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# Rebozo and maternal postures to prevent persistent occiput posterior position of the fetal head: protocol for a randomised clinical trial 'the ReMaP-POPP RCT'

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## ABSTRACT

**Introduction** Occiput posterior position is the most common fetal malposition, complicating up to 35% of initial labours, and its persistence can lead to increased risks of adverse maternal and perinatal outcomes. The role of maternal postures, such as lateral recumbent and hands-and-knees, in promoting the anterior rotation of the fetal head has been investigated in several randomised trials in the last two decades, with mostly negative results. However, both methodological and study design limitations may have contributed to such findings. Recently, the use of forward-leaning inversion and side-lying release procedures and of the Rebozo technique has been implemented into clinical practice as a non-invasive alternative to promote the anterior rotation of the fetal head. Yet, neither intervention has been rigorously assessed in a controlled study. Our aim is to conduct a randomised controlled trial to assess whether a combination of forward-leaning inversion and side-lying release procedures and the Rebozo technique in a pre-specified sequence during the first stage of labour of women with a posterior fetus would favour its anterior rotation.

**Methods and analyses** The ReMaP-POPP (*Re*bozo and *ma*ternal *p*rocedures to prevent *p*ersistent *o*cciput *p*osterior *p*osition of the fetal head) trial will be an open-label single-centre randomised controlled trial with two parallel groups. Women will be eligible if they are ≥18 years old, in labour (3 to 8 cm) and with a singleton term fetus (≥$37^{0/7}$ weeks) in an occiput posterior position confirmed by transabdominal sonography. Eligible women will be randomised into two groups: (1) intervention, a sequence of forward-leaning inversion and side-lying release procedures and Rebozo technique (duration 90–105 min); and (2) control, standard of care (maternal postures, including upright, lateral recumbent and hands-and-knees). Blinding will be guaranteed only for the physician assessing the fetal head position by sonography. Randomisation will be performed using randomly permuted blocks of varying sizes (4, 6 and 8), stratified by parity, in a 1:1 ratio. The primary outcome will be the probability of occiput posterior position of the fetal head 3 hours and 30 min after randomisation, diagnosed by sonography. Secondary outcomes will include the probability of occiput posterior position at full cervical dilation and at birth, maternal and neonatal health-related outcomes, as well as maternal pain intensity and ability to cope with pain and birth satisfaction level. We will also assess safety outcomes regarding challenges in adequate fetal heart rate monitoring during the time interval between randomisation and primary outcome assessment. Sample size estimation considered the possibility to decrease the probability of occiput posterior position from 35.8% (control, based on prior retrospective data at our Institution) to 22% with the proposed intervention. With a power of 0.90 and a two-sided value of 0.05, the estimated sample size will be n=462 (n=231/arm). Considering a potential attrition rate of 20%, n=578 women will be needed. Enrolment will require approximately 16 months. Primary and secondary outcomes will be analysed on an intention-to-treat basis. The effects of the intervention will be estimated by relative risks and their 95% CI.

**Ethics and dissemination** The study has been approved by the Lombardy Ethics Committee n.3 (n. 5499, 20 December 2024). Written informed consent will be obtained from all participants. Women will be free to decline participation or to withdraw at any time. Findings will be presented at scientific meetings and published in

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a randomised controlled trial with allocation concealment and blinded outcome assessment.
⇒ Suprapubic transabdominal sonography is used to assess fetal head position in a blinded fashion for eligibility screening and primary endpoint evaluation.
⇒ Stratified randomisation by parity allows control for a major confounding variable in labour progression.
⇒ Blinding of the randomisation arm is not feasible due to study design, thus possibly introducing performance bias.
⇒ The single-centre design may limit generalisability to other clinical settings.

peer-reviewed scientific journals in the field of midwifery and obstetrics. Also, they will be disseminated to the public through outreach activities involving families and healthcare specialists.

**Trial registration number** The study has been registered in the Clinical Trials database (NCT06887634).

## INTRODUCTION

### Background and rationale

Occiput posterior position (OPP), ie, when the back of the fetal head lies posteriorly in the mother's pelvis, is the most common fetal malposition, being identified in 35% of labouring women.[1 2]

Probabilities of OPP in labour vary among studies on the topic due to differences in OPP assessment, with research employing the gold standard technique of transabdominal suprapubic sonography alongside or alternatively to vaginal examination having the highest accuracy.[3–5]

Overall, the probability of OPP has been estimated to be 35% in the early phase of active labour, 20–30% at full cervical dilatation and 5–13% at delivery.[1 2]

The decrease of OPP probability throughout labour till delivery is due to spontaneous rotation of OPP fetuses in an occiput anterior position (OAP), the most favourable for labour and birth, usually before the start or at the beginning of the second stage of labour.[5–8] Spontaneous rotations are unlikely once the second stage has begun. The vast majority of OPP deliveries results from the failure of rotation from this position.[3–5]

Persistent OPP (POPP) during the second stage of labour has been shown to increase the risk of both maternal and neonatal adverse outcomes.

It exposes to prolonged labour, operative abdominal and vaginal delivery, high-degree perineal lacerations and postpartum haemorrhage. Also, POPP has been related to low Apgar scores and cord blood pH values at birth, admission to neonatal intensive care unit and neonatal encephalopathy.[2 9–17] Importantly, traumatic births, such as those that can be more frequently observed among women with POPP, have been associated with decreased birth satisfaction and higher rates of impaired postpartum emotional health.[18]

Several factors have been recognised to associate with heightened odds of POPP, including loose abdomen (ie, reduced muscular tone or laxity of the abdominal wall), nulliparity, late-term and post-term pregnancy, fetal macrosomia, high maternal body mass index, epidural analgesia, untimely amniotomy, anterior positioned placenta and narrow pubic arch angle typical of the android and anthropoid maternal pelvis.[5 16 19–25]

Different interventions have been evaluated to favour anterior rotation of an OPP fetus during labour, such as maternal posturing[26–28] and manual or instrumental rotation of the fetal head.[29–35]

Both manual and instrumental rotation are associated with high success rates but can be performed only at the end of the first or during the second stage of labour and may be associated with fetal and maternal complications. Also, they require the provider's skill and confidence.[30–39]

On the other hand, maternal postures, such as hands-and-knees and lateral recumbent position, seek to non-invasively promote flexion of the fetal head to favour its spontaneous rotation into the OAP through changes in the pelvic angles and diameters and forces of gravity and buoyancy.[40–42]

