Multi-centre randomised trial to compare Manual vs. Instrumental Rotation of the fetal head at full cervical dilatation
The ROTATE Trial

Trial Registration: ISRCTN10193017

Statistical Analysis Plan

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Statistical Analysis Plan (SAP) Amendments

SAP version number	SAP section number	Description of and reason for change	Timing of change with respect to interim analysis/ final analysis/ database lock	Blind Reviewer (if blind review not required put N/A in name row)	
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				Date:	

Abbreviations & Definitions	
Abbreviation / Acronym	**Meaning**
BCTU	Birmingham Clinical Trials Unit
CACE	Complier Average Causal Effect
CONSORT	Consolidated Standards of Reporting Trials
DMC	Data Monitoring Committee
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention to Treat
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SUSAR	Suspected Unexpected Serious Adverse Reaction
TSC	Trial Steering Committee
Term	**Definition**
International Standard Randomised Controlled Trial Number	A clinical trial registry
Protocol	Document that details the rationale, objectives, design, methodology and statistical considerations of the study
Randomisation	The process of assigning trial subjects to intervention or control groups using an element of chance to determine the assignments in order to reduce bias.
Statistical Analysis Plan	Pre-specified statistical methodology documented for the trial, either in the protocol or in a separate document.

TABLE OF CONTENTS

1. Introduction

This document is the Statistical Analysis Plan (SAP) for the ROTATE trial, and should be read in conjunction with the current trial protocol. This SAP details the proposed analyses and presentation of the data for the main paper(s) reporting the results for the ROTATE trial.

The results reported in these papers will follow the strategy set out here. Subsequent analyses of a more exploratory nature will not be bound by this strategy, though they are expected to follow the broad principles laid down here. The principles are not intended to curtail exploratory analysis (e.g. to decide cut-points for categorisation of continuous variables), nor to prohibit accepted practices (e.g. transformation of data prior to analysis), but they are intended to establish rules that will be followed, as closely as possible, when analysing and reporting data.

Any deviations from this SAP will be described and justified in the final report or publication of the trial (using a table as shown in Appendix A). The analysis will be carried out by an appropriately qualified statistician, who should ensure integrity of the data during their data cleaning processes.

2. Background and rationale

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 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 and reduction of life quality.
Caesarean section at full dilatation, however, is a risky procedure for mothers and babies and can cause preterm birth in future pregnancy.

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. Despite those initiatives, severe perineal tearing has risen from 1.8% in 2000 to 5.9% in 2011 among first-time mothers.
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.

3. Trial objectives

The primary objective is 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 are as follows:

- 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 head for future long-term follow-up
- 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

4. Trial methods

4.1. Trial design

ROTATE is a pragmatic, multi-centre, 2-arm parallel group, open-label, randomised controlled trial. Randomisation is 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 Appendix B for trial schema.

Participants will be recruited from NHS consultant-led maternity units in the UK.

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

4.2. Trial interventions

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.

4.3. Randomisation

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

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.

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)

The minimisation algorithm is provided by the Health Services Research Unit at the University of Aberdeen. Full details of the algorithm used will be stored in a confidential document at the Health Services Research Unit at the University of Aberdeen.

4.4. Timing of outcome assessments

The schedule of trial procedures and outcome assessments are given in Appendix C

4.5. Primary outcome measure

There are two co-primary outcomes:

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*)*

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).

See Appendix D: Data manipulations for how the primary outcomes will be derived.

4.6. Secondary outcome measures

The secondary outcomes are as follows:

NEONATAL

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

- A composite outcome assessed at discharge from hospital and comprising 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

- 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 before rotation (at diagnosis) using a pre-formatted ROTATE diagram (clock). One of:
  - right occiput anterior (ROA),
  - direct occiput anterior (DOA),
  - left occiput anterior (LOA),
  - right occiput transverse (ROT),
  - direct occiput transverse (DOT),
  - left occiput transverse (LOT),
  - right occiput posterior (ROP),
  - direct occiput posterior (DOP),
  - left occiput posterior (LOP).

- Use of ultrasound to diagnose position before rotation: Yes/No

- Position of the fetal head at birth using a pre-formatted ROTATE diagram (clock). One of:
  - right occiput anterior (ROA),
  - direct occiput anterior (DOA),
  - left occiput anterior (LOA),
  - right occiput transverse (ROT),
  - direct occiput transverse (DOT),
  - left occiput transverse (LOT),
  - right occiput posterior (ROP),
  - direct occiput posterior (DOP),
  - left occiput posterior (LOP).
- NB: If rotation to a direct occipito-posterior position took place, whether accidentally or on purpose (binary).

- If used, the position of the ventouse cup, using a pre-formatted ROTATE diagram. One of:
  - flexing median,

- deflexing median,
- flexing paramedian,
- deflexing paramedian.

- Forceps marks on the baby :
  - Right blade – any that apply of:
    - normal,
    - over >50% orbit,
    - not reaching jaw
  - Left blade - any that apply of:
    - 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).
- Change from rotational ventouse to rotational forceps (both rotational ventouse and rotational forceps are in the same trial arm).
- 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.

