**Pilot Trial Title**: *Use of the REBozoTEChnique in second stage labour to reduce the incidence of assisted vaginal births for nulliparous women with epidurals: A mixed methods feasibility study*

**Acronym:** *REBTEC Pilot Trial*

**Research Protocol**

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# 1.  Glossary of terms/abbreviations

|  |  |
| --- | --- |
| Term/Abbreviation | Meaning |
| ANZCTR | Australian New Zealand Clinical Trials Registry |
| Apgar | A score used by clinicians at 1, 5 and 10 minutes after birth, to ascertain the condition of the baby and the need for resuscitation |
| Assisted vaginal birth | Vacuum extraction and/or forceps used to assist with vaginal birth |
| Bromage | A score used to assess motor block following epidural insertion |
| CALD | Culturally and linguistically diverse |
| Cephalic | Fetus is positioned head down |
| Full dilation | Cervix is fully dilated at 10cm |
| Gestation | Number of weeks pregnant |
| LSCS | Lower section caesarean section |
| ITT | Intention to treat (an analysis used in RCTs) |
| Non-assisted vaginal birth/SVD | Spontaneous vaginal birth that did not require assistance with vacuum or forceps |
| Nulliparous | Women giving birth for the first time |
| OA | Occiput-anterior position - the best position for birth |
| OP/malposition | Occiput-posterior position – difficult position for birth |
| OT/malposition | Occiput-transverse position – difficult position for birth |
| Parity | Number of births |
| PICF | Participant Information and Consent Form |
| Pre-eclampsia | Dangerous complication characterised by high blood pressure |
| Primary midwife | Birth suite midwife caring for the woman |
| Rebozo technique | A centuries old traditional Mexican technique whereby a rebozo (‘cloth or shawl’ in Spanish), is used to rock the woman from side to side to help navigate the baby into the best position for birth. |
| RCT | Randomised controlled trial |
| Should dystocia | Fetus’s shoulder(s) get stuck behind the mother’s pubic bone |
| Singleton | One fetus in the uterus |
| Term | Pregnancy is considered full term from 37 to 40.6 weeks[[1]](#footnote-1) |
| UQ | The University of Queensland |
| VE | Vaginal exam |

# 2. Introduction

This study will investigate the feasibility of a full scale randomised controlled trial (RCT) to assess the use of the rebozo technique. The rebozo technique can be used by midwives to correct the position (malposition) of the baby for birth, to help reduce the incidence of vacuum or forceps births. However, in this research, the rebozo technique will be used on all nulliparous women (women giving birth for the first time) who are using epidural analgesia, regardless of malposition. There has been no research done on the efficacy of this technique in reducing the incidence of assisted vaginal births. To assist in building this evidence, this protocol refers to three different phases of the study. Firstly, a pilot study will be done to help in refining and assessing practicality of conducting a fully-powered RCT. Secondly, a survey of women’s attitudes and satisfaction of the intervention they received. Finally, interviews with midwives of their experiences in the trial and the intervention they implemented. This three-phased approach will add vital information for a fully-powered RCT.

# Background

Epidural use in labour has an association with assisted vaginal birth (AVB), which is the use of vacuum and/or forceps, particularly for nulliparous women (women giving birth for the first time) (Elvander et al., 2013). In Australia, 26.2% of nulliparous women have an AVB (AIHW, 2022). Of those women who have an AVB, approximately 43% had epidural analgesia in their labour (Newnham et al., 2021). In fact Shinar et al. (2019) emphases that, regardless of parity (whether it is the first or subsequent birth(s)), there is a three-fold increased risk of AVB with epidural analgesia. It is suggested that this is due to malposition, that can originate in first stage labour, is more likely to persist into second stage labour for those women who have epidural analgesia (Djaković et al., 2017; Verhaeghe et al., 2021). Fetal malposition may be further defined in a few ways. One such definition is fetus in longitudinal lie in occiput posterior (OP) position, which is described as direct OP (baby’s back lying against mother’s back) (Turner et al., 2020), inhibiting the normal mechanisms of labour. Approximately 20-40% of women begin active labour (first stage labour) with their baby in OP position, however, most fetuses will rotate spontaneously to the occiput-anterior (OA) position, the optimum position for vaginal birth, with only 5-8% persisting in the OP position into second stage labour. This persisting direct OP rate increases to 13% in nulliparous women with epidural analgesia (Cohen & Thomas, 2015; Le Ray et al., 2013). However, there are derivations of OP position where the fetus is not directly OP, but none-the-less will inhibit the normal mechanisms of labour if they persist into second stage. These can include left and right facing OP positions and occiput transverse (OT) position, where the fetal back is directly transverse, either left or right, of the mother’s pelvis (Pilliod & Caughey, 2017). These differing OP positions can produce deflexed and asynclitic fetal head positions (off centre from the birth canal), that further complicate the birth process, increasing the risk of AVB. Malposition during labour can have potentially serious consequences for the woman and her labour (Bueno‐Lopez et al., 2018; Hasegawa et al., 2013; Lieberman et al., 2005). These include irregular contractions, prolonged first stage and second stage labour and chorioamnionitis, leading to caesarean section (CS) or AVB. Severe perineal injury involving the anal sphincter (3-4th degree tears) and episiotomy may also occur. Postpartum haemorrhage (PPH) and postpartum infection may result from prolonged labours and AVBs (Elmore et al., 2020).