Several randomised clinical trials investigating hands-and-knees and lateral recumbent positions for increasing the probability of OAP in labouring women with an OPP fetus have been completed in the last twenty years, with contrasting results.[18 27 28 40 43–51] In a few studies, a positive effect of maternal postures was observed,[46–48 50] whereas in the majority of them, findings were negative.[27 28 40 43–45] However, in most negative trials, substantial limitations can be observed, including a clinical instead of a sonographic evaluation of OPP,[45] an inadequate sample size[43] and the maintenance of the investigated maternal posture for a too short period of time (≤30 min).[43–45] It is likely that fetal head rotation is induced by the combination of maternal posture and uterine contractility, thus making maintenance of a certain posture for a sufficient period of time (at least 1 hour) pivotal for its effectiveness.[18 28] In addition, in all but one trial, only one specific maternal posture represented the intervention under investigation.[28 43–50] Yet, 'active births', characterised by at least three changes in maternal posture during the active phase of labour, had been shown to associate with shorter labour and lower caesarean delivery rate than those observed in 'inactive' labouring women.[52]

Of note, little or no effect on health outcomes of women and their infants and on maternal satisfaction has been reported by a recent Cochrane review on maternal postures in labour in case of fetal malposition, and the need for further research on the topic has been highlighted.[18]

Although no clear benefits of maternal postures have been identified,[18 27 28 45] some trials have shown an improvement in maternal back pain and comfort.[43 44 49] Considering this, and the fact that maternal postures are safe, simple to execute, non-invasive and widely accepted by women, they are a cornerstone of the current obstetric practice employed by midwives in assisting labouring women with an OPP fetus in Italy as well as worldwide.

More recently, additional interventions have been proposed as non-invasive alternatives to classical maternal postures for favouring anterior rotation of an OPP fetus: the forward-leaning inversion (FLI) and the side-lying release (SLR) postures and the Rebozo technique.[53 54]

The FLI and SLR postures rely on the importance of the role of soft tissues, including ligaments, muscles and connective tissue, in fetal head's correct positioning (ie, anterior) and labour onset and progress (figure 1A,B). Briefly, the FLI uses stretch receptors to untwist and lengthen the utero-sacral ligament for increased maternal comfort, ease of dilation and improved fetal position, whereas the SLR allows uterus repositioning, pelvic floor softening and buttock and hip muscle release.[55]

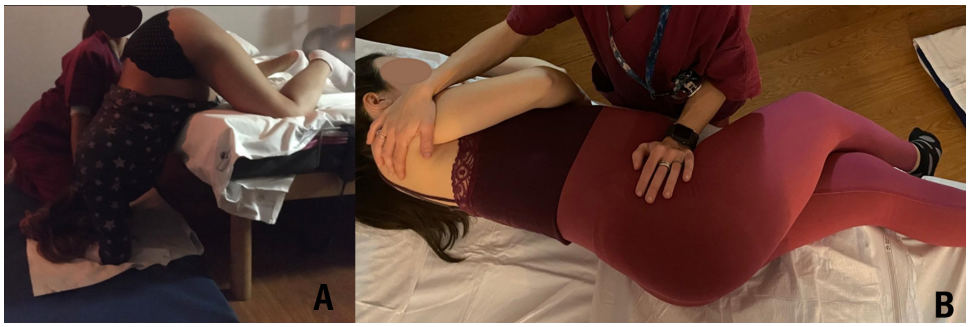


**Figure 1** The forward-leaning inversion and the side-lying release procedures. Pictures show the forward-leaning inversion (A) and the side-lying release (B).

The Rebozo technique is based on the use of the *rebozo* (a woven shawl) to massage or shift the woman's pelvis or uterus (figure 2A–D), thereby encouraging fetal rotation and optimum positioning, as well as promoting maternal comfort during labour. It is a long-standing traditional practice from central and southern Mexico, which, in recent years, has spread to other countries, including the USA, Denmark and Italy.[53 54]

Neither the FLI and SLR postures nor the Rebozo technique has been shown to harm the mother or the fetus.[53 55 56] Also, they are non-invasive and have been associated with a positive childbirth experience.[54 55] Yet, neither intervention has been rigorously evaluated in a research study as to its effectiveness in determining anterior rotation of an OPP fetus.

Given the complications that are associated with a POPP, it is important to rigorously evaluate interventions that may help fetuses to rotate to the OAP.

There are currently two trials registered on Clinicaltrials.gov and one registered on ANZCTR (Australian New Zealand Clinical Trial Register), not yet recruiting and located in the USA and New Zealand, respectively, aiming to investigate lateral recumbent position to promote anterior rotation of the fetal head in case of OPP (NCT05307393, 'Maternal Positioning to Correct Fetal Occiput Posterior', NCT05881629, 'Early Diagnosis and Intervention for Fetal Malposition in Active Labour and Its Impact on Mode of Delivery' and 'Evaluate the design of a randomised trial of posture for occiput posterior position in labour (POPPIL) to reduce operative births. A feasibility study', ACTRN12624000375550).[57 58]

It is well known in the field of medicine and public health that a bundle of interventions, grouped together in a single protocol, for improving a specific outcome is usually more effective than any single intervention delivered alone.[59] This concept is referred to as the 'care bundle'.[60 61] By acting on uterus repositioning and pelvic floor muscle and uterine ligaments and fascia release, the supposed mechanisms of action underlying both the FLI and SLR postures and the Rebozo technique are similar. Such mechanisms can possibly create the most favourable conditions to allow anterior rotation of the OPP fetal head.[53 55 56] Also, it is known that frequent changes in maternal postures during active labour can reduce labour length and operative delivery rate.[52]

Therefore, we hypothesised that a combination of FLI and SLR postures and Rebozo technique in a pre-specified sequence during the first stage of labour of women with an OPP fetus would favour fetal head flexion and, in turn, its anterior rotation, thus leading to lower probabilities of OPP at 3 hours and 30 min from randomisation compared with women using only maternal postures[28 40].