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): defined as 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)[9]

The CEQ has 22 statements assessing four domains of childbirth experience. 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)[7]

The CliSQ 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)

- Urinary incontinence:
  - ICIQ (International Consultation on Incontinence Questionnaire) score[11]
    - 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[12]
    - 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).

- 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*)

- PTSD symptoms:
    - CITY Birth Trauma Scale[13]

See Appendix D: Data manipulations for how the secondary outcomes will be derived.

4.7. Sample size

Superiority: We meta-analysed results from 5 recent studies[1–3, 5, 6] 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[4], 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.

4.8. Framework

The objectives of the trial are different for each of the two co-primary outcomes.

For the co-primary outcome of third/forth degree perineal trauma involving anal sphincter complex diagnosed on clinical vaginal/rectal examination after birth, the objective of the trial is to test the superiority of one intervention to another.

The null hypothesis is that there is no difference in the co-primary outcome of Third/forth degree perineal trauma involving anal sphincter complex diagnosed on clinical vaginal/rectal examination after birth (superiority co-primary outcome) between the intervention groups.
The alternative hypothesis is that there is a difference between the groups.

For the co-primary outcome of caesarean section, the objective of the trial is to test the non-inferiority of one intervention to another.

The null hypothesis is that the percentage of patients experiencing caesarean section is at least 3.5% higher in the manual rotation group than in the instrumental rotation group (i.e. manual rotation is inferior). The alternative hypothesis is that the percentage of patients experiencing caesarean section is less than 3.5% higher in the manual rotation group than in the instrumental rotation group (i.e. manual rotation is not inferior).

4.9. Interim analyses and stopping guidance

A separate Data Monitoring Committee (DMC) reporting template will be drafted and agreed by the DMC including an agreement on which outcomes will be reported at interim analyses. The statistical methods stated in this SAP will be followed for the outcomes included in the DMC report, where possible. Criteria for stopping or modifying the trial based on the information in the interim report will be ratified by the DMC.

4.10. Internal Pilot Progression Rules

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

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.

Progression Criteria

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%

Predicted site and patient recruitment for pilot phase

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

4.11. Timing of final analysis

The final 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). This is provided that the trial has not been stopped early for any reason (e.g. DMC advice or funding body request).

4.12. Timing of other analyses

Not Applicable

4.13. Trial comparisons

All references in this document to 'group' refer to manual or instrumental rotation of the fetal head in malposition at birth.

5. Statistical Principles

5.1. Confidence intervals and p-values

All estimates of differences between groups will be presented with two-sided 95% confidence intervals, unless otherwise stated. P-values will be reported from two-sided tests at the 5% significance level.

5.2. Adjustments for multiplicity

No correction for multiple testing will be made.

5.3. Analysis populations

All primary analyses (primary and secondary outcomes including safety outcomes) will be based on the intention-to-treat (ITT) principle. Participants will be analysed in the intervention group to which they were randomised, and all participants shall be included whether or not they received the allocated intervention. This is to avoid any potential bias in the analysis.

5.4. Definition of adherence

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

1. Randomised Technique
2. Rotational Technique used first – reasons why if different from 1.
3. Rotational Technique used second – if the first failed
4. 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.

Adherence will be monitored through a checklist on the Day 0 CRF (see Appendix D for more details).

5.5. Handing protocol deviations

A protocol deviation is defined as a failure to adhere to the protocol such as errors in applying the inclusion/exclusion criteria, the incorrect intervention being given, incorrect data being collected or measured, follow-up visits outside the visit window or missed follow-up visits. We will apply a strict definition of the ITT principle and will include all participants as per the ITT population described in section 5.3 in the analysis, in some form, regardless of deviation from the protocol[14]. This does not include those participants who have specifically withdrawn consent for the use of their data in the first instance; however these outcomes will be explored as per other missing responses.

A table on schedule of submission of each form can be seen below:

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
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

The 48 hours questionnaires (Follow up and Breastfeeding) will be considered to have been completed on time if they have been completed within 48 hours. The three month breastfeeding questionnaires will be considered on time provided they have been completed prior to four months since the birth. In the first instance, all data will be included in the primary

analysis regardless of date of completion, but proportion of forms that were completed outside of the acceptable window will be reported.

5.6. Unblinding

Not applicable, ROTATE is an Open study.
This is an unblinded study, and due to the nature of some secondary outcomes and measures of adherence, interim analyses will not be produced blind to trial arm (i.e. A vs. B).

6. Trial population

6.1. Recruitment

A flow diagram (as recommended by CONSORT[15, 16]) will be produced to describe the participant flow through each stage of the trial. This will include information on the number (with reasons) of losses to follow-up (drop-outs and withdrawals) over the course of the trial. A template for reporting this is given in Appendix E1.

6.2. Baseline characteristics

The trial population will be tabulated as per Appendix E2. Categorical data will be summarised by number of participants, counts and percentages. Continuous data will be summarised by the number of participants, mean and standard deviation if deemed to be normally distributed or number of participants, median and interquartile range if data are skewed, and ranges if appropriate. Tests of statistical significance will not be undertaken, nor confidence intervals presented.[17]

7. Intervention(s)

7.1. Description of the intervention(s)

A template for reporting information on the intervention(s) is given in Appendix E3.