As substantial evidence from observational studies shows such a large increase in the incidence of AVB with women who have epidural analgesia (Djaković et al., 2017; Hincz et al., 2014; Naito et al., 2019; Shinar et al., 2019), determining some reasons as to why this is happening is important. Although epidural analgesia is often requested in response to the woman’s prolonged labour associated with fetal malposition in first stage labour, epidurals may also contribute to malposition due to the interruption of the mechanism of labour, that is essential for normal labour progression (Djaković et al., 2017; Lieberman et al., 2005). Both Djakovic et al (2017) and Leiberman et al (2005) theorise that the relaxation effects of the epidural on the pelvic floor muscles, lead to inhibition of the head rotation into the pelvis. There is also an association between prolonged labour and persistent malposition into second stage labour with the use of epidural analgesia (Hasegawa et al., 2013). This is theorised by Djakovic et al (2017) to be due to the weakening of the contractions that can occur after epidural analgesia. A study by Lieberman et al’s (2005) found a strong association between malposition at birth and epidural analgesia, resulting in high rates of AVBs. This was hypothesised to be related to the woman’s inability to push effectively due to malposition. It is for this reason that malposition will not need to be confirmed at second stage, as there is a great deal of evidence that nulliparous women with an epidural are in a high risk group for AVB, where malposition may be a contributing factor. Additionally, not only is fetal position changeable throughout the course of labour, fetal position is also difficult to diagnose. Research has indicated that abdominal palpation to determine fetal position is inaccurate and relies too heavily on the expertise of the clinician performing this skill (Webb et al., 2011). This provides another reason as to why malposition will not be a determining factor for inclusion in this research. Therefore, as evidence finds a significant association with AVB for nulliparous women who use epidural analgesia, this population will be the focus of this research.

Clinicians use a number of standard methods in an effort to correct malposition. One such method is moving the women from side to side, or placing the woman on her hands and knees, depending on her mobility (Elmore et al., 2020). Manual rotation of the fetal head has also been tested. However, the success with these methods to correct malposition are not generally supported in the literature (Elmore et al., 2020). A less explored strategy to correct malposition is the rebozo technique. This centuries old procedure involves rocking a labouring woman from side to side using a cloth (called ‘rebozo’ in Spanish) or sheet as a sling. While this technique has not been formally studied for efficacy and safety, the rebozo technique is sometimes used by midwives as a means to correct fetal malposition (Cohen & Thomas, 2015; Elmore et al., 2020; Iversen et al., 2016). The rebozo technique is simple, low technology and versatile for use in any birthing setting (Iversen et al., 2016). This makes the intervention appealing in the context of woman-centred care. However, there is currently no primary research that explores the efficacy of the procedure. Formal RCTs are resource and time intensive, therefore we will undertake a pilot study testing the research processes for feasibility.

# Aims of study

## 4.1 Primary Aim

The primary aim of this project is to test the feasibility of recruitment, retention, data collection and analysis for a fully-powered randomised controlled trial (RCT) of the rebozo technique.

## 4.2 Secondary Aim

Evaluate the effectiveness of the rebozo technique in improving birth experiences and outcomes in nulliparous women utilising epidural analgesia.

# Research question

Is it feasible to conduct an adequately powered RCT to detect statistically significant differences in rates of AVB in nulliparous women with an epidural after using the rebozo technique compared to standard care?

# Part 1 – Methodology – Pilot RCT

## 6.1 Feasibility criteria

As the aim of the pilot trial is to assess whether a larger study would be possible, we established specific criteria for the assessment of feasibility. Although there are currently no clearly defined criteria or standards for the assessment of feasibility (Mbuagbaw et al., 2019), three common feasibility criteria for pilot trials have been suggested: i.e., trial recruitment, protocol adherence, and collection and completion of study data (Avery et al., 2017). The targets within these criteria that need to be met indicate feasibility at this pilot phase, which should indicate if a full RCT should proceed (Avery et al., 2017). Additionally, a conceptual framework for pilot RCTs is necessary to guide the implementation and interpretation of the study (Eldridge, Chan, et al., 2016; Eldridge, Lancaster, et al., 2016).

Based on the critical examination of the literature, previous studies and expert opinion (Avery et al., 2017; Keogh et al., 2016; Marsh et al., 2015), it was determined that the feasibility of a superiority RCT would be confirmed if the following conditions were met in the pilot study:

• At least 80% of screened patients would be eligible.

• At least 80% of eligible participants would be enrolled.

• At least 80% rate of protocol compliance (participants who receive their allocated

treatment).

• Less than or equal to 5% of participants lost to follow up or withdrawal from study

without access to final data collection.

## 6.2 Hypotheses for feasibility

The hypothesis for the feasibility outcomes of the pilot RCT were based on the interpretation provided by Thabane et al. (2010), and the CONSORT guidelines on pilot RCT feasibility trials (Eldridge, Chan, et al., 2016):

H1 : All criteria will be met and trial is feasible without modification.

