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The AEDUCATE Collaboration. Comprehensive antenatal education birth preparation programmes to reduce the rates of caesarean section in nulliparous women. Protocol for an individual participant data prospective meta-analysis

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ABSTRACT

Introduction Rates of medical interventions in normal labour and birth are increasing. This prospective meta-analysis (PMA) proposes to assess whether the addition of a comprehensive multicomponent birth preparation programme reduces caesarean section (CS) in nulliparous women compared with standard hospital care. Additionally, do participant characteristics, intervention components or hospital characteristics modify the effectiveness of the programme?

Methods and analysis *Population*: women with singleton vertex pregnancies, no planned caesarean section (CS) or epidural.

Intervention: in addition to hospital-based standard care, a comprehensive antenatal education programme that includes multiple components for birth preparation, addressing the three objectives: preparing women and their birth partner/support person for childbirth through education on physiological/hormonal birth (knowledge and understanding); building women's confidence through psychological preparation (positive mindset) and support their ability to birth without pain relief using evidence-based tools (tools and techniques). The intervention could occur in a hospital-based or community setting.

Comparator: standard care alone in hospital-based maternity units.

Outcomes *Primary*: CS.

Secondary: epidural analgesia, mode of birth, perineal trauma, postpartum haemorrhage, newborn resuscitation, psychosocial well-being.

Subgroup analysis: parity, model of care, maternal risk status, maternal education, maternal socio-economic status, intervention components.

Study design An individual participant data (IPD) prospective meta-analysis (PMA) of randomised controlled trials, including cluster design. Each trial is conducted independently but share core protocol elements to contribute data to the PMA. Participating trials are deemed eligible for the PMA if their results are not yet known outside their Data Monitoring Committees.

Strengths and limitations of this study

- The unique contribution of this study is to extend the generalisability of previous findings by determining the effectiveness of programmes of comprehensive childbirth education programmes when delivered through a range of maternity units internationally.
- This project uses an individual participant data (IPD), prospective meta-analysis (PMA) design, which is novel in this setting, to account for individual variation that exists within maternity systems, and will assess clinical effectiveness, quantify resource use and cost-effectiveness that will affect sustainability.
- The research outcomes will address national and international evidence gaps about the effectiveness of antenatal education models to improve maternal and neonatal outcomes; and inform policy for models of care in the management of normal labour and birth.
- This research will potentially contribute to advancing the methods for the development and evaluation of novel maternal models of care, informing debate about appropriate outcome measures and methods for economic evaluation.
- The number of participating trials will be limited by each trial's capacity to secure timely funding for an individual randomised controlled trial.

Ethics and dissemination Participants in the individual trials will consent to participation, with respective trials receiving ethical approval by their local Human Research Ethics Committees. Individual datasets remain the property of trialists, and can be published prior to the publication of final PMA results. The overall data for meta-analysis will be held, analysed and published by the collaborative group, led by the Cochrane PMA group.
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INTRODUCTION AND RATIONALE

Rates of medical interventions in normal labour and birth are increasing significantly internationally,[1–3] and in Australia are well above the Organisation for Economic Co-operation and Development (OECD) averages. Experts at the World Health Organisation (WHO) and authors of the Lancet Series on Caesarean Section, warned in 2018 against excessive use of obstetric interventions such as caesarean section (CS).[4 5] Reported rates of CS in Australia in 2006 were at 31%, compared with an OECD average of 22%,[6] and in 2016 the CS rate in New South Wales (NSW), Australia was 33%.[7] Interventions in labour, including CS, contribute significantly to morbidity and mortality,[8–17] and reviews of maternity services have made repeated recommendations for reductions in interventions.[3 6 18] The NSW Health 'Towards Normal Birth' policy directive,[18] has issued a call to hospitals to increase normal birth by introducing strategies to reduce interventions in low-risk normal labours, and to reduce rates of instrumental vaginal birth, and CS. Reducing rates of CS is emerging as an important maternal outcome.[19–22] This is of particular importance with the first birth, as a CS in the first birth, and repeat CS in subsequent births, is the primary driver for rising rates of CS.[22–24]