## Objectives

The aim of our study is to assess whether a sequenced approach including the FLI and SLR postures and the

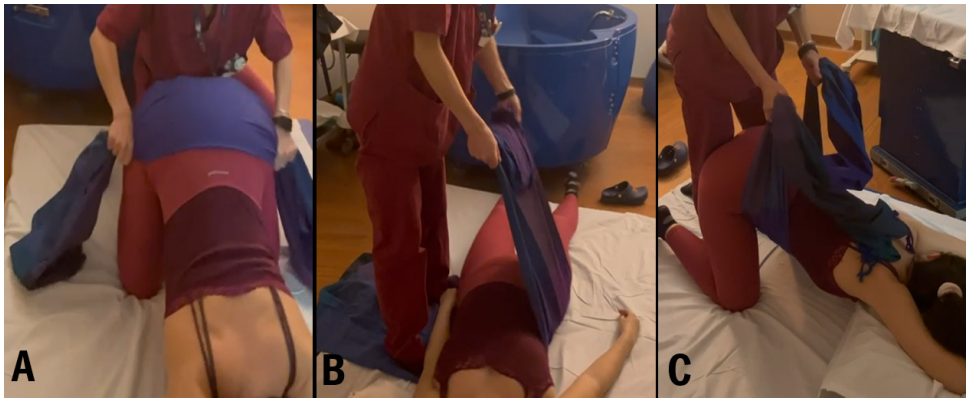


**Figure 2** The Rebozo technique. Pictures display the use of the Rebozo to massage the maternal pelvis in a woman in a hands-and-knees position (A), the maternal side ipsilateral to the fetal spine (B) and the uterus in a woman in a hands-and-knees position (C).

Rebozo technique favours fetal head rotation from OPP to OAP in a randomised controlled trial.

## METHODS AND ANALYSIS

### Patient and public involvement

Patients were not directly involved in the design or conduct of the study; however, a thorough literature review, which included evaluation of both quantitative and qualitative studies on patients' experience and preferences in case of labour with a posterior fetal head position, has been conducted before defining the research question and outcome measures.[18] The burden of the intervention will be assessed by evaluating maternal satisfaction of the childbirth event.

Study's results will be disseminated to participants by means of dedicated in-person events and online communications (Fondazione IRCCS San Gerardo dei Tintori Facebook page).

### Trial design and setting

#### Study design

The ReMaP-POPP (*Re*bozo and *ma*ternal *p*rocedures to prevent *p*ersistent *o*ccput *p*osterior *p*osition of the fetal head) trial will be a pragmatic, open-label, single-centre randomised controlled trial with two parallel groups.

Maternal postures, including upright, lateral recumbent and hands-and-knees, have been commonly used at our Institution by midwives assisting labouring women with OPP fetuses. Also, in the last couple of years, training sessions for both the FLI and SLR postures and the Rebozo technique have been undertaken by midwives at our institution to improve their knowledge and operational confidence in both interventions, which, in turn, have been progressively introduced in clinical practice. However, their use in labouring women with an OPP fetus is still inconsistent.

#### Study setting

The study will be conducted at the labour and birth (L&B) unit, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy. The research centre is an academic maternity unit with approximately 2600 births per year.

### Eligibility criteria

Eligible women will be ≥18 years old, in labour and with a singleton term fetus ($\geq 37^{0/7}$ weeks of gestation) in an OPP clinically diagnosed between 3 and 8 cm of cervical dilation and confirmed by transabdominal sonography.[62] Ultrasound will be performed by a trained clinician, who will be different from the clinician performing Leopold's manoeuvres and vaginal examination and blinded to the findings of these two steps and to the randomisation group.

Women with growth-restricted fetuses (FGR), defined according to the Delphi consensus, will be excluded.[63] Early FGR (<32 weeks) includes estimated fetal weight (EFW) or fetal abdominal circumference (AC) <3rd centile, absent end-diastolic flow in the umbilical artery (UA), or EFW/AC <10th centile with UA or uterine artery pulsatility index (PI) >95th centile. Late FGR (≥32 weeks) includes EFW or AC <3rd centile, or EFW/AC <10th centile, crossing >2 growth chart quartiles, cerebroplacental ratio (CPR) <5th centile or UA-PI >95th centile.[63] Fetuses with congenital anomalies or infections or with chromosomal abnormalities, intrauterine fetal demise, and fetal and/or maternal conditions requiring urgent or emergent delivery or impeding the use of the Spinning Babies procedures and/or the Rebozo technique (eg, non-reassuring fetal heart rate (FHR), abnormal vaginal bleeding, epidural analgesia resulting in reduced mobility, polyhydramnios, extrapelvic fetal head, body mass index ≥35 $kg/m^2$, hypertensive disorders of pregnancy (HDP) with inadequate control of blood pressure,[64] maternal heart disease in class III to V according to the modified WHO (mWHO) classification,[65] glaucoma or ocular surgery, oesophageal reflux disease, hypermobile sacro-iliac joint and severe symphysis dysfunction) will be excluded. Also, we will not enrol women in whom caesarean section is planned as mode of birth, who did not receive information regarding the study before onset of active labour, who do not understand Italian if an official translator cannot be present at the time of explaining the study and proposing enrolment, as well as women in whom the Spinning Babies procedures and/or the Rebozo technique have already been used before enrolment.

### Intervention and comparator

Specifically, the intervention group will receive a combination of FLI and SLR postures and Rebozo technique in a pre-specified order, as displayed in figure 3. The duration of the intervention ranges between 90 and 105 min, according to the rhythm of uterine contractions. The range of cervical dilation for eligibility (3–8 cm) has been chosen to allow completion of the intervention. The intervention will start within 30 min after randomisation; it can be interrupted at any time if needed, eg, placement of epidural analgesia or FHR abnormalities; it will be considered performed when the proposed sequence is completed (figure 3).

Women allocated to the control group will receive the standard of care, including upright, semi-recumbent, lateral recumbent and hands-and-knees positions. They will not receive FLI or SLR or Rebozo.

After completion of the sequence, women in the intervention group will be allowed to move freely and adopt different postures, such as upright, semi-recumbent, lateral recumbent or hands-and-knees. No FLI or SLR postures or the Rebozo technique will be further allowed until sonographic assessment of the fetal head is performed, at 3 hours and 30 min after randomisation. Similarly, the control group will continue to adopt maternal postures with no possibility of performing the FLI or SLR postures or the Rebozo technique until sonographic assessment of fetal head position is completed.

