TRIAL PROTOCOL

ROTATE

Rotation of the fetal head at full cervical dilatation

Randomised controlled trial of manual versus instrumental rotation of the fetal head in malposition at birth

This protocol has regard for the HRA guidance and is compliant with the SPIRIT guidelines (2013)

Version Number: **5.0**

Version Date: **15/12/2023**

FUNDED BY
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PROTOCOL DEVELOPMENT

Protocol Amendments

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
SA01	**10 June 2022**	**3.0**	**Substantial amendment**	**Addition of birth partner(s) element to the Qualitative Patient Evaluation**
NSA4	**18 Nov 2022**	**4.0**	**Non-substantial amendment**	**1. Removal of fecal and urinary incontinence questionnaires from 48 hour assessment** **2.Exclusion criteria modified to state that participants who cannot read or respond to questionnaires in English are ineligible** **3.Option of emailing ICFs and questionnaires to patients to complete at home added**
SA3	**04 Jan 2024**	**5.0**	**Substantial amendment**	**1.Update to data use process for patients who give verbal consent to participate but not written consent** **2. Option for research teams to contact patients via WhatsApp added** **3. Removal of the criterion excluding participants who cannot read or respond to questionnaires in English**

Funding and Support in Kind	
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This study is funded by the National Institute for Health Research (NIHR) HTA Programme (Project reference NIHR127818). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The NIHR HTA provides on-going help and support to the CI to ensure that the project progresses smoothly. Trial design, conduct, data analysis and interpretation, manuscript writing and dissemination of results are the responsibility of sponsor and their delegates, though the funder will monitor progress against key milestones via the submission of regular progress reports.

The funder requires to approve the initial protocol and amendments prior to submission for ethical/regulatory approval.

The funder requires to be provided with copies of project outputs at least 28 days before publication or presentation.

PROTOCOL SIGN OFF

Chief Investigator (CI) signature page

I, the Chief Investigator, confirm that I have read and agree with the following protocol and that I will conduct the trial in compliance with the version of this protocol approved by the REC and any other responsible organisations.

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

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

Trial Name:	ROTATE
Protocol Version Number:	5.0
Protocol Version Date:	15 Dec 2023
CI Name:	Dimitrios Siassakos
Trial Role: Signature and date:	Chief Investigator

Sponsor statement

By signing the IRAS form for this trial, University College London acting as sponsor, confirm approval of this protocol.

Compliance statement

This protocol describes the ROTATE trial only. The protocol should not be used as a guide for the treatment of participants not taking part in the ROTATE trial.

The trial will be conducted in compliance with the approved protocol, UK Policy Framework for Health and Social Care Research (2017), Data Protection Act (2018) and the Principles of Good Clinical Practice (GCP) as set out in the UK Statutory Instrument (2004/1031) and Mental Capacity Act 2005. Every care has been taken in the drafting of this protocol, but future amendments may be necessary, which will receive the required approvals prior to implementation.

Principal Investigator (PI) signature page

As PI, I confirm that the following protocol has been agreed and accepted and that I will conduct the trial in compliance with the approved protocol where this does not compromise participant safety.

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

Trial Name:	ROTATE
Protocol Version Number:	Version: __ __
Protocol Version Date:	__ __ / __ __ / __ __ __ __
PI Name:	
Name of Site: Signature and date:	 _____ __ __ / __ __ / __ __ __ __

ADMINISTRATIVE INFORMATION

Reference Numbers	
Sponsor number	UCL Ref: 3653311
ISRCTN reference number	< ISRCTN reference number >
IRAS reference number	301912

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Trial social media	https://twitter.com/RotateRct

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Stephen Gerry	Senior Medical Statistician (statistician)
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Graeme McLennan (Chair)	Director, The Centre for Healthcare Randomised Trials (CHaRT) (Statistician)
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Prof Glen Mola	Head of Reproductive Health and Obstetrics and Gynaecology (Clinician)

ABBREVIATIONS

Abbreviation	Term
AE	Adverse Event
BCTU	Birmingham Clinical Trials Unit
DCF	Data Clarification Form
DMC	Data Monitoring Committee
DOP	Direct Occipito-Anterior
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
CTG	Cardiotocography
CTRC	Clinical Trials Research Centre
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
LOT	Left Occiput Transverse
NCT	National Childbirth Trust
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
OA	Occiput Anterior
PI	Principal Investigator
PIS	Participant Information Sheet
QPE	Qualitative Process Evaluation
UKARCOG	UK Audit and Research Collaborative in Obstetrics and Gynaecology

RAG	Red, amber, green traffic light system
RBC	Red Blood Cells
RCOG	Royal College of Obstetricians and Gynaecologists
REC	Research Ethics Committee
RGT	University of Birmingham Research Governance team
RM	Research midwife
ROA	Right Occiput Anterior
ROBuST	RCOG Operative Birth Simulation Training
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UoB	University of Birmingham
UCL	University College London

TRIAL SUMMARY

Title

Rotation of the fetal head at full cervical dilatation (ROTATE) - Randomised controlled trial of manual versus instrumental rotation of the fetal head in malposition at birth

Objectives

Primary objective
To evaluate if manual rotation compared with instrumental rotation of babies with persistent head malposition at full cervical dilatation reduces the risk of severe maternal perineal trauma, without substantially increasing the risk of caesarean section.

Secondary objectives

- To evaluate whether there are differences between the two rotational techniques in important additional clinical outcomes for women and babies, including a key secondary outcome: severe neonatal trauma and morbidity as a safety signal
- To compare the experience of birth between the two different techniques of rotational birth, using validated patient satisfaction and experience questionnaires
- To establish a randomised cohort of women who have experienced malposition of the fetal
- To qualitatively explore the feasibility, acceptability and appropriateness of the intervention and trial processes, including consent to participate in time-critical research, for women and healthcare professionals

Trial Design

Pragmatic, multicentre, 2-arm parallel group, open-label, randomised controlled trial with an internal pilot and qualitative process evaluation.

Participant Population and Sample Size

Women at full cervical dilatation (second stage of labour) with persistent malposition of the fetal head. A total sample of 5,200 women from approximately 40 sites.

Setting

NHS consultant-led maternity units in the UK

Eligibility Criteria

Inclusion Criteria:

- ≥16 years of age at time of randomization
- Singleton pregnancy
- ≥36 weeks' gestation with cephalic presentation and persistent malposition of the fetal head occiput between 2 and 10 o'clock (diagnosed clinically or with ultrasound) requiring a rotational operative vaginal birth conducted or supervised by obstetricians signed-off as competent in both manual and instrumental rotation.

Exclusion Criteria:

- Women with contraindications for operative birth with either ventouse or forceps
- Women with fetal occiput between 11 and 1 o'clock
- Brow presentation;
- Intrauterine fetal death

Interventions

Manual rotation and instrumental rotation (either forceps or ventouse depending on practitioner preference) allocated on a 1:1 ratio.

Outcome Measures

Primary

- Third/forth degree perineal trauma involving anal sphincter complex diagnosed on clinical vaginal/rectal examination after birth (superiority co-primary outcome).
- Caesarean section (non-inferiority co-primary outcome).

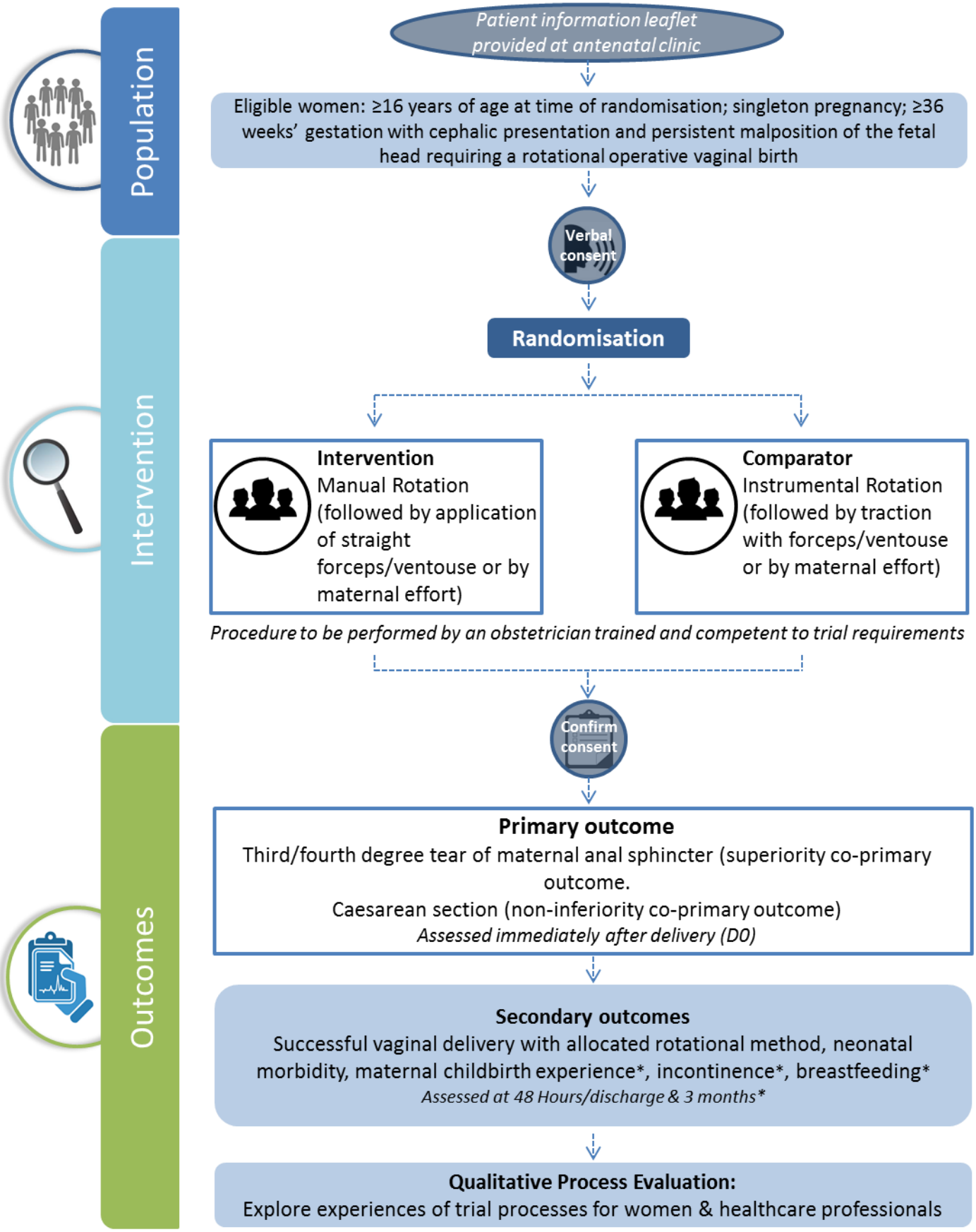
Secondary:

- Successful vaginal delivery with first method.
- Severe neonatal trauma and morbidity.
- Cross-over (instrumental rotation after failed manual rotation; or manual rotation after attempted instrumental rotation).
- Breast feeding intention after birth, at hospital discharge and at 3 months post randomisation.
- Estimated blood loss following birth.
- Need for blood transfusion (or use of cell salvage) before hospital discharge.
- Urinary incontinence at 3 months post randomisation.
- Other major maternal morbidity within 3 months post randomisation, including faecal incontinence
- Maternal experience (Childbirth Experience Questionnaire) and satisfaction (Client Satisfaction Questionnaire-8) at discharge and 3 months post randomisation.
- Post-traumatic stress disorder (PTSD) symptoms at 3 months post randomisation.

Qualitative Process Evaluation

- Explore the feasibility, acceptability and appropriateness of the trial processes and interventions for women, their birth partners and healthcare professionals, in order to inform decision-making around progression to a full trial.

TRIAL SCHEMA



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1. BACKGROUND AND RATIONALE

1.1. Background

Babies in labour tend to face maternal spine at the time of delivery (anterior position). Malposition of the fetal head affects one in twenty-five women (1) at full dilatation (second stage of labour) – about 30,000 per year in the UK. Malposition is a risk factor for failed vaginal birth requiring a caesarean section, and for trauma to mother and baby. Examples of malposition include transverse (baby faces mother's left or right side) and posterior position (baby faces mother's abdomen: 'back-to-back' position).

It is important to investigate if manual rotation will reduce the risk of severe trauma to a woman's perineum, specifically 3rd/4th degree perineal trauma involving the anal sphincter, and if it will increase caesarean section rate.

Severe perineal trauma has long-term consequences for the woman; studies have reported incontinence in more than 50% of women (2) and reduction of life quality (3).

Caesarean section at full dilatation, however, is a risky procedure for mothers and babies and can cause preterm birth in future pregnancy (4–7).

1.2. Trial Rationale

Making birth safer to prevent poor outcomes for mothers and their babies is now a national priority within the NHS Long Term Plan, with an explicit ambition to halve rates of maternal deaths and babies' brain injuries occurring during or soon after birth, stillbirths and neonatal deaths by 2025 (8). Despite those initiatives severe perineal tearing has risen from 1.8% in 2000 to 5.9% in 2011 among first-time mothers (9).