The concept of providing antenatal education to women and birth partners to prepare them for labour and birth has long been accepted by the maternity system and prospective parents.[25–28] Antenatal education as a formal structure was first introduced in Australia, the UK and the USA in the 1960s.[29 30] This was in response to increasing occurrence of hospital-based births and the accompanying loss of women's social support.[29 31] Such classes are now a routine part of antenatal care in most high-income nations.[32]

However, standard hospital-based antenatal classes, now well integrated into the maternity system, have shifted focus from childbirth preparation to providing overall parent education,[33] and show little evidence of benefit in improving obstetric outcomes for women and neonates.[29 34 35] Additionally, they potentially have the effect of normalising medical interventions for labour and birth as part of routine care.[36 37] In Australia, the current 2018 NSW Department of Health Pregnancy Care Guidelines,[38] state that antenatal education aims to do a variety of things, including: *developing networks for social support, influencing health behaviours and preparing women and their partners for childbirth.* The guidelines further propose that preparation for childbirth includes *building women's confidence in their ability to labour and give birth; preparing women for the pain of labour and supporting their ability to give birth without pain relief, as well as contributing to reducing perinatal morbidity and mortality.* However, there are no consistent recommendations for how to achieve these aims, nor evidence that these components inform the structure of antenatal education currently.

The effect of medical interventions in routine care, such as induction of labour, augmentation of labour and epidural analgesia, on increasing the risk of instrumental birth and CS, in what has been termed the 'cascade of interventions', is particularly evident for primiparous women.[16 39] The American College of Obstetricians and Gynecologists (ACOG),[19] has also noted that many common obstetric procedures provide limited benefit for low-risk women, including continuous fetal monitoring in labour, lying recumbent on the bed, and using pharmacological pain medication.

The ACOG,[19] and the National Institute for Health and Care Excellence (NICE) guidelines,[40] provide recommendations for labour including movement and upright or comfortable postures during labour, having known caregivers, using intermittent monitoring and non-pharmacological pain relief options, among other recommendations. These recommendations derive largely from the body of research that describes the benefit of practices that promote normal hormonal pathways for labour and birth.[41–43] Evidence suggests that the inclusion of components, such as education on physiological/hormonal birth, psychological preparation for normal labour and evidence-based tools for birth preparation contributes to the mechanism of action of the programme as a whole.[19 41 42 44–47]

An overview of Cochrane reviews for pain relief in labour suggests that the evidence supports using individual complementary medicine (CM) tools and techniques to support physiological and psychological preparation, and non-pharmacological pain management techniques in labour to avoid the side effects of pharmaceutical medication.[48] Concerns about safety have been raised with the use of CM interventions and upright positions in labour, including the risk of postpartum haemorrhage (PPH),[49] or neonatal complications.[50] However, the review did not find evidence to support these concerns.[48]

To address this need, authors KML, CAS and HGD developed and piloted an independent, low cost antenatal/childbirth education (CBE) programme (now called BirthCourse). The study course incorporated education about normal birth, supportive care techniques and five CM techniques for non-pharmacological pain relief in labour. The pilot study was conducted as a randomised controlled trial (RCT) in two Sydney hospitals and enrolled 183 women. Outcomes demonstrated significantly reduced rates of CS, epidural analgesia, augmentation with synthetic oxytocin, perineal trauma, reduced length of labour and requirement for resuscitation of the newborn.[51] A qualitative analysis of participants and midwives' experiences of the programme reported that women, partners and midwives found the programme helped women and partners *make sense*

of labour and once they understood the physiology of birth, they were able to *work for a normal birth* by using the *tools* introduced in the programme.[47] A subsequent economic analysis demonstrated a significant cost saving in the study group compared with the control group, with savings mainly due to the reduction in CS rates.[52] A major limitation of the pilot study was the study sample was not widely representative of the general antenatal population thus limiting generalisability. Women who participated in the study were highly educated, came from a higher socioeconomic background, and were largely Caucasian. A single educator delivered the programme; therefore, assessing effectiveness when delivered by other trained educators in more diverse settings is important. Therefore, a prospective meta-analysis (PMA) would be an appropriate study design to capture similar but varying interventions with diverse populations and settings, a variety of educators, with a large enough sample size to investigate a range of subgroups.[53]

The antenatal education/childbirth preparation programmes that will be included in the meta-analysis are those that provide multiple components for birth preparation (comprehensive programmes). These are designed to address all of the following three objectives: preparing women and their partners for childbirth through education on physiological/hormonal birth (knowledge and understanding); building women's confidence in their ability to labour and give birth, through psychological preparation for normal labour (positive mindset) and support their ability to give birth without pain relief using evidence-based tools for birth preparation (tools and techniques).

