	47						
Patwardhan	Preventative	1	1	2		2		1
	Therapeutic	5						
Tydeman tube	Preventative	0						1
	Therapeutic	1						
Head down tilt	Preventative	21	32	33	2	1		8
	Therapeutic	55						
Tocolysis	Preventative	13	25	23	8	4		7
	Therapeutic	54						
Extend uterine incision	Preventative	2	12	27	10	7		4
	Therapeutic	58						

Maternal and neonatal outcomes

Maternal and neonatal complications are summarised in *Table 10*. Overall, 230 (41%) women and 20 babies (3.5%) experienced complications. It is important to note that not all complications may have been attributable to the IFH and that some women and babies experienced more than one complication.

TABLE 10 Maternal and neonatal complications

Complication	*n* (%)
Maternal (N = 557)	
Uterine rupture before start of procedure	2 (0.4)
Extension of the uterine incision	120 (22)
Blood loss > 1000 ml	146 (26)
Median blood loss (IQR) in this group (ml)	1300 (1100–1700)
Bladder injury	5 (0.9)
Hysterectomy	3 (0.5)
Bowel injury	2 (0.4)
Sepsis	27 (4.8)
Intensive care (level 2 or 3)	34 (6.1)
Maternal death	0
Baby (N = 557 unless stipulated)	
Mean birthweight (IQR) (kg)	3.58 (3.24–3.88)
Cord arterial pH <7.1 (*n* = 417)	67 (16)
Apgar <7 at 5 minutes	46 (8.4)
Apgar <7 at 10 minutes	11 (2.3)
Hypoxic ischaemic encephalopathy	3 (0.5)
Skull fracture	5 (0.9)
Long bone fracture	1 (0.2)
Clavicular fracture	1 (0.2)
Brachial plexus injury	2 (0.4)
Facial palsy	1 (0.2)
Stillbirths[a]	2 (0.4)
Neonatal deaths	2 (0.4)
Neonatal unit admission	69 (12)
Cerebral cooling	7 (1.3)

a One diagnosed before CS and one during delivery.

Chapter 4 Delphi process and consensus building

Methods

We used online surveys delivered to key stakeholders (obstetricians, obstetric anaesthetists, midwives and parents (see *Chapter 2*, *Results*, *National survey*),[13] UKOSS results (see *Chapter 3*) and results from qualitative interviews (see *Chapter 2*, *Results*, *Qualitative study*) to identify techniques, maternal outcomes and neonatal outcomes for inclusion in round 1 of the Delphi survey. To achieve consensus on the final standardised set of techniques and primary outcome, we used a two-stage Delphi process comprising a series of questionnaires followed by a consensus meeting of UK-based stakeholders.

Delphi survey

We identified six techniques, 10 maternal outcomes and 13 neonatal outcomes from the results of the online surveys, UKOSS and the qualitative interviews. These were used to create an online Delphi survey using the Core Outcome Measures in Effectiveness Trials (COMET) Delphi Manager software,[14] which was completed by two groups: obstetricians and neonatologists.

Panel size and membership

There is currently no standard method for sample size calculation in a Delphi survey; thus, a pragmatic approach was adopted, guided by practicality, question scope and time available for analysis.[15] The aim was to recruit as large a panel as possible, encouraging individuals from each stakeholder group to participate.

All stakeholders who completed the preceding online surveys and provided contact details to indicate willingness to be approached to participate in the Delphi survey were invited to take part. Known contacts of the authors were also used.

Recruitment of the panel

A range of expertise within the panel was considered important; therefore, the Delphi study surveyed individuals with a stake in the management of IFH. All participants who completed the online surveys in *Chapter 2*, *Results*, *National survey* were invited to take part in the Delphi survey. The stakeholder groups were obstetricians (ST6–7 trainees in their final 2 years of training and consultants) and neonatologists (ST6–8 trainees in their final 3 years of training and consultants). The obstetricians were asked to comment on the techniques used for managing IFH during emergency CS and what they considered the most important maternal and neonatal outcomes for any RCT. The neonatologists were asked to consider only the neonatal outcomes.

Distributing the Delphi survey

The Delphi survey was managed using the COMET Initiative Delphi Management software. Stakeholders were invited via e-mail to participate. The survey was designed to ensure that each round was as concise and easy to complete as possible, with minimal time commitment. Initial e-mails contained a clear but brief explanation of the study, emphasising the importance of completing all rounds, an estimate of

the amount of time to complete the questionnaires (15 minutes per round), a request for participatory consent and a link to the Delphi survey. Invitation e-mails stated that individuals with relevant obstetric or neonatology experience were to be recruited and participants were asked to complete each round of the Delphi exercise within 3 weeks of receipt of the e-mail. Automated reminders were sent after weeks 1 and 2, a personal reminder was sent in week 3 and the survey round was closed after 4 weeks. Reminders were generated automatically by the Delphi Manager software.

Conducting the Delphi survey

Upon registration, participants were asked to provide their name, geographical location, primary professional role and year of training, if applicable. Participants' names and contact details were recorded to allow personalised reminders about survey completion to be sent. However, to maintain full anonymity following online registration, the COMET software assigned a unique study identifier to each participant, which was linked to their survey responses but could not be traced to individual names. The questions in the Delphi survey are presented in *Appendix 2*.

Participants were asked to score each of the techniques for managing IFH according to the importance of including them in a future RCT. The Grading of Recommendations Assessment Development and Evaluation (GRADE) scale was used, which suggests a nine-point Likert scale (1–9) to rank importance.[14] Scores of 7–9 denoted techniques of 'critical' importance, scores of 4–6 were 'important but not critical' and scores of 1–3 were deemed 'not that important'. An 'unable to score' option (score 10) and space for providing optional feedback on reasons for allocating particular scores were included. Participants were able to nominate additional techniques, maternal outcomes and neonatal outcomes in round 1 to be included in round 2. Additional techniques and outcomes suggested in round 1 were reviewed and coded by the study team. In the case of any uncertainty, the Delphi development team and collaborators were consulted as appropriate. For each technique and outcome, scores were calculated as a percentage of the total responses for all scores and a summary was provided. All techniques, maternal outcomes and neonatal outcomes were carried forward to the next round. In cases where participants scored 1–3 on the scale, techniques and outcomes were not dropped between rounds, to allow participants the visibility of decisions for all metrics. If two or more participants suggested its inclusion, a new outcome was added to the list for the next round.[16]

In rounds 2 and 3, each participant was presented with their own scores plus the number of respondents and distribution of scores for each technique and outcome from round 1. Participants were asked to consider responses from other members of the group and asked to re-score in the light of this information. The total number of participants invited to take part in round 2 was recorded, and, for each technique and outcome, the number of participants who scored the technique/outcome and the distribution of scores was summarised. Following round 3, each technique was classified as 'consensus in', 'consensus out' or 'no consensus' according to the classifications in *Table 1*. All 'consensus in' and 'no consensus' techniques were discussed at the consensus meeting, along with trigger levels for taking action.

Consensus criteria

The classifications described in *Table 11* were used to determine if consensus was reached or not.[17] Regarding the critical importance of the metric, ≥70% of survey participants were required to agree on the inclusion of an item in the subset to be discussed at the consensus meeting, with <15% considering it unimportant.

Consensus meeting

The final phase of this work package was a consensus-building meeting of 23 key representatives from the following stakeholder groups: obstetricians, obstetric anaesthetists, midwives, neonatologists, triallists and patient and public involvement (PPI) representatives. A non-clinical member of the research

TABLE 11 Definition of consensus

Consensus classification	Description	Definition
Consensus in	Consensus that the technique should be included	70% or more participants scoring 7–9 and <15% scoring 1–3
Consensus out	Consensus that the technique should not be included	70% or more participants scoring 1–3 and <50% scoring 7–9
No consensus	Uncertainty about importance of technique	Any other outcome

team chaired the meeting. Owing to the COVID-19 pandemic, the meeting was conducted virtually via Microsoft Teams® (Microsoft Corporation, Redmond, WA, USA). The results from round 3 of the Delphi survey were presented and used to inform the structure and content of the consensus meeting. Inclusion of an item in the subset to be discussed at the consensus meeting required agreement by the majority of survey participants regarding the critical importance of the metric, with only a minority considering it unimportant. The aim of the meeting was to reach consensus on the techniques to be included in the design of a future trial and to determine the choice of primary outcome for any future trial.

Results

Delphi survey

Figure 2 summarises the Delphi study. Data were collected for the three rounds of the Delphi survey between January 2020 and July 2020. Of 132 obstetricians and neonatologists who registered for the

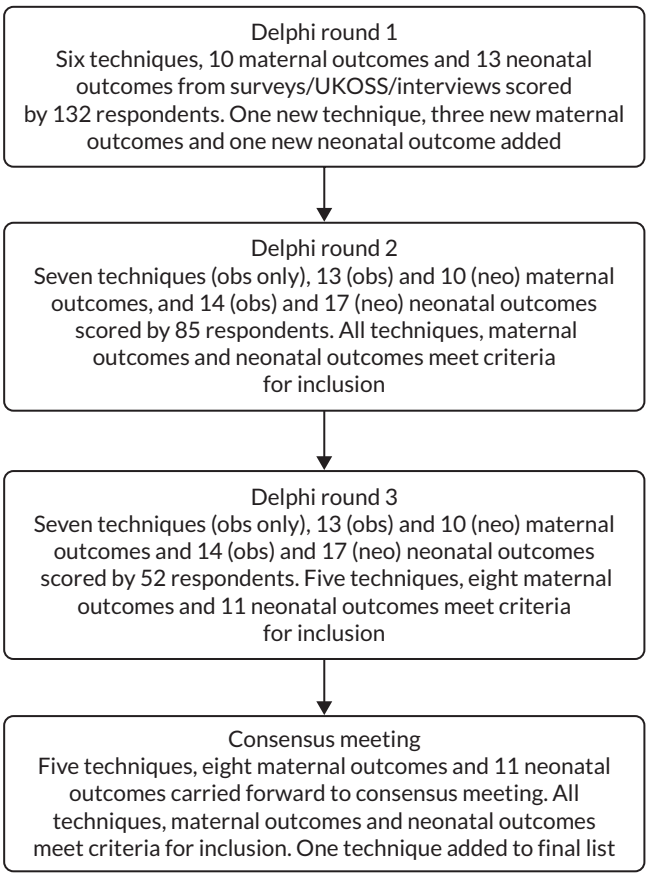

FIGURE 2 Summary results of Delphi survey and consensus meeting. Obs, obstetricians; neo, neonatologists.

survey, 132 (97 obstetricians, 35 neonatologists; 100%) completed round 1, 85 (72 obstetricians, 13 neonatologists; 64%) completed round 2 and 52 (44 obstetricians, 8 neonatologists; 39%) completed round 3. *Table 12* summarises the obstetrician results for each technique, maternal outcome and neonatal outcome by Delphi survey round. *Table 13* summarises the neonatologist results for each maternal and neonatal outcome by Delphi survey round.

Round 1

Obstetricians

Six techniques (numbered 1–6 in *Table 12*), 10 maternal outcomes (numbered 8–17 in *Table 12*) and 13 neonatal outcomes (numbered 21–33 in *Table 12*) met the criterion for inclusion in round 1. All techniques, maternal outcomes and neonatal outcomes were carried forward to round 2, and one new technique (numbered 7 in *Table 12*), three new maternal outcomes (numbered 18–20 in *Table 12*) and one new neonatal outcome (numbered 34 in *Table 12*) were added after round 1, following participant nominations.

Neonatologists

Ten maternal outcomes (numbered 1–10 in *Table 13*) and 13 neonatal outcomes (numbered 11–23 in *Table 13*) met the criterion for inclusion in round 1. All maternal outcomes and neonatal outcomes were carried forward to round 2, with no new maternal outcomes and five new neonatal outcomes (numbered 24–28 in *Table 13*) added after round 1, following participant nominations.

Round 2

Obstetricians

Seven techniques (numbered 1–7 in *Table 12*), 13 maternal outcomes (numbered 8–20 in *Table 12*) and 14 neonatal outcomes (numbered 21–34 in *Table 12*) met the criterion for consensus in after round 2. All techniques, maternal outcomes and neonatal outcomes were carried forward to round 3.

Neonatologists

Ten maternal outcomes (numbered 1–10 in *Table 13*) and 18 neonatal outcomes (numbered 11–28 in *Table 13*) met the criterion for consensus in after round 2. All maternal outcomes and neonatal outcomes were carried forward to round 3.

Round 3

Obstetricians

Collectively, five techniques (numbered 1, 2, 5, 6 and 7 in *Table 12*), seven maternal outcomes (numbered 8, 10–14, and 15 in *Table 12*) and nine neonatal outcomes (numbered 21, 24–29, 32 and 33 in *Table 12*) met the criterion for consensus in at the end of round 3 and were carried forward to the consensus meeting. The reasons reported for participants changing scores between rounds were being influenced by scores provided by others, having time to reflect on scores provided and reconsider the importance of the metrics, and recent clinical experience.

Neonatologists

Seven maternal outcomes (numbered 1–3, 5–9 in *Table 13*) and eight neonatal outcomes (numbered 14–19, 26 and 28 in *Table 13*) met the criterion for consensus in at the end of round 3 and were carried forward to the consensus meeting. The reasons reported for participants changing scores between rounds were being influenced by scores provided by others, having time to reflect on scores provided and reconsider the importance of the metrics, and recent clinical experience.