It is important to investigate approaches to reduce maternal and neonatal morbidity arising from assisted delivery. The risk for mothers and babies is increased if more than one technique or more than one instrument is used to deliver babies with malposition. Failure in achieving a vaginal delivery leads to caesarean section which can also increase maternal and neonatal morbidity. The proportion of caesarean births is also increasing across the NHS - between 2010 and 2015 the increase was 2.4% in England and 4.7% in Scotland (10). Caesarean section in labour, and particularly during the second stage of labour, is considered high risk for both mother and babies with substantially increased rates of maternal haemorrhage, additional uterine lacerations, and neonatal trauma (11). Caesarean section in the second stage of labour also has long term consequences such as increased risk of preterm birth in the subsequent pregnancy (4–7) as well as increased risk of uterine rupture, caesarean hysterectomy, and morbidly adherent placenta (12). A recent series published in the Lancet identified that equipping clinicians with confidence and skills for safe and effective vaginal birth is a key intervention for preventing unnecessary intervention and for optimising caesarean section use, whilst reducing maternal and neonatal morbidity (12–14). A International Federation of Gynecology and Obstetrics (IFGO) position paper, published alongside the series, identified the appropriate use of instrumental birth in the second stage of labour (fully dilated cervix), as one of six priorities (15).

1.2.1. Evidence for support

A literature review was conducted by NIHR before commissioning. An updated literature review by our team identified only three observational studies (16–18) comparing rotational birth techniques (manual, forceps, ventouse), with high heterogeneity of the demographics and the techniques studied. Success rates in achieving vaginal birth show a relatively wide range (manual rotation 82-96%, ventouse 76-93%, forceps 88-96%) as do rates of complications when reported (e.g. third/fourth degree tear 0-11%).

A national audit (REDEFINE) (19) by the trainee-led UK Audit and Research Collaborative in Obstetrics and Gynaecology (www.UKARCOG.org), prospectively collected data on births complicated by malposition of the baby's head in the second stage of labour (at full dilatation of the cervix). Out of 836 births from 66 units over 1 month observation, rotational forceps and rotational ventouse had similar success rates in achieving a vaginal birth with the use of the first instrument (79%) but manual rotation had a lower success rate (64%). Manual rotation was potentially associated with lower rates of harm to the baby and the mother: admission to special care: 6.8% versus 7.3% or 8.5%, third/fourth degree perineal tears: 4.3% versus 6.6% or 4.6%, comparing manual rotation with rotational forceps or rotational ventouse respectively.

2. AIMS AND OBJECTIVES

2.1. Internal Pilot/Feasibility Trial Objectives

Determine the feasibility of progression from pilot to full trial: The decision to continue to a full trial will be based on pre-defined independent stop-go criteria (red, amber, green (RAG) traffic-lights) supplemented with findings from the pilot qualitative process evaluation.

Qualitative process evaluation objectives

(1) With women: to explore their views and experiences of the recruitment approach, voluntariness, consent processes, randomisation, barriers and facilitators to participation, and acceptability of treatment allocations

(2) With healthcare professionals: to explore their views and experiences of recruitment, consent processes, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of treatment allocations, and perceptions of trial processes.

Please see section 8.1 for STOP-GO criteria.

2.2. Main Trial Objectives

2.2.1. Clinical aims and objectives

Primary objective

To evaluate if manual rotation compared with instrumental rotation of babies with persistent head malposition at full cervical dilatation reduces the risk of severe maternal perineal trauma, without substantially increasing the risk of caesarean section.

Secondary objectives

- To evaluate whether there are differences between the two rotational techniques in important additional clinical outcomes for women and babies, including a key secondary outcome: severe neonatal trauma and morbidity as a safety signal
- To compare the experience of birth between the two different techniques of rotational birth, using validated patient satisfaction and experience questionnaires
- To establish a randomised cohort of women who have experienced malposition of the fetal
- To qualitatively explore the feasibility, acceptability and appropriateness of the intervention and trial processes, including consent to participate in time-critical research, for women and healthcare professionals head for future long-term follow-up

3. TRIAL DESIGN AND SETTING

3.1. Trial Design

- Pragmatic, multi-centre, 2-arm parallel group, open-label, randomised controlled trial.
- Randomisation to either manual or instrumental rotation at the level of the individual using a 1:1 allocation ratio, minimised by centre and baby's position (occipito–transverse or posterior).
- The first 9 months of the ROTATE study will consist of an internal pilot with embedded qualitative process evaluation in approximately 12 geographically diverse units with clear progression criteria to the main trial (see section 8.1).

3.2. Trial Setting

NHS consultant-led maternity units in the UK.

3.3. Patient and public involvement

We put women and their families at the heart of this proposal and central to its design, development, dissemination and evaluation.

Our two PPI co-applicants are Rachel Plachcinski, Research Engagement Officer and National Childbirth Trust (NCT) VOICES Co-ordinator and Maureen Treadwell, Research Officer of the Birth Trauma Association (BTA). Both have extensive experience – over 40 years between them- of working with the target group; this will not be token engagement. They are experienced officers with the ability to work professionally with health care professionals to ensure that the user voice is heard. Importantly, they are both able to directly access an extensive pool of many thousands of current maternity service users from diverse cultural, social and socio-economic groups which will ensure robust engagement at all stages of the trial.

We recognise that views and opinions about childbirth are diverse and affected by ethnicity, culture, education and many other factors. We felt our approach to include two different charities with their capacity to engage a wide and diverse user group was important.

The NCT has for many decades supported families, many of whom will have had very positive experiences of childbirth whereas the BTA is focused entirely on families where the birth has been a traumatic experience. Having these two diverse organisations involved is particularly important; whilst we need to ensure the very best outcomes for women and babies who face complex deliveries, we also need to be mindful that the majority of women will experience straightforward births. This will help to ensure balance in the information, consent and feedback processes. Rachel and Maureen have prepared this section as well as several other relevant parts of the proposal, including the lay summary. They have been active members of the decision-making team, including critical issues such as the choice of primary outcome measures, non-inferiority margin, plans for consent and recruitment and qualitative research. This has been achieved via teleconferences, phone calls, PPI/lead investigator meeting and an extensive email exchange.

More specifically, our PPI co-applicants have been influential throughout the planning stage and as a consequence of which, a number of changes have been made. The antenatal consent process was completely reconfigured since our PPI team felt that informed consent could not reliably be achieved just during labour and that some prior information would be necessary. This has been incorporated in the plan. It was also felt that only women with malpositioned babies who consented to vaginal birth should be included in the trial, and that plans to support and standardise the consent process would be included in the site-specific education visit.

We have also convened a novel integrated physical and virtual lay PPI panel with parents typically under-represented in PPI: women from deprived areas, disabled, minorities (and in the near future partners as well). The lay PPI panel has gone beyond the tokenism of involving a single non-professional patient. They have already contributed to a revised design of ROTATE to include optimisation of antenatal information and consent, particularly for the forceps option, to address some concerns widespread in some communities. The lay panel will continue its active involvement, supported by a senior PPI Board.

3.4. Risk Assessment

All clinical trials can be considered to involve an element of risk and in accordance with Birmingham Clinical Trials Unit (BCTU) standard operating procedures, this trial has been risk assessed, to clarify any risks relating uniquely to this trial beyond that associated with usual care. A risk assessment has been conducted and concluded that this trial corresponds to the following categorisation:

Type A = No higher than the risk of standard medical care

3.5. Qualitative Sub-Study

We will qualitatively explore the feasibility, acceptability and appropriateness of the intervention and trial (including consent) processes for women and healthcare professionals. Please see section 16 for detailed information about the qualitative process evaluation.

4. ELIGIBILITY

PATIENT GROUP: Women at full cervical dilatation (second stage of labour) with persistent malposition of the fetal head

EQUALITY & DIVERSITY: The PPI co-applicants will specifically engage with the PPI panel. The dedicated PPI panel will involve previously under-represented cohorts in PPI activities and research (disabled, minorities, single young mothers, deprived and partners) to ensure that ROTATE tools and processes will be inclusive. We will adhere to the INCLUDE guidelines outlined by the NIHR (20).

4.1. Inclusion Criteria

- ≥16 years of age at time of randomisation;
- Singleton pregnancy;
- ≥36 weeks' gestation with cephalic presentation and persistent malposition of the fetal head occiput between 2 and 10 o'clock (diagnosed clinically or with ultrasound) requiring a rotational operative vaginal birth (21);
- Birth conducted or supervised by obstetricians signed-off as competent in both manual and instrumental rotation (at least one of forceps/ventouse).

4.2. Exclusion Criteria

- Women with contraindications for operative birth with either ventouse or forceps (21) - (Section 7.2).
- Women with occiput between 11 and 1 o'clock (occipito-anterior).
- Brow presentation
- Intrauterine fetal death

4.3. Co-enrolment

Co-enrolment into other peripartum studies may be considered on a case by case basis. Should centres wish to co-enrol patients to ROTATE and another intrapartum study, this **must** be discussed and agreed with the TMG **prior** to enrolment into ROTATE. Co-enrolment may have an impact on outcomes in each trial if any of the tested interventions are effective, and may pose challenges in the patient pathway.

5. CONSENT

5.1. Rationale

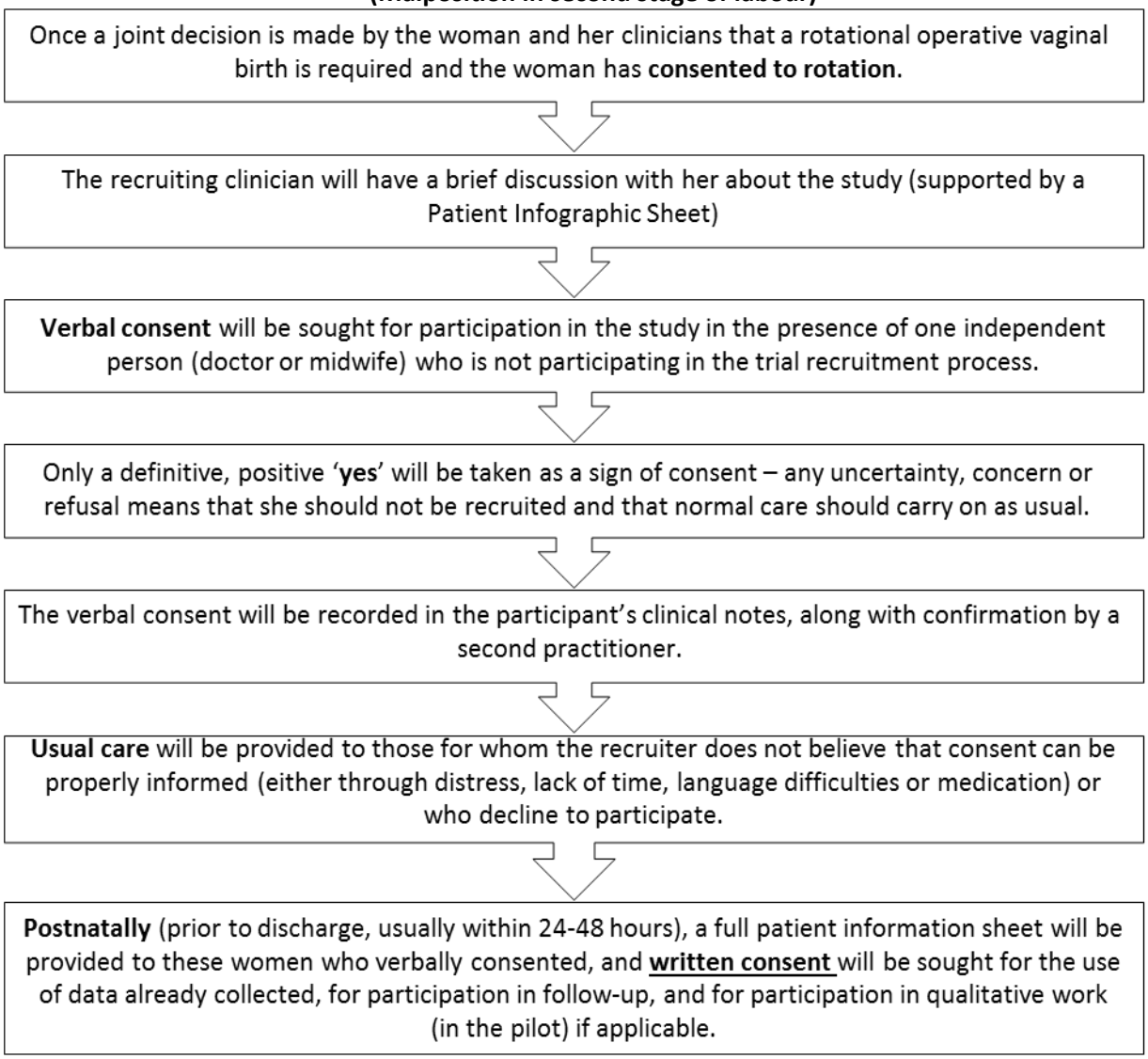
The consent process will follow the Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines for intrapartum consent for research in acute situations (22). Our approach is informed by consumer and patient input and by two previous studies of emergency interventions in labour ward settings which used the verbal consent approach (23,24). As the consent processes in these studies were given favourable opinions by the National Research Ethics Service (NRES) we would look to adopting the same/similar consent process. We will further refine this process for ROTATE together with the PPI co-applicants, lay PPI panel, and senior PPI Board, in light of research into trial processes, including consent, as part of the pilot.