H2 : One criterion will not be met and trial is feasible with close monitoring.

H3 : Two – three criteria will not be met and trial is feasible with modification.

H4 : Four or more criteria will not be met and trial is not feasible.

## 6.3 Null hypothesis for the rebozo technique

To replicate the research question for testing in a superiority trial, the following hypotheses for difference in AVB rates between rebozo and standard care groups are proposed:

Null hypothesis (H1): There will be no difference in AVB rates between groups.

Alternative hypothesis (H2): There will be significantly lower rates of AVB in the rebozo group compared to standard care.

# Study design

This is a pragmatic randomised controlled feasibility study (Zuidgeest et al., 2017). The Medical Research Council (MRC) framework provides the theoretical framework and the CONSORT statement for pilot RCTs will guide the design to this project (Eldridge, Chan, et al., 2016; Skivington et al., 2021).

# Study setting

The pilot RCT will take place in two locations, Metro South’s Logan Hospital birth suites and Mater Mothers’ Hospital birth suites. These settings cares for approximately 3500 public women per year at Logan Hospital (Metro South Health, 2021), and 6000 per year at Mater Mothers’ Hospital (Qld Gov, 2022). Logan is one of the most culturally diverse cities in Australia, with 27% born overseas, of which 16% speak a language other than English (Metro South Health, 2021). There is also a large Indigenous population at Logan. Regarding Mater Mothers’ Hospital, it is one of the largest maternity hospitals in Australia. The models of maternity care at these locations include GP shared care, hospital midwifery care, private midwifery care, specialist obstetric care, and community Maternity and Child Health Hubs (for eligible women).

# 9. Study duration

It is anticipated that the pilot RCT will begin once ethical and research governance processes are completed for Logan Hospital and Mater Mothers’ Hospital. Recruitment is expected to continue at both locations until approximately early 2024, with another twelve months expected for data analysis and writing.

# 10. Study population

Participants will be nulliparous women with a term singleton pregnancy admitted to Metro South’s Logan Hospital birth suites and Mater Mothers’ birth suites, in spontaneous or induced labour, and requesting an epidural.

10.1 Inclusion criteria

* Term.
* Cephalic.
* Singleton.
* Epidural/combined spinal epidural.
* Nulliparous.
* >18 years.
* Spontaneous or induced labour.
* Requesting epidural analgesia in first stage labour.

## 10.2 Exclusion criteria

* Unable to provide informed consent.
* Serious medical complication(s) of pregnancy and/or chronic medical condition(s) eg. pre-eclampsia, insulin controlled gestational diabetes, heart disease.
* Induction for pelvic instability/pubic symphysis separation.
* Small for gestational age, Intrauterine growth restriction, Intrauterine fetal death (IUFD).
* Maternal or fetal contraindications to vaginal birth.
* BMI >35.
* Culturally and linguistically diverse ([CALD](#CALD)) women without access to an interpreter.

10.3 Exclusion criteria prior to randomisation

* Station equal to or higher than -3 at full dilation (a high fetal station at full dilation may indicate other issues that are preventing descent, which will require the attention of the woman’s birth suite team).
* equal to or lower than +2 at full dilation (would indicate that the fetus has descended well without intervention, and is likely to birth unassisted).
* Continued and prolonged patterns of variables/complicated variables/late decelerations at full dilation (which would require the attention of the woman’s birth suite team).

## 10.4 Method of epidural analgesia

The epidural will be inserted and managed according to the preference of the attending anaesthetist. Details of the timing of the epidural insertion and the medications used will be documented.

# 11. Study outcomes

## 11.1 Primary outcomes

The primary outcomes have been developed based on the CONSORT pilot RCT statement to assess the feasibility of a fully powered RCT (Eldridge, Chan, et al., 2016):

* Proportion of women who meet inclusion criteria give consent to participate.
* Proportion of women who give consent are randomised.
* Proportion of women who receive allocated intervention.
* Proportion of participants who withdraw from the study.
* Proportion of participant data collection sheets completed.
* Number and nature of adverse events.

## 11.2 Secondary outcomes

**Maternal data:**

* Proportion of women who have an unassisted vaginal birth.
* Proportion of women who have an assisted vaginal birth, ie, vacuum/forceps.
* Proportion of women who have emergency LSCS.
* ICU admission.
* Length of stay.
* Maternal outcome (PPH; perineal injury, pyrexia).
* Proportion of shoulder dystocia.
* Fetal descent at full dilation via palpation and/or vaginal exam.
* Fetal position at birth.
* Maternal satisfaction via survey 1-2 weeks post birth.
* Participant demographic data.
* Gestation at enrolment.
* Parity.
* Socio economic status (via postcode/statistics)
* Indigenous status.
* Marital status.

**Fetal data:**

* Apgar scores.
* Requirement and nature of resuscitation.
* NICU admission >24-48hrs.
* Cord pH at birth (only if collected).
* Breastfeeding initiation.
* Antibiotics required.
* Fetal weight in grams.
* Fetal head circumference in cm.