Standard hospital-based antenatal education classes are those offered as part of routine care, and are referred to by a variety of names, including, but not limited to, antenatal education/classes, CBE/classes, birth education/classes, birth preparation, prenatal education, parent education.

For the purposes of this review, the intervention will be referred to as CBE, and the comparator (classes already offered in the study centre as part of routine care) will be referred to as standard antenatal education.

Childbirth education definition of components

1. Knowledge and understanding—providing education about normal labour physiological and hormonal processes for women and partners to understand how the body works in labour.
2. Positive mindset—positive psychological focus on women's ability and capacity for normal birth.
3. Tools and techniques for labour management—provide a range of different tools and techniques to give women choices for labour management. These can be further categorised as: manual therapies, such as acupressure and massage; relaxation techniques, such as breathing, and visualisation; a range of positions, such as yoga, movement, upright, forward, side lying or comfort positions and enabling women to listen and respond to bodily cues during labour.

Programmes that include these three components and are yet to be evaluated, may like to participate in evaluation of the programme and are eligible to collaborate. Eligible trials will include each component (1–3). Variations in CBE programmes between trials will be examined in subgroup analyses (see below).

Potential effect modifiers

Factors known to influence intervention rates in labour may modify the effectiveness of CBE programmes designed to facilitate a normal physiological (non-interventional) approach to birth. These include delivery of intervention (hospital staff vs independent educator), a continuity of care midwifery model of care,[54–56] a woman's insurance status (public, private),[57] parity, obstetric risk status,[58 59] socioeconomic status (SES), cultural background,[60] undiagnosed congenital abnormalities and comorbid conditions requiring induction of labour (eg, gestational diabetes mellitus (GDM)).[61]

Nulliparous women have been selected as the target population for the primary analysis as reducing the risk of CS in the first birth is likely to provide greater benefits overall.[23 24] Providing first-time mothers with alternative pain management strategies will potentially provide a greater benefit in preventing the cascade of interventions leading to a decreased risk of CS in the first birth, and therefore for all subsequent births. Nulliparous are also the majority of attenders of CBE classes.[35 62 63]

AIMS

The primary aim of the study is to assess the effectiveness of comprehensive CBE programmes in reducing rates of medical intervention in labour and birth in a large and diverse sample of women and settings. The PMA design will allow detection of a smaller clinically relevant effect of 5% reduction in the primary outcome of CS than could be detected within individual participating trials alone.

Secondary aims are to identify any subgroups that may benefit more than others. This will provide essential evidence for translation of findings into practice in hospitals in Australia and internationally.

Primary objective

To assess the effectiveness of CBE programmes plus usual care, versus usual care alone, in reducing rates of CS in nulliparous women.

Secondary objectives

a. To assess the effectiveness of CBE programmes in reducing rates of other medical interventions in nulliparous women.
b. To assess the safety outcomes of CBE programmes for women and their babies.
c. To assess factors that modify the effectiveness of the CBE programmes, including participation in different

maternity models of care, insurance status (on admission), parity, obstetric risk status, SES, cultural background (ethnicity) and comorbid conditions (eg, hypertension, GDM) requiring induction of labour, individual components of the intervention programme.

d. To assess economic outcomes of implementation of CBE programmes.

Hypothesis

We hypothesise that comprehensive CBE programmes that include the three core components outlined, in addition to usual hospital-based antenatal education programmes for nulliparous women in a wide range of hospital settings, are effective for reducing CS and rates of other interventions in labour and birth in diverse antenatal populations and settings.