7.2. Adherence to allocated intervention

A cross-tabulation of allocated intervention by the adherence categories stated in section 5.4 will be produced (proportions and percentages). A template for reporting adherence is given in Appendix E4.

8. Protocol deviations

Frequencies and percentages by group will be tabulated for the protocol deviations as per Appendix E5.

9. Analysis methods

Intervention groups will be compared using regression models to adjust for all covariates as specified in section 9.1, where possible.

9.1. Covariate adjustment

In the first instance, intervention effects between groups for all outcomes will be adjusted for the minimisation parameters listed in section 4.3: centre and baby's position. Categorised continuous variables (e.g. age) will be treated as continuous variables in this adjustment. Other covariate adjustment will be baseline values for parameters where available. All covariates will be included in the models as fixed effects, except centre which will be treated 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[18]. If this also fails to converge, unadjusted estimates will be produced from the log-binomial model. It will be made clear in the final report why this occurred (e.g. not possible due to low event rate/lack of model convergence).

9.2. Distributional assumptions and outlying responses

Distributional assumptions (e.g. normality of data and/or regression residuals for continuous outcomes) will be assessed visually prior to reporting the results of the analysis. Although in the first instance the proposed primary method of estimation in this analysis plan will be followed, if distributional assumptions are considered to be violated, the impact of this will be examined through sensitivity analysis; this may consist of transformation of responses prior to analysis (e.g. log transformation) in the first instance. If extreme values are apparent and considered to be affecting the integrity of the analysis, a sensitivity analysis consisting of removing the outlying response(s) and repeating the analysis will be performed. Output from these analyses, if performed, will be described and presented alongside the original analysis (or included, e.g. in appendices) with the excluded values clearly labelled. See section 9.9 for further details regarding sensitivity analyses.

9.3. Handling missing data

In the first instance, analysis will be completed on received data only with every effort made to follow-up participants to minimise any potential for bias. To examine the possible impact of missing data on the results, and to make sure we are complying with the intention-to-treat principle, sensitivity analysis will be performed on the primary outcome measure.[19] See section 9.9 for further details regarding sensitivity analyses.

9.4. Analysis methods – primary outcome(s)

See Appendix D for information on how variables will be derived for the analysis. A template for reporting the primary outcome is given in Appendix E6.

The co-primary outcomes of 3rd/4th degree perineal trauma and caesarean section will be analysed separately, both using mixed-effects log-binomial models to generate relative risks alongside risk differences with 95% confidence intervals, adjusting for baby's position as a fixed effect and centre as a random effect.

Statistical significance of the treatment group parameter will be determined from the p-value generated by the model.

See section 9.1 for covariate adjustment and model convergence.

9.5. Analysis methods – secondary outcomes

See Appendix D for information on how variables will be derived for the analysis. A template for reporting the secondary outcomes is given in Appendix E7.

Analysis will be performed as per the co-primary outcomes 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 differences between group means and 95% confidence intervals adjusting for the same minimisation parameters as the primary outcome.

For questionnaires, both the total scale score and the subscale scores (where applicable) at each time point will be presented.

9.6. Analysis methods – exploratory outcomes and analyses

Any data that does not form a pre-specified outcome will be presented using simple summary statistics by intervention group (i.e. numbers and percentages for binary data).

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.

9.7. Safety data

The number and percentage of participants experiencing any adverse events, serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) will be presented by intervention group. Statistical significance will be determined (p-value generated) through examination of the associated chi-squared statistic. The total number of SAEs and SUSARs in each group will also be given along with a descriptive table of the details of the events.

A template for reporting this safety data is given in Appendix E8.

9.8. Planned subgroup analyses

Interpretation of subgroup analysis will be treated with caution (output will be treated as exploratory rather than definitive[20]. Analysis will be limited to both co-primary outcomes, and the following subgroup:

- 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)

- Usual preferred (first) rotational method, of the obstetrician who conducted the rotation for this participant, outside the ROTATE trial?
  - Manual Rotation
  - Rotational Forceps (Kiellands)
  - Rotational Ventouse

For each co-primary outcome, the effect of this subgroup 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 subgroup. The results of subgroup analyses will be treated with caution and will be used for the purposes of hypothesis generation only. A template for reporting the subgroup analyses for the primary outcome is given in Appendix E9.

9.9. Sensitivity analyses

Sensitivity analyses will be limited to the co-primary outcomes and will consist of:

- Per-protocol analysis (population described in sections 5.3 and 5.4);
- CACE Analysis
- An analysis to assess the effect of missing responses using a multiple imputation approach[21]. The imputation model will include the following variables: position. Analysis will be then be performed on each set with the results combined using Rubin's rule to

obtain a single set of results (treatment effect estimate and confidence intervals). Each co-primary outcome will be imputed separately.

- An analysis to assess the generalisability of the results by comparing baseline characteristics of those who are lost to follow-up or withdrawn from the trial with the trial population.
- If the proportion of missing primary outcome data is >5%, an analysis to assess the generalisability of the results by comparing baseline characteristics of those who provide primary outcome data to those who do not provide primary outcome data.

10. Analysis of sub-randomisations

Not Applicable

11. Health economic analysis

No health economic analysis is planned for this trial.