**Epidural data:**

* Position during epidural insertion (supine or lateral).
* Time of epidural insertion (24 hour clock).
* Product used to secure epidural catheter.
* Epidural pump program (PCEA with PIB, PCEA with continuous infusion, other).
* Starting rate for infusion if used (mls/hr).
* Bromage score prior to randomisation.
* Sensory dermatomal level prior to randomisation.
* Complications of epidural insertion: multiple attempts, inadequate analgesia, re-site.
* Dislodgement of epidural catheter or cannula during the rebozo rocking process.

# 12. Study procedures

## 12.1 Recruitment and consent of participants

In the first instance, recruitment and consent will be obtained by the lead researcher if on site, during business hours. Contact details of the lead researcher will be available in the PICF, trial documents and birth suite handover room, which will also be communicated during phases one and two of the training of midwives for this trial. If the lead researcher is not available, and/or it is outside business hours, the clinical/team leader midwife, or midwives who are not the primary carer of the woman, who have completed the phase one online training and phase two in-person training, will undertake recruitment/consent. Appropriate training of midwives for the trial is essential, not only because pregnant women, and women in labour, are a vulnerable group, but because training in research consent procedures is important for gaining appropriate informed consent. There are two groups of midwives that will need to be trained. The antenatal clinic (ANC) midwives will be trained in the context of informing the women of the trial, which does not involve consent. Informing women of the trial from this group of midwives will be during the woman’s antenatal clinic appointments. The second group of midwives to be trained will be birth suite midwives, who will be appropriately trained to gain informed consent of the woman as per Good Clinical Practice (GCP) guidelines, highlighting that the midwife who gains consent is not the primary carer for the woman. It will be a requirement of recruitment and consent of women that the birth suite midwives gaining informed consent have received this training. Please see the training plan for midwives in Appendix 1.

Consent has successfully been obtained during labour in a previous RCT (Lee et al., 2022), where a staged approached had been used (Reid et al., 2011). Therefore, the staged approach for consent in this study trial is as follows. Firstly, information of the trial will be made available to all women at or around their 36 week, and subsequent, ANC appointments, which will begin in early 2023. The ANC midwife will provide for the woman a brochure with study information, where the PICF can be accessed via a QR code. The PICF will summarise the objectives of the trial as well as requirements of participation. Women can ask questions about the trial from their midwife, who has had training of the trial, but they will also be encouraged to contact the lead researcher, where contact details of the lead researcher will be available on both the brochure and PICF. Secondly, there will be a poster available in the ANC waiting room, and ANC appointment rooms, for all women attending ANC to view if they wish, for women giving birth in 2023. These women will be encouraged, via the poster, to not only discuss the trial with their ANC midwife, but to also access the QR code, that will link to the PICF for further information and lead researcher contact details. Thirdly, on admission to birth suite, provisionally eligible women who had an opportunity in their ANC visits to receive information of the trial, and have read the PICF, will be approached to participate in the trial if deemed appropriate to do so. Finally, other potential participants in birth suite who provisionally meet the inclusion criteria, but who were not made aware of the trial during their ANC visits, can be provided with study information in the early phases of labour. This is provided they are pain free, are not experiencing anxiety, have an opportunity to discuss participation with their support person(s), and are able to ask questions (Reid et al., 2011).

Formal recruitment and consent of women will commence once the epidural is sited and assessed as effective, that is, the woman is pain and anxiety free. During business hours the researcher will be available to provide information and explanation to gain written informed consent from the woman. Otherwise the clinical midwife on duty, or midwife who is not the primary carer, will fulfil this role, provided they have completed phases one and two of the training. It will be made clear that if at any point the woman chooses to withdraw from the trial, she may do so without explanation. If the woman does withdraw, consent will be obtained as to whether any information collected before withdrawal can be included in the data analysis. Participants at Logan will be provided with the original consent form with a second copy retained for study files and Logan Hospital’s Powertrials database. Another copy, with hospital ID sticker affixed, will also be uploaded to Metro South’s integrated electronic medical record (ieMR) system. Similarly, participants at Mater will be provided with the original consent form, with a second copy retained in the woman’s hospital file, and the third copy for the researcher. If the woman is eligible but declines to participate, or verbally consents, but is unable to provide written consent, then she will not be recruited. An enrolment log of eligible women will be in each birth suite room to document the number of women who both consent and decline. For women who decline there will be no identifying information recorded, however, information on women who are eligible, but decline, is important for feasibility purposes.

For clarity, the staged recruitment/consent approach is as follows:

* Information of the trial will be made available to women at or around their 36 week, and subsequent, clinic appointments. This is only to inform, there will be no recruitment/consent at this stage. This will be achieved via their midwife, a brochure, and posters throughout the clinic waiting room and appointment rooms.
* On admission to birth suite, women who have had information of the trial antenatally, and who provisionally meet inclusion criteria, will be approached to participate in the trial.
* Women who have not had an opportunity to access trial information antenatally, but who provisionally meet inclusion criteria, will also be approached to participate. This is provided they are pain free, not experiencing anxiety, have an opportunity to discuss with their support person(s), and are able to ask questions.
* Formal recruitment and consent will only commence once the epidural is sited and assessed as effective.
* Only midwives who have completed phases one and two of the training will be able to recruit/consent. The primary carer of the women will not recruit/consent.