5.2. Recruitment Process

- There will be ample **antenatal provision of information**. A large variety of strategies will be employed to enable this including leaflets in case notes and in antenatal clinics, social media campaigns, a study website, posters, newsletters and emails. Women attending antenatal clinics with elevated risk of operative birth will be targeted; for example, nulliparous women and women undergoing induction of labour. With this strategy, we aim for the vast majority of pregnant women to be aware of the study.
- There will be an opportunity to have any questions about the study answered by a midwife, doctor or researcher. This will be either directly, via a 'phone-back' service, social media or by email. If, following discussion, a woman decides that she does not want to take part, then she can **opt-out** by placing a small sticker on the inside cover of her file. The sticker will be replaced with a red flag in electronic notes. This sticker will be contained on all leaflets, which clearly state that women should attach the sticker to the inside cover of their case notes if they do not wish to be approached to participate in the study. **Digital flags** and other systems tested in practice via the HTA funded COPE RCT (EudraCT number: 2018-001829-11) will be used in units with electronic records. Women who decline, will be asked if they wish to participate in the qualitative interviews.
- The lay PPI panel has identified a potential issue: there is a wide perception in the community that forceps are dangerous, which might impede recruitment and randomisation as forceps is one of the interventions. Qualitative research during the pilot, with the support of PPI, will explore how best to provide **information to women about forceps** to help improve recruitment should this be identified as an issue within the trial.

5.3 Consent process

(Malposition in second stage of labour)



- Following informed verbal consent there will be **automated telephone randomisation**. Telephone randomisation has been shown to be efficient and pragmatic in several intrapartum trials in our experience. We have kept the number of minimisation factors to the minimum to enable an efficient and rapid randomisation process. Most of the clinicians in our national survey perform rotational deliveries in theatre which will increase the chances of recruiting – there is, in such deliveries, more time and more personnel available compared to deliveries in the labour ward room. In addition to telephone randomisation, we could also offer the option to randomise the patient via an internet-based portal. We have accounted for any missed opportunities in the very conservative estimates of recruitment rates (on average six women per site per month). Using an adaptive approach, we will monitor the randomisation process during the pilot period and amend as necessary based on the process evaluation.
- It will be the responsibility of the Principal Investigator (PI) to obtain written informed consent for each participant. This task can be delegated by the PI to other members of the local research team, most likely a Research Midwife, if local practice allows and this responsibility has been documented in the site signature and delegation log.

- Where a patient gives verbal consent and is randomised but does not give written consent anonymised data will be collected on the Day 0, 48 Hour Follow Up and Neonatal CRFs only (please see Section 5.3 for further details)
- Additional consent will be taken in the pilot for the **qualitative work** with women, partners, and healthcare professionals: interviews and audio recordings etc.

5.3. General Provisions

Participant Information Sheet (PIS) is provided to facilitate both the postnatal and prenatal consent and the qualitative work in the pilot process. An antenatal PIS will be given to women attending antenatal clinics, a patient infographic sheet will be used during labour, and a postnatal PIS will be provided before written informed consent is obtained. The PI or delegate(s) will ensure that they adequately explain the aim, trial intervention, and the anticipated benefits and potential hazards of taking part in the trial to the participant. They will also stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the trial at any time. The participant will be given sufficient time to read the PIS and to discuss their participation with others outside of the site research team.

The participant will be given the opportunity to ask questions before signing and dating the latest version of the relevant **Informed Consent Forms (ICFs).** The PI or delegate will then sign and date the ICF. A copy of the ICF will be given to the participant, a copy will be filed in the medical notes, and the original placed in the Investigator Site File (ISF). After the participant has provided verbal consent and entered into the trial, the participant's trial number will be entered on the ICF maintained in the ISF.

Additionally the ICF may be emailed to the patient, signed electronically by them and returned to the research team if this is their preference. The ICF would then be electronically signed by the PI or delegate and a copy returned to the participant. Electronic copies of the PIS and ICF will be available from the trial office and will be printed or photocopied onto the headed paper of the local institution.

Details of the informed consent discussions will be recorded in the participant's medical notes. **The discussion note** will include date of discussion, the name of the trial, summary of discussion, version number of the PIS given to participant, version number of ICF signed and date consent received. Where consent is obtained on the same day that the trial related assessments are due to start, a note should be made in the medical notes as to what time the consent was obtained and what time the procedures started.

At each encounter, the participant's **willingness to continue** in the trial will be ascertained and documented in the medical notes. Throughout the trial, the participant will have the opportunity to ask questions about the trial. Any new information that may be relevant to the participant's continued participation will be provided. Where new information becomes available which may affect the participants' decision to continue, participants will be given time to consider and if happy to continue, they will be re-consented. Re-consent will be documented in the medical notes. The participant's right to withdraw from the trial will remain.

Where participants do not give written consent after randomisation anonymous clinical data will be collected on the Day 0, 48 Hour Follow Up and Neonatal CRFs to allow monitoring of safety. The provision of anonymous data is in line with General Data Protection Regulations (2018) and Common Law. Participants who do not give written consent will not be asked to complete questionnaires give any follow up information.

5.4. Discharge / transfer to another hospital prior to written consent

It is expected that consent will be sought for all participants prior to discharge/transfer to another hospital.

In the rare instances where consent is not sought prior to discharge/transfer, the following should occur:

The Research Midwife (RM), or other designated member of the research team at site, will call the participants within 5 working days of randomisation to inform them and/or their family of the participant's involvement in the trial and provide details of the trial.

Once the telephone call has been completed, the RM, or other designated member of the research team at site, will post/email within 5 working days as applicable:

- Participant covering letter to home/email address
- Participant information sheet and consent form to home/email address

The covering letter will confirm that the participant has 4 weeks from the date of the letter to return the consent form confirming whether they would like to continue participation in in the trial.

If no response is received within 2 weeks (14 days), the RM, or other designated member of the research team at site will make a follow up call to the participant to check that they have received the information and request that the consent form be returned within 5 working days if they would like to continue participation in the trial. Written information and a consent form will be re-sent if the site team member is unable to contact the participant, or information has not been received.

If no response is received within 4 weeks (28 days), the participant's data will not be included within the trial as confirmed in the telephone conversation/covering letter. Consent is being sought in this scenario for the disclosure of confidential information in order to avoid a breach of the common law duty of confidentiality. If we find that consent in this scenario is not practicable and results in informative missing data (e.g. linked to severity of condition or duration of hospital stay) a future Section 251 application may be made for future participants.

5.5. Maternal death prior to written consent

This is likely to be a very rare occurrence.

All deaths, for women who have verbally consented should be reported on a Serious Adverse Event CRF and faxed to the Clinical Trials Office within 24 hours of the research team becoming aware.

5.6. Neonatal death prior to written consent

This is likely to be a rare occurrence.

Consent will be sought if considered appropriate; however, it is at the discretion of the site staff to determine if this is appropriate for each individual participant. In this situation, the usual information sheet and consent form would be used.

6. IDENTIFICATION, SCREENING, ENROLMENT AND RANDOMISATION

6.1. Identification

Identification of participants will be by the clinician performing the rotational birth, as described in the Consent section (section 5) of this protocol. The clinician will also confirm eligibility.

Following automated randomisation, the local PI, Research Midwife, or delegated members of the local team, will obtain postnatal written consent prior to discharge, normally within 24-48 hours.

6.2. Enrolment

Enrolment will take place upon confirmation of eligibility and verbal consent of the woman taken by the clinician performing the rotational birth.

Details of all patients approached about the trial for verbal consent will be recorded on the ROTATE **Participant Eligibility Log** which will be kept in the ISF, and should be available to be sent to the Trials Office upon request.

If a woman with a relative contraindication (section 7.2) is considered ineligible by the clinician assessing eligibility, this decision and reason will be recorded in this Participant Eligibility Log and the case report form (CRF) will capture the reason.

If women with these conditions (suspected fetal bleeding disorder / suspected fetal predisposition to fracture / blood borne viral infection) are excluded this will be recorded in the Participant Eligibility Log.

6.3. Randomisation

Randomisation must be able to take place at any time of day, therefore a 24-hour telephone and online randomisation service is provided by the Health Services Research Unit at the University of Aberdeen available at https://w3.abdn.ac.uk/hsru/ROTATE. Unique log-in usernames and passwords will be provided to those who wish to use the online randomisation system and who have been delegated the role of randomising participants into the trial as detailed on the ROTATE Site Signature and Delegation Log. The randomisation system is available 24 hours a day, 7 days a week, apart from short periods of scheduled maintenance. A telephone toll-free randomisation service 0800 2802 307 is available 24-hours, seven-days a week.

6.3.1. Randomisation Process

After participant eligibility for randomisation has been confirmed and informed verbal consent has been given, the participant can be randomised into the trial. Randomisation Forms will be provided to investigators and may be used to collate the necessary information prior to randomisation. All questions and data items on the Randomisation Form must be answered prior to a potential participant being randomised into the trial and a Trial Number being issued.

Following randomisation, a confirmatory e-mail will be sent to the nominated email address(s). This can be, but not exclusive to, the local PI, research midwife, or research mailbox.

The local research team should add the participant to the **Participant Recruitment and Identification Log**, which links participants with their allocated trial number. PIs (or their delegates) must maintain this document securely, and which is **not** for submission to the Trials Office. The **ROTATE Participant Recruitment and Identification Log** should be held in strict confidence.

6.3.2. Randomisation Method

Participants will be randomised by telephone and online at the level of the individual in a 1:1 ratio to either manual or instrumental rotation.

A minimisation algorithm will be used within the randomisation system to ensure balance in the treatment allocations over the following variables:

- Centre
- Position
    - Occipito-Transverse: occiput between 8 to 10 o'clock or 2 to 4 o'clock
    - Occipito-Posterior: occiput between 4 and 8 o'clock (diagrams will be provided to standardise the classification)

6.4. Blinding

This is not a blinded trial because it is not pragmatic to blind the rotational methods; therefore there will be no procedures for unblinding.

6.5. Informing the Participant's GP and Other Parties

No other parties outside of the trial team will be informed of the participant's entry into the study. Participants can inform their GP if they wish.

7. TRIAL INTERVENTION

7.1. Trial Intervention(s)

INTERVENTION – MANUAL ROTATION

Rotation of the fetal head by manual rotation - followed by direct forceps or direct ventouse or maternal effort. The instrument to be used for direct traction after the rotation is at the choice of the obstetrician and will be recorded for further analysis on the Day 0 CRF.

COMPARATOR – INSTRUMENTAL ROTATION

Rotation of the fetal head by rotational instrument (rotational forceps or rotational ventouse) at the choice of the obstetrician.

Instrument to be used for direct traction after the rotation at the choice of the obstetrician – usually the same type of instrument (forceps or ventouse), but use of maternal effort after rotation by instrument is also possible.

STANDARDISATION OF INTERVENTIONS

Obstetricians taking part in the study and performing the rotational births will be Good Clinical Practice (GCP) trained and competent (trainees signed-off as competent on the national RCOG trainees' logbook; and consultants agreed as competent by PI in each site at the site initiation training) in both manual rotation and at least one rotational instrument; or they will be supervised directly by someone competent and GCP trained.

Rotation from occipito-transverse or left occipito-posterior /right occipito-posterior to a direct occipito-posterior position prior to operative delivery will be discouraged in the site-specific visits/ site initiation training. We will collect relevant data in the Day 0 CRF for analysis as needed, including if such rotation was accidental or performed on purpose.

The site initiation training will include a standardisation educational session for manual rotation and diagnosis of anal sphincter injury.

7.2. Contraindications

Women with contraindications for operative birth with either ventouse or forceps as per national RCOG guidance (21) will not be eligible:

Contraindications to either ventouse/vacuum or forceps

- Forceps and vacuum extraction are contraindicated before full dilatation of the cervix.

Contraindications to ventouse/vacuum alone

- The vacuum extractor is contraindicated with a face presentation.

Note: Women with pregnancies under 36 weeks' gestation are excluded from the trial – see Section 4: Eligibility.

The following are <u>not</u> absolute contraindications:

- Suspected fetal bleeding disorders or a predisposition to fracture are relative contraindications to assisted vaginal birth with either ventouse or forceps. However, there may be considerable risks if the fetal head has to be delivered abdominally from deep in the pelvis. Experienced obstetricians should be involved in the decision-making for exceptional indication. Low forceps may be acceptable for assisted vaginal birth with suspected fetal bleeding disorders, but vacuum extraction should be avoided.
- Blood borne viral infections in the woman are not an absolute contraindication to assisted vaginal birth. However, it is sensible to avoid difficult assisted vaginal birth where there is an increased chance of fetal abrasion or scalp trauma.

Note: The use of a vacuum is not contraindicated following a fetal blood sampling procedure or application of a fetal scalp electrode as per national guidance (RCOG).

7.3. Intervention Modification

Changes from the allocated intervention will be documented, alongside possible reasons:

- Participant refusal to allow the randomised intervention – with reasons and detail of the discussion with the accoucheur/midwife.

7.4. Accountability

We will capture data with a dedicated **ROTATE Manual Rotation Checklist** on the conduct of steps essential to the manual rotation technique.

7.5. Adherence & Cross-over

Adherence to the intervention, modifications, and their reasons, will be recorded on a dedicated **Adherence Checklist on the CRF**:

I) Randomised Technique
II) Rotational Technique used first – reasons why/if different from I
III) Rotational Technique used second – if the first failed
IV) Clinical reasons for changes/cross-over – with detail; it is anticipated, and will be reinforced at site-specific training, that cardiotocography (CTG) abnormalities would not be a reason for changing intervention as there is no evidence for superiority of one intervention over the other in such context.

It is encouraged that the first rotational method is used appropriately with adherence to key steps that maximise effectiveness. If the first rotational method fails, the accoucheur can decide if a second rotational method or a Caesarean section is necessary, and must record the reason(s) for this decision.