METHODS/DESIGN

Study design: prospective meta-analysis

The PMA study design requires that each of the trials that will be included are deemed eligible for the PMA before their results are known to anyone outside their Data Monitoring Committees.[53]

The Cochrane Prospective Meta-analysis Methods Group[64] describe one of the distinguishing features of a PMA versus a multicentre trial is that there is no requirement in a PMA for the protocols to be identical across studies. Variety in the design of the studies may be viewed by some as a desirable feature of PMA to allow assessment of real-world effectiveness, across different settings. Thus, some variation in trial populations or in aspects of the intervention and comparator is considered acceptable. This will accommodate different programmes and practices in CBE, antenatal education and antenatal care across settings and countries. Additionally, if there is a particular group for whom the programme is more beneficial, this may be more readily detectable within a pooled analysis across several trials, than within an individual trial.

In a PMA, individual trials may define their own entry criteria (such as including women for their first birth only or all parities; different models of care; teaching various non-pharmacological pain relief techniques), and outcome measures using site-specific endpoints while sharing the same core pre-specified protocol elements with other participating trials (such as specifying CS as an outcome). The PMA process attempts to maximise the harmonisation of common core outcomes across the trials, while accommodating variation.[53]

Additionally, by establishing collaboration of the eligible studies, it is possible to collect individual participant data (IPD) to be incorporated into the meta-analysis. Using IPD, rather than aggregate data from each trial, can improve the power and scope of the meta-analysis. In particular, a meta-analysis using IPD can enable more flexible and detailed subgroup analyses.[65 66]

For participating trials, the benefits of participating in an IPD PMA is the opportunity to develop a standardised protocol in partnership with other trial groups, receive training for the delivery of the education programme, but retain the responsibility for leading the design, conduct and reporting of their individual RCT, and later contribute data to the PMA to address questions that cannot be addressed in individual trials. A common data collection form, coding sheet and detailed analysis plan will be developed and agreed by members of the Collaboration prior to the collection and analysis of data from the individual trials.

Setting and total number of studies

Hospital or community based settings. The conduct of a PMA requires a minimum of two studies to meta-analyse. Studies of comprehensive CBE that meet the trial eligibility criteria outlined below and follow the study protocol for collection of the minimum dataset are eligible for inclusion (see characteristics of currently included trials).

Search methods for identification of studies

Efforts to identify ongoing trials that are eligible for participation in this PMA include searches for published protocols on online databases such as MEDLINE, EMBASE and clinical trial registries, as well as internet searches for media articles, non-peer reviewed articles and other publications using Google. Further efforts include informing networks of the proposed PMA through conference presentation and approaching other presenters at relevant conferences and meetings.

Trial-level inclusion criteria

- Each trial has to be randomised (including cluster randomisation) with an adequate level of allocation concealment, as outlined in the Cochrane Handbook for Systematic Reviews of Interventions.[67]
- Intervention includes all three components (knowledge and understanding; positive mindset and tools and techniques (including at least three individual evidence-based non-pharmacological techniques)) in addition to standard antenatal care.
- Pregnant women—parity status recorded, model of care recorded, risk status recorded, enrolled some low-risk women (trialist defined, but able to identify individual line-by-line data for women at low risk).
- Outcomes include CS.
- Comparator group must consist of the standard antenatal care available in their setting (different levels of background care).
- All participating trials to be registered on a publicly accessible clinical trial registry.
- Participating investigators to be blinded to their trial's outcome data by intervention group at the time of inclusion in the PMA.

Trial-level exclusion criteria

- Where the comparator group is not considered standard care (trialist defined), for example, a trial that compares BirthCourse against YogaBirth.

Language requirements

- Sufficient language proficiency to participate in the designated course, or for languages other than the designated language, where an educator or translator is able to provide the full class in the language of choice.

Participant-level inclusion criteria

Women with a low-risk to medium-risk singleton pregnancy in vertex presentation, receiving routine antenatal care (from a doctor or a midwife), which includes hospital-based antenatal education, and planning a vaginal birth.

A secondary analysis will be undertaken to assess effectiveness in women in continuity of midwifery care programmes.

Participant-level exclusion criteria

Women with a high-risk pregnancy (including existing health conditions that modify care in pregnancy, conditions of pregnancy such as high blood pressure, obesity and multiple pregnancy, age <17 years, lifestyle risk factors, psychological risk factors), and any indication for planned CS or epidural. Planned participation in similar independent CBE that is not the intervention under investigation.