TABLE 12 Summary of techniques, maternal outcomes, and neonatal outcomes by survey round: obstetricians

Metric	Round 1 scores, *n* (%)				Round 2 scores, *n* (%)				Round 3 scores, *n* (%)			
	1–3	4–6	7–9	10	1–3	4–6	7–9	10	1–3	4–6	7–9	10
Techniques												
1. Fetal pillow – prophylactic	12 (12.1)	21 (21.2)	64 (64.6)	2 (0.02)	2 (2.8)	16 (22.2)	53 (73.6)	1 (1.4)	2 (4.5)	6 (13.6)	34 (77.3)	2 (4.5)
2. Fetal pillow – treatment	12 (12.1)	20 (20.2)	63 (63.6)	4 (0.04)	5 (6.9)	14 (19.4)	51 (70.8)	2 (2.8)	3 (6.8)	8 (18.2)	31 (70.5)	2 (4.5)
3. Head down tilt of the operating table	12 (12.1)	48 (48.5)	39 (39.4)	0 (0.0)	6 (8.3)	38 (52.8)	28 (38.9)	0 (0.0)	3 (6.8)	22 (50.0)	17 (38.6)	2 (4.5)
4. Administration of tocolytic agent to the mother	6 (0.06)	34 (34.3)	58 (58.6)	1 (0.01)	4 (5.6)	23 (31.9)	44 (61.1)	1 (1.4)	2 (4.5)	7 (15.9)	33 (75.0)	2 (4.5)
5. Reverse breech extraction (pull technique)	4 (0.04)	27 (27.3)	68 (68.7)	0 (0.0)	3 (4.2)	15 (20.8)	54 (75.0)	0 (0.0)	0 (0.0)	11 (25.0)	31 (70.5)	2 (4.5)
6. Vaginal push technique	8 (8.1)	17 (17.2)	72 (72.7)	2 (0.02)	3 (4.2)	6 (8.3)	63 (87.5)	0 (0.0)	3 (6.8)	4 (9.1)	35 (79.5)	2 (4.5)
7. Extend uterine incision (J-shaped or T-shaped)	–	–	–	–	4 (5.6)	21 (29.2)	45 (62.5)	2 (2.8)	3 (6.8)	8 (18.2)	31 (70.5)	2 (4.5)
Maternal outcomes												
8. Bladder injury	1 (1.0)	37 (37.8)	60 (61.2)	0 (0.0)	1 (1.4)	23 (31.9)	48 (66.7)	0 (0.0)	0 (0.0)	11 (24.4)	32 (71.1)	2 (4.5)
9. Bowel injury	4 (4.1)	42 (42.9)	52 (53.1)	0 (0.0)	4 (5.6)	28 (38.9)	40 (55.6)	0 (0.0)	2 (4.5)	15 (33.3)	26 (57.8)	2 (4.5)
10. Ureteric injury	2 (2.0)	33 (33.7)	63 (64.3)	0 (0.0)	2 (2.8)	20 (27.8)	50 (69.4)	0 (0.0)	0 (0.0)	8 (17.8)	35 (77.8)	2 (4.5)
11. Extension of uterine incision	3 (3.1)	31 (31.6)	64 (65.3)	0 (0.0)	5 (6.9)	14 (19.4)	53 (73.6)	0 (0.0)	4 (8.9)	4 (8.9)	35 (77.8)	2 (4.5)
12. Haemorrhage > 1000 ml	2 (2.0)	20 (20.4)	76 (77.6)	0 (0.0)	2 (2.8)	9 (12.5)	61 (84.7)	0 (0.0)	2 (4.5)	1 (2.2)	40 (88.9)	2 (4.5)
13. Caesarean hysterectomy	0 (0.0)	10 (10.2)	88 (95.7)	0 (0.0)	0 (0.0)	4 (5.6)	68 (94.4)	0 (0.0)	0 (0.0)	1 (2.2)	42 (93.3)	2 (4.4)
14. Sepsis	2 (2.0)	41 (41.8)	55 (56.1)	0 (0.0)	1 (1.4)	22 (30.6)	49 (68.1)	0 (0.0)	1 (2.2)	9 (20.0)	33 (73.3)	2 (4.4)
15. Need for critical care	0 (0.0)	27 (27.6)	71 (72.4)	0 (0.0)	0 (0.0)	11 (15.3)	61 (84.7)	0 (0.0)	0 (0.0)	3 (6.7)	40 (88.9)	2 (4.4)
16. Acute adverse mental health outcomes	5 (5.1)	47 (48.0)	46 (46.9)	0 (0.0)	1 (1.4)	41 (56.9)	30 (41.7)	0 (0.0)	0 (0.0)	29 (64.4)	14 (31.1)	2 (4.4)
17. Chronic adverse mental health outcomes	5 (5.1)	51 (52.0)	42 (42.9)	0 (0.0)	1 (1.4)	43 (59.7)	28 (38.9)	0 (0.0)	0 (0.0)	29 (64.4)	14 (31.1)	2 (4.4)

continued

TABLE 12 Summary of techniques, maternal outcomes, and neonatal outcomes by survey round: obstetricians (*continued*)

Metric	Round 1 scores, *n* (%)				Round 2 scores, *n* (%)				Round 3 scores, *n* (%)			
	1–3	4–6	7–9	10	1–3	4–6	7–9	10	1–3	4–6	7–9	10
18. Broad ligament haematoma	–	–	–	–	5 (6.9)	31 (43.1)	35 (48.6)	1 (1.4)	3 (6.7)	20 (44.4)	20 (44.4)	2 (4.4)
19. Cervical laceration	–	–	–	–	4 (5.6)	36 (50.0)	31 (43.1)	1 (1.4)	2 (4.4)	24 (53.3)	17 (37.8)	2 (4.4)
20. Vaginal haematoma	–	–	–	–	7 (9.7)	45 (62.5)	19 (26.4)	1 (1.4)	2 (4.4)	32 (71.1)	9 (20.0)	2 (4.5)
Neonatal outcomes												
21. Fractured skull	0 (0.0)	14 (14.4)	84 (85.7)	0 (0.0)	0 (0.0)	4 (5.6)	68 (94.4)	0 (0.0)	0 (0.0)	2 (4.5)	40 (90.9)	2 (4.5)
22. Fractured clavicle	6 (6.2)	47 (48.5)	44 (45.4)	0 (0.0)	3 (4.2)	45 (62.5)	24 (33.3)	0 (0.0)	2 (4.5)	28 (63.6)	12 (27.3)	2 (4.5)
23. Fractured long bone	8 (8.2)	43 (44.3)	46 (47.4)	0 (0.0)	5 (6.9)	34 (47.2)	33 (45.8)	0 (0.0)	3 (6.8)	17 (38.6)	22 (50.0)	2 (4.5)
24. Brachial plexus injury	3 (3.1)	25 (25.8)	69 (71.1)	0 (0.0)	2 (2.8)	16 (22.2)	54 (75.0)	0 (0.0)	1 (2.3)	4 (9.1)	37 (84.1)	2 (4.5)
25. Intracranial haemorrhage	0 (0.0)	5 (5.2)	92 (94.8)	0 (0.0)	0 (0.0)	1 (1.4)	71 (98.6)	0 (0.0)	0 (0.0)	0 (0.0)	42 (95.5)	2 (4.5)
26. Moderate encephalopathy	0 (0.0)	11 (11.3)	85 (87.6)	1 (1.0)	0 (0.0)	3 (4.2)	69 (95.8)	0 (0.0)	0 (0.0)	1 (2.3)	41 (93.2)	2 (4.5)
27. Severe encephalopathy	0 (0.0)	4 (4.1)	92 (94.8)	1 (1.0)	0 (0.0)	0 (0.0)	72 (100)	0 (0.0)	0 (0.0)	0 (0.0)	42 (95.5)	2 (4.5)
28. Active cooling	0 (0.0)	4 (4.1)	92 (94.8)	1 (1.0)	1 (1.4)	0 (0.0)	71 (98.6)	0 (0.0)	1 (2.3)	0 (0.0)	41 (93.2)	2 (4.5)
29. Death	0 (0.0)	0 (0.0)	97 (100)	0 (0.0)	0 (0.0)	0 (0.0)	72 (100)	0 (0.0)	0 (0.0)	0 (0.0)	42 (95.5)	2 (4.5)
30. Scalp laceration	18 (18.6)	53 (54.6)	26 (26.8)	0 (0.0)	11 (15.3)	51 (70.8)	10 (13.9)	0 (0.0)	7 (15.9)	32 (72.7)	3 (6.8)	2 (4.5)
31. Blunt abdominal trauma	8 (8.2)	40 (41.2)	49 (50.5)	0 (0.0)	5 (6.9)	33 (45.8)	34 (47.2)	0 (0.0)	2 (4.5)	24 (54.5)	16 (36.4)	2 (4.5)
32. Seizures treated with anticonvulsant medication	1 (1.0)	6 (6.2)	89 (91.8)	1 (1.0)	1 (1.4)	5 (6.9)	66 (91.7)	0 (0.0)	0 (0.0)	1 (2.3)	41 (93.2)	2 (4.5)
33. Admission to NICU >4 hours	4 (4.1)	26 (26.8)	67 (69.1)	0 (0.0)	3 (4.2)	13 (18.1)	56 (77.8)	0 (0.0)	2 (4.5)	5 (11.4)	35 (79.5)	2 (4.5)
34. Jaundice requiring phototherapy	–	–	–	–	8 (11.1)	46 (63.9)	17 (23.6)	1 (1.4)	5 (11.4)	32 (72.7)	5 (11.4)	2 (4.5)

NICU, neonatal intensive care unit.
Score 1–3, 'not important'; 4–6, 'important but not critical'; 7–9, 'critical'; 10, unable to score.

TABLE 13 Summary of maternal outcomes and neonatal outcomes by survey round: neonatologists

Metric	Round 1 scores, *n* (%)				Round 2 scores, *n* (%)				Round 3 scores, *n* (%)			
	1–3	4–6	7–9	10	1–3	4–6	7–9	10	1–3	4–6	7–9	10
Maternal outcomes												
1. Bladder injury	0 (0.0)	7 (21)	22 (67)	5 (15)	0 (0.0)	3 (23)	9 (69)	1 (8)	0 (0.0)	1 (13)	7 (88)	0 (0.0)
2. Bowel injury	0 (0.0)	7 (21)	22 (67)	5 (15)	0 (0.0)	1 (8)	11 (85)	1 (8)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
3. Ureteric injury	0 (0.0)	8 (24)	21 (64)	5 (15)	0 (0.0)	1 (8)	11 (85)	1 (8)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
4. Extension of uterine incision	3 (9)	18 (55)	7 (21)	5 (15)	2 (15)	9 (69)	1 (8)	1 (8)	2 (25)	5 (63)	1 (13)	0 (0.0)
5. Haemorrhage > 1000 ml	0 (0.0)	10 (30)	18 (55)	6 (18)	0 (0.0)	3 (23)	9 (69)	1 (8)	0 (0.0)	2 (25)	6 (75)	0 (0.0)
6. Caesarean hysterectomy	1 (3)	1 (3)	27 (82)	5 (15)	0 (0.0)	0 (0.0)	12 (92)	1 (8)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
7. Sepsis	1 (3)	14 (42)	14 (42)	5 (15)	0 (0.0)	4 (31)	8 (62)	1 (8)	0 (0.0)	2 (25)	6 (75)	0 (0.0)
8. Need for critical care	0 (0.0)	7 (21)	23 (70)	4 (12)	0 (0.0)	1 (8)	11 (85)	1 (8)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
9. Acute adverse mental health outcomes	0 (0.0)	15 (46)	13 (39)	5 (15)	0 (0.0)	6 (46)	6 (46)	1 (8)	0 (0.0)	2 (25)	6 (75)	0 (0.0)
10. Chronic adverse mental health outcomes	2 (6)	13 (39)	14 (42)	5 (15)	1 (8)	7 (54)	4 (31)	1 (8)	0 (0.0)	3 (38)	5 (63)	0 (0.0)
Neonatal outcomes												
11. Fractured skull	0 (0.0)	14 (40)	20 (57)	1 (3)	0 (0.0)	6 (46)	7 (54)	0 (0.0)	0 (0.0)	3 (38)	5 (63)	0 (0.0)
12. Fractured clavicle	7 (20)	21 (60)	6 (17)	1 (3)	3 (23)	10 (77)	0 (0.0)	0 (0.0)	3 (37.5)	5 (63)	0 (0.0)	0 (0.0)
13. Fractured long bone	3 (9)	20 (57)	11 (31)	1 (3)	1 (8)	11 (85)	1 (8)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)	0 (0.0)
14. Brachial plexus injury	0 (0.0)	13 (37)	21 (60)	1 (3)	0 (0.0)	3 (23)	10 (77)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
15. Intracranial haemorrhage	0 (0.0)	5 (14)	29 (83)	1 (3)	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
16. Moderate encephalopathy	1 (3)	4 (11)	29 (83)	1 (3)	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
17. Severe encephalopathy	0 (0.0)	1 (3)	32 (92)	1 (3)	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
18. Active cooling	0 (0.0)	3 (9)	31 (89)	1 (3)	0 (0.0)	2 (15.4)	11 (85)	0 (0.0)	0 (0.0)	1 (13)	7 (88)	0 (0.0)
19. Death	1 (3)	0 (0.0)	33 (94)	1 (3)	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
20. Scalp laceration	8 (23)	22 (63)	4 (11)	1 (3)	6 (46)	7 (54)	0 (0.0)	0 (0.0)	4 (50)	4 (50)	0 (0.0)	0 (0.0)

continued

TABLE 13 Summary of maternal outcomes and neonatal outcomes by survey round: neonatologists (*continued*)

	Round 1 scores, *n* (%)				Round 2 scores, *n* (%)				Round 3 scores, *n* (%)			
Metric	1–3	4–6	7–9	10	1–3	4–6	7–9	10	1–3	4–6	7–9	10
21. Blunt abdominal trauma	3 (9)	19 (54)	11 (31)	2 (6)	1 (8)	7 (54)	5 (39)	0 (0.0)	1 (13)	4 (50)	3 (38)	0 (0.0)
22. Seizures treated with anticonvulsant medication	0 (0.0)	8 (23)	26 (74)	1 (3)	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
23. Admission to NICU >4 hours	3 (8.6)	15 (43)	16 (45.7)	1 (3)	0 (0.0)	7 (54)	6 (46)	0 (0.0)	0 (0.0)	5 (63)	3 (38)	0 (0.0)
24. Breastfeeding rates	–	–	–	–	2 (15)	6 (46)	5 (39)	0 (0.0)	0 (0.0)	4 (50)	4 (50)	0 (0.0)
25. Intracranial haemorrhage	–	–	–	–	0 (0.0)	0 (0.0)	13 (100)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)
26. Long-term neurodevelopmental outcome for infant	–	–	–	–	0 (0.0)	2 (15)	11 (85)	0 (0.0)	0 (0.0)	1 (13)	7 (88)	0 (0.0)
27. Subgaleal haemorrhage	–	–	–	–	1 (8)	5 (39)	7 (54)	0 (0.0)	1 (13)	3 (38)	4 (50)	0 (0.0)
28. Spinal injury	–	–	–	–	1 (8)	2 (15)	10 (77)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100)	0 (0.0)

NICU, neonatal intensive care unit.
Score 1–3, 'not important'; 4–6, 'important but not critical'; 7–9, 'critical'; 10, unable to score.