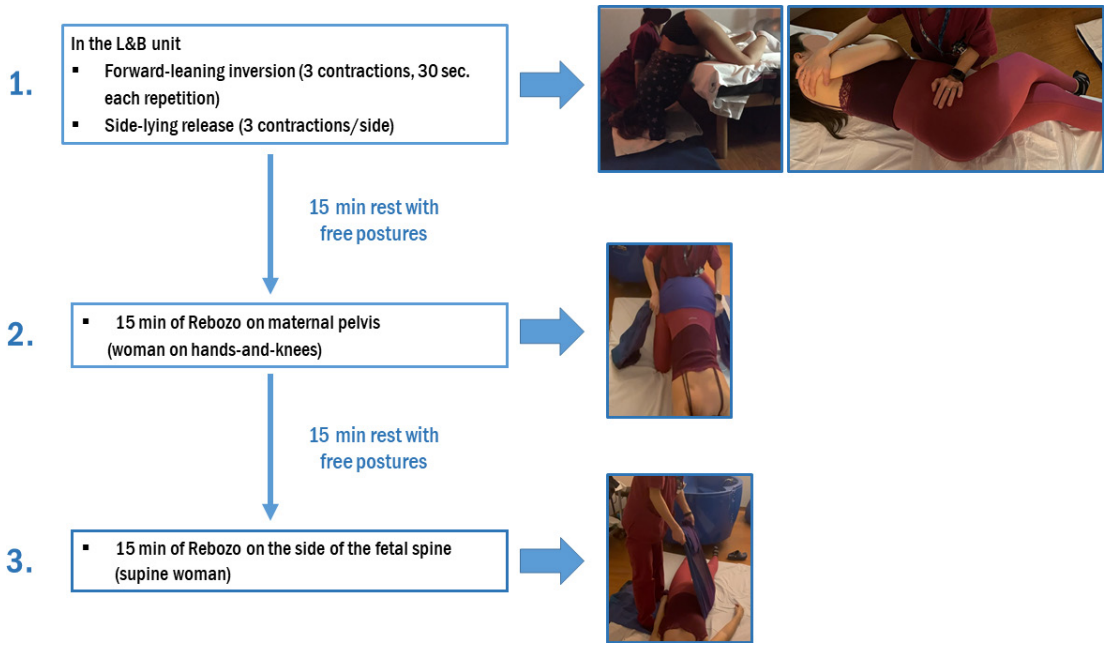


**Figure 3** Sequence of forward-leaning inversion and side-lying release procedures and the Rebozo technique in the intervention group. L&B, labour and birth.

The choice of this time frame for primary outcome assessment was based on several considerations. First, it ensures adequate time for transferring the woman to the labour room and for the midwife's initial assessment, including evaluation of pain intensity and coping ability. The subsequent 3 hours are expected to allow for full implementation of the intervention sequence in most women in the intervention group—even in the presence of low-frequency uterine contractions or temporary interruptions due to epidural placement or FHR abnormalities. Moreover, this time frame provides a reasonable balance between protocol adherence and clinical flexibility, while also minimising the risk of contamination in the control group: after this period, FLI, SLR and Rebozo may be used in the control group as well, at the midwife's discretion.

Once sonography is performed at 3 hours and 30 min after randomisation, findings will be communicated to the midwife and obstetrician in charge to allow proper labour management among women in both groups, with the possibility of using maternal postures, FLI and SLR postures and Rebozo technique, according to the L&B unit's practices.

An additional ultrasound to assess fetal head and spine position will be performed once full cervical dilation is reached. Also, sonography will be performed to confirm fetal head and spine position before performing operative vaginal or abdominal delivery.

Before the beginning of the trial, all participating midwives and obstetricians will receive didactic instructions on the protocol procedures and review the proposed sequenced approach to ensure consistency. A graphical abstract of the study protocol will also be available as a poster in the L&B unit. One senior midwife and one obstetrician per shift will be identified as the clinicians in charge of coordinating and overseeing the trial procedures during the shift. In addition, a PhD candidate, who has a strong background in midwifery (M.P.), will be dedicated to the study and, thus, present daily in the research setting to monitor implementation, support the clinical team and ensure adherence to the protocol throughout the study period.

## Outcomes

The primary outcome is the probability of OPP of the fetal head 3 hours and 30 min after randomisation, diagnosed by suprapubic transabdominal sonography by a trained clinician blinded to the randomisation group. The fetal head position will be classified into one of three categories (figures 4 and 5): occiput anterior (OA) (right and left), occiput transverse (OT) (right and left) and OP (right and left).[62] If the fetal head position cannot be clearly defined, sonography will be repeated by another trained, senior clinician. For women who will give birth before the end of the 3 hours and a half after randomisation, fetal head position at birth will be considered as the fetal head position for this outcome.

The main secondary outcomes are as follows: (1) probability of OPP confirmed by ultrasound examination at full cervical dilation (before the beginning of active maternal pushing efforts); for women who will give birth before sonography at full dilation can be performed, information regarding fetal head position at this timing will be considered as 'missing'; and (2) probability of OPP at delivery (in women undergoing operative delivery, the fetal head position diagnosed by sonography right before delivery will be considered as the position at birth).

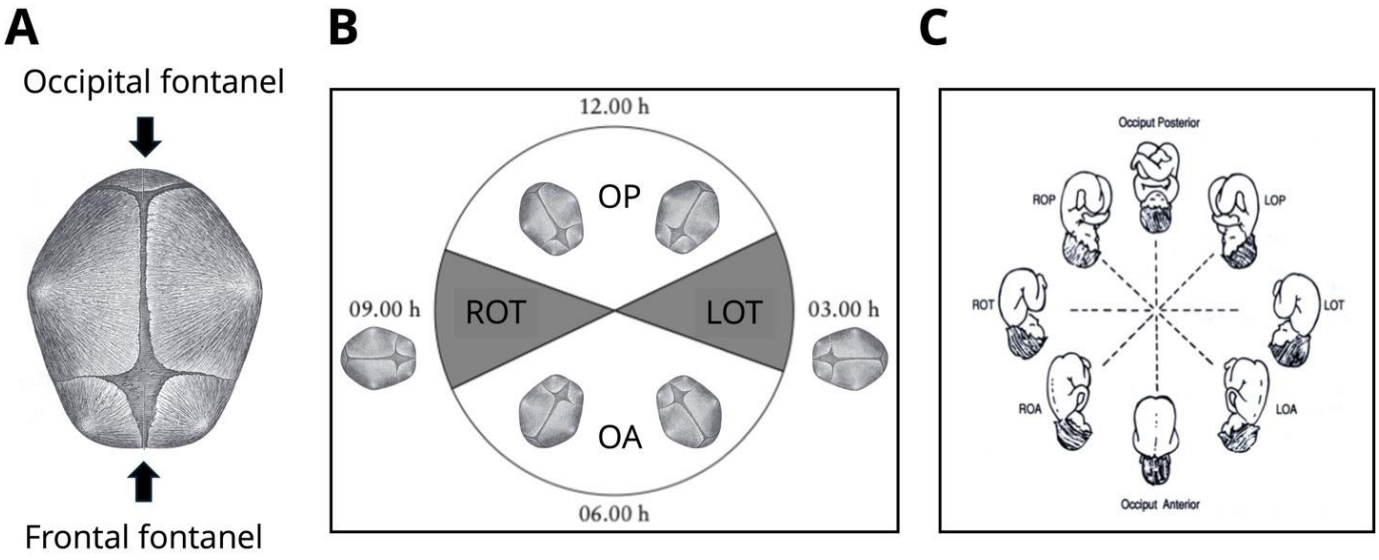


**Figure 4** Fetal head fontanels and the potential location of fontanels and spine in the maternal pelvis. The figure displays the occipital and the frontal fontanel of the fetal head (A), as well as their location inside the maternal pelvis (B), alongside the location of the fetal spine (C). LOT, left occiput transverse; OA, occiput anterior; OP, occiput posterior; zr; ROT, right occiput transverse.