Should the participant request or the obstetrician think it clinically necessary to use another method (other than the allocated intervention), this will take precedence over the study, with the needs of the woman and her baby being paramount at all times.

8. OUTCOME MEASURES AND TRIAL PROCEDURES

8.1. Pilot Stage of Trial Outcomes

Trial Outcomes

All the main trial outcomes will be collected in the pilot stage and will be included in the analysis.

Progression Criteria

The decision to continue to a full trial will be decided by pre-defined independent stop-go criteria (red, amber, green (RAG) traffic lights) and supplemented with the findings from the pilot qualitative process evaluation.

8.1.1. Table for the stop-go criteria for progression from the pilot phase to full trial

Pilot (9 months)	Red	Amber	Green
Trial recruitment	<80%	80-99%	≥100%
Recruitment rate/ site/ month	<5	5-6	>6
Number of sites opened (staggered)	<9	9-11	12
Total number of participants recruited	<350	350-432	≥437
Adherence of women to randomised procedure	<90%	90-95%	>95%
Follow-up of women randomised – 3 months	<80%	80-95%	>95%
Written consent not received for women randomised	>10%	5-10%	<5%

8.1.2. Predicted site and patient recruitment for pilot phase

	Month	# Sites open	# Recruits per month	Cumulative total recruited per month
Pilot Phase	Nov-21	1	0	0
	Dec-21	3	17	17
	Jan-22	6	37	52
	Feb-22	9	51	105
	Mar-22	9	52	157
	Apr-22	12	70	227
	May-22	12	70	297
	Jun-22	12	70	367
	Jul-22	12	70	437

RAG Criteria:

- *Green Light:* If all green criteria are met, we will proceed to a full trial with the protocol unchanged (unless there is a clear message from the process evaluation that would improve the protocol).
- *Amber Light:* If one or more of amber criteria are met, we will adapt the protocol with feedback from the Process Evaluation and our experience; and assess whether adaption of the protocol requires an extension of the internal pilot and further feasibility study. This plan was supported strongly by the Intrapartum Care Clinical Study Group.

- *Red Light:* If one or more of these criteria are met, we would discuss with the Trial Steering Committee whether proceeding with the trial is feasible.

Qualitative process evaluation data

We will collect data to explore the feasibility, acceptability and appropriateness of the trial processes (including consent) and interventions for women and healthcare professionals, in order to support and inform decision-making around progression to a full trial.

8.2. Main Trial Outcomes

8.2.1. Primary Outcomes

These will be recorded after birth by the accoucheur or attending midwife using a dedicated CRF on the day of the birth/delivery – Day zero (D0).

1. Third/forth degree perineal trauma involving anal sphincter complex diagnosed on clinical vaginal/rectal examination after birth (superiority co-primary outcome)

   Identification will be by clinical examination as this is a pragmatic study; the principles of diagnosis will be refreshed at the site-specific trial education visit.

   Adherence to the principles of diagnosis will be collected as Process Data.
2. Caesarean section (non-inferiority co-primary outcome*)*

8.2.2. Secondary Outcomes

NEONATAL

Severe neonatal trauma and morbidity – at neonatal discharge (captured on the neonatal CRF)

- Composite: After discussion between the perinatal outcome experts in the study team and PPI advisers, we propose a composite safety signal outcome, for what would be rare neonatal events, to summarise the potential adverse outcomes for the baby. We have aligned with the outcome designed in the national Birthplace in England Research Programme [28]. The ROTATE composite outcome is assessed at discharge from hospital and comprises any of:
  - stillbirth after study entry
  - early neonatal death (≤7 days)
  - evidence of intrapartum hypoxia (Apgar score ≤7 at 5 minutes after birth)
  - the presence of neonatal encephalopathy receiving treatment with therapeutic hypothermia
  - neonatal seizure(s)
  - meconium aspiration syndrome
  - brachial plexus injury, fractured humerus or fractured clavicle

  These reflect the potential outcomes relating to intrapartum hypoxia and potential trauma from a physically difficult birth and meet the target of a “take-home healthy baby” as identified by our wider PPI activities including the new lay PPI panel. All are relatively rare events hence the use of a composite measure, but we anticipate a higher rate compared to that found in the Birthplace study (4.4 (95% CI 3.3 - 5.9) per 1000 deliveries in obstetric units), in which women were all of low risk (25).

- Individual Outcomes: Each component of the neonatal composite outcome will also be reported separately.

PROCESS DATA - SOON AFTER BIRTH (D0)

Completed by the accoucheur or attending midwife (D0 CRF):

- Position of the fetal head (right occiput anterior (ROA) occiput anterior (OA), left occiput transverse (LOT), direct occipito-anterior (DOP), etc) before rotation (at diagnosis) using a pre-formatted ROTATE diagram (clock).
- Use of ultrasound to diagnose position before rotation: Yes/No
- Position of the fetal head at birth using a pre-formatted ROTATE diagram (clock)
  NB: If rotation to a direct occipito-posterior position took place, whether accidentally or on purpose (binary).
- Position of the ventouse cup, using a pre-formatted ROTATE diagram (flexing median, deflexing median, flexing paramedian, deflexing paramedian).
- Forceps marks on the baby :
  - Right blade - (normal, over >50% orbit, not reaching jaw)
  - Left blade - (normal, over >50% orbit, not reaching jaw)
- Adherence to all key steps of the manual rotation process using a dedicated ROTATE checklist supported by pictures from the ROBuST manual. (Yes: all tick-boxes / No: partially/none)
- Adherence to standardised assessment of the primary outcome (anal sphincter injury) (Supported by pictures) using a dedicated study checklist (Yes: all tick-boxes / No: partially/none)

MATERNAL - SOON AFTER BIRTH (D0)

- Vaginal birth after successful rotation with first allocated method (manual or instrumental rotation) (D0 CRF).
- Change from rotational ventouse to rotational forceps (both rotational ventouse and rotational forceps are in the same trial arm). This change will be recorded and measured as an important event (D0 CRF).
- Severe/complex 2nd degree vaginal tears and/or cervical tears (Y/N) - any of: cervical, spiral, multiple, bilateral, high, or requiring complex suturing as determined by the accoucheur (D0 CRF).

MATERNAL – AT DISCHARGE/48 HOURS (whichever sooner)

- Estimated blood loss following birth – up to 24 hours after birth so as to capture only primary haemorrhage (continuous variable). Need for blood transfusion (including use of cell salvage): Any red blood cell (RBC) blood transfusion or cell salvage of ≥ 300mls commenced any time between randomisation and 48 hours after birth (or hospital discharge if earlier than 48 hrs) (Y/N)

- Breast-feeding: Any breastfeeding, defined in accordance with the UK Infant Feeding Survey ‘as infant being breastfed (including being given expressed breastmilk), within the past 24 hours, even if they are also receiving infant formula, solid food or other liquids’.

- Maternal Experience:

Childbirth Experience Questionnaire (CEQ)

The CEQ has 22 statements assessing four domains of childbirth experience (27). For 19 of the items the response format is a 4-point Likert Scale and three of the items

are assessed using a visual analogue scale (VAS). Higher scores indicate better childbirth experience.

*Client Satisfaction Questionnaire-8 (*CliSQ)

The CliSQ (28) is an 8-item questionnaire which measures three aspects of satisfaction: environment condition, care procedures and provided education. Total scores are converted into percentages and bands of 0–39, 40–59 and 60–100 are used to represent dissatisfaction, neutral, and satisfaction respectively.

MATERNAL – AT 3 MONTHS AFTER BIRTH (± 7 days)

- Breast-feeding (CRF): Any breastfeeding, defined in accordance with the UK Infant Feeding Survey 'as infant being breastfed (including being given expressed breastmilk), within the past 24 hours, even if they are also receiving infant formula, solid food or other liquids'.
- Maternal Experience (same questionnaires as at Discharge/48h: *CEQ, CESQ-8*)
-
- Urinary incontinence:
    - *ICIQ (International Consultation on Incontinence Questionnaire) score* (29).
        - The questionnaire has 4 Question items:
            - Frequency or urinary incontinence
            - Amount of leakage
            - Overall impact of urinary incontinence
            - Self-diagnostic item (not scored)
        - Scoring scale: 0-21 total
- Faecal incontinence:
    - *Fecal Incontinence Quality of Life Scale* (30)
        - The questionnaire is composed of a total of 29 items; these items form four scales:
            - Lifestyle (10 items),
            - Coping/Behaviour (9 items),
            - Depression/Self-Perception (7 items)
            - Embarrassment (3 items).
        - Items are scored 1-4 and averaged (total score is 4-16 with no cut-off).

- PTSD symptoms:
    - CITY Birth Trauma Scale (31)

9. TRIAL PROCEDURES

9.1. Schedule of assessments

Assessment		Screening	Day 0	48 hours (or maternal discharge if sooner)	Neonatal Discharge	3 months ±7 days
Eligibility check		x	x			
Valid informed consent			**Verbal**	x[1]		
Randomisation			x			
Co-primary Outcomes	Anal sphincter injury		x			
	Caesarean		x			
Neonatal Composite & Components					x	
Assessment of Adverse Events				x	x	x
Process Outcomes	Use of ultrasound to diagnose position before rotation	x				
	Position of fetal head before rotation	x				
	Position of fetal head at birth		x			
	Position of the ventouse cup		x			
	Forceps marks on the baby (diagrams)		x			
	Adherence to key steps of the manual rotation process		x			
	Adherence to standardised assessment of the primary outcome		x			
Maternal	Vaginal birth after successful rotation with the first instrument		x			
	Change from rotational ventouse to rotational forceps		x			
	Severe/complex 2nd degree vaginal/cervical tears		x			
	Breastfeeding *(UK Infant Feeding Survey)*			x		x
	Estimated blood loss			x		
	Need for red blood cell transfusion (or use of cell salvage)			x		
	Urinary Incontinence *ICIQ*					x
	Fecal Incontinence Quality of Life Scale					x
Maternal Experience	Childbirth Experience Questionnaire (CEQ)			x		x
	Client Satisfaction Questionnaire (CliSQ)			x		x
Maternal PTSD symptoms	CITY Birth Trauma Scale					x

[1] Where participants do not give written consent routine clinical data will be collected on the Day 0, 48 Hour Follow Up and Neonatal CRFs only

Any paper CRFs should be submitted upon completion. Quality of life questionnaires may be emailed directly to participants for completion if they are not in hospital at the assessment timepoint; or may be completed over the phone with the research midwife.

9.2. Discontinuation of Trial Intervention

Participants should be made aware at the beginning during the consent process that they can freely discontinue their participation in the trial at any time without giving a reason. The details of changes of levels in participation within the trial (date, reason and category of status change) should be clearly documented in the source documents and captured on the Trial Withdrawal CRF.

Types of discontinuation are:

- Participant would like to withdraw from the trial but has agreed to attend follow-up visit and/or provide follow-up data for use in the trial analysis
- Participant would like to withdraw from the trial and does not wish to attend follow-up visits but is willing to be followed up at standard clinic visits (the participant has agreed that follow-up data can be collected at standard clinic visits and used in the trial analysis)
- Participant is not willing to be followed up for trial purposes at any further visits (the participant has agreed that any data collected prior to the withdrawal of consent can be used in the trial analysis)
- Participant wishes to withdraw and that none of their data collected to date be used for any trial purposes

Women who have not given consent will not be considered study participants. Anonymised data used at randomisation after verbal consent is given will be retained and could inform our understanding of the (basic) characteristics of women eligible who decline to participate, alongside the formal qualitative study: we will talk to a small number of women who decline to help understand in more detail why they decline.

Clinical data collected on women eligible(for example, standardised assessments of perineal tears) who provided verbal consent but declined to provide full written consent will remain as part of each individual's medical records but neither used for completion of any additional study documentation nor uploaded to the study database.

9.3. Changes in Levels of Participation

Participants found to be ineligible post randomisation should be followed up according to all trial processes and will still have their data analysed unless they explicitly change their level of participation

Any participant who would no longer like to receive their allocated trial intervention, but is willing to be followed up in accordance with the schedule of assessments and if applicable using any central UK NHS bodies for long-term outcomes (i.e. the participant has agreed that data can be collected and used in the trial analysis) will be documented and followed-up separately.

10. ADVERSE EVENT REPORTING

10.1. Definitions

Severity Definitions	Mild Moderate Severe	Awareness of signs or symptoms that do not interfere with the participant's usual activity or are transient and resolved without treatment and with no sequelae. A sign or symptom, which interferes with the participant's usual activity. Incapacity with inability to do work or perform usual activities.
Adverse Event	AE	Any untoward medical occurrence in a participant participating in the trial which does not necessarily have a causal relationship with the intervention received.
Related Event	RE	An event which resulted from the administration of any of the research procedures.
Serious Adverse Event	SAE	An untoward occurrence that: • Results in death • Is life-threatening* • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly/ birth defect • Or is otherwise considered medically significant by the Investigator**
Unexpected Event	UE	The type of event that is not listed in the protocol as an expected occurrence.
Related and Unexpected Serious Adverse Event	N/A	A SAE that meets both the definition of a Related and Unexpected Event.

* The term life-threatening is defined as diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

** Medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definitions above.

10.2. Adverse Event Recording – General

The recording and reporting of Adverse Events (AEs) will be in accordance with the UK Policy Framework for Health and Social Care Research (2017), the Principles of GCP as set out in the UK Statutory Instrument (2004/1031; and subsequent amendments) and the requirements of the Health Research Authority (HRA)

Definitions for adverse event reporting are listed in table of definitions in section 10.1.