Consensus meeting

A total of 127 UK-based obstetricians and neonatologists were invited to participate in the consensus meeting, of whom 19 accepted and nine attended the virtual meeting. In addition, three obstetric anaesthetists, two PPI representatives (one antenatal educator and one woman with lived experience of IFH) and two midwives attended. Seven members of the study team also attended, of whom three voted, equating to a total of 23 attendees and 12 voting participants.

In addition to the five techniques, eight maternal outcomes and 11 neonatal outcomes reaching the criterion for inclusion after round 3 of the Delphi survey, one further technique was discussed and voted on at the meeting. This was because the Tydeman tube had been well received by women in the qualitative study reported in *Chapter 2*. Although the Delphi study had not demonstrated popularity of the Tydeman tube, this was felt to be due to its lack of availability as it is not yet CE (Conformité Européene) marked.

Among participants, there was a high level of agreement. Among the six techniques, eight maternal outcomes and 11 neonatal outcomes that were discussed, four out of six techniques, all eight maternal outcomes and all 11 neonatal outcomes received over 75% of the vote for inclusion in the final set. The final set is given in *Table 14*.

TABLE 14 Final techniques and maternal and neonatal outcomes with the percentage of consensus meeting participants who voted to include them

Metric	Proportion of participants who voted to include the technique/outcome (%)
Technique	
Tydeman tube	83
Vaginal push technique	82
Fetal pillow –prophylactic	78
Fetal pillow –treatment	71
Maternal outcomes	
Caesarean hysterectomy	100
Haemorrhage > 1000 ml	94
Need for critical care	88
Ureteric injury	82
Bladder injury	76
Extension of uterine incision	76
Sepsis	76
Bowel injury	71
Neonatal outcomes	
Death	100
Severe encephalopathy	100
Intracranial haemorrhage	100
Fractured skull	94
Moderate encephalopathy	88

continued

TABLE 14 Final techniques and maternal and neonatal outcomes with the percentage of consensus meeting participants who voted to include them (*continued*)

Metric	Proportion of participants who voted to include the technique/outcome (%)
Active cooling	88
Long term adverse neurodevelopmental outcome	83
Brachial plexus injury	76
Admission to NICU > 4 hours	72
Seizures treated with anticonvulsant medication	72
Spinal injury	72

NICU, neonatal intensive care unit.

Chapter 5 Design of a randomised trial

Objectives

- To design a randomised trial comparing techniques for managing IFH during emergency CS.

Methods

Using data from previous work packages, key stakeholders and co-investigators from the Nottingham Clinical Trials Unit (NCTU) held several meetings to design a randomised trial.

Results

Detailed discussions included the following aspects of the study design, which are summarised here.

Choice of intervention

Four techniques were considered for testing in a randomised trial: the fetal pillow (used prophylactically), the fetal pillow (used as treatment), the vaginal push technique and the Tydeman tube. All four options were deemed worthy of inclusion in a randomised trial, but some of the practicalities of the timing of the use of fetal pillow are discussed in the next paragraph. The Tydeman tube is not currently CE marked or available to the NHS, and the group felt that this would make it impractical for use in a randomised trial at this time.

Timing of the intervention

There are two potential timings for the intervention: (1) 'prophylactic', or early disimpaction prior to starting the CS, and (2) 'treatment', or late disimpaction after delivery has been attempted at CS.

It was felt that the term 'prophylactic' is confusing in this context as the head may or may not be impacted at the time of the early intervention, and so it is not possible to 'prevent' the head being impacted. Terminology in this context is important, and therefore 'early disimpaction' (prior to attempting delivery at CS) versus 'late disimpaction' (after delivery has been attempted at CS) was preferred and will be used from now on.

The time it takes to insert the fetal pillow (approximately 60 seconds) would make it inappropriate to use for late disimpaction, as it would delay the uterine incision to delivery interval. This decision was supported by the output from the consensus meeting where early use of the fetal pillow was preferred over later use. Given that many obstetric units use a technique for early disimpaction and many clinicians are unwilling to 'do nothing' when IFH is anticipated, a trial of early disimpaction was recommended.

Two-arm versus three-arm trial

As it had been agreed that the timing of the intervention should be early disimpaction, detailed discussions were held about whether or not a third arm (i.e. waiting to see whether or not IFH is encountered at CS) should be included. This suggestion was made as there is currently no randomised evidence on whether or not the use of any technique makes a difference, and so it would be ideal to test how the technique compares with watchful waiting. It was strongly agreed that it would be unethical to randomise some participants to an arm where nothing was done if early disimpaction (vaginal push technique or use of the fetal pillow) is widely practised when IFH is anticipated. It would be difficult to

approach women to join a trial where they had a one in three chance of being randomised to waiting or 'doing nothing' in the event of CS, knowing that using a technique might make their CS safer.

Choice of primary outcome

We discussed which of the following should be the primary outcome for the trial:

- a co-primary outcome of composite serious adverse maternal and composite serious adverse neonatal outcomes
- a primary outcome of composite serious adverse neonatal outcomes.

Discussions at the consensus meeting had strongly favoured a co-primary outcome of two composites, serious maternal and serious neonatal outcomes, and this was echoed during trial planning discussions.

We discussed the components of each of the composite outcomes at length. The co-primary outcome with the lowest event rate would determine the sample size. Ideally, all components of the composite should be equally weighted. We discussed whether or not to include post-partum haemorrhage (PPH) or PPH requiring blood transfusion as a component of the serious maternal composite; this would have had a significant impact on the sample size calculations.

These decisions formed a key part of our proposed trial design, alongside discussions about the feasibility of such a trial.

Proposed trial design

The proposed population, intervention, comparison, outcome (PICO) for the trial are outlined in *Box 2*.

BOX 2 Proposed PICO

Population

All women having an emergency CS where the clinician anticipates IFH and feels it may be appropriate to use a technique (fetal pillow or vaginal push technique) to disimpact the head (i.e. early disimpaction prior to attempting delivery of the fetal head by hand at CS).[a]

Intervention

Insertion of the fetal pillow.

Comparison

Vaginal push technique.

Outcomes

Co-primary: composite serious adverse maternal and composite serious adverse neonatal outcomes.

a We have confirmed with the manufacturers of the fetal pillow that it can be use prior to full dilatation: 'The CE certification covers all caesareans (in which) difficulty in delivery of head at a CS is anticipated' (Innes Taylor, Safe Obstetric Systems, personal communication).

Primary outcome

The following co-primary outcomes were chosen: composite serious adverse maternal (objective measures only) and composite serious adverse neonatal outcomes.

The composite serious adverse maternal outcomes comprise bladder injury, bowel injury, caesarean hysterectomy, haemorrhage requiring blood transfusion, ureteric injury and maternal death.

The composite serious adverse neonatal outcomes comprise neonatal intensive care unit admission of >24 hours, brachial plexus injury, intrapartum stillbirth, neonatal death, active cooling, fractured skull, intracranial haemorrhage, moderate encephalopathy, seizures treated with anticonvulsant medication, severe encephalopathy and spinal injury.

Secondary outcome (long term)

The secondary outcome of the trial is the 2-year developmental quotient for each baby, which is not routinely collected and can be measured using questionnaires.

Participant pathway

Consent

Written, pictorial and video information about the trial could be displayed in recruiting centres, with participant information sheets available to women on request. Women could be approached before a late-labour CS and oral assent for the trial taken.[18] Verbal consent prior to randomisation can be obtained with written consent obtained post randomisation and post birth when the woman has had sufficient time to recover. The oral assent pathway is chosen when time is scarce and the provision of full written information to women, at a sensitive and emotional time, might be difficult. Further there is reason to believe that 'consent' obtained without sufficient time for discussion and reflection doesn't represent informed consent with its typically understood attributes. This is a standard approach when clinical trials are conducted in an emergency situation.

Other approaches that were considered but rejected by the group included an opt-out consent model and consent exemption.

Randomisation would be via a brief electronic randomisation (accessible to all clinical staff, not just those trained in good clinical practice) following oral assent for the trial. After women recover from labour, they will be approached for written consent for ongoing use of their data.

Randomisation

Randomisation would take place electronically using mobile devices provided to the site.

We will register the level (e.g. consultant, trainee) of the clinician performing the CS pre randomisation. We will stratify randomisation based on the level of the clinician performing the CS.

Owing to the nature of the intervention, it is not possible for clinicians or women to be blinded to randomised allocation. However, blinded outcome assessment will be conducted. Mother and baby notes will be redacted, photocopies made and any trial group identifiers removed; a blinded outcome assessor will then be asked to complete the mother and baby outcome information for the trial. The trial statistician will be blinded to treatment allocation until the final database lock.

Sample size for the definitive trial

The sample size for a future definitive trial will be based on a two-arm parallel trial design comparing the fetal pillow (intervention) with the vaginal push technique (control), and co-primary composite serious

adverse maternal and composite serious adverse neonatal outcomes. The trial will be powered for both outcomes, with the final sample size determined by the outcome with the lowest event rate (and larger sample size). The success of the intervention will be concluded if a treatment effect is demonstrated on both outcomes; therefore, there will be no requirement for multiplicity adjustment. A sample size of 9396 participants will have 90% power to detect a 40% relative reduction in maternal adverse events from 2.3% to 1.38%, using 5% level of significance and 1 : 1 allocation. If we were to include post-partum haemorrhage > 1000 ml in the composite serious adverse maternal outcome (rather than haemorrhage requiring blood transfusion), increasing the event rate to 27%, then the sample size (driven by the neonatal event rate of 13.1%) required to detect a 40% relative reduction in the event rate would be 1508. The target effect size of a 40% relative reduction in the event rate was judged as the minimum clinically worthwhile difference to justify the invasiveness and cost-of-use of the prophylactic pillow. *Table 15* shows other sample size scenarios for different event rates and detectable effect sizes.

We acknowledge that a variety of techniques were used in the UKOSS data to manage IFH, rather than just the vaginal push technique proposed as the control arm in the trial, and this could have an impact on the observed event rates in any trial.

We anticipate no missing data for the primary outcome.

Feasibility

We propose including women in the first stage of labour in whom IFH is anticipated.

Using data from the prospective observational study (see *Chapter 3*), we anticipate that 626 women in the UK per annum will experience IFH at second-stage CS (see *Table 16*).

TABLE 15 Sample size scenarios based on the choice of primary outcome and detectable effect size. Event rates based on the rates for each component of the outcome from UKOSS data (see *Chapter 3*)

Control event rates	Effect size	Sample size per group	Total sample size
Co-primary outcomes: • Composite serious adverse maternal event rate = 2.3% (without PPH > 1000 ml) • Composite serious adverse neonatal event rate = 13.1%	Control event rate of 2.3% and a 40% reduction in the event rate to 1.4%	4698	9396
	Control event rate of 2.3% and a 30% reduction in the event rate to 1.6%	8746	17,492
	Control event rate of 2.3% and a 25% reduction in the event rate to 1.7%	13,118	26,236
Co-primary outcomes: • Composite serious adverse maternal event rate = 27% (including PPH > 1000 ml) • Composite serious adverse neonatal event rate = 13.1%	Control event rate of 13.1% and a 40% reduction in the event rate to 7.9%	754	1508
	Control event rate of 13.1% and a 30% reduction in the event rate to 9.2%	1395	2790
	Control event rate of 13.1% and a 25% reduction in the event rate to 9.8%	2047	4094
Single primary outcome: • Serious adverse maternal composite event rate = 27% (including PPH > 1000 ml)	Control event rate of 27.0% and a 40% reduction in the event rate to 16.2%	322	644
	Control event rate of 27.0% and a 30% reduction in the event rate to 18.9%	589	1178
	Control event rate of 27.0% and a 25% reduction in the event rate to 20.3%	860	1720

TABLE 16 UK birth statistics 2019–20

Event (%)	Annual frequency (*n*)
Births in the UK	626,203
All CS (28.4%)	175,336
All emergency CS (56.3%)	98,714
All second-stage emergency CS (5%)	4935
IFH at second-stage CS (12.7%)	626

In a retrospective cohort study[19] of 838 women undergoing emergency CS during 1 year (2016) at one large UK maternity unit, IFH complicated 11.3% of all emergency CS births, and 55% of cases of IFH occurred prior to the second stage. In this study,[19] 8% of first-stage emergency CS births and 32% of all second-stage emergency CS births were complicated by IFH. This estimate for IFH at second-stage emergency CS birth is much higher than rates prospectively observed in our UKOSS study (12.7%). If we conservatively estimate that 3% of all first stage emergency CS births are complicated by IFH, then we estimate that equates to 2813 births per annum. We estimate that a total of 3439 women per year in the UK would be eligible for this randomised trial. It is important to note that the event rate of serious maternal and neonatal morbidity may be lower in women undergoing a first-stage emergency CS birth.

Chapter 6 Determining the acceptability of our proposed randomised trial

Objective

- To determine the acceptability of our proposed randomised trial among health-care professionals and pregnant women in the UK.

Aims

- To understand current practice, level of expertise and training requirements for managing IFH during emergency CS among consultant obstetricians, senior trainee obstetricians, obstetric anaesthetists and midwives.
- To understand parents' opinions of various techniques and their willingness to participate in a clinical trial in this area.

These aims were addressed through two approaches: (1) national online surveys of lead obstetricians, pregnant women and midwives; and (2) telephone interviews with health-care professionals and women.

National surveys

Methods

National online surveys of lead obstetricians (via UK labour ward leads group), pregnant women (via the National Childbirth Trust) and midwives (via the Royal College of Midwives) were carried out to determine the feasibility and acceptability of the randomised trial described in *Chapter 5*.

Results

A total of 146 obstetricians, 46 midwives and 30 pregnant women completed an online survey.

At the time of survey completion, 146 (100%) obstetricians were currently working as a consultant obstetrician or trainee obstetrician in the UK. Thirty-four (23%) were consultant obstetricians and the rest were trainees. Overall, 129 (88%) obstetricians would be willing to participate in the clinical trial proposed. In addition, 38 (83%) midwives would be willing to participate in the proposed clinical trial. The reasons given by the 17 obstetricians and eight midwives who were unwilling to participate in the clinical trial proposed are in *Table 17*. The training requirements for obstetricians in order to take part in the proposed clinical trial are given in *Table 18*.

Of the 30 pregnant women who completed the survey, two (7%) were aged 20–24 years, two (7%) were aged 25–29 years, 20 (67%) were aged 30–34 years and six (20%) were aged 35–39 years. Seventeen (57%) women were primiparous. Of the 13 multiparous women, two (15%) had experienced IFH in the past.