Additional secondary outcomes are as follows: (3) duration of labour; (4) mode of delivery; (5) perineal lacerations (episiotomy or third-degree and fourth-degree perineal tears); (6) primary postpartum haemorrhage (quantitative blood loss >1000 mL[66 67]); (7) woman's pain intensity and ability to cope with pain, assessed using the Pain Intensity Scale and the Pain Coping Scale at two time points (within the first 30 min and at 3 hours and 30 min

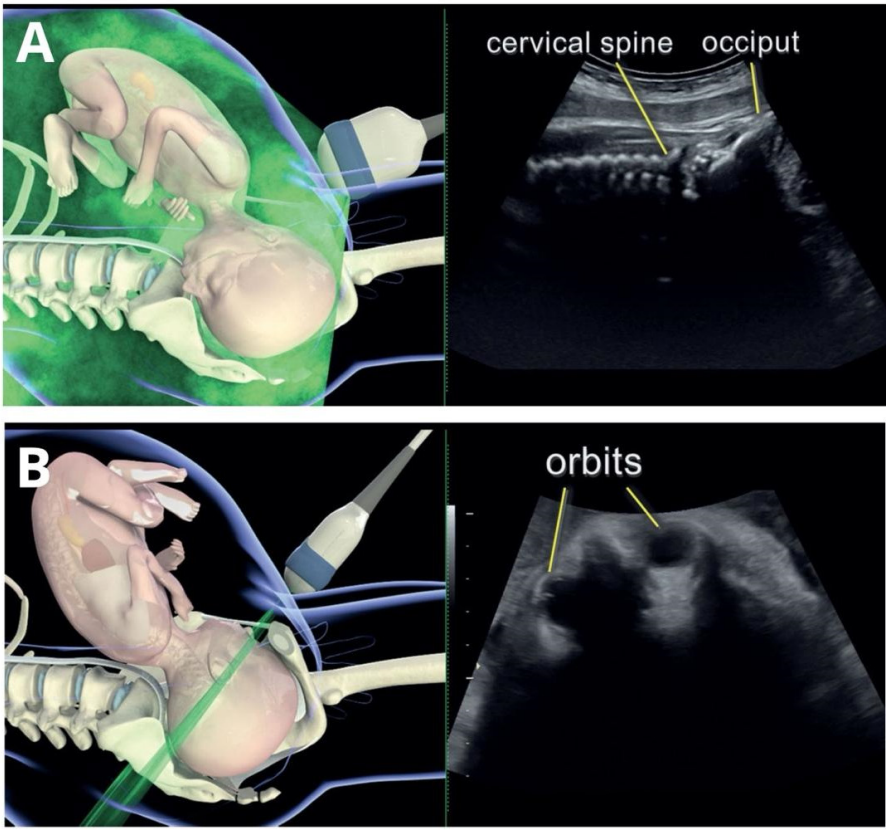


**Figure 5** Sonography for diagnosing fetal spine and head position during labour. A suprapubic transabdominal sonography identifies an anterior fetal spine and occiput in an occiput anterior fetus (A) and anterior fetal orbits in an occiput posterior fetus (B). Adapted from Ghi *et al*.[61] Reproduced with permission from: Ghi T, Eggebø T, Lees C, *et al* ISUOG Practice Guidelines: intrapartum ultrasound. Ultrasound in Obstetrics & Gynecology. 2018;52(1):128–139.

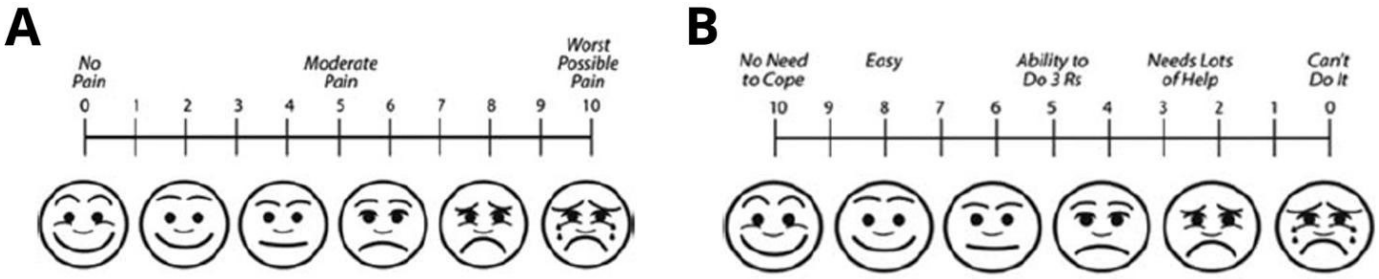


**Figure 6** The Pain Intensity Scale (A) and the Pain Coping Scale (B). Adapted from Simkin *et al*.[67]

after randomisation) (figure 6A,B); presence of epidural analgesia will also be recorded[68]; (8) maternal birth satisfaction level, assessed using the 10-item Birth Satisfaction Scale-Revised (BSS-R) at least 24 hours after birth and before hospital discharge[69]; (9) admission to neonatal intensive care unit; and (10) signs and symptoms of pelvic floor and sexual dysfunction at 6–9 months postpartum, including presence of urinary/faecal incontinence, pelvic pressure and dyspareunia, assessed through clinical interview, validated questionnaires (Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)), vaginal manometry, electromyography, the Modified Oxford Grading System, Pelvic Organ Prolapse Quantification (POP-Q) score, stress test for incontinence and 2D/3D ultrasound assessment of bladder neck descent and/or genital ballooning.[70–76]

## Data collection methods

### Data collection process

Midwives and obstetricians will perform Leopold's manoeuvres, vaginal examination and sonography at the time of the woman's assessment for eligibility. Sonography will be performed by a physician blinded to the randomisation group. Midwives and obstetricians involved in eligibility assessment will enrol eligible women and obtain the signed informed consent. The senior midwife or obstetrician in charge of coordinating and overseeing the trial procedures during the shift will randomise the eligible women.