12. Statistical software

Statistical analysis will be undertaken in the following statistical software package: SAS software (v9.4 or above), with plots produced using R (v4.0.2 or above).

13. References

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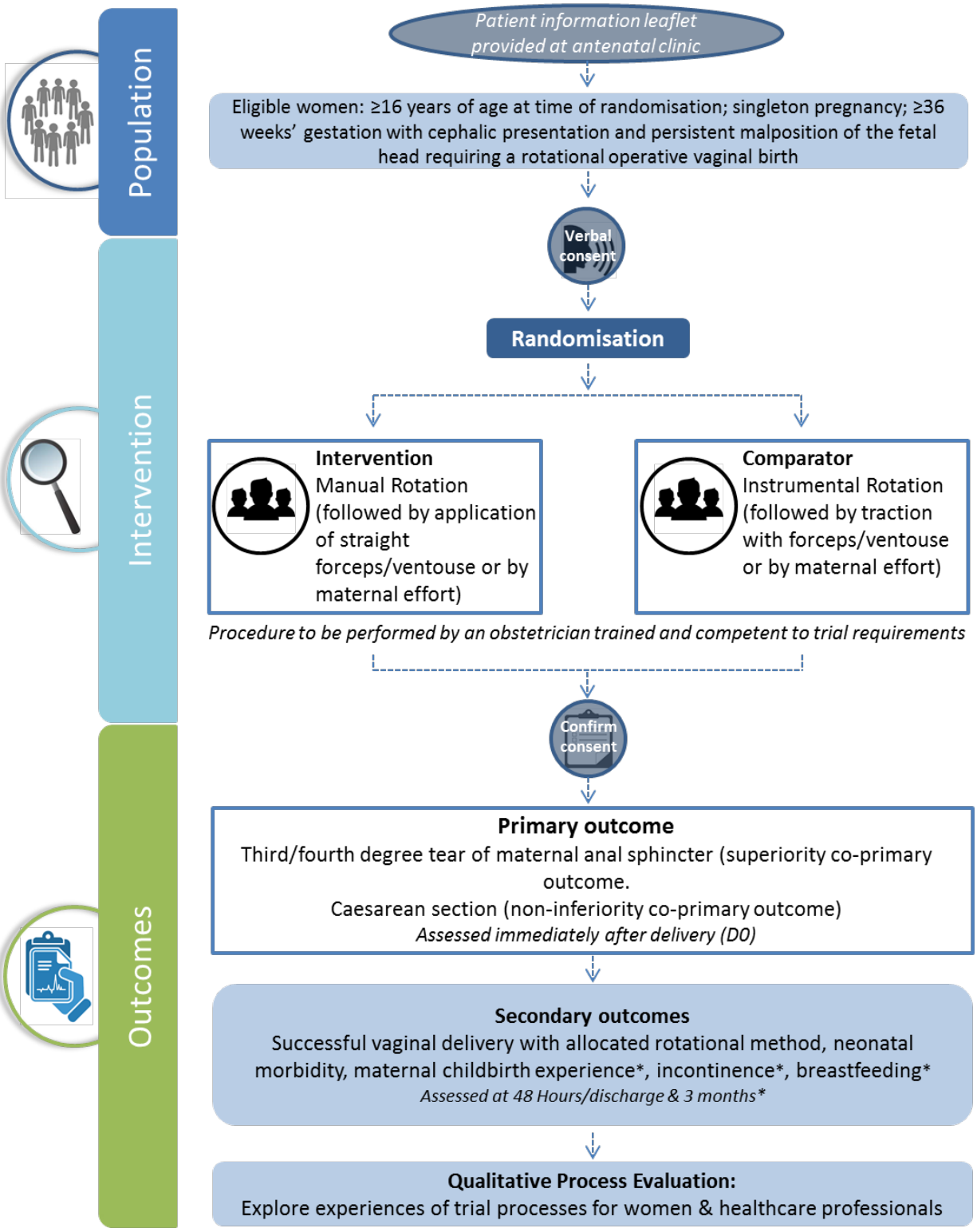
Appendix A: Deviations from SAP

This report below follows the statistical analysis plan version *<x.0>* dated *<insert effective date of latest SAP>* apart from following:

Section of report not following SAP	**Reason**
<insert section >	<insert, e.g. exploratory analyses request by TMG>

Appendix B: Trial schema



Appendix C: 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		
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			x		

	salvage)					
	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

Appendix D: Data manipulations

The Trial Statistician will derive all responses from the raw data recorded in the database:

Other:

- **Maternal age at randomisation (years)**

(Date of randomisation-date of birth)/365.25.

Outcome Measures:

Primary Outcome

Both co-primary outcomes are derived from the **CRF:** Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0

- **Third/forth degree perineal trauma involving anal sphincter complex diagnosed on clinical vaginal/rectal examination after birth (superiority co-primary outcome)**
- **Question:**
    - '7.1 Did the woman have a 3rd/4th degree perineal trauma involving the anal sphincter complex diagnosed on vaginal/rectal examination after birth?' = Yes;
- **Caesarean section (non-inferiority co-primary outcome)**
- **Question:**
    - '6.17 After the unsuccessful first rotational method was the baby delivered by:' = Caesarean section

Participants will be censored if they withdraw or are lost to follow-up before pregnancy end. They will be censored at the point of withdrawal/lost to follow-up.