Parents were given a description of the proposed clinical trial and asked to report on the likelihood [on a Likert scale of 1 (least likely) to 5 (most likely)] that they would take part in this trial. Eleven (37%) respondents scored 4 or 5, eight (27%) respondents scored 3 and 11 respondents (37%) scored 1 or 2. Participants were asked to report reasons why they would be unlikely to take part in such a study. Of the six women who responded to this question, three respondents selected that they would prefer for

TABLE 17 Reasons for obstetricians and midwives being unwilling to participate in the proposed clinical trial

Reason	Obstetricians[a] (*N* = 17), *n* (%)	Midwives (*N* = 8), *n* (%)
Unwilling to randomise to vaginal push technique	7 (41)	1 (11)
Unwilling to randomise to use fetal pillow	4 (24)	1 (11)
Unwilling to use a technique prior to encountering difficulty at the caesarean	6 (35)	–
Other	2 (12)	–
Wish to use a different technique	1 (6)	–
Wish to use the fetal pillow	1 (6)	–
Do not consider informed consent can be obtained from women in this situation	–	4 (44)
I don't have enough information about either technique to make a decision	–	1 (11)
I don't work on labour ward	–	1 (11)

a Some survey respondents gave two reasons for non-participation.

TABLE 18 Training requirements among obstetricians for participation in the proposed clinical trial

Response	*n* (%)
No, I would not need any further training	76 (52)
Yes, I would need training in both techniques	25 (17)
Yes, I would need training on the fetal pillow	35 (24)
Yes, I would need training on the vaginal push technique	10 (7)

the doctor to deliver the baby in the way they felt most comfortable, one did not like the concept of randomisation, one did not like the techniques described and three would not like to have to think about a research study while in labour.

Telephone interviews

Methods

Design

We undertook a qualitative interview study of health-care professionals' and women's views on the acceptability and feasibility of RCTs designed to determine the most effective technique for managing IFH at second-stage CS.

Ethics approval

Ethics approval was obtained from the West Midlands, Solihull, Research Ethics Committee (REC 19/WM/0118). The study was conducted in accordance with the ethical principles originating from the Declaration of Helsinki, 1996 (World Medical Association, 2013);[20] and the Principles of Good Clinical Practice and the UK Department of Health and Social Care Policy Framework for Health and Social Care, 2017 (Health Authority Research, 2017).[21]

Sample

Three samples of participants were identified for the purposes of this study: obstetric consultants or senior obstetric trainees, primiparous women, and women who had experienced an emergency CS in the 18 months preceding the interviews.

Obstetricians

Senior trainee obstetricians were recruited with the assistance of the UKARCOG committee, which represents a network of obstetric trainees throughout the UK. UKARCOG promoted the study to their regional leads located within the geographic areas classified by Health Education England ('Deanery') and their leads in the devolved nations, and cascaded a survey to trainees within their regions (see *Chapter 2*). Those who took part in the survey were asked about their willingness to participate in the interviews.

An identical survey was carried out of consultant obstetricians via the UK Labour Ward Leads Group (see *Chapter 2*). This group were asked of their willingness to participate in the interviews.

Obstetricians were also recruited through social media.

Obstetricians were eligible if they were NHS staff working as either the lead obstetric consultant on an obstetric unit or an obstetric trainee, ≥16 years, and able to provide consent.

Twenty-three obstetricians expressed an interest in participating and 11 consented to take part. Of the 11 obstetricians who consented, 10 were available to be interviewed on the dates available.

Women

Women were recruited through an NHS teaching hospital in England and via social network channels [e.g. Twitter (Twitter, Inc., San Francisco, CA, USA), LinkedIn (LinkedIn Corporation, Sunnyvale, CA, USA) and Facebook (Facebook, Inc., Menlo Park, CA, USA)]. Women were eligible if they either (1) had experienced a second-stage CS in the 18 months preceding the date of interview or (2) were primiparous (either pregnant with their first child or had their first child in the previous 18 months); were aged ≥16 years (no upper age limit); had adequate spoken English; and were able to give informed consent. There were no exclusion criteria.

Twenty-six women expressed an interest in participating and 18 (69%) consented to take part. All 18 women were interviewed but the audio files were corrupted for two interviews, so these were not able to be transcribed. Results therefore include interview data from 16 women.

Procedure

Women

Women who had experienced a second-stage CS in the prior 24 months were identified from hospital records by a research midwife. Both urgency of CS (emergency vs. elective) and indication for CS (failed instrumental delivery) are mandatory reporting fields on the maternity data set enabling eligible women to be identified. To try to ensure a representative sample, all women who were eligible over a 24-month period were identified from medical records. Of these, 80 were invited to participate: 43 who lived in deprived areas (i.e. an IMD decile of 1 or 2) and 37 in other areas (IMD decile of 3–10).

Women who had experienced a second-stage CS were sent a letter of invitation and participant information sheet. Those interested in taking part returned a pre-paid postal card to the research team indicating their interest and providing contact details, and a signed consent form. Consent forms were signed and dated by the participant before they entered the study and checked by the research team, who provided a countersignature on receipt. The master files and documents were held by City, University of London, in secure, locked archiving facilities.

Pregnant and primiparous women were invited to take part in letters of invitation from Nottingham University Hospitals NHS Trust and via social media networks (e.g. Twitter, LinkedIn, Facebook). The letters of invitation were sent to 80 pregnant women under the care of the NHS teaching hospital. Social media invitations used a digital poster that provided brief information about the study and contact details of the research team. Women who were interested in taking part were asked to contact the research team. All participants were sent a participant information sheet and consent form, which they returned to the research team.

With women in both groups, telephone interviews were arranged for a suitable time and conducted by a research psychologist experienced in conducting qualitative research with vulnerable groups. At the beginning of the interview, participants were asked to provide basic sociodemographic information such as age, ethnicity and relationship status. A semistructured interview was then conducted, which lasted approximately 45 minutes. The interview covered (1) acceptability of different techniques, (2) willingness to be involved in a trial of this type and (3) views on different trial designs. The interview was conducted using the topic guide in *Report Supplementary Material 3*.

The interview was conducted by a researcher who was blinded to the participants' childbirth details. If women wanted more information about their birth events and/or a referral to an obstetrician they were encouraged to contact their GP. The number of interviews conducted was dependent on women's availability and data saturation. All interviews were audio-recorded and transcribed.

Obstetricians

Obstetricians were recruited after showing an interest when they completed the survey described in *Chapter 2*, or through social media. A digital poster was designed and shared with brief information about the study and how to contact the research team. The research psychologist responded to potential participants via e-mail to send them a participant information sheet and consent form. Participants who returned a completed consent form were then offered a telephone interview. Interviews were conducted using a semistructured interview schedule and lasted approximately 45 minutes. The interview covered (1) acceptability of different techniques, and (2) acceptability and (3) feasibility of a trial generally as well as of different trial designs. The interview was conducted using the topic guide in *Report Supplementary Material 4*.

Different trial designs

Two trial designs were proposed from previous work in the Management of the Impacted head At caesarean Section (MIDAS) programme. These are described in a visual guide in *Report Supplementary Material 5*. The first was a trial with two arms to compare the use of the vaginal push technique with the fetal pillow. Women would be randomised during emergency CS once it was established that the fetal head was impacted. The second trial design had three arms and randomisation was to occur prior to emergency CS at the point where IFH is anticipated. Women would be randomised to early disimpaction of the fetal head using the vaginal push technique, insertion of the fetal pillow or no action. The visual guide in *Report Supplementary Material 5* was used during interviews with obstetricians and women to help them consider the different designs.

Data analysis

Audio-recordings were analysed using systematic thematic analysis.[8] A combined inductive and deductive approach was used. Data were analysed using the following steps. First, all transcripts were read so that the data became familiar. The transcripts were then re-read and all initial codes identified and coded. When no further codes emerged (i.e. data saturation), all the codes were examined by two researchers (Gabriella Romano and SA, or Georgina Constantinou and SA) who reached agreement on those that were most frequent or could be combined into main themes. Interviews for obstetricians and women were analysed separately and then compared to identify the main themes and subthemes from the different groups. The themes were relatively similar, so they are reported together. It is noted in the results section if themes or subthemes arose from only obstetricians or only women. Finally, the main

themes were cross-checked against quotations to ensure that the quotations were reliably coded and represented the main themes. Analysis was facilitated by NVivo (QSR International, Warrington, UK), a specialist computer software package for qualitative analysis.[9] The approach used in this study was adopted from Ritchie and Lewis,[22] who described the three inter-related stages involved, namely (1) data management, (2) descriptive accounts and (3) explanatory accounts.

Results

Sample characteristics

Sample characteristics of women are given in *Table 19*. Women were all from white British, Scottish or European backgrounds. Two-thirds (69%) of women were educated to undergraduate or postgraduate

TABLE 19 Sample characteristics of women (*N* = 16)

Characteristic	*n* (%)
Parity/birth group	
Pregnant with first baby	5 (31)
Primiparous (gave birth in last 18 months)	1 (6)
Emergency second-stage CS	10 (63)
Ethnicity	
White British	14 (88)
White Scottish	1 (6)
White European	1 (6)
Level of education	
High school (GCSE)	1 (6)
High school (A Level/diploma)	4 (25)
Undergraduate degree	6 (38)
Postgraduate degree	5 (31)
Relationship status	
Married	7 (44)
Living with partner	7 (44)
Single/not living with partner	2 (12)
Employment	
Employed	13 (81)
Self-employed	2 (13)
Unemployed	1 (6)
Job sector	
Health, research and social care	7 (44)
Education	2 (12.5)
Customer services	2 (12.5)
Other	5 (31)
Number of children	
0 (pregnant at time of interview)	6 (38)
1	8 (50)
2	2 (12)

A Level, Advanced Level; GCSE, General Certificate of Secondary Education.

degree level. The majority were married or living with their partner (88%) and in employment (94%). The average age was 32 years [standard deviation (SD) 4.9 years].

Sample characteristics of obstetricians are given in *Table 20*. The data show an even sex balance and that half of the sample were consultants. Mean years since qualifying were 18 (SD 7.2 years). Exposure to cases of IFH in the previous year ranged from 0 to 20 with a mean of 7 cases (SD 6.4 cases). Exposure to cases of IFH over the previous 5 years ranged from 0 to 150 with a mean of 41 cases (SD 44.2 cases).

Thematic analysis

Analysis of the interviews with obstetricians and women identified four main themes: (1) recruitment and consent; (2) feasibility and acceptability; (3) design considerations; and (4) outcomes. Each theme had a number of subthemes, which are shown in *Table 21* and outlined in more detail below.

TABLE 20 Sample characteristics of health-care professionals (*N* = 10)

Characteristic	*n* (%)
Sex	
Male	5 (50)
Female	5 (50)
Grade of qualification	
Consultant	5 (50)
Specialty registrar	3 (30)
Specialty trainee year 6	1 (10)
Post clinical competency training	1 (10)

TABLE 21 Main themes and subthemes

Main theme	Subtheme
Theme 1: recruitment and consent	Tackling the timing of consent
	Information presentation
	Recruiting health-care professionals and women
Theme 2: feasibility and acceptability	Conflict between the trial and individual/site practice[a]
	Importance of training[a]
	Trust in health-care professionals' judgement[b]
Theme 3: design considerations	Which trial design is preferable
	Research protocols vs. safety in what you know[a]
	Authenticity of results
	When to randomise[a]
Theme 4: outcomes	Outcomes relevant to obstetricians[a]
	Outcomes relevant to women[b]

a Theme or subtheme arose from obstetricians only.
b Theme or subtheme arose from women only.

Theme 1: recruitment and consent

The first theme identifies a number of issues raised by obstetricians and women about barriers to and facilitators of recruiting women and health-care professionals into a trial. A number of ideas were shared on what to consider when engaging individuals in a trial. In relation to women's recruitment, tackling the timing of consent was thought to be critical, and women and obstetricians frequently reflected on how best to present information to women to truly offer informed consent in an emergency situation:

> *It's difficult because it's already well known that taking consent for an emergency caesarean in itself isn't full capacity consent-giving because women in that situation aren't able to remember or retain what they've been told.*
>
> *HCP08*

> *I understand that you give the full clinical trial participant information 48 hours, erm, within a delivery but, you know, informed consent at that point it can be very difficult, especially if she hasn't got an epidural.*
>
> *HCP03*

Obstetricians were mindful of the need to consult women to identify the optimal way to approach to consent and randomisation:

> *These are extremely sort of tumultuary circumstances that someone finds themself in when they're delivering their baby and I think how you do that sort of consent procedure and randomisation would be, would have to be very carefully studied with PPI [public and patient involvement].*
>
> *HCP07*

Women also highlighted the barrier of trying to recruit under difficult circumstances when the woman is stressed and how this may influence the numbers of women willing to take part:

> *I think for most women in that situation, it's going to be quite a fraught time, and um, and a stressful time, and I'm guessing it would be that moment that we would be introducing the . . . the . . . the study and the trial. Um, and I think that could cause undue stress to the mum, having to make a decision as to whether, oh, I need to be doing this, and I worry that that might mean that your um, er, numbers or women that were prepared to take part, would be quite low.*
>
> *Primiparous W017*

Information presentation was raised by women and obstetricians as important when recruiting and consenting women. This included consideration over when to present women with information about the trial, how much information to present, the content of the information and the format it should be presented in.