Women will be assessed sonographically at enrolment, at the end of the three and a half hours after randomisation, at full cervical dilation and before any operative delivery to define fetal head and spine position. In women undergoing operative delivery, the fetal head position diagnosed by sonography right before delivery will be considered as the position at birth. The position of the fetal head will also be prospectively collected at each vaginal examination during labour, alongside the fetal head level and at birth by the physicians managing the labouring woman, and recorded in a dedicated study's data collection chart. Also, details of the postures employed by the women and their duration will be recorded, as well as the number and duration of interruptions in the intervention sequence, if any, and its completion. Further, deviations to the protocol (eg, use of Rebozo in a woman in the control group) will be recorded.

Two research assistants independent of the local medical team will assess the collected study's data collection chart and record the included data in the Research Electronic Data Capture (REDCap) database; all paper printouts of the ultrasound assessment will be collected, scanned and safely stored in the system. Another independent research assistant will monitor and assess the quality of data for all participants.

Race and ethnicity will be classified according to the method recommended by the National Institute of Health, notice number NOT-OD-15–089. The following categories will be considered: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander and White[77] . [78]Immigrant status will be defined as any person who is not a citizen or national of Italy but who is living permanently in Italy. This group will also include refugee claimants.

The data will be treated confidentially, stored securely on laptops that will be password protected and disposed of properly at the completion of the study (Data Protection Code, 2003; GDPR, 2018).

### Data collection tool

Data will be collected online using the REDCap system provided by the University of Milan-Bicocca Clinical Research Office (BiCRO).

REDCap assures maintenance of data confidentiality by the automatic generation of a research code for each enrolled woman by means of an electronic document.

A paper logbook containing information on all women screened for eligibility and the reasons for ineligibility or lack of inclusion if eligibility is met will be kept separately, in a locked cabinet accessible only by the principal investigator and the research assistants. This logbook will also contain research codes and personal data of enrolled women.

The REDCap database is constituted by different modules to collect data regarding maternal general characteristics, medical and obstetric history, ultrasound scans and clinical course of the pregnancy, labour and birth outcomes and neonatal outcomes (online supplemental material 1).

The research assistants involved in data collection and recording in the REDCap database will be trained to use the system before the commencement of the study; only

these research assistants and the principal investigator will be granted access to the system.

Before the beginning of the trial, all participating midwives and obstetricians will be specifically trained on the execution of transabdominal ultrasound to assess fetal head and spine position to ensure adequacy and consistency in outcome assessment.

For participants who discontinue or deviate from the intervention protocol, all outcome data specified above will be collected. Reasons for non-adherence (eg, discomfort, perceived inefficacy, adverse effects or other personal or clinical factors) will be systematically recorded in the case report forms. Similarly, reasons for non-retention (eg, withdrawal of consent and loss to follow-up) will be documented when available. To support retention at the 6 month follow-up, participants will be offered a free-of-charge gynaecological assessment, including clinical evaluation and counselling, as an incentive and opportunity for continuity of care. Additional periodic reminders (via phone or email) will be sent to participants to minimise attrition.

## Harms

Safety outcomes will include (1) rate of FHR assessments that are considered to be of poor quality (satisfactory/acceptable/unsatisfactory) in women with both intermittent and external continuous FHR monitoring; (2) frequency of FHR signal loss (<10%, 10–25%, 25–50%, >50%) in women with external continuous FHR monitoring; and (3) need of an internal electrode to allow proper continuous FHR monitoring because of maternal positions during the first 3 hours and a half after randomisation. These outcomes will be assessed systematically by the attending midwives or obstetricians managing the randomised women's labour; these professionals will not be blinded to group allocation. Data will be recorded in real time using predefined criteria and structured forms integrated in the case report form. Harms will be monitored continuously from randomisation until birth, and any unanticipated adverse event will be documented according to clinical records and reported to the Data and Safety Monitoring Board (DSMB) as per trial procedures. All adverse events will be coded by the clinical research team using standard obstetric definitions and graded by severity (mild, moderate and severe) and causality (related or unrelated to the intervention). Coding and grading will be reviewed by an independent member of the research team not involved in participant care and blinded to allocation. Serious adverse events or events leading to early discontinuation of the intervention will be promptly reported to the DSMB.

## Participant timeline

A detailed flowchart outlining the trial timeline has been developed to support clinical staff in the consistent implementation of the study procedures. This visual tool is available as the online supplemental material 2.

## Sample size

Power analysis was conducted by means of Pearson's $\chi^2$ test comparing two independent proportions.

According to a prior retrospective analysis performed on labouring women managed at our Institution in 2017 (ie, when only maternal postures, including upright, semi-recumbent, lateral recumbent and hands-and-knees, were used) and in 2023 (ie, after the introduction of the FLI and SLR procedures and the Rebozo technique into clinical practice), we observed a probability of POPP at complete dilation of 35.8% (95% CI 0.31 to 0.40) and 27.7% (95% CI 0.22 to 0.34), respectively (risk difference−0.081, 95% CI −0.15 to −0.008; p=0.031).[79] The 2017 value is in line with findings from prior trials on maternal postures in fetal malposition.[28 40]

Considering the potential benefits of an approach based on a pre-specified, >1 hour-long sequence of FLI, SLR and Rebozo procedures, we assume that women in the intervention group can reach a probability of OPP of the fetal head at sonography assessment 3 hours and a half after randomisation of 22% (lower limit of the 95% CI of the probability observed in our 2023 retrospective analysis, 27.7%, when FLI, SLR and Rebozo procedures had been introduced into clinical practice, although inconsistently used). This leads to a clinically meaningful Δ between the intervention (22%) and the control group (35.8%) of 13.8%. To show this difference with a power of 0.90 (1-β) and a two-sided α value of 0.05, the study will require the inclusion of 231 women in each group, for a total of 462 participants with a 1:1 ratio (figure 7). Considering a potential attrition rate of 20%, the final estimated sample size will be n=462/(1–0.20)=578 participants.

According to our prior retrospective analysis, approximately n=450 women per year will be eligible in the study. Thus, we anticipate a total duration of the enrolment period of ~16 months.

## Recruitment

Participants will be recruited at a single academic maternity centre located in Northern Italy. The enrolment phase is expected to begin in October 2025, with study completion anticipated by November 2027. All women accessing our L&B unit will be assessed to (1) define fetal spine position by the second Leopold's manoeuvre (figure 8A–D), (2) diagnose cervical dilation and fetal head position and level by vaginal examination and (3) confirm fetal head and spine position by transabdominal sonography.