Secondary outcomes: Neonatal

- **Severe neonatal trauma and morbidity – at neonatal discharge: Composite (any one of the following will fulfil the composite outcome):**

- **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**

If any of the following is yes/fulfils each component of the outcome:

- **stillbirth after study entry**

CRF: Follow-up at 48 hours (or maternal discharge if sooner)
Question:
- '2.11 Birth outcome' = Still birth;

- **early neonatal death (≤7 days)**

CRF: Neonatal Form
Question:
- '5.1 Was this baby known to have died at the time this form was completed?' = Yes;
- '5.2 and 5.3 Date and time of baby's death' is populated

AND
CRF: Follow-up at 48 hours (or maternal discharge if sooner)
Question:
- '2.1 Date of delivery' is populated

Then ensure:

Date of death – Date of birth is ≤7 days

- **evidence of intrapartum hypoxia (Apgar score ≤7 at 5 minutes after birth)**

CRF: Follow-up at 48 hours (or maternal discharge if sooner)
Question:
- '2.14 Apgar at 5 minutes' = ≤7;

- **the presence of neonatal encephalopathy receiving treatment with therapeutic**

hypothermia

CRF: Neonatal Form

Question:

- '3.2 Was this baby diagnosed with neonatal encephalopathy?' = Yes;

AND

- '3.2.5 Was the baby treated with therapeutic hypothermia (cooling)?' = Yes;

- **neonatal seizure(s)**

CRF: Neonatal Form

Question:

- '3.3 Was this baby diagnosed with isolated seizures?' = Yes;

- **meconium aspiration syndrome**

CRF: Neonatal Form

Question:

- '3.1 Was this baby diagnosed with meconium aspiration syndrome?' = Yes;

- **brachial plexus injury, fractured humerus or fractured clavicle**

CRF: Neonatal Form

Question:

- '3.5 Brachial plexus injury' = Yes;
  OR
- '3.6 Fractured humerus' = Yes;
  OR
- '3.7 Fractured clavicle' = Yes;

<u>Secondary outcomes: PROCESS DATA - SOON AFTER BIRTH (D0)</u>

- **Position of the fetal head before rotation (at diagnosis) using a pre-formatted ROTATE diagram (clock). One of:**
  - **right occiput anterior (ROA),**
  - **direct occiput anterior (DOA),**
  - **left occiput anterior (LOA),**
  - **right occiput transverse (ROT),**
  - **left occiput transverse (LOT),**
  - **right occiput posterior (ROP),**
  - **direct occiput posterior (DOP),**
  - **left occiput posterior (LOP).**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0

Question:

- '3.6 Please select the position of occiput prior to rotation'

- **Use of ultrasound to diagnose position before rotation: Yes/No**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.1 Use of ultrasound to diagnose position before rotation?'

- **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). One of:
  - **right occiput anterior (ROA),**
  - **direct occiput anterior (DOA),**
  - **left occiput anterior (LOA),**
  - **right occiput transverse (ROT),**
  - **left occiput transverse (LOT),**
  - **right occiput posterior (ROP),**
  - **direct occiput posterior (DOP),**
  - **left occiput posterior (LOP).**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.19 Please select the position of occiput after to rotation'
  AND
- '6.20 If the baby was rotated from OT to OP position was that'

- **Position of the ventouse cup, using a pre-formatted ROTATE diagram (flexing median, deflexing median, flexing paramedian, deflexing paramedian)**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.16 Please indicate how the baby was delivered following rotation (if applicable):' = Ventouse
  AND
- '6.21 If ventouse was used, using the diagram below, please select the position of the ventouse cup'

- **Forceps marks on the baby :**
- **Right blade - (normal, over >50% orbit, not reaching jaw)**
- **Left blade - (normal, over >50% orbit, not reaching jaw)**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.16 Please indicate how the baby was delivered following rotation (if applicable):' = Forceps

AND

- '6.22 Were there forceps mark(s) on the baby?' = Yes

AND

- '6.23 If Yes, please select where the forceps mark(s) occurred:'

- **Adherence to all key steps of the manual rotation process using a dedicated ROTATE checklist**

To be adherent, participant would need a 'Yes' response to 6.4.1, 6.4.2, 6.4.3, 6.4.4,6.4.5, 6.4.6 and 6.4.7.