In terms of when to present women with information about the trial, views of obstetricians varied. Some thought women should be approached months before the birth and then, should an impacted head occur, at least women would already be aware of the trial when entering the labour ward. Others thought that information should be given on arrival at the labour ward:

> *I mean I think it would perhaps make more sense I think if all women in labour are actually given a leaflet about this so that they have time to think about it, just in case this were to happen to them. To give them more time to think about it. So any woman, I think, who is in labour and who is happy to take part in this trial, should be given this leaflet beforehand.*
>
> *HCP06*

However, most women stated that they would rather be told about the trial taking place earlier to allow them to process information before undergoing a CS:

> *Personally I feel like I would want to be approached before I went in theatre really 'cos I feel like that's, it's such an intense thing. You know, if, if they think a caesarean or emergency caesarean is looming, I would want someone to approach me before everything starts going, you know. The chance to, the midwife to give it to me and give me chance to just read it in my own time so I can process it, ask some questions about it, but then to be reminded of it, you know, before, before it goes too crazy.*
>
> *ECS W02*

Women appreciated that IFH was rare but would like to be given information about the trial in their antenatal midwife appointments to minimise the impact of being asked to give assent when in labour:

> *I know obviously you say you don't know until that point that it's going to happen but whether it can be brought up in midwife appointments that there is, this trial ongoing and that obviously if this happens, this may come up, just so that when that does happen it, it's maybe not a shock, it's like, oh yes, I've read this about, I've read about this in, in the leaflet the midwife gave me, kind of thing.*
>
> *ECS W09*

Of those women who stated a preference to be given information early, some pinpointed the 20th to the 26th week of pregnancy as an ideal time to be approached about a trial taking place in the hospital:

> *I think the earlier the better, so maybe, at the point where they're obviously, I wouldn't say too early just in case there's more complications with the pregnancy, or whatever, but maybe around the, the 26 week mark or, kind of when they know what's happening more with the pregnancy, so they're over that worry, you know, of actually being pregnant and what's happening and getting that out the way and they're used to that.*
>
> *ECS W010*

Being made aware earlier in pregnancy that a trial was taking place was also thought to improve the likelihood of women wanting to take part:

> *I think if I had the information about the trial before I gave birth, so then I'd be aware of it, that if an impacted head came up, oh this trial's going to be discussed with me. I think if I knew about the trial before I went to give birth, then I would, I would be all for it, yeah, yeah.*
>
> *ECS W013*

In terms of how much information should be given, obstetricians argued this was very dependent on the context. They felt that when asking women to consent in emergency situations the information needs to be short and simple, whereas when providing information during pregnancy or after birth more detailed information can be given:

> *Because if you've done an instrumental, and you have been unsuccessful, you've got about three or four minutes, so at that point you're going to say to them verbal, a verbal consent, but normally we would take a consent for a trial of instrumental in theatre. At that point, you should do the 'do you want to join the trial, if this is unsuccessful?'*
>
> *HCP02*

Women had similar views, explaining that the language needs to be as simple as possible owing to the intensity of the situation:

> *Well it, it needs to be simple language, 'cos you're just kind of in a, in a space and in a zone where you're not really understanding anything, and you, you're that worried, because there is a complication and there is a problem.*
>
> *ECS W013*

> *When the time comes that the information is presented to you erm, in a really, in layman's terms and make sure that I'm completely clued up about what's going to happen.*
>
> *Primiparous W018*

Women stated that information given at the time of a CS should be kept to a minimum:

> *But I think definitely at the point of asking, the amount of information given should be the bare minimum if possible and if they want to know more and they're in the right state of mind to ask more than they can.*
>
> *ECS W009*

In terms of the content of the information, obstetricians emphasised the importance of outlining the problem the trial is trying to solve:

> *In the . . . in the information, it would be really useful to have some, not necessarily figures, but some kind of idea as to the nature of the problem we're trying to solve. So some kind of idea how frequent a problem occurs with a head that is difficult to deliver, either vaginally, or by a caesarean section. And that sometimes babies do have a lack of oxygen and we're trying to improve on that. Something like that, but in laymen's terms.*
>
> *HCP02*

Women thought that it would be useful to be given information about why the techniques had been chosen, including their effectiveness and safety as well as the potential impacts on both them and their baby. It was also deemed important to have a clear understanding of what will happen if a woman agrees to take part, particularly if the technique she is randomised to is not successful:

> *. . . be able to have some maybe facts or some science around why test this versus that and what is gonna happen to you and information on the safety of the baby and obviously if that technique doesn't work how long is it tried for and then what happens, so just loads of information.*
>
> *ECS W003*

Women also would like to be reassured that either technique is appropriate and safe and that the obstetrician is well trained and confident in performing either technique:

> *I think I'd want to feel that being part of it. . . either option is great and the obstetrician would be equally as trained to do both, both of them are, well you can't say both of them are as effective as the other 'cos you're trying to work that out aren't you whether they are, which ones the most effective? So I think, I guess it would be a reassurance that both of them are good.*
>
> *ECS W002*

Obstetricians discussed providing information in different formats (i.e. verbal, written and visual) and that the trial should be explained as clearly and simply as possible:

> *I would feel that a written version should be shown as well, so apart from verbal like a laminated simple version, so it would have to be very simple, it couldn't have all the complexities that many studies do have, it would.*
>
> *HCP08*

Women frequently discussed information being provided verbally and in written format and also the use of diagrams to help them understand the techniques. Women collectively felt that posters displayed in the clinics and waiting rooms were not as useful in providing information to women:

> *I think maybe considering, I think if I was in the waiting area and I saw it, I'd probably read it, but the fact that I'd never expect it to happen to me.*
>
> *ECS W010*

> *You said that the information was like available in antenatal clinics, but whether or not actually that's enough, 'cos I mean there's loads of leaflets when you go to an antenatal clinic, you know, I mean I read them all because I get bored. But lots of women won't, I think posters are quite passive.*
>
> *Primiparous W001*

It was thought that being actively given a leaflet to take away would be helpful, as opposed to having information available in waiting rooms, which they would probably not engage with:

> *. . . do you kind of make sure they have the information, when the lady's come for their scans is that something that you could, is there a leaflet that you can give them when they come to the scan or. I don't know whether that would be beneficial to you, you know, because I mean I see leaflets on the table and I'll be very honest, I didn't really pick any up because I got kind of leaflets and paperwork from my midwife appointments that I didn't pick anything extra up when I was at the hospital.*
>
> *ECS W012*

Several women said that they preferred to receive information verbally from their midwife or clinician as a way to make them aware about the trial and also to reinforce information provided separately or at a different time. It was discussed that this reminder could be provided when arriving for labour:

> *I think it should be a clinician who's involved in her care. So if she's under consultant lead care, then it can be the consultant, if they're under community midwife, then it can be the community midwife. And actually their part to play would be fairly small in . . . in that it's just making them aware this study's ongoing, here's the information sheet.*
>
> *Primiparous W017*

> *So, if, you know, you do then go in, when you do go into labour and you know, the midwife who's looking after you might say oh, have you, you know, did you read the information about the research trial that you were given at your scan? So, if they say yes, obviously you know there's already some kind of understanding there and that kind of opens up the topic of conversation I suppose as to whether it is something they'd be happy to take part in if they needed to.*
>
> *ECS W012*

Barriers to and facilitators of recruiting health-care professionals and women were discussed by each group. Obstetricians reflected on how to engage other health-care professionals in a trial and recruitment in order to maximise participation. Advice included having a lead midwife for the trial to make sure midwives were engaged and recruiting during the day when consultants are present:

> *You need to make some kind of provision for somebody to be the lead midwife on the trial, not the lead obstetrician, the lead midwife, because if you don't get midwives on board, it doesn't happen.*
>
> *HCP02*

> *I think it would be feasible, I think recruitment would be better in daytime and when the consultants are around.*
>
> *HCP03*

Variation between sites was clear. Obstetricians working in sites with no access to the fetal pillow saw this as an attractive reason to take part in the trial, whereas obstetricians working at sites that were already using the fetal pillow saw this as less of an advantage:

> *I think it has to be really easy, has to be really er, clear, as to what is required. I think your er, possibly your jewel in the crown is that somebody is going to get the fetal pillow, so that's attractive.*
>
> *HCP02*

> *In the last 5 years we've used the fetal pillow a lot more so the usual technique would be, well the current usual technique would be the fetal pillow.*
>
> *HCP01*

Obstetricians also emphasised the importance of the research team being accessible in case issues arise:

> *I think the most important thing is making sure that the research team are as accessible as possible for any issues which can happen. Making sure that the documentation is sent in a timely basis. Erm, obviously all the documentation needs to be as simply written as possible.*
>
> *HCP06*

Women reported factors that may influence recruitment to the trial. These included that introducing the trial early to primiparous women may cause them to worry about the birth of their baby or cause confusion:

> *I suppose there is a little concern now as to, would that make them worry because most women are not planning for a caesarean birth, and so if you start talking about caesarean birth at that point, will they get confused and think oh gosh, they're going to force me into having a caesarean just for their study.*
>
> *Primiparous WP17*

In addition, it was discussed that knowledge of what to expect during birth may influence women's willingness to take part, particularly first-time mothers, and that a woman birthing their second child may view the trial as more acceptable:

> *Maybe for not first-time parents because you're only, you've already got no real idea, well I certainly don't at the minute of what, what is going to go on. But if parents, if there's a woman who's had children before and has got a bit more experience in just the whole set-up of being, being in that situation and they have more of an understanding then may, then I'd think it's more acceptable . . . but the preference would maybe to have women who are more, who have had children in the past, maybe.*
>
> *Primiparous W018*

> *Mm, I don't know if it's for my first child maybe not so much I've probably been through the situation and know for next time then you're a bit more clued up aren't you and probably a bit more relaxed about things.*
>
> *Primiparous W018*

Some women said that primiparous women may become aware of the possibility of a complicated birth through taking part in the study, and if they had not previously considered this then it may cause them to worry:

> *So, then you're having that discussion about, you're introducing the idea of a traumatic birth, you know quite far you know in the antenatal period. Yeah, I just it's really difficult.*
>
> *ECS W006*

Women said that they may perceive being asked to take part in a trial as meaning there is something wrong with their baby and were worried this would cause panic:

> *I think if I was being asked, you know, are you happy to take part in this I'd be, like, what's going on, like, is my baby still alive, like, it was such a panicked situation that I don't know if that would make, that would kind of affect my decision making I guess.*
>
> *ECS W002*

Women also said that the word 'trial' could be perceived negatively as including 'new' or 'poor' techniques that might impact on safety. Therefore, the language used to present information about the trial was felt to be key to enhancing recruitment:

> *I feel like people, they hear the word 'trial', maybe they'd be a little scared and put off, just because you know, you view trials as something that's not certain.*
>
> *ECS W010*

> *I think I'd just be a bit cautious of whether they would feel comfortable being used to test out these new techniques in case, you know, it didn't work or something went wrong.*
>
> *ECS W012*

> *I think, as long as I had confidence that either technique was still potentially equally as successful as the other, you know, I wouldn't want to think I was almost being a guinea pig for a technique which maybe was less um, less successful than the other one.*
>
> *ECS W014*

Theme 2: feasibility and acceptability

The second theme identifies a number of issues raised by obstetricians and women about the acceptability and feasibility of conducting a trial into ways of managing IFH. A key subtheme raised by obstetricians was about being randomised to a technique that might cause conflict between the trial and individual/site practice for managing IFH, which might be a barrier to taking part in a trial. At an individual level, obstetricians said that different individuals preferred or were familiar with different management techniques:

> *We're all . . . even though the procedure is similar but we're all completely different because we are influenced by previous outcomes, bad outcomes, by how many you have done.*
>
> *HCP06*

> *I would need to be demonstrated how to use the fetal pillow because I haven't done that.*
>
> *HCP08*

> *I actually haven't had much training to be honest with you because we are so used to using the push technique here and I'm so used to using it.*
>
> *HCP06*

Similarly, obstetricians mentioned that techniques required by the trial might conflict with existing site practices:

> *Getting us to revert to doing the push technique will require some bit of groundwork done just to convince our clinicians to also give it a bit of a trial so yeah . . . already we . . . we use the fetal pillow anyway.*
>
> *HCP09*

> *So, I think for me, in my unit, I wouldn't want to take part in the study. . . because my trainees are trained to anticipate an impacted head when they have done an unsuccessful forceps delivery. And to then ask them not to do those things.*
>
> *HCP05*

However, obstetricians were aware that a trial is needed to reduce this variation in practice between obstetricians and sites to provide safer care:

> *I know that there is no recommended ideal and I also know that the way we improve quality in our service is to minimise variation and, therefore, having a trial-proven best approach would potentially make for a safer obstetric care.*
>
> *HCP08*

Given the variation between individuals and sites, obstetricians emphasised the importance of receiving training in the different techniques prior to the trial so that health-care professionals taking part would have clarity and confidence around using the techniques:

> *I would want to know what appropriate training consists of for fetal pillow, given the lack of any validated training, and if, if it's within an actual research context, then yes.*
>
> *HCP04*

> *Training will be, you said that, you know, maybe training developed, delivered by your team that will be great . . . Because that would have more credibility and give people confidence.*
>
> *HCP03*

> *I mean I would suppose that the training would have to be done through a simulator to begin with, it's probably much easier.*
>
> *HCP06*

Women were less explicitly aware of variation between individuals and sites but were concerned that the obstetricians may be more experienced in, or favour, a particular technique. Women felt that this would affect the obstetrician's confidence, and this would therefore influence women's willingness to be a part of the trial:

> *I just want the tried and tested technique and it might be that this particular doctor's better at one than the other, or more experienced in one than the other.*
>
> *ECS W014*

> *If they're not confident then that's gonna be a major issue. Um, that's it, I think.*
>
> *ECS W011*

Women also highlighted that it may not be acceptable to ask obstetricians to perform a technique they were not comfortable with:

> *I think the other, in terms of acceptability for me would be more is it, is it, is it acceptable to make an obstetrician do something that they don't feel as comfortable with.*
>
> *ECS W002*

Overall, women said that they would trust health-care professionals' judgement if IFH arose and would expect the team to use the most appropriate technique regardless of the trial. Women had confidence that the obstetrician would use their expertise to deliver the baby safely and would be happy to trust in their judgement:

> *Any interventions during birth, I know that I'd actually be quite happy to, I would be pretty oblivious and would just go with whatever the doctor wanted to do. . . there's not enough of a difference between the two that would strike me as wanting a preference but I don't know if that's down to my nature of I've always sort of said to myself I am quite happy to trust the team, the medical team's judgement.*
>
> *Primiparous W015*

> *Obviously the, the discretion of the midwife or the obstetrician who is, thinks it's the best care for the child. But then ultimately if the OB [obstetrician] says well this is the best thing for it then you have to listen to a professional opinion.*
>
> *Primiparous W018*

Several women said that it was important to them to be made aware of the plans in place if the technique they were randomised to did not successfully manage IFH. Specifically, their opinion of acceptability was dependent on having confidence that the obstetrician could move on to a different technique if needed:

> *I suppose I'd be comfortable if you said OK, we'll try it for X period of time and then there's plan B which we can move to quickly . . . then that would give me some confidence.*
>
> *ECS W003*

Most women also considered the idea of a trial acceptable and valued its importance in improving care:

> *I think they're an important part to you know, research and study and the only way we can improve is by trying things out.*
>
> *ECS W010*

> *There's no evidence one way or another, that either technique is better, so you, we need that evidence So, I think it's, I feel like it's acceptable, because we don't know the right one, so you know . . . we should find out.*
>
> *Primiparous W001*

Theme 3: design considerations

This theme consolidates reflections by obstetricians and women on the most appropriate trial design and details of this kind of trial that might need to be considered.