Vaginal examination can diagnose fetal OPP by finding the junction of the sagittal and lambdoidal sutures of the fetal head (occipital fontanel) located at least 45 degrees posterior to the transverse diameter of the maternal pelvis (figure 4A–C), whereas sonography can locate the position of the fetal orbits anteriorly or the cervical spine posteriorly to the maternal pelvis (figure 5A,B).[62] Training for performing transabdominal sonography will be completed by all the participating midwives and obstetricians before starting the trial. The training includes

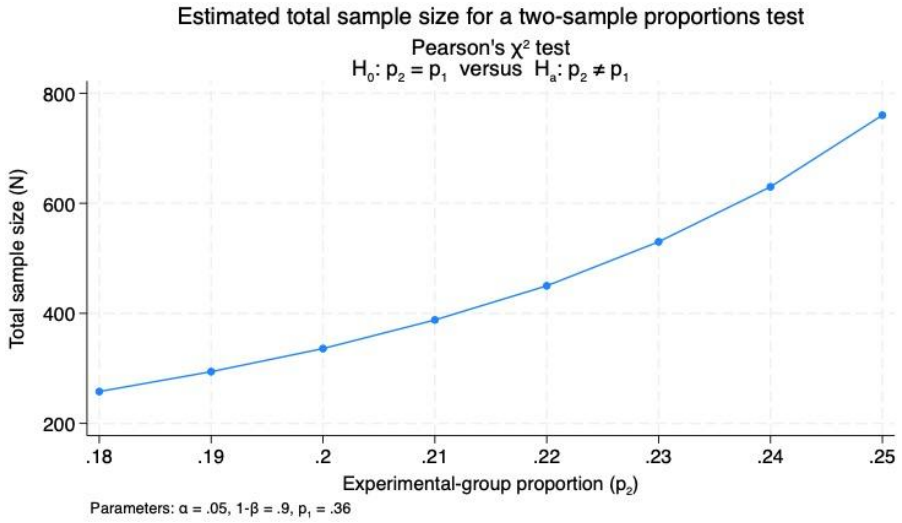


**Figure 7** Pearson's $\chi^2$ test for two independent proportions for sample size estimation. The graph displays the different total sample sizes needed (y axis) according to 1% increment (from 18% to 25%, x axis) of the rate of POPP in the intervention group, as assessed at 3 hours and 30 min after randomisation, considering a baseline POPP rate (control group) of 36%.

both a theoretical component and a practical hands-on session. During the practical part, participants (midwives and obstetricians) perform supervised ultrasound assessments on pregnant women admitted to the maternity unit where the trial will take place. This training model will ensure an adequate level of theoretical and practical expertise among clinicians, supporting the reliability and consistency of the ultrasound-based assessment of the primary outcome.[80]

To increase acceptability and participation, information regarding the study will be provided to all eligible women and their partners during an antenatal visit in the third trimester of pregnancy by clinicians.[81] Fliers about the study will also be posted in the outpatient clinic, the antenatal ward and the L&B unit. Importantly, all women who plan to give birth at the study centre—regardless of where they receive their antenatal care—are routinely offered a dedicated pre-labour consultation around 36 weeks' gestation. This appointment provides an opportunity for early engagement and personalised explanation of the study. Such information will be repeated in the L&B unit to women in labour and their partners after sonographic confirmation of fetal OPP.[81] Women will be asked to confirm their participation and provide written consent. After inclusion, they will be randomly assigned to the intervention or the control group.

Active engagement of women will be pursued through public dedicated website communications (Fondazione IRCCS San Gerardo dei Tintori Facebook page), digital content and leaflets reporting on the implications of the study and webinars. The involvement of relevant professional categories (eg, midwives and obstetricians) will be achieved by means of online and in-person meetings.

### Randomisation: sequence generation, allocation concealment mechanism and implementation

As soon as the written consent is signed, the randomisation will be performed by an automated web-based system to ensure allocation concealment (24-hour accessibility with personal login and password), provided by BiCRO. The senior midwife or obstetrician in charge of

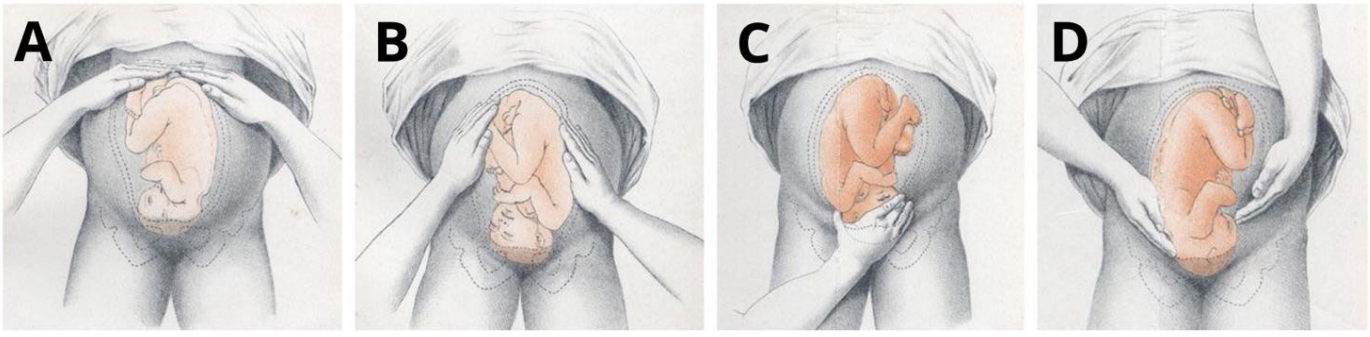


**Figure 8** The Leopold's manoeuvres. The four Leopold's manoeuvres are shown: the first manoeuvre or fundal grip, assessing the uterine fundus to determine its height and which fetal pole occupies the fundus (A), the second manoeuvre or umbilical grip, for identifying the location of the fetal spine (B), the third manoeuvre or the Pawlik's grip, to aid in confirmation of fetal presentation (C) and the fourth manoeuvre, to define confrontation of the cephalic extremity with the birth canal (D).

coordinating and overseeing the trial procedures during the shift will be responsible for randomisation.

Considering the unblinded nature of our study and that parity is an important predictor of our primary outcome, randomisation will be performed using randomly permuted blocks of varying sizes (4, 6 and 8), stratified by parity (nulliparous/multiparous). This strategy will not be known by local investigators. A blocked randomisation with fixed block size will not be employed since the reduced suitability of this type of randomisation in an unblinded trial is due to potential anticipation and manipulation of treatment assignment of the participant at the end of each block.

The ratio for intervention vs control will be 1:1.