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0

Question:

- '6.4 If manual rotation was performed, please complete the following checklist:'
- '6.4.1 Was pain relief adequate for the patient?' = Yes

AND

- '6.4.2 Was the whole hand, including the thumb in the posterior of the vagina? ' = Yes

AND

- '6.4.3 Was the head held with the whole hand and thumb applied to the head (between midline and parietal bone)? ' = Yes

AND

- '6.4.4 Was there flexion of the fetal head via extension of the palm? ' = Yes

AND

- '6.4.5 Was the head disengaged before rotation by pushing upwards after the flexion? ' = Yes

AND

- '6.4.6 Did the hand rotate with/without contraction with fetal head in grasp? ' = Yes

AND

- '6.4.7 Was there a complete rotation to the occipito-anterior position? ' = Yes

- **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)**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0

Question:

- 7.2.1 'Was the woman in a lithotomy position' = Yes
- 7.2.2 'Was there adequate lighting?' = Yes
- 7.2.3 'Did the woman confirm that effective local or regional analgesia is in place?' = Yes
- 7.2.4 'Was there visualisation of the full length of the tear from the vaginal apex to the lower perineal end?' = Yes
- 7.2.5 'Was there significant bleeding?' = Yes
- 7.2.6 If yes to question 7.2.5, was there good visibility by appropriate haemostasis (swabs, stitches, clamps/clips)?' = Yes
- 7.2.7 'Was there combined digital and rectal examination of the full length of the tear as per

question 7.2.4?' = Yes
- 7.2.8 'Was there a flicker ('pill-roll') of the anal sphincter ring between the index rectal finger and the thumb to establish continuity or tear of the sphincter?' = Yes
- 7.2.9 'Was there identification of the internal sphincter separately, lying between the external anal sphincter and the anal epithelium?' = Yes
- 7.2.10 'If yes to question 7.2.9, is it paler than the external sphincter and its fibres are circular?' = Yes

Secondary outcomes: MATERNAL - SOON AFTER BIRTH (D0)

- **Vaginal birth after successful rotation with first allocated method (manual or instrumental rotation)**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.15

- **Change from rotational ventouse to rotational forceps (both rotational ventouse and rotational forceps are in the same trial arm).**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '6.5 Change from rotational ventouse to rotational forceps or vice-versa?'

- **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).**

CRF: Screening, Eligibility, Consent, Process and Maternal Outcomes - Day 0
Question:
- '7.3 Severe/complex 2nd degree vaginal tears and/or cervical tears?'

Secondary outcomes: 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**

CRF: Follow-up at 48 hours (or maternal discharge if sooner)
Question:
- '3.2 What was the estimated blood loss of the patient - up to 24 hours after birth?'

- **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)**

CRF: Follow-up at 48 hours (or maternal discharge if sooner)
Question:
- '3.1 Did this woman receive any red blood cell (RBC) blood transfusion or cell salvage of > 300mls any time between randomisation and 48 hours after birth (or hospital discharge if earlier than 48 hrs)?

- **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'.**

CRF: Breastfeeding Form - 48 hours post-birth (or maternal discharge if sooner)
Question:
- '2.3 In the last 24 hours, how many times has your baby been breast fed?':

0 times = No breastfeeding;
1-3 times OR 4-7 times OR 8-11 times OR More than 11 times = Any breastfeeding

- **Maternal Experience: Childbirth Experience Questionnaire (CEQ)**

The CEQ has 22 statements assessing four domains of childbirth experience. 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.

CRF: CHILDBIRTH EXPERIENCE QUESTIONNAIRE
Question:
- Q2.1 – Q2.19: Q2.1 + Q2.2 + Q2.3 + Q2.4 + Q2.5 + Q2.6 + Q2.7 + Q2.8 + Q2.9 + Q2.10 + Q2.11 + Q2.12 + Q2.13 + Q2.14 + Q2.15 + Q2.16 + Q2.17 + Q2.18 + Q2.19 = Total CEQ score

<u>Scoring criteria:</u>

Scoring for questions: Q2.3, Q2.5, Q2.8 and Q2.12
Totally agree = 1
Mostly agree = 2
Mostly disagree = 3
Totally disagree = 4

Scoring for questions: Q2.1, Q2.2, Q2.4, Q2.6, Q2.7, Q2.9, Q2.10, Q2.11, Q2.13, Q2.14, Q2.15, Q2.16, Q2.17, Q2.18 and Q2.19
Totally agree = 4
Mostly agree = 3
Mostly disagree = 2
Totally disagree = 1

- Q20 – Q22: Q20 + Q21 + Q22 = Total VAS Score

Scoring criteria: Higher scores indicate positive scorings

Scoring for question: Q2.20
0 = Worst imaginable pain, 10 = No pain

Scoring for question: Q2.21
0 = No Control, 10 = Complete control

Scoring for question: Q2.22
0 = Not at all secure, 10 = Completely secure

Categorise VAS scores into the following categories:

0 - 40 = 1
41 - 60 = 2
61 - 80 = 3
81 – 100 = 4

Item ratings are aggregated to scale scores by summing the coded values of the items in each scale and dividing by the number of items in that scale (mean). If the respondent has answered at least half of the items in a scale then mean values of the items that have been answered should be computed. Scoring range is 1 to 4 where higher ratings reflect more positive experiences.

- **Maternal Experience: Client Satisfaction Questionnaire-8 (CliSQ)**

  The CliSQ 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. Scores therefore range from 8 to 32, with higher values indicating higher satisfaction.