Obstetricians had mixed views on which trial design is preferable. Six expressed a direct preference, with two preferring design 1 (two-arm trial of vaginal push technique vs. fetal pillow) and four preferring design 2 (three-arm trial of prophylactic use of vaginal push technique, fetal pillow and waiting). Obstetricians recognised that the two designs address slightly different questions:

> *If the question you're asking is . . . 'how do we prevent impacted fetal head?' you want design 2. If it's 'how do we deal with impacted fetal head?' it's design 1.*
>
> *HCP04*

> *Actually, the two different arms do represent two different approaches, a prophylactic approach and a treatment approach, which would be [difficult to] compare in themselves . . . I think clinicians who thought like I did would be more likely to take part in a trial where they could actually diagnose . . . the condition rather than acting prophylactically.*
>
> *HCP07*

The design that obstetricians preferred varied for several reasons. Those who preferred design 1 tended to do so because it was in keeping with their current practice and/or addressed the question directly (rather than prophylactically):

> *I mean yeah, personally I would say the design 1 is more comfortable for me because it's like clear and straightforward, which is I am, I've been doing now.*
>
> *HCP10*

> *I wouldn't be as keen on design 2 because I think that's looking at prophylactics, how you reduce the impact of impacted fetal head, which . . . seems to be a different question of how do we deal with impacted fetal head and caesarean section.*
>
> *HCP04*

Those who preferred design 2 said that it was because it gave them more options in terms of clinical management and/or was in keeping with their current practice:

> *I'd rather go with the second one because you've got more options, so including more possible outcomes in your trial data. And if you think about it, the wait is you know, more in line with first do no harm, than the other two.*
>
> *HCP02*

Women also had mixed views on which design was preferable, with 13 women stating the design they would prefer. Of these, seven preferred design 1 as it would prevent the situation progressing to IFH and six preferred design 2 as it accounted for obstetrician discretion:

> *The idea of waiting doesn't fill me with confidence, because again if you've got a qualified person suspecting it, that is almost enough for me to go OK, well do something about it (laughs), and to start with the two techniques whereas waiting just feels like you're increasing the risk of something horrible happening to the baby's head. I don't know, I might just be incorrect, but that's sort of my feeling with it.*
>
> *ECS W003*

> *If that was me, I think I'd go for the 1 because you've got, you're sort of thinking ahead of time . . . So, to me, it's like you're trying to prevent a problem from happening, rather than deal with the problem when it occurs.*
>
> *ECS W011*

Design 2 was favoured by some women as it allowed for the inclusion of a wait arm which would rely on obstetrician discretion:

> *Yeah. I . . . I personally feel more comfortable with the second option, I think that um, my instinct is to trust the obstetrician's instinct, and with that being an option, that they then would continue with whichever technique they're most comfortable with.*
>
> *Primiparous W017*

However, the concept of waiting caused much discussion, with women worrying that this would impact the safety of the baby and would cause time to be wasted resolving the issue:

> *Um from what I am assuming, that could create more consequences, medical consequence and psychological consequences to the baby. And probably more traumatic you know, experience for mum and the partner, you know, the partner being in the room, I'm assuming during the C-section, probably would be pretty, pretty in, in distress too. Um, so you know, when, forget about the partner and the mum, thinking about the baby and the baby's damage, probably for psychological and, and physical health, I'd, I'd rather not wait.*
>
> *Primiparous W016*

Obstetricians reflected on the conflict of research protocols compared with the safety of what they knew. This was similar to the earlier theme of 'conflict between the trial and individual/site practice', where obstetricians questioned whether they would stick to the protocol in emergency situations or revert to what they would usually do:

> *When you're doing something surgically I think you have to really believe in what you're doing. And so . . . what's going to be a really important thing in your trial design is whether or not you allow people to deviate and if you do, do they then come off the trial completely or do you still say that in itself is kind of an interesting thing to measure?*
>
> *HCP01*

> *Absolutely yeah, you want to do something . . . you want to rely on something at a critical time which you are most comfortable with isn't it, not something which you have hardly ever used. But then where it says like in the middle of the column, push technique and fetal pillow, have some sort of asterisk and say however if the clinician feels uncomfortable, or if the delivery is extremely difficult or whatever, they can switch to the other method they are more comfortable with, or something like that.*
>
> *HCP06*

> *If I was very concerned that time was of the essence, to deliver a baby safely, I would be more concerned about doing a technique that isn't my known best, efficient technique for me.*
>
> *HCP08*

Obstetricians reflected on how this and other factors might affect the authenticity of results. Variation in how health-care professionals carry out techniques and whether or not they deviate from the protocol would be important in determining whether or not the results of a trial are robust and relevant to practice, so these aspects should be recorded as part of a trial:

> *What part of their wrist or arm or muscles are they using to do the pull, are they using the flexion of their wrist to create a pull, are they using the triceps by having an ergonomic straight arm, but all of these things will also affect your outcomes and so you will get some variability between practitioners.*
>
> *HCP08*

> *I'd want to know how you randomise, and making sure that that's robust and all of your practitioners are truly comfortable using both [techniques], otherwise, you get skewing.*
>
> *HCP04*

Obstetricians thought that another key issue to consider was when to randomise and whether this should be before or during CS. A key concern was the time that it would take to randomise a woman in an emergency situation:

> *So my main worry about this was randomising a woman, the time taken to randomise and the discussion with the woman in the heat of the moment.*
>
> *HCP03*

> *I'd want to know how you randomise, and making sure that that's robust and all of your practitioners are truly comfortable using both, otherwise, you get skewing.*
>
> *HCP04*

Because of the potential delay, obstetricians thought it was preferable to randomise women before the CS and for health-care professionals to be aware of the allocated technique before going into the operating theatre or as soon as they knew the fetal head was impacted:

> *I think you'd need to go to theatre knowing what you were going to do.*
>
> *HCP01*

> *So you're going to have to randomise before that, so that's going to tweak it a bit, because some of those won't have had an impacted head. Or you randomise . . . before you go into theatre, but then you don't open the answer until you've got the impacted head. But you don't want to delay.*
>
> *HCP02*

Some obstetricians suggested that consent for the trial should be taken at the time when women consent to an emergency CS:

> *We always consent them for caesarean section. So, our consent form has trial of forceps plus or minus caesarean section. So, it's at that point that I think you should take consent and randomise them.*
>
> *HCP05*

Women supported obstetricians' views that in emergency situations they would want the obstetrician to abandon the trial and perform the technique they thought was best suited:

> *I mean you could have someone going down for a C-section and you going down design 1, erm, but then when you get in there within a minute you could think no, we just need to get this baby out now and then I suppose, you know, they are going to do what they feel most comfortable with if it's, if it's safer for the baby. Erm, if you've got the time then by all means it's safe for mum and baby to take that little bit more time to pick which technique they're going to use then I think fine, as long as obviously the mums have of course consented to it, erm, but if it is an emergency then, you know, it needs to be acted on there and then, then they just need to do what they need to do to get the baby out.*
>
> *ECS W012*

Women also discussed their views on being randomised to one of the techniques. Concerns were raised regarding whether or not the technique they were allocated to was suitable for them and would be the preferred technique in the obstetrician's opinion:

> *I guess if it was me on the table, and some, somebody, well not somebody, the computer says 'This procedure should be done', um I would, I would think about, well you know, is this procedure most, most sensible for me at this time or did the clinician think about, you know, perhaps the other procedure would be more suitable for me, and for the person next door, it would be more suitable another procedure. But I think that there might be an unacceptable one for me, you know, or somebody else.*
>
> *Primiparous W016*

Theme 4: outcomes

Both obstetricians and women suggested outcomes that might be relevant in a future trial. The results are shown in *Table 22* for women and *Table 23* for obstetricians. Outcomes important to women were mostly about the health and safety of the woman and the infant, and the woman and her partner's experience. By contrast, obstetricians generated many more detailed clinical outcomes for women and the infant, as well as staff outcomes. There was very little overlap between the outcomes mentioned by women and obstetricians, with the exception of safety of the mother and baby, and the woman's experience. However, many of the outcomes specified by obstetricians were consistent with women's concerns for maternal/infant safety and well-being.

TABLE 22 Important outcomes for women (*N* = 16)

Outcome measure	*n* (%)
Infant outcomes	
Time taken to resolve IFH	8 (50)
Long-term disability/impact on QoL	2 (13)
Psychological/physical trauma	2 (13)
Infant stress	2 (13)
Infant death	2 (13)
Developmental outcomes	1 (6)
Maternal outcomes	
Women's/partner's experiences of birth	7 (44)
Invasiveness	4 (25)
Stress	2 (13)
Increased time in recovery	2 (13)
Internal damage or tearing	1 (6)
Excessive pain	1 (6)
Clinical staff	
Experience/views on performing techniques	3 (19)

QoL, quality of life.

TABLE 23 Important outcomes for obstetricians (*N* = 10)

Outcome measure	*n* (%)
Infant outcomes	
Neonatal trauma/damage to the baby	5 (50)
Safety of the baby	4 (40)
NICU/special care for 48 hours	4 (40)
Neonatal mortality	3 (30)
Fractured skull	3 (30)
Ease of delivery of baby's head	2 (20)
Scalp injury/bruising	2 (20)
Hypoxia	2 (20)
Abnormal cord gases	2 (20)
Low Apgar score	2 (20)
Acidosis	2 (20)
Bleeding	1 (10)
Ventilatory support	1 (10)

TABLE 23 Important outcomes for obstetricians (*N* = 10) (*continued*)

Outcome measure	*n* (%)
Maternal outcomes	
Blood loss/PPH	8 (80)
Uterine tear	3 (30)
Extension to the uterine incision	2 (20)
Speed of recovery and discharge	2 (20)
Mother's experience	2 (20)
Safety of the mother	1 (10)
Physical trauma to other structures	1 (10)
Mother needing surgical repair	1 (10)
Uterine atony	1 (10)
Tying off ureters	1 (10)
Uterine angle tears	1 (10)
Hysterectomy	1 (10)
Infection	1 (10)
Clinical staff	
How comfortable staff feel to use technique	2 (10)
Stress on staff	1 (10)
How difficult it is to teach	1 (10)
Clinical outcomes	
Surgical/operating time	4 (40)
Cost	2 (20)
Methodological confounders	
Who deviates from the protocol and why	1 (10)

NICU, neonatal intensive care unit.

Chapter 7 Discussion

Main findings

The majority (89%) of health-care professionals stated that a clinical trial in this area would help to guide their clinical practice and 87% would be willing to participate in such a trial. In addition, 37% of parents reported that they either felt neutral or would be likely or very likely to take part, and 62% stated that they would be unlikely to participate.

Overall, 80% of midwives and 47% of obstetric anaesthetists would require further training in techniques for managing IFH to allow their participation in a clinical trial in this area. In addition, 50% of obstetricians would require further training in the fetal pillow and 27% would require further training in the vaginal push technique to allow them to participate in a clinical trial in this area.

Women varied in which technique for IFH they thought was most acceptable. Women's trust in medical expertise and prioritising the safety of the baby were important moderators of their acceptability of techniques. Greater consensus was found on factors important to consider in a future RCT. These included timing of consent, capacity to consent in emergency situations, the importance of birth outcomes and good rapport with the consenting clinicians. Women also reflected on antenatal education and post-partum information being important when complications such as IFH arise.

Our UKOSS study found that IFH is common and leads to complications for both mother and baby. It is currently most often treated by an assistant pushing the head up vaginally during the CS.

A total of 132 (obstetricians, n = 97; neonatologists, n = 35) health-care professionals took part in the Delphi process. Five techniques, eight maternal outcomes and 11 neonatal outcomes met the criterion for inclusion after round 3 of the Delphi survey.

A total of nine UK-based obstetricians and neonatologists attended the consensus meeting. In addition, three obstetric anaesthetists, two PPI representatives (one antenatal educator and one woman with lived experience of IFH) and two midwives attended. Seven members of the study team also attended, of whom three voted, resulting in a total of 23 attendees and 12 voting participants. Among participants, there was a high level of agreement. Among the 6 techniques, 8 maternal outcomes and 11 neonatal outcomes that were discussed, 4 out of 6 techniques, all 8 maternal outcomes and all 11 neonatal outcomes met the threshold of 75% of the vote required for inclusion in the final set.

Using data collected in previous work packages, we designed a randomised trial of techniques for managing at IFH. To ensure we propose a randomised trial which is feasible to conduct in the UK, we propose two sample sizes for this trial depending on the choice of the components of the primary outcome:

1. components of composite serious adverse maternal outcome include PPH > 1000 ml – 1500 women
2. components of composite serious adverse maternal outcome include PPH requiring blood transfusion – 9000 women.

Our recommendation would be a trial of 1500 women (750 women per group).

The vast majority of health-care professionals (83% of midwives and 88% of obstetricians) would be willing to participate in the proposed clinical trial. Regarding parents' involvement in our proposed clinical trial, 37% reported that they would be likely or very likely to take part, 27% were neutral and 37% stated that they would be unlikely to participate.

Our qualitative study found that most participants thought the trial would be feasible and acceptable. However, women and obstetricians raised a number of issues for consideration under the four themes of recruitment and consent, feasibility and acceptability, design considerations, and outcomes.

'Recruitment and consent' considered the issue of when consent is obtained and the difficulty of trying to obtain consent under emergency situations. Women thought a good time to provide information about the RCT was in the second trimester when more detailed information could be given and they had time to ask questions and consider the trial fully. Women and obstetricians also raised the importance of the content and format of information being tailored to the circumstances under which it is given.

'Feasibility and acceptability' outlined potential barriers to and facilitators of recruiting health-care professionals and women to the RCT. Barriers were predominantly the conflict between the preferred techniques or practices of obstetricians and obstetric units and the RCT protocol. Facilitators were the attractiveness of being provided with fetal pillows (in units that did not have them), good training in the techniques included in the RCT and the ability to over-ride the RCT protocol in critical situations when clinical judgement and safety warranted it. Women also said they would trust health-care professionals to use the most appropriate technique and abandon the RCT protocol if necessary.

A range of important maternal, infant and clinical outcomes were raised by women and obstetricians. These were slightly different in focus, with women focusing on the well-being and safety of themselves and the infant, as well as the woman and her partner's experience. Outcomes mentioned by obstetricians were more clinically focused and specific, but most were consistent with women's concerns.

Strengths and limitations

The MIDAS programme of work includes the views of a wide range of stakeholders, including, importantly, the voices of parents.