## Blinding

Both the enrolled women and their managing midwives and physicians will be unblinded to the randomisation group, due to the nature of the intervention. In turn, blinding will be guaranteed for the physician assessing the fetal head position by suprapubic transabdominal sonography, the gold standard technique to objectively define fetal head and spine position.[3–5]

## Data management

Trial data will be initially recorded on dedicated paper charts during clinical care and later entered into a secure REDCap database by trained research assistants. REDCap includes built-in range and logic checks, as well as standardised coding, to ensure data accuracy and quality. Paper source documents (eg, monitoring charts and ultrasound reports) will be securely stored in locked cabinets, and scanned copies will be uploaded to REDCap when needed. Access to both paper and digital data will be restricted to authorised personnel only. Data will be stored securely for a minimum of 10 years, in compliance with institutional and regulatory requirements. A full data management plan is available on request.

## Statistical methods

Data reporting will be performed according to the Consolidated Standards of Reporting Trials guidelines.[82 83]

A descriptive table of the baseline characteristics will be reported for the participants for both groups. Primary and secondary outcomes will be analysed on an intention-to-treat basis. Sub-group analyses for parity and cervical dilation at inclusion (3–4 cm or 5 to 8 cm) will be conducted.

For continuous variables, distribution will be visually assessed and means and SD or medians and interquartile ranges will be calculated for normally and not normally distributed variables, respectively; Student's t-test and Mann Whitney U-test will be used to compare the outcomes between groups. For dichotomous variables, proportions will be calculated, and Chi-Square and Fisher exact tests will be used as appropriate to assess differences in outcomes between groups. The effects of the intervention will be estimated by relative risks and their 95% CI.

Probabilities of episiotomy and perineal lacerations and the total duration of the second stage of labour will be calculated only among women with vaginal deliveries. The speed of cervical dilation will be calculated only on women who reach complete dilation; it will be defined as mean cervical dilation measured in centimetres per hour of labour and calculated with the following formula: (10 – cervical dilation at randomisation)/(time at complete dilation – time at randomisation).

A Cochran-Mantel-Haenszel homogeneity test will be performed to assess the consistency of the primary outcome according to parity.

Analyses will be performed with the open-source R software V.4.4.2 (R Foundation for Statistical Computing) and STATA software V. 16 (College Station, TX: StataCorp LLC). Significance will be set at <0.05.

## Data monitoring committee

An independent DSMB will be established prior to trial initiation. The board will consist of three members with expertise in obstetrics, biostatistics and clinical epidemiology. The DSMB will operate independently from the study investigators and funders, and all members will be required to declare any conflict of interest before appointment and throughout the study. The DSMB will be responsible for overseeing participant safety, assessing protocol adherence and data quality and reviewing unblinded interim data. It will meet after the enrolment of the first participant and subsequently when approximately 25%, 50% and 75% of the target sample has been recruited. After each review, the DSMB will provide written recommendations to the trial Steering Committee. A detailed DSMB charter outlining roles, procedures and governance is available on request.

Interim analyses will be conducted by an independent statistician and will be accessible only to the DSMB. Trial investigators and staff will remain blinded to group allocation. Interim reviews will be descriptive in nature and focused on safety, recruitment progress and data quality. Formal statistical testing will be performed only if serious concerns arise. The DSMB may recommend early termination or protocol modifications in the event of significant safety issues, clear evidence of benefit or futility, or other ethical or feasibility concerns. Final decisions regarding trial continuation will be made by the Steering Committee, based on DSMB recommendations.

## Trial monitoring

A risk-based monitoring strategy will be implemented to ensure trial integrity and adherence to the study protocol. Monitoring activities will include regular on-site visits and centralised data checks. Throughout the study period, biweekly audit meetings will be conducted to review recruitment progress, assess protocol compliance and promptly address any operational issues, including deviations or potential contamination. Monitoring will be coordinated by the study's core research team, independently from clinical staff involved in day-to-day patient care.

## ETHICS AND DISSEMINATION

### Research ethics approval

The study has been approved by the Lombardy Ethics Committee n.3 (n. 5499, 20 December 2024) before starting enrolment.

### Dissemination policy

The dissemination plan includes the presentation of the findings at national and international scientific meetings and the publication in peer-reviewed scientific journals in the field of midwifery and obstetrics.

The findings will also be disseminated to the public through reach-out activities involving families and healthcare specialists in order to promote a culture of a positive experience of childbirth that benefits from evidence-based research and further contributes to the long-term promotion of a woman-centred approach to childbirth.

### Protocol amendments

Any important protocol amendments will be decided by the principal investigator in consultation with the Steering Committee. Substantive changes will be promptly communicated to the relevant ethics committee, regulatory authorities and trial registries. Investigators and study staff will be informed through formal communications, and updated documents will be distributed accordingly.

### Consent or assent

Written informed consent will be obtained from all participants (online supplemental material 3). Women will be free to decline participation or to withdraw at any time.

All participants will be provided with the name, telephone number and email address of the principal investigator, in case any question about the study should arise.

### Confidentiality

All the procedures will be consistent with the Declaration of Helsinki ethical principles for research involving human subjects.[78] The procedures do not imply any change to mother-infant care programmes in place at our Institution.

### Trial registration

The study was registered in the Clinical Trials database (ClinicalTrials.gov, NCT06887634) on 20 March 2025 (https://clinicaltrials.gov/study/NCT06887634?term=id5499_18.12.2024_mbis&rank=1).

### Protocol and statistical analysis plan

The full trial protocol was registered in the Clinical Trials database (ClinicalTrials.gov, NCT06887634), where a summary will be accessible. The detailed statistical analysis plan (SAP) will be finalised prior to database lock and uploaded as an online supplemental file in the trial registry and journal repository. Both documents will also be available on reasonable request from the corresponding author.

### Data sharing

De-identified individual participant data, the data dictionary and statistical analysis code will be made available on reasonable request after publication of the primary results. Materials related to the intervention (including any instructional tools used in the trial) will also be shared if applicable. Data access will require submission of a brief proposal outlining the intended use, which will be reviewed by the study team. Approved data will be shared via secure data transfer platforms. Consent for future data sharing will be obtained from all participants at the time of enrolment. No commercial use of the data will be permitted.

**Contributors** SO: conceptualisation, methodology, formal analysis, project administration, supervision, validation, writing the original draft, writing the review and editing. SFu: conceptualisation, methodology, project administration, supervision, validation, writing the original draft, writing the review and editing. LA: methodology, formal analysis, writing the review and editing. MP, RS, SFe, AN and MM: conceptualisation, writing the review and editing. AL: conceptualisation, methodology, supervision, validation, writing the review and editing. AL is the guarantor.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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