The local investigators will record AEs in the participant's medical notes and include the documentation of the assessment of severity and seriousness and also relatedness to the intervention(s) in accordance with the protocol.

10.3. Adverse Event Reporting in ROTATE

The reporting period will cease after 3 months (+/- 7 days) from commencement of protocol defined treatment. The majority of Related AEs will be captured with the primary and secondary outcome measures on the trial CRF.

The safety profile for this trial population and interventions are well established so although it is recommended that the severity, seriousness and causality of all AEs should be recorded in the source documents, a strategy of targeted reporting of AEs will not affect the safety of participants.

- Adverse events that occur during the trial intervention and follow-up period (up to 3 months +/- 7 days after birth).

Only some AEs (as detailed below) will be reported on the Day 0 CRF.

- Difficulty in delivering the fetal head (impaction)
- Need for additional manoeuvres/devices used to deliver the fetal head
- Uterine incision extension by surgeon
- Uterine tear extension spontaneously
- Shoulder dystocia

10.4. Serious Adverse Advents (SAE) Reporting in ROTATE

For all SAEs the PI must do one of the following:

1. **Record safety reporting-exempt SAEs** in the medical notes but **not report** them to the trials office on an SAE form as per Section 10.4.1 Serious Adverse Events not requiring reporting to the Trial Office.
2. **Report SAEs to the trial office in a non-expedited manner**. This can only be done for a pre-defined subset of SAEs as per section 10.4.2 Serious Adverse Events requiring non-expedited reporting to the Trial Office.
3. **Report SAEs to the trial office in an expedited manner** (within 24 hours of the site research team becoming aware of the event). All SAEs not covered by the above 2 categories must be reported as per Section **Error! Reference source not found. Error! Reference source not fo und.**.

Note: when an SAE occurs at the same hospital at which the participant is receiving trial intervention or is being followed up for trial purposes, processes must be in place to make the trial team at the hospital aware of any SAEs, regardless of which department first becomes aware of the event, in an expedited manner.

10.4.1. Serious Adverse Events not requiring reporting to Sponsor or BCTU

At whatever time they occur during an individual's participation, from commencement of protocol defined treatment to end of participant follow-up, the following are not considered to be critical to evaluations of the safety of the trial:

- Pre-planned hospitalisation
- Hospital admission of mother lasting less than 24 hours

All events which meet the definition of serious must be recorded in the participant notes, including the causality and severity, throughout the participant's time on trial, including follow-up, but for trial purposes these events do not require reporting on the SAE Form. Such events are "safety reporting exempt".

10.4.2. Serious Adverse Events requiring non-expedited reporting to BCTU

Where the safety profile is well established, the causal relationship between either the intervention (or the participant's underlying condition), and the SAE, may be known. That is, such events are protocol-defined as "expected" (see Section 10.5.2 Assessment of expectedness of an SAE by the CI). Such events should still be recorded by the trial team in the participant's notes and reported to BCTU on the trial SAE CRF but do not require expedited reporting (immediately on the site becoming aware of the event) since the assessment of expectedness for the specified events has been pre-defined. These should be reported to the trial team within 4 weeks of the site being made of the SAE.

- Unplanned admission of the baby within the follow-up period
- Unplanned admission of the mother for more than 24 hours within the follow-up period

10.4.3. Serious Adverse Events requiring expedited reporting to the Trial Office

All SAEs not listed in Sections 10.4.1. and **Error! Reference source not found.** must be reported to t he Trial Office on a trial specific SAE form within 24 hours of the site research team becoming aware of the event from the date of commencement of protocol defined treatment until 3 months +/- 7 days after randomisation.

10.5. SAE Expedited reporting process to Sponsor, BCTU and REC

On becoming aware that a participant has experienced an SAE which requires reporting on an SAE form, the PI or any person appearing on the delegation log who is allocated the relevant task should report the SAE to their own Trust in accordance with local practice and to the BCTU trials office as per the requirements of section 10.4 above.

To report an SAE to the BCTU trials office the PI or delegate(s) must complete, date and sign the trial specific SAE form. The copy of the completed form together with any other relevant, appropriately anonymised, data should be submitted to the BCTU trial team using the information below in accordance with the timelines given in section 10.4.

To report an SAE, submit the SAE Form to:

ROTATE@trials.bham.ac.uk

Where an SAE Form has been completed by someone other than the PI initially, the original SAE form will need to be countersigned by the PI to confirm agreement with the causality and severity assessments.

On receipt of an SAE form, the BCTU trial team will allocate each SAE a unique reference number and notify the site via email to the site as proof of receipt. The site and the BCTU trial team should ensure that the SAE reference number is quoted on all correspondence and follow-up reports regarding the SAE and filed with the SAE in the ISF.

If the site has not received confirmation of receipt of the SAE from the BCTU or if the SAE has not been assigned a unique SAE identification number within one working day, the site should contact the BCTU trial team.

10.5.1. Assessment of causality of an SAE

When completing the SAE form, the PI (or medically trained delegate) will be asked to define the nature of the seriousness and causality (relatedness; see Table 10.5.1) of the event. In defining the causality the PI (or medically trained delegate) must consider if any concomitant events or medications may have contributed to the event and, where this is so, these events or medications should be reported on the SAE form. It is not necessary to report concomitant events or medications which did not contribute to the event. As per table 10.5.1, all events considered to be 'possibly', 'probably', or 'definitely' related to the intervention will be reported by the trial office as 'related'; all events considered at site to be 'unlikely' or 'unrelated' to the intervention will be reported by the trials office as 'unrelated'. The same categorisation should be used when describing AEs and protocol-exempt SAEs in the source data.

Table 10.5.1 – SAE relatedness categories

Category	Definition	Causality
Definitely	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.	Related
Probably	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.	
Possibly	There is some evidence to suggest a causal relationship. However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events or medication)	
Unlikely	There is little evidence to suggest there is a causal relationship. There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant events or medication).	Unrelated
Not related	There is no evidence of any causal relationship.	

On receipt of an SAE Form the Trials Office will forward it, with the unique reference number, to the Chief Investigator (CI) or delegate(s) who will independently review the causality of the SAE. An SAE judged by the PI or CI "or delegate(s)" to have a reasonable causal relationship with the intervention will be regarded as a related SAE (i.e., SAR). The severity and causality assessment given by the PI will not be downgraded by the CI or delegate(s). If the CI or delegate(s) disagrees with the PI's causality assessment, the opinion of both parties will be documented, and where the event requires further reporting, the opinion will be provided with the report.

10.5.2. Assessment of Expectedness of an SAE by the CI

The CI or delegate(s) will also assess all related SAEs for expectedness with reference to the criteria in table 10.5.2:

Table 10.5.2 – SAE Expectedness categories

Category	Definition
Expected	An adverse event that is consistent with known information about manual or instrumental rotational birth.
Unexpected	An adverse event that is not consistent with known information about the trial related procedures.

If the event is unexpected (i.e. it is not defined in the protocol as an expected event) it will be classified as a Related and Unexpected SAE.

The CI will undertake review of all SAEs and may request further information from the clinical team at site for any given event(s) to assist in this.

10.5.3. Provision of SAE follow-up information

Following reporting of an SAE for a participant, the participants should be followed up until resolution or stabilisation of the event. Follow-up information should be provided using the SAE reference number provided by the BCTU trial team. Once the SAE has been resolved, all critical follow-up information has been received and the paperwork is complete, a copy of the final version of the completed SAE form must be submitted to the BCTU trials office and the original kept in the ISF.

10.6. Reporting SAEs to third parties

The independent Data Monitoring Committee (DMC) may review any SAEs at their meetings.

BCTU will report all events categorised as Unexpected and Related SAEs to the Research Ethics Committee (REC), and Sponsor within 15 days.

The main REC and RGT will be notified immediately and their advice sought if a significant safety issue is suspected/identified during the course of the trial.

Details of all Unexpected and Related SAEs and any other safety issue which arises during the course of the trial will be reported to PIs. A copy of any such correspondence should be filed in the ISF and Trial Master File (TMF).

10.7. Urgent Safety Measures

If any urgent safety measures are taken, BCTU shall immediately, and in any event no later than 3 days from the date the measures are taken, give written notice to the REC of the measures taken and the reason why they have been taken.

11. DATA HANDLING AND RECORD KEEPING

11.1. Source Data

Source data is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction

and evaluation of the trial. In order to allow for the accurate reconstruction of the trial and clinical management of participants, source data will be accessible and maintained.

Some data variables may be entered directly onto the CRFs, these are clearly identified and detailed below:

- Use of ultrasound to diagnose position before rotation
- Position of fetal head before birth
- Position of fetal head after birth
- Allocated rotational method (manual/instrumental)
- Rotational method used first (manual/rotational ventouse/rotational forceps)
- Rotational method used second (if any)
- Adherence to key steps of the manual rotation process
- Method used to pull/push the baby after rotation (maternal pushing/ventouse/direct forceps)
- Position of the ventouse cup/forceps marks on the baby (diagrams)
- Adherence to standardised assessment of the primary outcome
- Severe/complex 2nd degree vaginal/cervical tears
- Breastfeeding (UK Infant Feeding Survey)
- Estimated blood loss
- Need for red blood cell transfusion (or use of cell salvage)
- Urinary Incontinence ICIQ
- Fecal Incontinence Quality of Life Scale
- Childbirth Experience Questionnaire
- Client Satisfaction Questionnaire
- CITY Birth Trauma Scale

Source data is kept as part of the participants' medical notes generated and maintained at site.

Source data should be clearly identified with awareness of the variation in practice at sites. Below is an example of the way in which source data can be identified.

Data	**Source**
Participant Reported Outcomes	The original participant-completed CRF is the source and will be kept with the participant's trial record at site, whilst copies will be provided to the trial office.
Clinical event data	The original clinical annotation is the source document. This may be found on clinical correspondence, or electronic or paper participant records. Clinical events reported by the participant, either in or out of clinic (e.g., phone calls), must be documented in the source documents.
Recruitment	The original record of the randomisation is the source. It is held on BCTU servers as part of the randomisation and data entry system.

Withdrawal	Where a participant expresses a wish to withdraw, the conversation must be recorded in the source documents.

11.2. Case Report Form (CRF) Completion

Only CRFs specified in this protocol must be used (See Table 11.2.1). The delegated staff completing the CRF should ensure the accuracy, completeness and timeliness of the data reported. This will be evidenced by signing and dating the CRF.

11.2.1. Case report forms in ROTATE

Form Name	**Schedule for submission**
Day 0 – Screening, eligibility, consent and randomisation CRF	As soon as the assessments and randomisation have been performed – within 4 week **Please note the Day 0 CRF should be completed by the recruiting clinician immediately after delivery.**
Follow-up at 48 hours (or maternal discharge if sooner) CRF	As soon as possible after the assessment time point – within 4 weeks
Neonatal CRF	As soon as possible after the assessment time point – within 4 weeks
Protocol deviation CRF	As soon as a protocol deviation has been identified – within 4 weeks
Trial withdrawal CRF	Upon a participant withdrawal from the trial – within 4 weeks
Serious Adverse Event form	If expedited: emailed within 24 hours of site research team becoming aware of event If non-expedited: emailed within 4 weeks of site research team becoming aware of event

A CRF is required and relevant forms should be completed for each individual participant.

It is the responsibility of the PI to ensure the accuracy of all data entered in the CRFs and confirm accordingly. The ROTATE Site **Signature & Delegation Log** will identify all those personnel with responsibilities for data collection.

- Data reported on each form will be consistent with the source data and any discrepancies will be explained. All missing and ambiguous data will be queried. Staff delegated to complete CRFs will be trained to adhere to GCP requirements and trial-specific guidelines, which will be provided separately.

The following guidance applies to data and partial data:

- Time format and unknown times – all times should be in accordance with the 24hr clock
- Rounding conventions – rounding should be to the nearest whole number: If the number you are rounding is followed by 5, 6, 7, 8, or 9, round the number up. **Example**: 3.8 rounded to the nearest whole number is 4. If the number you are rounding is followed by 1, 2, 3 or 4, round the number down. **Example**: 3.4 rounded to the nearest whole number is 3

- Trial-specific interpretation of data fields – where guidance is needed additional information will be supplied
- Missing/incomplete data – should be clearly indicated – all blank fields will be queried by the trial office
- Repeat laboratory tests – the data used to inform clinical decisions should always be supplied. If a test is repeated it is either to confirm or clarify a previous reading. Confirmatory tests should use the original test values.
- Protocol and GCP non-compliances should be reported to the Trials Office on discovery.

In all cases it remains the responsibility of the site's PI to ensure that the CRF has been completed correctly and that the data are accurate. This will be evidenced by the signature of the site's PI, or delegate(s), on the CRF.

Data collected on paper CRFs will be transcribed onto the ROTATE REDCap database by site staff. Original paper copies must be retained at site in the ISF.

11.3. Participant Completed Questionnaires

Participant completed questionnaires can be completed using the participant's favoured mode of communication (letter, telephone, email, online), with a letter or telephone reminder if no response provided within 2 weeks.

11.4. Data Management

Processes will be employed to facilitate the accuracy and completeness of the data included in the final report. These processes will be detailed in the trial specific Data Management Plan and include the processes of data entry, data queries and self-evident corrections on trial data.

11.5. Data Security

The University of Birmingham has policies in place, which are designed to protect the security, accuracy, integrity and confidentiality of Personal Data.

The trial will be registered with the Data Protection Officer at UoB and will hold data in accordance with the Data Protection Act (2018 and subsequent amendments). BCTU has arrangements in place for the secure storage and processing of the trial data which comply with UoB policies.