We circulated our surveys through a variety of routes (i.e. professional organisations, social media and the networks of the co-applicants). However, owing to the method of distribution, it was impossible to establish a survey response rate.

Despite systematic sampling to ensure diversity among the women who participated in our qualitative studies based on ethnicity and postcode indices of deprivation, the samples were not representative of the population. Both qualitative studies included a high proportion of women educated to degree level or above, all women were working and, incidentally, one-third of women in both samples worked in health care. All women were white British. These samples are therefore not representative of the wider UK population. In addition, owing to time constraints, the first qualitative study only included nine of the 17 women who consented, which further limits the generalisability of findings.

Run by the National Perinatal Epidemiology Unit at the University of Oxford, UKOSS is a well-established national network used to collect data prospectively with a high level of engagement from obstetric units. However, the data presented are limited in that, although they refer to contemporaneous real cases, they are self-reported by the surgeon and collected after the event. Clinicians were asked every month to report cases, so cases are collected a maximum of 1 month in retrospect. The definition of IFH is unavoidably subjective, and practice is confounded by unit policies, clinical experience and skill

of the operator. However, the data reflect real-life diagnosis of IFH and this is the first prospective data set of current practice regarding IFH reported in the literature. It provides the most accurate estimate of the true incidence of IFH and the rate of maternal and neonatal complications arising from it. To our knowledge, it is the first prospective study in the world to estimate the rate of IFH.

We recommend using a simple two-arm parallel design trial to evaluate techniques for managing IFH. We have already discussed in *Chapter 5* why we chose a two-arm instead of a three-arm trial design. We considered other designs such as a factorial or crossover design, but these were rejected as the nature of the interventions does not allow for these designs. We also considered a cluster randomised trial and its variants such as the stepped-wedge cluster design, but these were rejected on the grounds that there was no strong rationale to support them. The specific grounds were that (1) the proposed interventions are meant to be applied to individual women and there is no justification to implement any of them to an entire hospital as there is no risk of contamination, and (2) these designs have both statistical and cost-efficiency limitations. Both would require much larger sample sizes and, given the incidence of IFH, it would take a considerable amount of time to recruit the required number of participants. In addition, MIDAS has demonstrated the large variation in practice among health-care professionals: implementing a cluster design, where a hospital would adopt a specific procedure for all cases of IFH, would be logistically challenging.

The willingness of women with IFH to participate in a hypothetical trial, with limited information on the purpose of a proposed scenario, may not translate into recruitment to a real trial. It is possible that, with proper counselling about the condition and an explanation of the uncertainties about best treatment modality, a higher proportion of women may be willing to participate.

Conclusions

We recommend that a randomised trial with an internal pilot phase comparing a new device, the fetal pillow, with a procedure used for many years, the vaginal push technique, for managing IFH be conducted.

This trial is widely supported by health-care professionals.

We recommend that the definitive trial be powered to test an effect on important short-term maternal and baby outcomes, which would require 754 participants per group. A sufficient number of women would be willing to be join such a trial, making it likely to be feasible in the UK.

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We would like to acknowledge Natalie Wakefield, Study Co-ordinator, NCTU, for all her hard work co-ordinating the project.

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Patient and public involvement

Our PPI co-applicant Rachel Plachcinski was involved in every aspect of the project from the start and helped to shape the research. Rachel Plachcinski co-designed both of the national parent surveys, reviewed the interview schedules produced for the qualitative work, and reviewed all patient-facing materials. We had PPI representation at the consensus meeting and trial design meetings. A woman with lived experience of IFH, Corrienne McCulloch, re-wrote the *Plain English summary* for this report.

Contributions of authors

Kate F Walker (https://orcid.org/0000-0001-5794-7324) (Clinical Associate Professor in Obstetrics) was chief investigator, led the design and delivery of the project, participated in all project stages, led on the Delphi survey, wrote sections of the report and finalised the report

Eleanor J Mitchell (https://orcid.org/0000-0002-6998-4533) (Clinical Associate Professor in Clinical Trials) participated in all project stages, led on the national surveys and wrote sections of the report.

Susan Ayers (https://orcid.org/0000-0002-6153-2460) (Professor of Maternal and Child Health) led on the qualitative work and wrote sections of the report.

Nia W Jones (https://orcid.org/0000-0003-0793-0967) (Clinical Associate Professor in Obstetrics) led on the UKOSS study, performed quantitative data analysis for the UKOSS study and wrote sections of the report.

Reuben Ogollah (**https://orcid.org/0000-0002-5777-4117**) (Associate Professor of Medical Statistics) and Lucy Bradshaw (**https://orcid.org/0000-0001-8382-6040**) (Medical Statistician) contributed to the trial design and wrote sections of the report.

Natalie Wakefield (**https://orcid.org/0000-0001-5474-3115**) (Trial Manager) participated in all project stages and was responsible for administration of the whole project.

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Rachel Plachcinski (**https://orcid.org/0000-0001-9908-0773**) (Research Engagement Officer and NCT VOICES Co-ordinator) participated in all project stages and took part in interviews for the qualitative work.

Marian Knight (**https://orcid.org/0000-0002-1984-4575**) (NIHR Professor of Maternal and Child Population Health) participated in the UKOSS study and contributed to the trial design.

Jim G Thornton (**https://orcid.org/0000-0001-9764-6876**) (Emeritus Professor of Obstetrics and Gynaecology) participated in all project stages.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

References

1. NHS Digital. *NHS Maternity Statistics – England 2013–14*. URL: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2013-14 (accessed 29 July 2022).
2. Unterscheider J, McMenamin M, Cullinane F. Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. *Eur J Obstet Gynecol Reprod Biol* 2011;**157**:141–4. https://doi.org/10.1016/j.ejogrb.2011.03.008
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* 2005;**112**:986–90. https://doi.org/10.1111/j.1471-0528.2005.00615.x
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 Gynecol Reprod Biol* 2005;**121**:24–6. https://doi.org/10.1016/j.ejogrb.2004.09.014
5. Saha PK, Gulati R, Goel P, Tandon R, Huria A. Second-stage caesarean section: evaluation of patwardhan technique. *J Clin Diagn Res* 2014;**8**:93–5. https://doi.org/10.7860/JCDR/2014/6709.3782
6. Vousden N, Tydeman G, Briley A, Seed PT, Shennan AH. Assessment of a vaginal device for delivery of the impacted foetal head at caesarean section. *J Obstet Gynaecol* 2017;**37**:157–61. https://doi.org/10.1080/01443615.2016.1217514
7. Romano G, Mitchell E, Plachcinski R, Wakefield N, Walker K, Ayers S. The acceptability to women of techniques for managing an impacted fetal head at caesarean section and of randomised trials evaluating those techniques: a qualitative study. *BMC Pregnancy Childbirth* 2021;**21**:103. https://doi.org/10.1186/s12884-021-03577-z
8. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. https://doi.org/10.1191/1478088706qp063oa
9. Richards L. *Using NVivo in Qualitative Research*. London: SAGE Publications Ltd; 1999.
10. Knight M, Kurinczuk JJ, Tuffnell D, Brocklehurst P. The UK Obstetric Surveillance System for rare disorders of pregnancy. *BJOG* 2005;**112**:263–5. https://doi.org/10.1111/j.1471-0528.2005.00609.x
11. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, *et al.* The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007;**370**:1453–7. https://doi.org/10.1016/S0140-6736(07)61602-X
12. NHS Digital. *NHS Maternity Statistics, England 2018–19*. Leeds: NHS Digital; 2019.
13. Hanley SJ, Walker KF, Wakefield N, Plachcinski R, Pallotti P, Tempest N, *et al.* Managing an impacted fetal head at caesarean section: a UK survey of healthcare professionals and parents. *Eur J Obstet Gynecol Reprod Biol* 2022;**271**:88–92. https://doi.org/10.1016/j.ejogrb.2022.01.033
14. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, *et al.* The COMET handbook: version 1.0. *Trials* 2017;**18**(Suppl. 3):280. https://doi.org/10.1186/s13063-017-1978-4
15. Blackwood B, Ringrow S, Clarke M, Marshall J, Rose L, Williamson P, McAuley D. Core Outcomes in Ventilation Trials (COVenT): protocol for a core outcome set using a Delphi survey with a nested randomised trial and observational cohort study. *Trials* 2015;**16**:368. https://doi.org/10.1186/s13063-015-0905-9

16. Devane D, Begley CM, Clarke M, Horey D, OBoyle C. Evaluating maternity care: a core set of outcome measures. *Birth* 2007;**34**:164–72. https://doi.org/10.1111/j.1523-536X.2006.00145.x

17. Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, Williamson PR. 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;**14**:70. https://doi.org/10.1186/1745-6215-14-70

18. Kenyon S, Ewer A. *Obtaining Valid Consent to Participate in Perinatal Research Where Consent is Time Critical*. London: Royal College of Obstetricians and Gynaecologists; 2016.

19. Cornthwaite K, Draycott T, Bahl R, Hotton E, Winter C, Lenguerrand E. Impacted fetal head: a retrospective cohort study of emergency caesarean section. *Eur J Obstet Gynecol Reprod Biol* 2021;**261**:85–91. https://doi.org/10.1016/j.ejogrb.2021.04.021

20. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. *JAMA* 2013;**310**:2191–4. https://doi.org/10.1001/jama.2013.281053

21. Health Research Authority. *UK Policy Framework for Health and Social Care Research*. 2017. URL: www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ (accessed 4 November 2022).

22. Ritchie J, Lewis J. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE Publications Ltd; 2003.

Appendix 1 Text for the national surveys in *Chapter 2*

Obstetricians, Obstetric Anaesthetists, Midwives and Parents Surveys

Obstetricians/Trainee Obstetricians

1. Have you had any personal experience in delivery of an impacted head at second stage caesarean section?
   Yes/No/Unsure

2. Approximately how many cases have you dealt with?
   Open Answer

3.

	Have you used this technique?		Have you received training in this technique? Tick all that apply.							
	Yes	No	Yes, I have received training via an online resource	Yes, I have received training via a lecture	Yes, I have received training via hands-on training	Yes, I have received via a demonstration	No, I have not received training	Other	If you selected Other, please specify	If you have received training, how long ago was this received?
Asked an assistant to push the baby's head upwards through the vagina: "push technique"										

Baby's feet delivered first: reverse breech extraction or "pull technique"										
Baby's shoulders delivered first: "Patwardhan method"										
Insertion of a fetal pillow into the vagina to elevate the head										
Asked for the operation table to be titled head down										
Administration of a tocolytic agent to the mother										
Insertion of a Tydeman tube into the vagina, to										

elevate the head										

a) If you have used any techniques other than those listed above, please specify here.

4. What is your preferred technique(s)? (tick up to 2)
    - Asked an assistant to push the baby's head upwards through the vagina: "push technique"
    - Baby's feet delivered first: reverse breech extraction or "pull technique"
    - Baby's shoulders delivered first: "Patwardhan method"
    - Insertion of a fetal pillow into the vagina to elevate the head
    - Asked for the operation table to be titled head down
    - Administration of a tocolytic agent to the mother
    - Insertion of a Tydeman tube into the vagina, to elevate the head
    - Other

a) If you selected Other, please specify.

5. Do you think that any further training would improve your skill in delivery of an impacted head at caesarean section?

    Yes/No

6. What training do you think should be provided for the management of an impacted fetal head?
    - Lecture
    - Online training
    - Demonstration
    - Hands-on training
    - Other

a) If you selected Other, please specify.

7. Have you ever worked in a unit that has access to the equipment below?

	Yes	No
Fetal pillow		
Tydeman Tube		

8. Do you currently work in a unit that has access to the equipment below?

	Yes	No
Fetal pillow		

Tydeman Tube		

9. Do you think that a clinical trial in methods of delivery of an impacted fetal head at caesarean section would provide information to guide your clinical practice?
   Yes/No
10. Would you be willing to participate in such a clinical trial?
    Yes/No

a) Do you feel that you would need any further training in delivery of an impacted fetal head prior to a clinical trial on the topic? If so, what training do you feel you would need?

	Yes, I would need training via a lecture	Yes, I would need training via an online resource	Yes, I would need training via a demonstration	Yes, I would need hands-on training	No, I would not need training
Asked an assistant to push the baby's head upwards through the vagina: "push technique"					
Baby's feet delivered first: reverse breech extraction or "pull technique"					
Baby's shoulders delivered first: "Patwardhan method"					
Insertion of a fetal pillow into the					

vagina to elevate the head					
Asked for the operation table to be titled head down					
Administration of a tocolytic agent to the mother					
Insertion of a Tydeman tube into the vagina, to elevate the head					

b) Which techniques would you consider most appropriate for a clinical trial? (select up to 4)
   - Asked an assistant to push the baby's head upwards through the vagina: "push technique"
   - Baby's feet delivered first: reverse breech extraction or "pull technique"
   - Baby's shoulders delivered first: "Patwardhan method"
   - Insertion of a fetal pillow into the vagina to elevate the head
   - Asked for the operation table to be titled head down
   - Administration of a tocolytic agent to the mother
   - Insertion of a Tydeman tube into the vagina, to elevate the head
   - Other

c) If you selected Other, please specify.

11. What is your specialty?

Obstetrics/Obstetrics and Gynaecology

a) What percentage of your time is spent in obstetrics?

Open answer

12. What is your current grade?

Consultant/Staff grade/Specialty trainee (year 6-7)/Specialty trainee (year 3-5)/Specialty trainee (year 1-2)

a) We would like to invite you to take part in a further stage of our study. Following the results of this survey, we will be conducting a Delphi survey. The Delphi survey will help us know which techniques should be tested in a randomised controlled trial. The Delphi survey will consist of three rounds, each taking around 15 minutes to complete. If you would like to take part in our Delphi survey, please provide your email address below. Your responses to this survey remain anonymous.

Option open answer to provide email address

13. Total time spent in obstetrics (years)

Open answer

14. Duration of time in obstetrics in UK (years)

Open answer

15. Current employment

Full-time/part-time

16. Number of deliveries annually in your current hospital

Open answer

17. Thank you very much for your time. If there is anything else you would like to tell us, please use the box below.

Open answer

Obstetric anaesthetists

18. Approximately how many caesarean sections have you been part of in the past three months?

0/1-5/6-10/>10

19. During you career, can you recall any incidents of impacted fetal head or the operating surgeon experiencing difficult delivering the head in a second stage caesarean section?

Yes/No

a) How many times has this happened during your career?