Study variables (baseline, hospital, maternal, newborn)

- *Baseline and hospital characteristics*: maternal age, parity, gestational age, socio-economic status (SES) (tertiles of household income), highest education level attained, measures of well-being, country of birth, primary language spoken at home, ethnicity, pre-pregnancy body mass index (BMI), smoking and alcohol consumption, diagnosed GDM, hypertensive conditions, public/private care status, model of care, hospital capability level, special care nursery (SCN)/neonatal intensive care unit (NICU) level.

Sample size

Primary outcome

A total sample size of 2000 is required to detect a clinically important 5% absolute difference in CS rates from 30% to 25%, with 80% power and a significance level of p<0.05. Individual trials have indicated they will be powered to demonstrate a larger difference in CS rates (eg, a 12% absolute reduction from 30% to 18%, the sample size requirement is 396 women).

This sample size calculation is based on the average intrapartum proportion in Australia,[68] and will also allow exploration of treatment effects for specified secondary outcomes, such as pharmacological pain relief (epidural), onset of labour and instrumental vaginal birth. We will examine for treatment interactions between subgroups, such as parity, risk status and model of care.

The study sample size will have >80% power for the overall study population (1000 per group) to detect differences in the following secondary outcomes:

1. Epidural analgesia, with an estimated incidence in the control group of 50%, can detect a 5.6% absolute difference in the overall population.
2. Instrumental vaginal birth, with an estimated incidence in the control group of 12%, can detect a 3.4% absolute difference in the overall population.

Outcomes

Primary outcome

- Any CS.

Secondary outcomes

- *Maternal*: onset of labour, indications for induction, failed induction, epidural analgesia, other pharmacological pain relief, augmentation of labour (synthetic oxytocin, artificial rupture of membranes), mode of birth, length of the three stages of labour, perineal trauma (labial graze/s first, second, third, fourth tear) and episiotomy, perineal suturing, commencement of skin-to-skin contact with baby (immediate, within first hour, first 2 hours), total length of stay (prenatal, postnatal), postnatal Edinburgh Post Natal Depression Score (EPDS), key safety measures including PPH and readmission and a salutogenic scale (which measures positive outcomes from the intervention, such as well-being or increased agency). We recommend using the most well-validated scale, the Warwick-Edinburgh Mental Well-being Scale.[69] However, other scales, such as Capture My Mood,[70] the MADM (Mother's Authority in Decision Making) scale,[71] or the MORi (Mothers on Respect Index) scale,[72] can be used.
- *Newborn*: low Apgar score at 5 min (usually scored <7), any resuscitation, birth weight, timing of cord clamping, breast feeding (within the first hour, first 2 hours), respiratory distress, observation or admission to special care units, antibiotic administration, duration of stay in special care units, duration of stay in hospital, any assisted ventilation, any medical investigations, perinatal mortality.
- *Economic*: using codes for International Classification of Disease (ICD) and diagnosis-related group (DRGs) (or equivalent) for each individual admission, clinical outcomes will be used to classify women into DRGs, or similar international code (see table 1). The DRG codes are mutually exclusive classifications that will be used to analyse the cost of implementing the programme compared with standard care.

Description of the intervention

Study intervention: treatment arm

Included in the PMA will be individual trials of comprehensive antenatal education childbirth preparation programmes, which include multiple components for birth preparation, and are designed to address the three objectives of; preparing women and their partners for

Table 1 Inclusions in each AR-DRG codes

AR-DRG code	Categorisation and intervention included in AR-DRG code
O60C	Normal vaginal birth±induction, augmentation, epidural
O60B	Instrumental vaginal birth±PPH, perineal trauma, episiotomy
O60A	Vaginal birth+severe/catastrophic outcome (eg, DVT/PE, embolism, HELLP syndrome)
O01C	CS±labour
O01B	CS+PPH (>650 mL blood loss)
O01A	CS+severe/catastrophic outcome (eg, DVT/PE, amniotic embolism, HELLP syndrome)

CS, caesarean section; DVT, deep vein thrombosis; HELLP, haemolysis, elevated liver enzymes, low platelet count; PE, pulmonary embolism; PPH, postpartum haemorrhage.

childbirth through education on physiological/hormonal birth (knowledge and understanding); building women's confidence in their ability to labour and give birth, through psychological preparation for normal labour (positive mindset) and support their ability to give birth without pain relief using evidence-based tools for birth preparation (tools and techniques). The additional intervention component could occur in either a hospital-based, or a community setting.