CRF: CLIENT SATIFACTION QUESTIONNAIRE (CSQ-8)

Question:

- Add up scores: Q1 + Q2 + Q3 + Q4 + Q5 + Q6 + Q7 + Q8 = Total CSQ-8 Score

Score to percentage/bands conversion:

8 = 0%
9 – 17 = 1% – 39%
18 – 22 = 40% – 59%
23 – 32 = 60% - 100%

Secondary outcomes: MATERNAL - AT 3 MONTHS AFTER BIRTH (+ 7 days)

- **Urinary incontinence: ICIQ (International Consultation on Incontinence Questionnaire**

The ICIQ has four question items: Frequency or urinary incontinence, Amount of leakage, Overall impact of urinary incontinence and Self-diagnostic item (not scored). Scores range from 0 to 21, the higher the score, the more severe the urinary incontinence.

CRF: ICIQ-UI Short Form
Question:

- Add up scores: Q3 + Q4 + Q5 = Total ICIQ Score

Scoring criteria:

Q3: How often do you leak urine?

- Never = 0
- about once a week or less often = 1
- two or three times a week = 2
- about once a day = 3
- several times a day = 4
- all the time = 5

Q4: We would like to know how much urine you think leaks. How much urine do you usually leak (whether you wear protection or not)?

- None = 0
- a small amount = 2
- a moderate amount = 4
- a large amount = 6

Q5: Overall, how much does leaking urine interfere with your everyday life?

- 0 (not at all) – 10 (a great deal)

- **Faecal incontinence: Fecal Incontinence Quality of Life Scale**

Section A - Fecal Incontinence Quality of Life Instrument:

The Fecal Incontinence Quality of Life Scale 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) and Embarrassment (3 items).

Scales range from 1 to 4, with a 1 indicating a lower functional status of quality of life. Scale scores are the average (mean) response to all items in the scale (e.g. add the responses to all questions in a scale together and then divide by the number of items in the scale).

CRF: Fecal Incontinence Quality of Life Instrument
Question:

Scale 1. Lifestyle, ten items:

(Q2.1 + Q2.2 + Q2.3 + Q2.4 + Q2.5 + Q2.7 + Q2.8 + Q3.2 + Q3.12 + Q3.13) / 10 = Lifestyle score

Scale 2. Coping/Behaviour, nine items:

(Q2.6 + Q2.9 + Q2.10 + Q2.11 + Q2.13 + Q3.3 + Q3.8 + Q3.10 + Q3.14) / 9 = Coping/Behaviour score

Scale 3. Depression/Self Perception, seven items:

(Q1.1 + Q3.4 + Q3.6 + Q3.7 + Q3.9 + Q3.11 + Q4.1) / 7 = Depression/Self Perception score

Scale 4. Embarrassment, three items:

(Q2.12 + Q3.1 + Q3.5) / 3 = Embarrassment score

Scoring criteria:

Q1.1: In general, would you say your health is:

- Excellent = 1
- Very Good = 2
- Good = 3
- Fair = 4

- Poor = 5

Q2.1 – Q2.13

- Most of the time = 1
- Some of the time = 2
- A little of the time = 3
- None of the time = 4

Q3.1 – Q3.12

- Strongly agree = 1
- Somewhat agree= 2
- Somewhat disagree = 3
- Strongly disagree = 4

Q4.1

- Extremely so - To the point that I have just about given up = 1
- Very much so = 2
- Quite a bit = 3
- Some - Enough to bother me = 4
- A little bit = 5
- Not at all = 6

Section B - Fecal Incontinence Severity Index:

Each of the four items (types of leakage) Gas, Mucus, Liquid stool and solid stool is awarded a number of points, depending on the frequency at which that type of incontinence is experienced.

The maximum of points that can be awarded for one individual item is 19. The final result is the sum of all points and varies from 0 to 61, where the higher the score, the higher the perceived severity of the fecal incontinence.

CRF: Fecal Incontinence Quality of Life Instrument
Question:

Q1.1 + Q1.2 + Q1.3 + Q1.4 = Fecal Incontinence Severity Index score

Scoring criteria:

Q1.1: Gas

- Never = 0
- 1 to 3 times a month = 4
- Once a week = 6
- 2 or more times per week = 8
- Once a day = 11
- 2 or more times a day = 12

Q1.2: Mucus

- Never = 0
- 1 to 3 times a month = 3
- Once a week = 5
- 2 or more times per week = 7
- Once a day = 10
- 2 or more times a day = 12

Q1.3: Liquid stool

- Never = 0
- 1 to 3 times a month = 8
- Once a week = 10
- 2 or more times per week = 13
- Once a day = 17
- 2 or more times a day = 19

Q1.4: Solid stool

- Never = 0
- 1 to 3 times a month = 8
- Once a week = 10
- 2 or more times per week = 13
- Once a day = 16
- 2 or more times a day = 18

- **PTSD symptoms: CITY Birth Trauma Scale**

CRF: CITY Birth Trauma Scale Form
Question:
Symptom Subscales
• Re-experiencing symptoms: Q3.1 + Q3.2 + Q3.3 + Q3.4 + Q3.5
• Avoidance symptoms: Q3.6 + Q3.7

• Negative cognitions and mood: Q3.8 + Q3.9 + Q3.10 + Q4.1 + Q4.2 + Q4.3 + Q4.4
• Hyperarousal: Q4.5 + Q4.6 + Q4.7 + Q4.8 + Q4.9 + Q4.10

Total PTSD symptoms
• Total score from Q3.1 to Q4.10 inclusive. Total range 0 - 60

Dissociative symptoms
• Q4.11 + Q4.12

Scoring criteria:

Sections 3 and 4
- Not at all = 0
- Once = 1
- 2 – 4 times a week = 2
- 5 or more times per week = 3

Q5.1 When did these symptoms start?