Open answer

b) How many times has this happened in the past year?

Open answer

c) Of the techniques listed below, please specify if you have personally used them to help deliver an impacted fetal head, or if you have received training.

	Have you used this technique?		Have you received training in this technique? Tick all that apply.								Who provided your training?		
	Yes	No	Yes, I received training via a lecture	Yes, I have received training via an online resource	Yes, I have received hands-on training	Yes, I have received training via a demonstration	No, I have not been trained	Unable to recall	Other	If you selected Other, please specify	Employer	External	If you have received training, how long ago was this received?
Administration of tocolytic agents to the mother													
Asked for the operation													

table to be titled head down													

d) What is your preferred technique(s)? (tick up to 2)

Administration of tocolytic agents to the mother/Head down tilt of the operating table/Other

i) If you selected Other, please specify.

Open answer

20. What is your preferred tocolytic agent?

Salbutamol/Terbutaline/Nifedipine/Indomethacin/Magnesium sulphate/Glyceryl trinitrate (GTN)/Atosiban

a) What is your preferred route?

Oral/Sublingual/Intravenous/Intramuscular/Subcutaneous/Other

i) If you selected Other, please specify.

b) What is your preferred dose? Please provide dose and unit.

Open answer

c) Do you ever give a second dose?

Frequently/Sometimes/Rarely/In the past/Never

21. How confident are you about your role and responsibilities when assisting at an operative birth with an impacted fetal head?

1 = not confident at all, 10 = very confident

22. Do you think that any further training would improve your skill in delivery of an impacted head at caesarean section?

Yes/No/Unsure

a) What training for the management of impacted fetal head would you like?

- Lecture
- Online training
- Demonstration
- Hands-on training
- Other

If you selected Other, please specify.

Open answer

b) Do you think management of an impacted fetal head at caesarean section should be part of yearly training updates (mandatory study days)?

Yes/No

23. Do you think that a clinical trial in methods of delivery of an impacted fetal head at caesarean section would provide information to guide your clinical practice?

Yes/No

a) Would you be willing to participate in such a clinical trial?

Yes/No

b) Would you feel that you needed any further training in the anaesthetic techniques used in aiding the delivery of an impacted head at caesarean section prior to a clinical trial on the topic?

Yes/No/Not interested

c) What training do you feel you would need?

Lecture/Online/Demonstration/Hands on/Other

If you selected Other, please specify.

Open answer

d) Which techniques would you consider most appropriate for a clinical trial? (select up to 4)

- Asking an assistant to push the baby's head upwards through the vagina: "push technique"
- Baby's feet delivered first: reverse breech extraction or "pull technique"
- Baby's shoulders delivered first: "Patwardhan method"
- Insertion of a fetal pillow into the vagina to elevate the head
- The operation table to be titled head down
- Administration of a tocolytic agent to the mother
- Insertion of a Tydeman tube into the vagina, to elevate the head
- Other
- Unable to comment

If you selected Other, please specify.

Open answer

24. What is your speciality?

Open answer

25. What is your current grade?

Consultant/Staff grade/Specialty trainee (year 6-7)/Specialty trainee (year 3-5)

b) We would like to invite you to take part in a further stage of our study. Following the results of this survey, we will be conducting a Delphi survey. The Delphi survey will help us know which techniques should be tested in a randomised controlled trial. The Delphi survey will consist of three rounds, each taking around 15 minutes to complete. If you would like to take part in our Delphi survey, please provide your email address below. Your responses to this survey remain anonymous.

Option open answer to provide email address

26. Total time spent in obstetric anaesthesia (years)

Open answer

27. Duration of time in obstetric anaesthesia in UK (years)

Open answer

28. Current employment

Full-time/part-time

29. Number of deliveries annually in your current hospital

Open answer

30. Thank you very much for your time. If there is anything else you would like to tell us, please use the box below.

Open answer

Midwives

1. How many (approximately) caesarean section have you been part of in the past three months?

0/1-5/5-10/>10/Other

If you selected Other, please specify.

Open answer

2. Do you ever scrub up for a caesarean section?

Frequently/Sometimes/Rarely/In the past/Never

3. Can you recall of any incidents of impacted fetal head or the operating surgeon experiencing difficulty delivering the head in a second stage caesarean section?

Yes/No

a) Approximately how many times has this happened during your career?

Open answer

b) Approximately how many times has this happened in the past year?

Open answer

c) Of the techniques listed below, please indicate whether you have personally used the technique to help deliver an impacted fetal head or received training.

	Have you used this technique?		Have you received training in this technique? Tick all that apply.							
	Yes	No	Yes, I have received training via an online resource	Yes, I have received training via a lecture	Yes, I have received training via hands-on training	Yes, I have received via a demonstration	No, I have not received training	Other	If you selected Other, please specify	If you have received training, how long ago was this received?
Pushed the baby's head upwards through the vagina: "push technique"										
Insertion of a fetal pillow into the vagina to elevate the head										

Administration of a tocolytic agent to the mother										
Insertion of a Tydeman tube into the vagina, to elevate the head										

d) What is your preferred technique(s)? (tick up to 2)

Pushed the baby's head upwards through the vagina: "push technique"/Insertion of a fetal pillow into the vagina to elevate the head/Administration of tocolytic agents to the mother/Insertion of a Tydeman tube into the vagina, to elevate the head/Other

ii) If you selected Other, please specify.

Open answer

31. How confident are you about your role and responsibilities when assisting at an operative birth with an impacted fetal head?

1 = not confident at all, 10 = very confident

32. Do you think that further training would improve your skill in delivery of an impacted fetal head at caesarean section?

Yes/No

a) What training for the management of impacted fetal head would you like?

Lecture/Online/Demonstration/Hands on/Other

If you selected Other, please specify.

33. Do you think management of an impacted fetal head at caesarean section should be part of yearly training updates (mandatory study days)?

Yes/No

34. Do you think that a clinical trial in methods of delivery of an impacted fetal head at caesarean section would provide information to guide your clinical practice?
    Yes/No

e) Would you be willing to participate in such a clinical trial?
    Yes/No

f) Would you feel that you needed any further training in delivery of an impacted fetal head at caesarean section prior to a clinical trial on the topic?
    Yes/No/Not interested

g) What training do you feel you would need?
    Lecture/Online/Demonstration/Hands on/Other

    If you selected Other, please specify.

    Open answer

h) Which techniques would you consider most appropriate for a clinical trial? (select up to 4)
    - Asking an assistant to push the baby's head upwards through the vagina: "push technique"
    - Baby's feet delivered first: reverse breech extraction or "pull technique"
    - Baby's shoulders delivered first: "Patwardhan method"
    - Insertion of a fetal pillow into the vagina to elevate the head
    - The operation table to be titled head down
    - Administration of a tocolytic agent to the mother
    - Insertion of a Tydeman tube into the vagina, to elevate the head

35. What is your band?
    Open answer

36. What is your job title?
    Open answer

37. Total time spent on birth unit/delivery suite or equivalent in the UK? (years)
    0-5/5-10/>10

c) We would like to invite you to take part in a further stage of our study. Following the results of this survey, we will be conducting a Delphi survey. The Delphi survey will help us know which techniques should be tested in a randomised controlled trial. The Delphi survey will consist of three rounds, each taking around 15 minutes to complete. If you would like to take part in our Delphi survey, please provide your email address below. Your responses to this survey remain anonymous.
    Option open answer to provide email address

38. Number of years qualified
    Open answer

39. Current employment

    Full-time/part-time

40. Number of deliveries annually in your current hospital

    Open answer

41. Thank you very much for your time. If there is anything else you would like to tell us, please use the box below.

    Open answer

Parents

42. Have you or your partner given birth in the last 5 years?

    Yes/No

43. How old are you?

    Under 18/Under 20/20-24/25-29/30-34/35-39/40 and over

44. Please select the correct statement.

    I have given birth in the last 5 years/I have given birth in the last 5 years

45. During the past 5 years, how many times have you or your partner given birth?

    1/2/3/4/5

46. Please complete the table below to show how many times you/your partner have given birth in the last 5 years.

	How was this baby delivered?	If this birth was performed by emergency caesarean section, do you remember if the	If you do remember the doctor having difficulty delivering the baby during emergency caesarean section, do you remember if the doctor used any of the following techniques to help deliver your baby (they may have told you afterwards)?

					doctor encountered any difficulty at the point of delivering your baby?								
	Vaginally	Planned caesarean section	Emergency caesarean section	N/A	Yes	No	Asked an assistant to push the baby upwards through the vagina	Baby's feet delivered first	Baby's shoulders delivered first	A device that looks like a balloon inserted into the vagina before the caesarean section called a 'fetal	Asked for the operating table to be tilted head down	Given you a medication called a 'tocolytic' to relax your womb (given as a spray under the tongue or	Silicone tube inserted into the vagina to push the baby's head upwards	I don't remember

										pillow’		by a drip in your vein)		
Baby 1														
Baby 2														
Baby 3														
Baby 4														
Baby 5														

For the next few questions, we would like you to imagine a scenario:

You/your partner are in labour and you are told you need an emergency caesarean section. You are told that occasionally the doctor can encounter difficulty delivering the baby's head, because the baby has become deeply stuck in the pelvis, which means the doctor needs to take action quickly to avoid complications for the mother and baby.

Due to a lack of research in this difficult area, doctors do not know the best technique to deliver your baby and could choose from a number of different techniques. There is no evidence to suggest which techniques are better than others.

47. Which of the following techniques would you prefer your doctor to undertake? Please rate each technique using the table below.

	Please rate each technique				
	Very acceptable	Somewhat acceptable	Neutral	Somewhat not acceptable	Not at all acceptable
Asked an assistant to push the baby's head upwards through the vagina					
Baby's feet delivered first					
Baby's shoulders delivered first					
A device that looks like a balloon inserted into the vagina before the caesarean section					

started called a 'fetal pillow'					
Give you a medication called a 'tocolytic' to relax your womb (given as a spray under the tongue or by a drip in your vein)					
Silicone tube inserted into the vagina to push the baby's head upwards					
I would prefer the doctor to undertake the procedure he/she felt most comfortable in					
I do not have a preference					

Still considering the same scenario, now think about being approached and asked to take part in a research study, whilst in labour.

In order to gain evidence on the best technique to deliver the baby in the situation, comparing different techniques could be undertaken. In this situation, neither the mother

nor doctor could choose which technique they would use to help deliver the baby; instead this would be randomly allocated by a computer.

48. If you were approached to take part in such a study during labour, on a scale of 1-5 (1 being the least likely, 5 being the most likely), how likely would you be to agree to take part?

    1-5 scale

49. If you would not like to take part in this study, why not?
    - I would prefer for my doctor to deliver my baby in the way they feel is best for me and my baby
    - I would not like a computer choosing the way in which my baby would be delivered
    - I would not like to have to think about a research study whilst in labour
    - Other

    If you selected Other, please specify.

    Open answer

Thank you very much for your time. If there is anything else you would like to tell us, please use the box below.

Appendix 2 Delphi questions

We are conducting a survey to hear the views and opinions of obstetricians and neonatologists about a possible research study in the future. Around one in four women give birth by Caesarean section and about five in one hundred of these operations are done at the end of labour. Sometimes the baby's head can be deeply wedged in the pelvis making delivery difficult which sometimes results in problems for both the mother and baby. Sometimes the baby can experience skull fractures and hypoxic brain injury whilst stuck and occasionally, babies can die.

There are a variety of ways in which births like this can be made easier. However, at the moment, we do not know which is the best way for both the mother and baby. The research arm of the NHS, called the National Institute of Health and Care Research (NIHR) have asked us to conduct research into this issue.

Before a clinical trial is undertaken, however, it is important for us to understand the views and opinions of health care professionals on the techniques that could be tested in a research study so that any study designed is acceptable to them. We also need to decide which outcomes they feel are most important.

We have already sought the opinions of obstetricians, obstetric anaesthetists, midwives and parents about current practices and opinions on the management of an impacted fetal head. We've also interviewed parents. This data has helped guide us on to this part of our project, where we aim to seek a consensus view on which techniques for the management of an impacted fetal head should be tested in a future clinical trial and which maternal and neonatal outcomes should be measured.

The Delphi survey is comprised of three rounds, each round will take around 10-15 minutes to complete. In the first round you will be asked to score which techniques, maternal and neonatal outcomes should be included in a clinical trial. In the second and third round you will see what scores other respondents gave to the techniques and outcomes, and you will be asked if, now you have seen this information, you want to change your score. This process enables us to find consensus on which techniques should be tested and which are the most important maternal and neonatal outcomes to collect in a future clinical trial.

Thank you for taking the time to read this information and completing the survey. Your help will ensure any study designed to look into this area will have the views and interests of obstetricians and neonatologists in mind.

In your opinion, which technique (s) should be tested in a clinical trial for managing an impacted fetal head at second stage caesarean section?

- Fetal pillow (prophylactic i.e. inserted prior to a second stage caesarean section)
- Fetal pillow (treatment i.e. inserted when an impacted fetal head is encountered at a second stage caesarean section)
- Head down tilt of the operating table
- Administration of tocolytic agents to the mother
- Reverse breech extraction (pull) technique (the fetus is delivered feet first)
- Push technique (the head is flexed and pushed upwards through the vagina by an assistant)

Question 2

In your opinion, what are the most important maternal and neonatal outcomes we should measure in a clinical trial testing different techniques for managing an impacted fetal head at second stage caesarean section? Note these are presented in alphabetical (or random) order so you may wish to read through the whole list before answering.

Maternal outcomes

Bladder injury

Bowel injury

Ureteric injury

Extension of uterine incision

Haemorrhage > 1000ml

Caesarean hysterectomy

Sepsis

Need for critical care

Acute adverse mental health outcomes e.g. anxiety, PTSD

Chronic adverse mental health outcome e.g. anxiety, PTSD

Neonatal outcomes

Fractured skull

Fractured clavicle

Fractured long bone

Brachial plexus injury

Intracranial haemorrhage

Moderate Encephalopathy, treated with active cooling, defined by https://www.npeu.ox.ac.uk/downloads/files/tobyregister/Register-Clinicans-Handbook1-v4-07-06-10.pdf

Severe Encephalopathy, treated with active cooling, defined by https://www.npeu.ox.ac.uk/downloads/files/tobyregister/Register-Clinicans-Handbook1-v4-07-06-10.pdf

Active Cooling

Death

Scalp laceration

Blunt abdominal trauma

Seizures treated with anticonvulsant medication

Admission to NICU for > 4 hours

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