## 12.2 Intervention group (rebozo technique)

In Cohen and Thomas (2015), there were a variety of rebozo techniques, depending on the position of the woman, to be used over 5-10min. The rebozo technique for this research is a variation of the two person ‘lying on the back: two person rocking’ technique described by Cohen and Thomas (2015). Following consultation with senior midwifery practitioners who are skilled in the technique, the rebozo is adapted for use in women with epidurals and to ensure consistency of practice and application. Cohen and Thomas (2015) do not specifically define how many times the rocking should occur or for how long, or the maternal position between contractions and following the procedure. Therefore, we have included instructions for this in our procedure to ensure consistency and safety. Cohen and Thomas (2015) do describe two other manoeuvres (short tug and knee bounce) along with the rocking manoeuvre, however, the ‘short tug’ requires the midwife to lean forward to achieve the rocking effect, which we determined would not be optimal from an occupational safety perspective. The ‘hands and knees’ approach is not feasible for women with epidurals. The adaptation from Cohen and Thomas (2015) is as follows:

* Prior to the commencement of the rebozo technique, the midwife will check the epidural catheter and cannula are secure.
* The bed will be at the appropriate height for both midwives to ensure back safety, in keeping with standard occupational health and safety regulations.
* BMI >35 is an exclusion criteria to protect back safety. If BMI is <35, and either midwife deem it unsafe for back safety to implement the rebozo technique, then do not proceed.
* The woman will be advised that if she feels any discomfort during the rocking process, to alert the midwife immediately.
* The rebozo is a standard sheet, placed underneath the woman’s back and hips.
* Once second stage is confirmed, but before pushing commences, with two midwives, one on each side, the woman is to be rocked side to side with the rebozo 4 times, then allow her to rest on her left side for 2 minutes (Figure 1) (Cohen & Thomas, 2015).
* Immediately repeat rocking movement 4 times, and finish with woman on left side.
* The epidural catheter and cannula will be checked immediately post rebozo rocking for any dislodgement.
* The rebozo technique is not to be repeated hereafter, which completes the requirements of the intervention for this woman.

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**Figure 1** *Image of REBozo TEChnique from Cohen and Thomas, 2015.*

## 12.3 Control group (standard care)

As this is a pragmatic study, where standard care is viewed as the comparator (Zuidgeest et al., 2017), standard care refers to actions the midwife would routinely use to try to correct malposition, exclusive of the rebozo technique. Standard care can be both non-invasive and/or medicalised/invasive, which is left to the discretion and experience of the primary carer and her medical team. Depending on the clinical situation, this can include changing the position of the woman, widening the diameter of the pelvis with pillows or a peanut ball between the woman’s knees, oxytocin augmentation or manual rotation of the fetus.

## 12.4 Staff training

Training of midwives will be done in two phases over several weeks, in both an online format and in-person (see Appendix 1). The lead researcher will undertake this training, in consultation with Logan Hospital’s midwifery educator, who is an associate investigator on the research team, and Mater Mothers’ midwifery educator. Phase two of the rebozo technique in-person training has been designed in consultation with an experienced midwife, who has 25 years extensive experience in the use of the rebozo technique, and is a highly regarded midwifery educator and researcher. As the lead researcher is Good Clinical Practice (GCP) trained regarding the requirements for gaining informed consent, phases one and two of the training will be compliant with GCP guidelines. The reason for the training is to instruct midwives on the purposes of the study, the use of the rebozo technique, and trial processes such as inclusion criteria and consent. As there are challenges in providing training to all midwives in a 24 hour clinical area such as birth suite, we intend to use a blended learning approach consisting of two phases in both online and in-person training:

* The Logan Hospital’s online staff training platform routinely available to midwives via Microsoft Teams will be used to present a series of short video presentations providing information on:
* Introduction to the study (including a summary of relevant GCP and ethical principles
* Recruitment, consent and withdrawal.
* Randomisation
* Data collection
* The Microsoft Teams platform records the details of the midwives undertaking the training that will enable us to track completions and provides the user with a certificate of completion.
* Second phase will involve in-person hands on training of the rebozo technique during their routine in-service training sessions that midwives attend prior to handover, between morning and afternoon shifts. This captures both morning and afternoon staff. This will involve a 20-30min demonstration and practicum of the rebozo technique. Details of midwives’ attendance at these in-services is routinely documented.

Midwives will have to complete both phases of this training, the on-line learning and in-person training, to participate in the study. A log of attendance at both of these sessions will be kept. Evaluation of this learning will be via the usual feedback processes required from in-service training, where relevance, impact on learning, and understanding, are evaluated routinely. In-service for clinic midwives, obstetrics and anaesthetics will also be done to inform multidisciplinary groups of the trial objectives and processes.