- Before the birth = 0
- In the first 6 months after birth = 1
- More than 6 months after birth = 2
- Not applicable (I have no symptoms) = BLANK

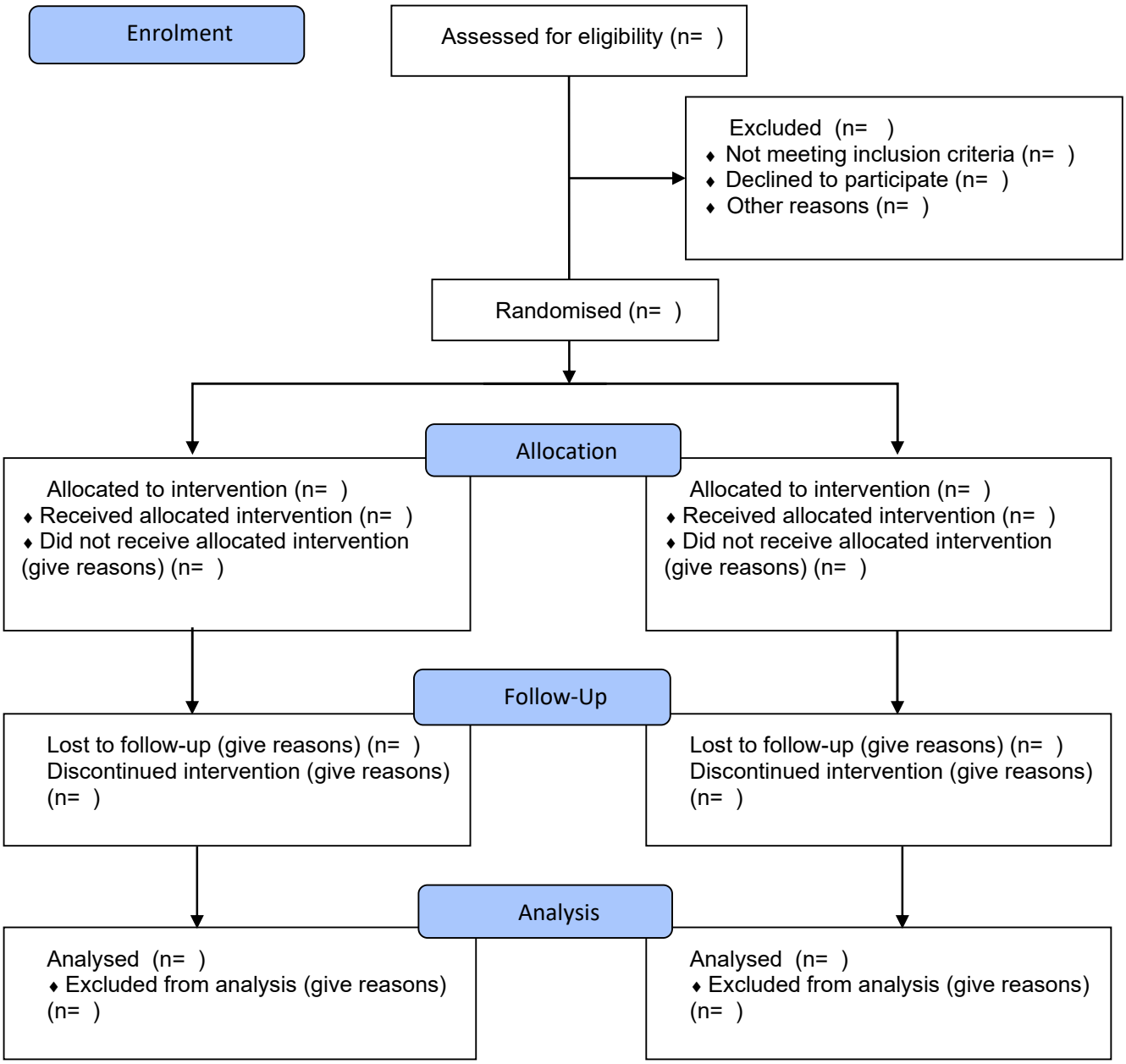
Q5.2 How long have these symptoms lasted?

- Less than 1 month = 0
- 1 to 3 months = 1
- 3 months or more =2
- Not applicable (I have no symptoms) = BLANK

Q5.3 – 5.5

- Yes = 2
- No = 0
- Sometimes (Q5.3 and Q5.4) / Maybe (Q5.5) = 1

Appendix E1: CONSORT flow diagram



<Check that the correct flow diagram for the trial design is used, e.g. there is a different flow diagram for cluster trials. See CONSORT website.>

<Flow diagram can be adapted and/or expanded as necessary to include, e.g. multiple time-points; some studies will not collect screening logs, in these cases the 'Assessed for eligibility' box may be removed.>

Appendix E2: Tables

Final analyses tables will be provided in a separate document.

Appendix E3: Template report

A template report for the final analyses will be provided in a separate document.