The Trial Database System incorporates the following security countermeasures:

- Physical security measures: restricted access to the building, supervised onsite repairs and storages of back-up tapes/disks are stored in a fire-proof safe.
- Logical measures for access control and privilege management: including restricted accessibility, access controlled servers, separate controls of non-identifiable data.
- Network security measures: including site firewalls, antivirus software and separate secure network protected hosting.
- System Management: the System will be developed by the Programming Team and will be implemented and maintained by the Programming Team.
- System Design: the System will comprise of a database and a data entry application with firewalls, restricted access, encryption and role based security controls.
- Operational Processes: the data will be processed and stored within BCTU.
- System Audit: The System will benefit from the following internal/external audit arrangements:
    - Internal audit of the system

- Periodic IT risk assessment
- Data Protection Registration: The UoB's Data Protection Registration number is Z6195856.

11.6. Archiving

All records created by following trial procedures and all documents listed in guidance relating to the conduct of the trial must be retained and archived for the specified period.

The trial master file will be composed of a sponsor file, held by the sponsor organisation, and an investigator site file, held by the site investigator. Documents will be archived following any regulatory requirements and any local procedures.

It is the responsibility of the PI to ensure all essential trial documentation and source documents (e.g. signed ICFs, Investigator Site Files, participants' hospital notes, copies of CRFs) at their site are securely retained for the contractual period. Archiving will be authorised by BCTU on behalf of the Sponsor following submission of the end of trial report. No documents should be destroyed without prior approval from the BCTU Director or their delegate.

The TMF will be stored at BCTU for at least 3 years after the end of the trial. Long-term offsite data archiving facilities will be considered for storage after this time; data will be stored securely and confidentially for at least 25 years. BCTU has standard processes for both hard copy and computer database legacy archiving.

12. QUALITY CONTROL AND QUALITY ASSURANCE

12.1. Site Set-up and Initiation

All PIs will be asked to sign the necessary agreements including a Site Signature and Delegation log between the PI and BCTU and supply a current CV and GCP certificate. All members of the site research team are required to sign the Site Signature and Delegation Log, which details which tasks have been delegated to them by the PI. The Site Signature and Delegation Log should be kept up to date by the PI. It is the PI responsibility to inform the BCTU trial team of any changes in the site research team.

Prior to commencing recruitment, each recruiting site will undergo a process of site initiation, either a meeting or a teleconference, at which key members of the site research team are required to attend, covering aspects of the trial design, protocol procedures, adverse event reporting, collection and reporting of data and record keeping. Sites will be provided with an ISF containing essential documentation, instructions, and other documentation required for the conduct of the trial.

12.2. Monitoring

The Central and On-site monitoring requirements for this trial have been developed in conjunction with the trial specific risk assessment and are documented in the trial specific monitoring plan.

12.1.1. On-site monitoring

For this trial, all sites will be monitored in accordance with the trial risk assessment and monitoring plan. Any monitoring activities will be reported to the Trial Office and any issues noted will be followed up to resolution. Additional on-site monitoring visits may be triggered. PIs and site research teams will allow the ROTATE trial staff access to source documents as requested. The monitoring will be conducted by BCTU/UoB staff.

12.1.2. Central monitoring

The Trial Office will check received ICFs and CRFs for compliance with the protocol, data consistency, missing data and timing at a frequency and intensity determined by the Data Management Plan. Sites will be sent DCFs requesting missing data or clarification of inconsistencies or discrepancies.

12.3. Audit and Inspection

The Investigator will permit trial-related monitoring, audits, ethical review, and regulatory inspection(s) at their site and provide direct access to source data/documents. The investigator will comply with these visits and any required follow up. Sites are also requested to notify BCTU of any relevant inspections or local audits.

12.4. Notification of Serious Breaches

The sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with that trial or of the protocol relating to that trial. Sites are therefore requested to notify the Trial Office of any suspected trial-related serious breach of GCP and/or the trial protocol as soon as they become aware of them. Where the Trial Office is investigating whether or not a serious breach has occurred sites are also requested to cooperate with the Trial Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment.

13. END OF TRIAL DEFINITION

For participants, trial data collection ends at withdrawal, or at 3 months post-randomisation follow-up (+/- 7 days), whichever occurs first. The end of trial will be the date of the last data capture including resolution of queries, and this will be six months after the date of last trial data collection, as defined above. This will allow sufficient time for the completion of protocol procedures, data collection and input and data cleaning. The Trial Office will notify the REC, and the Sponsor within 90 days of the end of trial. Where the trial has terminated early, the Trial Office will notify the REC within 15 days of the end of trial. The Trial Office will provide the REC and the Sponsor with a summary of the clinical trial report within 12 months of the end of trial.

14. STATISTICAL CONSIDERATIONS

14.1. Sample Size

Superiority: We meta-analysed results from 5 recent studies (16–18,32,33)to calculate a pooled estimate for the control group rate. The pooled incidence of third/fourth degree perineal trauma was 5% (95% confidence interval (CI) 2% to 7%). This is in line with the national REDEFINE audit (19), where the incidence was 6.6% for rotational forceps, 4.6% for rotational ventouse, and 4.3% for manual rotation. To detect a reduction of third/fourth degree perineal trauma from 6% to 4% (equivalent to a risk ratio of 0.67) with 90% power, 5% two-sided significance level using the standard method of difference between proportions and based on a superiority hypothesis, requires 4,988 women in total. We considered an incidence of 6% of perineal trauma, as this closely reflected the rates reported in the REDEFINE audit, and a 2% clinically relevant reduction after consultation with co-applicants. We anticipate drop out or loss to follow-up for this outcome to be low (around 4%) and will aim to recruit 5,200 women (2,600 in each group) to account for this. The sample size has been calculated according to the normal approximation to the binomial distribution. The trial is designed as a pragmatic study to provide real-world evidence, and as such, the sample size has been

calculated according to an intention-to-treat analysis, i.e. the primary analysis will be based on the group to which the woman was randomised whether or not she crossed-over. The number of women for whom cross-over to the opposite rotational method occurs is expected to be minimal (<1%), based on previous studies (0-0.6%) as detailed in the Analysis section, and will therefore have a negligible impact on the treatment effect. The degree of cross-over will be monitored closely. A sensitivity analysis excluding cross-overs will assess the robustness of the conclusions.

Non-inferiority: The pooled incidence for caesarean section in the meta-analysis, based on observational research, was 9% (95% CI 6% to 13%). We assumed a conservative estimate of 12% as the control group rate for this outcome.

We have calculated sample sizes for the CS outcome with varying non-inferiority (NI) margins. The table below provides the sample size required based on a 12% or a 15% control group (forceps/ventouse) CS rates, at 90% power, and a one-sided 2.5% alpha, with the knowledge that we are aiming for a total sample size of 5200, assuming negligible loss to follow-up for this outcome as mode of delivery is captured in hospital notes.

Control rate	NI margin	Total sample size
12%	2.9%	5278
	3.0%	4932
	3.5%	3624
	4.0%	2774
15%	3.0%	5956
	3.2%	5234
	3.5%	4376
	4.0%	3350

Therefore, the planned study of 5,200 women would be able to identify with more than 90% power a non-inferiority margin of 3.5% if the control group rate is 15%.

Both of our PPI co-applicants have discussed the issue of the non-inferiority margin extensively with women through their networks and social media. Despite the large range in experiences, a common theme is that the actual non-inferiority margin does not matter much to women; what matters is the provision of adequate information about the interventions and the research, a focus of our qualitative research and pilot.

We have therefore selected 3.5% as the non-inferiority margin, which represents a relative risk increase of CS of 23% (from 15% to 18.5%), noting that the originally proposed margin of 3% represented a relative risk increase of 20% (from 15% to 18%).

Other outcomes: The proposed sample size would also have 90% power in detecting an absolute risk difference in serious neonatal morbidity and trauma composite of 1.65% (assuming risks of 4% and 2.35% in the two groups). However, we consider the neonatal composite an important secondary outcome to provide a safety signal, and we have powered ROTATE for maternal outcomes as per the commissioning brief. This sample size of 5,200 is therefore justified for a trial with the potential to change obstetric practice and improve outcomes that truly matter for mothers, babies, and their families.

14.2. Analysis of Outcomes

A separate Statistical Analysis Plan will be produced and will provide a more comprehensive description of the planned statistical analyses. A brief outline of these analyses is given below.

The primary comparison groups will be composed of those randomised to manual rotation versus those randomised to instrumental rotation. In the first instance, all analyses will be based on the

intention to treat principle, i.e. all participants will be analysed in the intervention group to which they were randomised irrespective of adherence to randomised intervention or protocol deviations.

For all relevant outcomes, appropriate summary statistics and differences between groups be presented, with 95% confidence intervals and p-values from two-sided tests also provided. Intervention effects will be adjusted for the minimisation listed in section 6.3.2 where possible. No adjustment for multiple comparisons will be made.

14.2.1. Primary outcome

The co-primary outcomes of 3rd/4th degree perineal trauma and caesarean section will be analysed using mixed-effects log-binomial models to generate relative risks alongside risk differences with 95% confidence intervals, adjusting for the position as a fixed effect and centre as a random effect. If the log-binomial model fails to converge, a Poisson regression model with robust standard errors will be used to estimate the same parameters. If this also fails, unadjusted estimates will be produced from the log-binomial model.
We have not adjusted for Type II error, as we will not be considering a joint effect of both outcomes. Interpretation of the results will be based on the treatment effect and 95% confidence intervals for each outcome.

14.2.2. Secondary outcomes

Analysis will be performed as per the primary outcome for all binary secondary outcomes (e.g. successful vaginal birth, breastfeeding intention after birth) as well as any safety output (e.g. SAEs). For continuous outcomes (e.g. estimated blood loss), a mixed-effects linear regression model will be used to generate difference between group means and confidence intervals adjusting for the same minimisation parameters as the primary outcome.

14.2.3. Subgroup analyses

Subgroup analyses will be limited to the same variables used in the minimisation algorithm (see section 6.3.2) and performed on the co-primary outcomes. The effects of these subgroups will be examined by including an intervention group by subgroup interaction parameter in the regression model, which will be presented alongside the effect estimate and 95% confidence interval within subgroups. The results of subgroup analyses will be treated with caution and will be used for the purposes of hypothesis generation only.

14.2.4. Exploratory analyses

A series of exploratory analyses will be conducted in which the co-primary outcomes and neonatal outcomes will be summarised by the following variables:

- instrument used (rotational forceps versus rotational ventouse)
- type of anaesthesia at randomisation
- parity (nulliparous/parous)
- baby's position (transverse/posterior)
- choice of method for completing birth after rotation.

For each of these exploratory analyses, summary statistics will be presented for each group and results will be treated with caution and will be used for the purposes of hypothesis generation only.

14.2.5. Missing Data and Sensitivity Analyses

Every attempt will be made to collect full follow-up data on all study participants; it is thus anticipated that missing data will be minimal. Participants with missing primary outcome data will

not be included in the primary analysis in the first instance. This presents a risk of bias, and sensitivity analyses will be undertaken to assess the possible impact of the risk.

Per protocol, populations are 1) women having manual rotation as the first method, 2) women having instrumental rotation as the first method (regardless of instrument used). As we anticipate some cross-overs for participants having a failed attempt at rotation with one method to the other (instrumental rotation after failed manual rotation; and manual rotation after instrumental rotation), we will examine the robustness of the conclusions using appropriate sensitivity analyses including a per protocol analysis (i.e. restricting the analysis data set to those women who received the allocated intervention only) on the two co-primary outcomes. In two recent studies (16,17) the rate of cross-over was 0% after rotational forceps, and 0.6% (1/163) after manual rotation, representing a single case in one study (17). In the same study (17), although a second instrument was used in 36.9% of cases after rotational ventouse, this typically involved the use of forceps to complete the birth and therefore was not a cross-over from ventouse to manual rotation . Therefore, we expect the rate of cross-over between the two intervention groups to be very low – the 95% confidence interval for a rate of 1/163 is: 0.01 to 3.37%.

Full details will be included in the Statistical Analysis Plan.

14.3. Interim Analyses

Interim analyses of safety and efficacy will be presented to the independent DMC/Trial Oversight Committee during the trial. This is likely to include the analysis of the primary and major secondary outcomes and full assessment of safety (SAEs) at least at annual intervals. Criteria for stopping or modifying the trial based on this information will be ratified by the DMC. Details of the agreed plan will be written into a DMC Charter and the Statistical Analysis Plan. Further details of DMC arrangements are given in section 17.5.

14.4. Planned Final Analyses

The primary analysis for the trial will occur once all participants have completed the 3-month follow up assessment and corresponding outcome data has been entered onto the trial database and validated as being ready for analysis. This analysis will include data items up to and including the 3-month follow up assessment and no further.

15. HEALTH ECONOMICS

No Health Economic evaluation is planned for this trial.

16. SUB-STUDY 1: QUALITATIVE PROCESS EVALUATION

16.1. Aim

To qualitatively explore the feasibility, acceptability and appropriateness of the intervention and trial (including consent) processes for women and their birth partners, and healthcare professionals involved in delivering the pilot trial.