## 12.5 Randomisation

A separate randomisation schedule for each site will be prepared by a statistician not associated with the study, using variable block randomisation. The schedule for randomisation will be developed using 1:1 allocation. Opaque envelopes will be arranged numerically and will be kept in the birth suite handover room. A log book will record participants hospital identification information, with the corresponding number of the envelope. The trial will be unblinded at allocation due to the nature of the intervention, however, researchers involved in data analysis will be blinded to allocated group. The control group will be assigned to standard care, as defined above in paragraph 11.3, and the intervention group will be assigned to the rebozo technique group, as defined above in paragraph 11.2.

## 12.6 Measurement tools used

There will be two case report forms (CRFs) to collect the relevant data. There will be one CRF for women who are consented, but not randomised, and another CRF for women who are consented and who are randomised. These CRFs will collect relevant bedside data, as well as routine data collected through Metro South’s electronic medical record system, ieMR, and Mater’s medical record system, Matrix, for the study.

## 12.7 Data management, storage and monitoring

For Logan Hospital participants, routinely collected demographic, pregnancy, labour and birth data will be extracted directly from Metro South’s integrated electronic medical record system, ieMR. Similarly, data extraction for Mater participants will be drawn directly from their medical record system, Matrix. The process for providing the consent forms on completion of recruitment and for extraction of the participant data will be done securely as per the requirements of these medical record systems, and liaison with the Metro South and Mater Data Custodians. To ensure secure transfer of data, there are different processes approved for each hospital. For Logan Hospital, the data custodian has given approval for access to this data via ieMR. An associate investigator on the research team can access this data, and extract the data required. For Mater, access of data via Matrix is to be done via a secure compression method process of encryption for the purposes of sharing data. This data will then be stored on the secure UQ data storage system UQRDM (UQ research data manager). The research team will not have access to the ieMR (integrated electronic medical record) system to extract study data. Trial packs, and data collected via CRFs, will be kept in a locked box in the birth suite handover room in each location, where the key will be held by the clinical midwife on duty. Any paper copies will be stored in a locked cabinet in the lead investigator’s office, and accessible only by the UQ research team. Data will be stored, for 32 years as per ethics guidelines (National Health and Medical Research Council, 2018), in The University of Queensland’s secure data storage system, UQRDM (UQ research data manager), which will be used to securely store data from this research project. UQRDM complies with the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council, 2018) and UQ’s research data management policy 4.20.06a. Data will also be managed, stored and monitored as per Metro South Health Research Management policy, policy number PL2017/55, and Mater’s relevant legislation and policies, which are the Privacy Act and Mater’s Information Privacy Policy. The participant information and consent form (PICF) will also outline assurance of confidentiality, that any data collected will be kept on a password protected file. Only the UQ lead researcher and advisors have access to this password protected storage site.

# 13. Sample size

The sample size of this pilot RCT needs to be large enough to identify feasibility. A rule of thumb approach by Hertzog (2008) considered that 30-40 participants per group is a reasonable sample size to test for feasibility, Johanson and Brooks (2010) came to a similar conclusion. Therefore, this pilot RCT will recruit 120 participants (60 per arm), to compensate for the expected attrition rates. The intention will be to recruit 60 women at Logan Hospital and 60 women at Mater Mothers’ Hospital.

# 14. Data analysis plan

Demographic and other baseline characteristics will be analysed for comparability between groups to assess the adequacy of randomisation. Descriptive statistical analysis will be used to assess the primary feasibility outcomes. Distribution will be assessed for normality with parametric or non-parametric tests applied accordingly.  Differences in categorical variables will be explored using relative risk and T tests for continuous variables (Schneider, 2016). The level of statistical significance will be set at <0.05.

# 15. Adverse events

Both de Wolff et al. (2022) and Iversen et al. (2016) found that the rebozo technique was a safe, harmless, non-invasive and non-pharmacological technique. However, if an adverse or serious adverse event occurs, the primary carer midwife in the first instance should report to their team leader and then the hospital’s existing incident reporting system. If the incident involves dislodgement of the epidural catheter and/or cannula, immediate referral to the on-duty anaesthetist will also be required. Additionally, midwives will be instructed to follow Logan Hospital’s ‘adverse events for trials’ flowchart (Appendix 2), and Mater’s adverse events flowchart (Appendix 3), and notify the research team. This entails reporting any adverse events via the case report form, and any serious adverse events to be reported to the Metro South Ethics Committee. The research team will review any potential adverse events on a fortnightly basis. Importantly, the associate investigators, who are Logan Hospital employees, and Mater employees respectively, are routinely advised of all adverse incidents as part of the hospital’s incident reporting system, so will notify the research team of any incidents that potentially involve the study. This will help the research team to be efficient in following up any adverse events. For The University of Queensland (UQ), as per standard practice, insurance will be provided by UQ for clinical trial insurance and be subject to the adverse events for clinical trials processes for UQ. This includes a risk assessment and management plan to be reported to UQ, and adherence to safety reporting of adverse/serious adverse events as per NHMRC safety monitoring and reporting guidelines (Appendix 3).