16.2. Objectives

1. With women: to explore their views and experiences of the recruitment approach, voluntariness, consent processes, randomisation, barriers and facilitators to participation, and acceptability of treatment allocations

2. With healthcare professionals: to explore their views and experiences of recruitment, consent processes, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of treatment allocations, and perceptions of trial processes.
3. With partners: to explore their views and experiences of being present during the trial recruitment approach, and their perception of acceptability of treatment allocations

16.3. Outcomes

This pragmatic qualitative process evaluation is aligned with the MRC framework for evaluation of complex interventions (34). The primary outcome of the qualitative process evaluation is to explore the feasibility, acceptability and appropriateness of the trial and intervention for women, their birth partners and healthcare professionals (HCPs). The results will dynamically inform decision-making around progression to a full trial and study design and processes. In addition, the results may help to (a) inform improvements to NHS care for women with persistent malposition of the fetal head; (b) inform future national guidelines and compulsory obstetric training.

16.4. Methodological approach and theoretical positioning

The qualitative research will be guided by interpretive descriptive (ID) methodology.(35) ID is aligned with a constructivist and naturalistic orientation to inquiry (36), the purpose of which is to capture themes and patterns within subjective perceptions of experiences and generate an interpretive account capable of informing clinical understanding and decision making (37). This is directly aligned with the aim of the qualitative process evaluation within ROTATE. ID acknowledges the theoretical and practical knowledge that researchers bring to a study and clinical expertise is acknowledged as a useful starting place for orienting and designing the research particularly when the area of inquiry has yet to be evaluated rigorously (36) as is the case with malposition of the fetal head. Knowledge from a range of sources (e.g. current evidence base and clinical expertise) will form the theoretical scaffolding from which the researchers will undertake the qualitative inquiry within ROTATE and this will be challenged and refined as the research progresses (36,37).

16.5. Eligibility

16.5.1. Inclusion

- All women eligible for ROTATE and who are approached about the trial, irrespective if they agree to participate or not
- The birth partners of all those participants who are approached about the trial, and agree that their partner(s) can be contacted by the qualitative study team
- All healthcare professionals caring for women in and involved in the delivery of ROTATE
- Those able and willing to give informed consent

16.5.2. Exclusion

- Participants who would be unable to take part in an interview due to language barriers (interviews will be undertaken in English)
- Birth partner(s) whose partner had declined them being contacted by the qualitative study team

16.6. Participant identification and-recruitment

Women:
Women will be approached to participate in an interview after they are approached to participate in the trial, whether they consent to the trial or not. If they verbally consent to potentially taking part

in an interview, they will be asked to provide their contact details (via a consent to contact form) to the recruiting clinician who will pass these details on to the qualitative research team.

In addition, recruiting clinicians and midwives will review their site-specific screening logs and notes of all women approached about the trial. Where there is no documented evidence of discussion about the qualitative process evaluation or where women have asked to be contacted about the qualitative study at a later time the research midwives will follow up women with a letter specific to their decision about participating in the trial (e.g. decliner or randomised). The notes review and follow up letters will be sent within approximately 4 weeks of the approach about the trial. Women who have clearly declined participation in the qualitative study will not be contacted via letter.

Birth Partners:

Birth partners will be approached for recruitment via the HCP following consent from their partner.

Where a woman is approached about the qualitative process evaluation at site, and completes the consent to contact form which indicates they are happy for their partner(s) to be approached about the QPE. Where this is the case a consent to contact form will be completed at site and these details will be passed to the qualitative research team using the same mechanisms as for the birthing partner consent to contact.

HCPs:

HCPs (clinicians involved in recruitment and randomisation and midwives involved in the care of women approached about the trial) involved in delivery of ROTATE will be approached directly by the qualitative process evaluation research team after being identified from the delegation logs, snowballing within sites, and through collaborator events and established clinical networks.

16.7. Consent and withdrawal

Written record of informed consent to participate in a qualitative interview will be sought wherever possible. However, for example, in cases where the study related paperwork has not been received, not fully completed, or there are issues around written literacy then we will seek alternative forms of informed consent including electronically completed (e.g. electronic completion of the form and scanning/photo of the completed consent form returned) or verbal (e.g. where the consent form will be read out in full and audio recorded as a separate audio file at the start of the interview).

Informed consent (including written, electronically completed and/or verbal (that is audio recorded)) will include agreement to participate, demographic data collection, audio recorded discussion, and anonymised data sharing.

At the beginning of each audio recording, participants who have completed written or electronic consent processes will be asked to verbally re-confirm consent. Where formal verbal informed consent is being sought at the start of a virtual interview, then the audio recorder will be switched on and the consent form will be read out, and the participant asked to consent to each statement. Should the participant not consent to any of the statements then the interview will be terminated at that point having explained to that participant that data collection cannot continue, as they did not consent to participate.

Following consent, a new audio recording will be started for the interview. Once verbal consent has been sought the first audio file will be closed. A member of the Qualitative research team within the University of Birmingham will transcribe the consent audio file to create formal record of consent or

declined consent. This transcript will be stored securely and separately from the transcript of the main interview (if consent was gained).

If the participant does give consent then the study interview will commence and be recorded in a second audio file. Only this second file will be sent to a third party company for transcription.

Interview participants will be free to withdraw within two weeks after the data collection event without having to explain or justify their decision.

16.7.1. Inconvenience Allowances and Expenses

Women and their birth partners will receive a £25 electronic voucher (e.g. Amazon) for participation in an interview. This covers £20 for participating and £5 for consumables such as electricity/internet access given that we anticipate the majority of interviews will be held remotely. Participants who take part face to face will still receive £25. If women travel to participate (e.g. to the University) then all reasonable travel expenses will be reimbursed. Healthcare professionals who travel to participate (e.g. to the University) will have any reasonable travel expenses reimbursed.

16.8. Data collection

In the first instance, participants will be invited to participate in an interview via telephone/video conference (e.g. Zoom, Skype or WhatsApp). To ensure inclusivity, where participants are unable to participate virtually, we may consider face to face interviews in the clinic where they were treated/work, at the University of Birmingham or University College London (if local to either), in the participant's home or in an appropriate public space. We will ensure that we are following appropriate COVID related guidance if interviews are undertaken face to face. From experience, we anticipate that the vast majority will be done virtually.

For women, we will aim to conduct interviews within four to eight weeks of them being approached to participate (decliners) or being randomised (women who consent to randomisation). This will however remain flexible to accommodate the needs of the women. For birth partners, we will aim to interview them within two to four weeks of interviewing the woman within their dyad. Again, this will remain flexible.

A discussion guide to facilitate the interviews will be developed informed by existing literature (for example the domains proposed in the Theoretical Framework for Acceptability of Healthcare Interventions (38), patient and public involvement, and discussions within the ROTATE team. Interviews will be conducted in a participant-focused manner allowing issues and perspectives important to participants to arise naturally (39).

For women, interviews will explore their views and experiences of the treatment options (including perceived risks around instrumental intervention such as forceps), the recruitment approach, voluntariness, consent processes, randomisation, barriers and facilitators to participation, acceptability of randomisation, and experiences of care pre- and post-intervention.

For partners, interviews will explore their views and experiences of being present during the recruitment approach, their perceptions of voluntariness and consent processes of the trial. The acceptability of randomisation, and perceptions and experiences of their partners care pre- and post-intervention.

For healthcare professionals, interviews will explore their familiarity with, and exposure to, different types of interventions (manual, instrumental); training and confidence in the different interventions; views and experiences of recruitment, consent processes, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of the intervention, and perceptions of trial processes.

Participants will be given the choice as to where an interview takes place (e.g. via phone, video call, or face to face). We anticipate that we will use a blended approach of face-to-face and virtual data collection given the current COVID situation, social distancing and to maximise the facilitation of a large number of interviews/focus groups in a short period of time. There is also growing evidence that rapport can be readily established using remote techniques (40); and that the flexibility and adaptability afforded by technology minimises inconvenience and disruption to participants (41,42).

All participants will be asked to complete a brief demographic questionnaire prior to or at the end of the interview to facilitate purposive sampling and a description of the sample.

16.9. Anticipated sample sizes

We aim to undertake semi-structured one to one interviews across the sites (anticipated n = 12) involved in the internal pilot and will attempt to purposively recruit participants from the following groups (number of interviews per group provided in brackets):

a. women who decline to participate (n~5-7)
b. women randomised to instrumental rotation group (n~10-14)
c. women randomised to manual rotation group (n~10-14)
d. birth partner(s) of participants in the afore-mentioned groups (n~5-7)
e. healthcare professionals involved in recruitment and randomisation (n~12-15)
f. midwives involved in the care of women who are approached (n~8-10)

The internal pilot will be open for 9 months across approximately 12 trial sites. Based on recruitment projections for the trial, approximately 437 women will have been recruited and randomised during the 9 months of qualitative data collection. Our aim is therefore to interview roughly 6-8% of these women.

From experience, we expect the final sample to include approximately 35-70 interviews (both women, birth partners and HCPs) but the numbers will remain flexible to ensure that we collect sufficiently rich data to address the aim and objectives of the study.

16.10. Data analysis

Interviews will be audio recorded, with data collection and initial analysis taking place iteratively (43). Data collection will continue until the research team judge that the data and sample had sufficient depth and breadth to address the study aims (44). We will not be aiming for saturation of data, as this concept is not epistemologically aligned with the methodological approach. Rather, meanings will be generated and constructed through situational, interpretative engagement with the data. Audio files will be auto transcribed via the online platform (e.g. Zoom) or will be transcribed clean verbatim by an external specialist transcription company who will comply with GDPR. The framework approach (FM) (45) used to facilitate a systematic and flexible approach to the analysis. The FM is not aligned with a particular epistemological, philosophical or theoretical stance (i.e. it is a-theoretical) rather it is a flexible tool that facilitates the generation of themes (45). It can therefore be adapted for use with ID methodology as ID aims to identify thematic patterns and commonalities, as well as accounting for individual variation in experience within the interpretive account. Data management will be supported by the use of NVivo software and inductive analysis will be guided by the seven stages of FM proposed by Gale et al. (45): (1) transcription, (2) familiarisation, (3) coding, (4) development of a working analytical framework, (5) application of the analytical framework, (6) charting date in the framework matrix, and (7) interpretation of data [6]. We will provide dynamic feedback to the Trial Management Group to improve and streamline processes and ensure we learn lessons and continuously improve the trial processes during the pilot.

Data from the qualitative process evaluation will support Trial Steering Committee decision making about progression to a full trial.

Demographic questionnaire data will be entered into an appropriate statistical software to facilitate descriptive analysis and reporting.

16.11. Management of risk

Given the nature of the discussions, there is potential that the participants in this study will be distressed as a result of participating in an interview. Trained qualitative researchers will undertake data collection guided by Dempsey *et al* framework of essential elements for conducting qualitative research given the potentially sensitive issues that may emerge in discussions (46). Distressing topics will be handled sensitively and we will follow a study specific distress pathway including signposting to additional support as appropriate (47).

All participants will self-select to take part. The welfare of the participants will always be placed ahead of the knowledge to be gained and emotionally distressing topics will be handled with sensitivity and sympathy. The interviewer will also signpost the distressed participant towards services for additional support should this be appropriate. Information on support services is also provided in the participant information leaflet. We have sought PPI input to ensure that all participant facing materials and the interview questions are appropriate.

If a participant raises issues about their care that the qualitative research team deem as potentially harmful to them (or others) then the researcher will advise them to contact their local Patient Advice and Liaison Service (PALS) (or equivalent) whose contact details are provided in the PIS. The leads for the QPE, Dr Laura Jones and Dr Jacqueline Nicholls, will also inform the CI. The CI, where appropriate, will ensure that the local unit PI is aware of the woman and potential concerns so that follow-up can be arranged if required. Should a participant have questions about their clinical care then the qualitative research team will advise the woman to contact her clinical team and/or her GP.

It is likely that the majority of interviews will be undertaken virtually thus reducing the potential research related risks to the research team. If interviews are conducted face to face then the relevant lone worker policy (e.g. University of Birmingham, University College London) will be followed alongside relevant COVID guidance. Researchers will complete a reflective note after each interview. They will also be provided with safe spaces to debrief with the senior qualitative researchers to support the potentially difficult stories heard as part of the data collection and analysis.

16.12. Nesting within the ROTATE Trial

Recruitment to the qualitative study will begin in parallel with the pilot trial with qualitative data collection for 9 months. This will include dynamic feedback in real time to allow the TMG to be adaptive to any problems identified and increase the likelihood of the pilot moving to full RCT. Final analysis and initial write up will be undertaken prior to the pilot review DMC meeting.

17. TRIAL ORGANISATIONAL STRUCTURE

17.1. Sponsor

UCL is the Sponsor

17.2. Coordinating Centre

The trial coordinating centre (Trial Office) is Birmingham Clinical Trials Unit, based at UoB.

17.3. Trial Management Group

We will follow NIHR guidance for project oversight and governance.

A Trial Management Group (TMG) will direct and oversee the running of the trial and will include the two PPI co-applicants as active members, and the CIs' mentor (Brocklehurst).

The Trial Management Group will be responsible for the day-to-day management of the trial and also include: one CIs, statistician(s), trial team leader, trial manager, data manager, and core co-applicants. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself. The TMG will meet sufficiently frequently to fulfil its function; this will be fortnightly or monthly dependent on trial stage.

17.4. Trial Steering Committee

A Trial Steering Committee (TSC), with an independent chair, will be constituted to oversee, advise on and monitor the trial.

The role of the Trial Steering Committee (TSC) is to provide oversight of the trial. The TSC will monitor trial progress and conduct, and provide advice on scientific credibility. The TSC will meet at least annually.

The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring Committee (DMC). The TSC will operate in accordance with a trial specific TSC Charter.

The role of the TSC will be:

- To provide advice, through its Chair, to the Trial/Project Funder, the Trial/Project Sponsor, the Chief Investigator, the Host Institution and the Contractor on all appropriate aspects of the project
- To concentrate on progress of the trial/project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the trial/project.

The composition of the TSC will include 75% independent members including:

- An Independent Chair (UK based and/or holding a substantive UK based appointment)
- Independent statistician/methodologist
- At least 2 PPI members from: PPI co-applicants, lay PPI panel, senior PPI Board
- At least one topic expert
- The TSC will invite observers, including a representative of the sponsor and a representative from the research network to meetings as appropriate. Attendance at TSC meetings by non-members will be at the discretion of the Chair.

Only appointed members will be entitled to vote, and the Chair will have a casting vote. The minimum quoracy for a meeting will be two/thirds of appointed members. The Chair and members will sign and maintain a log of potential conflicts and/or interests. The NIHR Programme Director will review the nominees and appoint the Chair and members.

17.5. Data Monitoring Committee

A Data Monitoring Committee (DMC), with independent members, will be constituted to oversee, advise on and monitor the trial. DMC will meet at least annually, and will have 3-4 independent (as per NIHR guidance) members, including topic and methodology experts, a statistician and at least one member who is UK based and/or holding a substantive UK based appointment.

The DMC's main role will be as follows:

- It will be the only body with access to unblinded comparative data
- DMC will monitor these data and make recommendations to the TSC on whether there are any ethical or safety reasons why the trial should not continue
- The DMC will consider the need for any interim analysis advising the TSC regarding the release of data and/or information
- The DMC may be asked by the TSC, Project Sponsor or Project Funder to consider data emerging from other related studies. The DMC chair might be asked by the Project Funder to provide a confidential interim or futility analysis if serious concerns are raised about the viability of the study or if the research team are requesting significant extensions.

Data analyses will be supplied in confidence to an independent Data Monitoring Committee (DMC). The DMC will be asked to give advice on whether the accumulated data from the trial, together with the results from other relevant research, justifies the continuing recruitment of participants. The DMC will operate in accordance with a trial specific DMC Charter. The DMC will meet at least annually as agreed by the Committee and documented in the Charter. More frequent meetings may be required for a specific reason (e.g. safety phase).

Additional meetings may be called if recruitment is much faster than anticipated and the DMC may, at their discretion, request to meet more frequently or continue to meet following completion of recruitment. An emergency meeting may also be convened if a safety issue is identified. The DMC may consider recommending the discontinuation of the trial if any issues are identified which may compromise participant safety. The DMC may recommend early stopping of the trial if the interim analyses shows differences between treatments that are deemed to be convincing to the clinical community. Further details on the trial stopping guidelines will be outlined in the DMC Charter and the Statistical Analysis Plan.

17.6. Finance

The research costs of the trial are funded by Health Technology Assessment grant awarded to Dimitrios Siassakos of University College London. The trial has been designed to minimise extra 'service support' costs for participating hospitals as far as possible. Additional costs, service support costs and excess intervention costs associated with the trial, e.g., gaining consent, are estimated in the Statement of Activities. These costs should be met by accessing the Trust's Support for Science budget via the Local Comprehensive Research Network.

The study will be eligible for portfolio adoption. The network has well established infrastructure that has previously delivered several large HTA funded studies nationally.

18. ETHICAL CONSIDERATIONS

The trial will be conducted in accordance with the UK Policy Framework for Health and Social Care Research 2017 and applicable UK Acts of Parliament and Statutory Instruments (and relevant subsequent amendments), which include Data Protection Act 2018; and the Principles of GCP as set out in the UK Statutory Instrument (2004/1031; and subsequent amendments). The protocol will be submitted to and approved by the REC prior to the start of the trial.

Before any participants are enrolled into the trial, the PI at each site will obtain local R&D approval/assurance. Sites will not be permitted to enrol participants until written confirmation of R&D approval/assurance is received by the BCTU trial team.

It is the responsibility of the PI to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual clinicians' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.

19. CONFIDENTIALITY AND DATA PROTECTION

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 2018 (and subsequent amendments). Personal data categories that will be collected and analysed include date of birth, NHS hospital number, medical history.

Participants will always be identified only by their unique trial identification number (or qualitative study ID), on the CRF, audio recordings and on any correspondence with the BCTU/qualitative study team. Participants will acknowledge the transfer and storage of their informed consent form to the Trial Office. This will be used to perform in-house monitoring of the consent process.

The PI must maintain documents not for submission to BCTU (e.g. Participant Identification Logs) in strict confidence. In the case of specific issues and/or queries from the regulatory authorities, it will be necessary to have access to the complete trial records, provided that participant confidentiality is protected.

BCTU will maintain the confidentiality of all participant's data and will not disclose information by which participants may be identified to any third party other than those directly involved in the treatment of the participant and organisations for which the participant has given explicit consent for data transfer. Representatives of the trial office and sponsor may be required to have access to participant's notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times. If any risks are disclosed to the participants or researchers, then the relevant authority will be informed e.g.:

- Occupational health for members of staff
- Hospital security for immediate threats
- GP and/or social services for disclosure of women or families at risk e.g. suicide, domestic abuse
- Line managers for disclosure of harm to patients

20. FINANCIAL AND OTHER COMPETING INTERESTS

The Chair and members of the TSC will sign and maintain a log of potential conflicts and/or interests. There have been no declared conflicts of interest. The co-applicants lead several national initiatives to improve operative birth on a strict not for-profit basis, for example ROBUST training.

21. INSURANCE AND INDEMNITY

UCL has in place Clinical Trials indemnity coverage for this trial which provides cover to UCL for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at UCL's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility for the care of the patients remains with the NHS organisation responsible for the Clinical Site and is therefore indemnified through the NHS Litigation Authority.

UCL is independent of any pharmaceutical company and as such, it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation.

22. AMENDMENTS

The decision to amend the protocol and associated trial documentation will be initiated by the TMG.

As sponsor, UCL will be responsible for deciding whether an amendment is substantial or non-substantial.

Substantive changes will be submitted to REC and HRA for approval. Once this has been received, R&D departments will be notified of the amendment, and requested to provide their approval. If no response is received within 35 days, an assumption will be made that the site has no objection to the amendment and it will be implemented at the site.

All amendments will be tracked in the 'Protocol Amendments' section of the protocol.

23. POST-TRIAL CARE

All patients will continue to receive standard medical care following participation in the clinical trial. There are no interventions that participant's will be prevented from accessing after their participation in the trial has been completed.

24. ACCESS TO FINAL DATASET

The final dataset will be available to members of the Trial Management and co-applicant group who need access to the data to undertake the final analyses.

24.1. Data Sharing

Requests for data generated during this study will be considered by BCTU. Data will typically be available within six months after the primary publication unless it is not possible to share the data (for example: the trial results are to be used as part of a regulatory submission, the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).

Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the Chief Investigator and, where appropriate (or in absence of the Chief Investigator) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent Trial Steering Committee (TSC).

A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers transfer of patient identifiable information. Any data transfer will use a secure and encrypted method.

25. PUBLICATION POLICY

The publication policy will be governed by the Trial Steering Committee.

25.1. Public engagement

We will create a dedicated website to communicate the progress and findings. Our patient/public partners (NCT, BTA, Bliss, and the Senior PPI Board) as well as other charities and parent support groups that we work with closely will disseminate the results to parents through their networks. The study team, supported by academic and patient/public partners will actively use their highly visible social media profiles (Twitter, Facebook, Mumsnet, Instagram) to disseminate approved short vignettes, graphics, and videos of the study findings to the widest possible audience.

25.2. Professional stakeholder engagement

We will work with the NIHR research networks, Academic Health Science Networks and Applied Research Collaborations. Our findings will inform evidence to support the professional evaluation of guidance on operative birth via the RCOG and NICE. We will prepare a slide set for participating professionals to disseminate findings. We plan to present ROTATE findings to NHS England Specialist Commissioning through the Women and Children's Programme of Care so that findings are considered within their parallel Quality and Safety Reviews, as part of the ongoing quality improvement programme. We are working closely with NHS England on optimising consent in maternity and particularly operative birth.

25.3. Academic stakeholders & outputs

We expect the results to be published in high impact factor peer reviewed journals including The Lancet, British Medical Journal and An Intonation Journal of Obstetrics and Gynaecology. We will also submit the study protocol to a relevant journal (e.g. Trials).. The National Institute for Health Research Library will promote key messages and reports.

We are proactive members of societies, including key positions to promote best practice (through courses and guidelines). Examples include Royal College of Obstetricians and Gynaecologists, Royal College of Midwives, and the British Maternal and Fetal Medicine Society. National and international congresses will be targeted to disseminate knowledge through the academic community.

25.4. Training at the frontline of care – pathway to practice improvement

The CI is national Convenor for the ROBuST (RCOG Operative Birth using Simulation Training) course. He will oversee quality assurance including of local trainee and train-the-trainer courses across the UK, as well as future development of this educational package. Key findings from ROTATE will inform future iterations of the course, which is mandatory for RCOG trainees; for example, by placing emphasis on the rotational birth intervention that is proven more effective and safer, and/or by informing the consent process with regards to accurate rates of risks involved for all rotational interventions; as described previously in the 4 possible scenarios for the primary outcomes (superiority & non-inferiority).

25.5. Publication

On completion of the trial, the data will be analysed and a Final Study Report prepared. Results of this trial will be submitted for publication in a peer reviewed journal.

Authorship will be determined by this trial publication policy:

25.5.1. Group authorship

- Group authorship will be appropriate for some publications. This will apply when the intellectual work underpinning a publication has been carried out by a group, and no one person can be identified as having substantially greater responsibility for its contents than others. In such cases the authorship will be presented by the collective title - **The ROTATE Study Group** - and the article should carry a footnote of the names of the people (and their institutions) represented by the corporate title.
- Local Principal Investigators and Local Trainee Champions would be named as 'collaborators' as part of the Rotate Study Group in the publication of main trial results.
- In some situations, one or more authors may take responsibility for drafting the paper but **all** group members qualify as members; in this case, this should be recognised using the by-line 'Jane Doe, John Doe … ***and*** the ROTATE Study Group'. In such instances where individual authors are named, Prof Siassakos and Dr Napolitano have agreed to alternate first and senior (or joint first, if allowed by the journal) authorship.

- Group authorship may also be appropriate for publications where one or more authors take responsibility for a group, in which case the other group members are **not** authors but may be listed in the acknowledgement (the by-line would read 'Jane Doe, John Doe … ***for*** the ROTATE Study Group'). On secondary papers where others might be first authors, Prof Siassakos and Dr Napolitano will alternate senior authorship as applicable.

25.5.2. Individual authorship

Other papers, such as describing satellite studies, will have individual authorship. In order to qualify for authorship an individual must fulfil the following criteria:

- Each author should have participated sufficiently in the work represented by the article to take public responsibility for the content.
- Participation must include three steps:
    - Conception or design of the work represented by the article OR analysis and interpretation of the data OR both; AND
    - Drafting the article or revising it for critically important content; AND
    - Final approval of the version to be published.

Participation solely in the collection of data is insufficient by itself. Those contributors who do not justify authorship may be acknowledged and their contribution described.

Local Principal Investigators and Local Trainee Champions would be named as 'co-authors' in secondary publications should the journal allow a large numbers of named authors.'

Individual journal policies will be followed as appropriate.

25.5.3. Determining authorship

Tentative decisions on authorship should be made as soon as possible. These should be justified to, and agreed by, the Trial Management Group. Any difficulties or disagreements will be resolved by the Trial Steering Committee. If individual members of the group are dissatisfied by a decision, they can appeal to the Trial Management Group for reconciliation. If this cannot be achieved, the matter should be referred to the Trial Steering Group.

25.5.4. Quality assurance

Ensuring quality assurance is essential to the good name of the study group. For reports of individual projects, internal peer review among members of the Trial Management Group is a requirement

prior to submission of papers. All reports of work arising from the ROTATE study including conference abstracts should be peer reviewed by the Trial Management Group.

The internal peer review for reports of work arising from the ROTATE Study is mandatory and submission may be delayed or vetoed if there are serious concerns about the scientific quality of the report. The Trial Management Group will be responsible for decisions about submission following internal peer review. If individual members of the group are dissatisfied by decisions, the matter may be referred to the Trial Steering Group.

Any secondary publications and presentations prepared by Investigators must be reviewed and approved by the TMG. Manuscripts must be submitted to the TMG in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. The Trial Management Group undertakes to respond to submission of articles for peer review at Trial Management Group Meetings following submission (assuming the report is submitted to the CI at least two weeks prior to the meeting).

We will submit the trial protocol for publication in an open access journal for public scrutiny, before submission of the trial findings.

In all publications, authors must acknowledge that the trial was performed with the support of UCL and BCTU.

Intellectual property rights will be addressed in the *Clinical Study Site Agreement* between Sponsor and site.

All funding and supporting bodies, including NIHR HTA, NIHR Biomedical Research Centre and Wellcome/EPSRC Centre for Interventional and Surgical Sciences (WEISS), will be acknowledged within the publications.

We will notify the participants of the outcome of the trial by provision of the publication and via a specifically designed newsletter. Participants can specifically request results from their PI after the results have been published.

The costs for dissemination include open-access fees for the final results publication, to enable parents and parent representatives to read and discuss the findings. This includes NCT practitioners, Positive Birth Movement groups, reps on the Maternity Voice Partnership and Maternity Services Liaison Committees, doulas and other health educators who do not have access to a medical library.

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