# 16. Part 2 - Postnatal survey of women

## 16.1 Sampling

Women who consented to being contacted postnatally to participate in the survey will be approached within two weeks following the birth of their baby, by the principal investigator Mrs Kathy Ball, via a text or email link, with two reminders thereafter. This follow-up will require participants to undertake a brief Likert scale survey of their attitudes and experiences. As there have been no studies done on the rebozo technique in this context, survey questions were based on previous studies on midwifery interventions. Survey questions were pilot tested to assess face validity before distribution to the target population (Siedlecki et al, 2015). The Likert scale survey questions include measuring levels of satisfaction, relaxation, perceived success of the randomly allocated intervention, and likelihood of using these techniques in future pregnancies, and if they would recommend it to other women. Women will also have an opportunity for some free text responses. As the survey is an integral aspect of the pilot RCT in providing vital information for further research, the PICF will provide an opportunity for the participant to express interest in participating in this specific part of the study and provide consent for this part.

## 16.2 Data collection

A brief survey one to two weeks postnatally will be developed using Qualtrics software and sent to consenting participants via email or text. The data from the survey will then be collected with Qualtrics software by the principal investigator.

## 16.3 Data analysis

Descriptive statistics will be calculated for all variables, including mean, median, standard deviation, range, and percentages as appropriate. The descriptive statistical analysis will help to further assess the primary outcomes of this research project.

## 16.4 Managing potential risks

As the survey will be asking the woman to reflect on her birth experience, recollecting memories and events from labour and birth may recall distressing thoughts and emotions for the woman. In the event that the woman does become distressed as a consequence of undertaking the survey, it will be made clear to the woman that they do not need to proceed with the survey. Additionally, women will be made aware of the availability of counselling services either via their General Practitioner, Beyond Blue or Lifeline, should they wish to seek support to discuss their experiences further.

# 17. Part 3 - Interview with midwives – qualitative study

## 17.1 Aim

The aim of this qualitative study is to explore the points of view and experiences of the primary midwives who were involved in the care of the women in the REBTEC Pilot Trial. Alongside the survey data of participants, this qualitative study of the involved midwives will provide further vital information for the aim, primary outcomes, and answering the research question, of the REBTEC Pilot Trial.

## 17.2 Sampling

The selection criteria for participating midwives will be all midwives who were involved in caring for women in the REBTEC Pilot Trial. An email will be sent to all midwives at Logan Hospital, and Mater Mothers’ Hospital, inviting those who participated in the trial to take part in the interviews. A member of the research team at each location, who are hospital employees, will be responsible for sending the email to birth suite midwives at each location. Midwives who respond to this email expressing interest in participation will be contacted via email individually, for the more formal process of informed written consent to participate in the qualitative study via the PICF, with contact details of the lead researcher available for further enquiry if needed. Upon receipt of written consent, individual interviews will be arranged at a mutually agreeable time, either before or after a shift, or via Zoom technology. As COVID restrictions can impact the ability to meet face to face, Zoom will be a useful tool to mitigate this. As it is anticipated that 120 midwives will be involved in the REBTEC pilot trial, it is estimated that 15 midwives would constitute a sufficient sample size for interviews, and provide a good cross-section of different perspectives (Vasileiou et al., 2018).

## 17.3 Data collection

The information from midwives will be collected through semi-structured, in-depth interviews. The interviews will be recorded and will take approximately 60 minutes. Follow up contact by phone or email may be required to clarify responses. Participants will be provided an opportunity to review the transcripts prior to data analysis.

## 17.4 Data analysis

All interviews will be audio recorded, transcribed verbatim by a third party, and verified by the researcher conducting the interview. Individual participants will be offered an opportunity to review the transcripts for accuracy. Pseudonyms will be allocated to each midwife to protect anonymity. Other identifying features such as references to staff or women, will be similarly disguised. The thematic analysis process, outlined by Braun and Clarke (2022), will be iterative and inductive as transcripts are read and re-read to identify and clearly define potential themes and sub-themes of relevance. Data will be coded by independent researchers. Inconsistencies will be reconciled by mutual agreement and a final coding scheme agreed. Themes and definitions will be reviewed against the transcribed text to ensure that they accurately reflect the data. Thematic analysis is a useful method in examining the different perspectives of the midwives involved in the pilot trial, by highlighting both the similarities and differences, where unanticipated insights may become apparent (Braun & Clarke, 2022). This approach allows for a very well structured, clear and organised summary of the data from the interviews.

## 17.5 Managing potential risks

Interviews will be conducted at a time and place convenient to the participant. In the event that a midwife becomes upset during an interview, data collection will cease and they will be offered a break from the interview. When they have recovered, they will be invited to resume, or halt, the interview (and data collection). All participants will be made aware of the availability of counselling services at both Logan Hospital and Mater Mothers’ Hospital, and Lifeline, should they wish to seek support to discuss their experiences further.

## 17.6 Confidentiality

Transcripts and audio files will be stored, and password protected and backed up daily on The University of Queensland’s secure data storage system, UQRDM (UQ research data manager). Interview transcripts will be de-identified and given unique participant codes. These unique participant codes will be recorded in a separate password protected spreadsheet and will only be used to re-identify the transcripts upon request from participants to review their data prior to analysis. Only the UQ research team will have access to this aforementioned data. Pseudonyms will be used in all field notes and reporting. Data will be stored, for 32 years as per ethics guidelines (National Health and Medical Research Council, 2018), in The University of Queensland’s secure data storage system, UQRDM, which will be used to securely store data from this research project. UQRDM complies with the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council, 2018) and UQ’s research data management policy 4.20.06a. Data will also be managed, stored and monitored as per Metro South Health Research Management policy, policy number PL2017/55, and Mater’s relevant legislation and policies, which are the Privacy Act and Mater’s Information Privacy Policy. Materials in hard copy will be stored in a locked cabinet accessible only to the UQ research team. The participant information and consent form (PICF) will also outline assurance of confidentiality, that any data collected will be kept on a password protected file. Only the UQ lead researcher and UQ advisors have access to this password protected storage site. No Metro South or Mater Mothers member of the research team will have access to data collected or password protected files.

# 18.  Ethical considerations

The study will commence following approval from both Metro South and The University of Queensland’s (UQ) ethics committees, who will also require written informed consent from all participants. Participants will be respected and informed regarding their confidentiality, anonymity, where and how data will be stored, and informed that as this is a feasibility trial, that the trial may not necessarily proceed to further study. Information about the research’s aims and objectives will be included in the PICF so that women, and midwives, are able to understand the decision to participate, or not. As women in labour are a vulnerable group, the PICF will outline that they are under no obligation to participate, and this will be highlighted to midwives in their training sessions. It will be made clear to the women that withdrawal from the study can be done at any time, without the need for explanation. If the woman, or midwife, withdraw after consent, they will be given an option as to whether any data collected up to that point is included in the data analysis, or removed from data analysis. For participants who would like a summary of the research findings on completion of the research project, they will be provided with contact information of the lead researcher via the PICF to attain this information. Finally, it is imperative that women from culturally and linguistically diverse (CALD) backgrounds have access to interpreters for the discussions and consenting processes for the pilot trial. Therefore, for CALD women, the pilot trial will utilise Logan Hospital’s and Mater Mothers’ Hospital interpreter services. However, in the event a suitable interpreter is not available, inclusion in the pilot trial will not be offered. None of the researchers or midwives involved in this research project have financial interest in this project.

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# Appendix 1 – Training plan for midwives

|  |
| --- |
| **Phase 1 – online learning via Microsoft Teams** |
| **Title**  | **Synopsis** | **Duration** |
| Introduction to the study (including a summary of relevant GCP and ethical principles | * The aims and objectives of the study.
* A short description of the rebozo technique.
* How the study will be in keeping with national NHMRC and GCP guidelines. In particular, these sessions will highlight the importance of protecting participants from unequal relationships, for example, the primary midwife will not recruit/consent the woman in their care, this will be done by other midwives who have had the appropriate training.
* Information on managing adverse or serious adverse events.
* The duration of the study.
* Where to find contact details of the research team and ethics committee.
 | 5 minutes |
| Recruitment and consent | * Inclusion/exclusion criteria of recruitment and consent.
* Provisionally eligible women on admission to birth suite can be approached provided they have received information of the trial during their antenatal visits.
* Provisionally eligible women who have not received information of the trial during antenatal visits can be approached on the condition that they are not in pain, or anxious, and can discuss the trial with a support person(s).
* When formal consent and recruitment can take place (once the epidural is sited and effective).
* Emphasising GCP guidelines for consent and recruitment.
* Detailing ethical requirements of withdrawal by participant, emphasising this can be done at anytime, without explanation.
 | 5 minutes |
| Randomisation | * Additional exclusion criteria specific to randomisation.
* The processes of randomisation.
* When to randomise.
 | 5 minutes |
| Data collection | * How to fill out the data form.
* How to fill out the audit form for women who are eligible who either consent or decline.
* How to access the opaque envelopes for randomisation, and how to document appropriately.
* Where each of these documents can be found.
 | 5 minutes |
| **Phase 2 – In-person training** |
| **Title** | **Synopsis** | **Duration** |
| In-person hands on training of the rebozo technique | * A demonstration of the rebozo technique by the PI, as outlined in paragraph 12.2 of the protocol.
* Opportunity of hands-on practice for midwives in attendance.
* Discussion of back safety in line with standard occupational health and safety practices.
* Discuss possible risks, including possible dislodgment of catheter/IVC, and to check these, both before and after the rebozo is implemented.
* Emphasise that while there is an exclusion criterion of >35 BMI to protect back safety, that it will be at the discretion of the midwives involved if it is safe for their back to perform the rebozo technique, regardless of BMI, and to not proceed if they think this is a risk.
* This will take place in the routine timeslot between morning and afternoon shifts that is specifically allocated to in-service sessions, capturing both morning and afternoon staff.
 | 20-30 minutes |

# Appendix 2 – Logan Hospital’s adverse events for Trials flowchart



# Appendix 3 – NHMRC/UQs safety reporting flowchart



1. Early term: 37-38.6 weeks; Full term 39-40.6 weeks; Late term: 41-41.6 weeks; Post term: >42 weeks. [↑](#footnote-ref-1)