For inclusion in the PMA analysis, individual trials are required to deliver an educational component, encourage a positive approach to labour and birth and at least three CM techniques outlined below.

The intervention group will continue to attend usual antenatal care, including options for hospital-based antenatal education programmes (see table 2 for timeline).

Comparator

Standard care (antenatal care and education) alone in hospital-based maternity units.

Example

As an example, the author (KML) has collaboratively developed the programme called BirthCourse that combines techniques to support physiological birth, in four modules for teaching. BirthCourse is the subject of at least two RCTs in Australia, and will be described here.

The approach to BirthCourse, includes positive mindset, knowledge and understanding of birth and a range of CM techniques, which are designed to enhance a natural state of relaxation, hormonal stimulation and maternal comfort for optimal birth outcomes. The programme introduces women and partners to a variety of resources to conceptualise birth as a natural physiological process, and supportive tools for comfort positions and pain management to assist in facilitating the birth process.

CBE example: evidence-based complementary therapies included in BirthCourse

- *Relaxation and guided visualisation*: involves a description of the relaxation response and how to evoke it physiologically.[73] Relaxation techniques, includes progressive relaxation and visualisation, addressing fear of birth, visualisation of the birth process.[74–76] Guided visualisation provides instructions that are positive, directive, achievable and focused towards a desired outcome.[75 76] Guided visualisation techniques and progressive muscle relaxation include suggestions for the relaxation response, normal physiological birth progress, the baby coming into an optimal position and being ready for birth and the releasing of fear. These visualisations employ various senses and easily imagined scenarios.
- *Acupressure*: involves the location and use of a variety of acupressure points that assist the physiological processes of labour,[77] as well as emotional support for the woman. The points are taught to the woman and her birth partner. A booklet will accompany this

Table 2 Time schedule for participants

Gestation weeks	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40+	Bth	6+
Randomisation	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Programme modules	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Practise techniques	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
CM use questionnaire	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Postnatal questionnaire	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Follow-up mother	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Follow-up baby	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

CM, complementary medicine.

session to facilitate review and home practice, with suggestions for most appropriate uses of certain points and point combinations.[77 78]

- *Breathing*: mindfulness of breath or conscious breathing combined with relaxation are powerful tools for labour. There are several breathing techniques taught in the BirthCourse,[74] which can be practised during pregnancy in preparation for labour.
- *Movement, yoga and labour and birth positions*: includes using movement and positions that encourage maternal comfort, pelvic softening and opening and the use of gravity and alignment to assist with labour progress.[79 80] Standing, leaning, using furniture, fit balls, partner support to aid maternal comfort and the baby's descent. Upright birth and comfort positions will be taught that aid labour and can be performed by women in labour.
- *Massage*: two types of massage are useful during birth: strong technique to counter the sensations of the contraction in the place where the woman is experiencing it most, such as the lower back, sacrum or legs,[81–83] and moderate pressure [84 85] technique to increase the release of natural opiates and to stimulate the skin receptors and vagal response.[81–83] Massage during the last 4–8 weeks of pregnancy, which uses soft to moderate pressure, will also be demonstrated as this has been shown to reduce anxiety and pain perception in labour.[85]

Control group

- Participants in the control group will continue to attend usual care, including the standard antenatal education classes offered by the hospital, which should not include more than two components described above.
- Participation in any hospital-based programme is the woman's choice, as per usual care. Planned participation in any independent CBE course similar to the intervention course, but is not the intervention being examined, will be considered an exclusion criteria.

Content of usual care programmes

Content varies across settings and may include some elements in common with BirthCourse. Antenatal education classes have been influenced strongly by the work of Svennson *et al*.[33] Following this research into antenatal education, many hospitals in Sydney, NSW, have taken on suggestions from this work. There has been a general shift towards providing information for women and their partners covering the entirety of pregnancy and the early postnatal period. Issues surrounding pregnancy, birth options, interventions during labour, breast feeding and the early parenting period are addressed. Current antenatal education is meant to reflect unbiased general information, and the classes are not specifically directed to natural birthing support as the study programme is.

The programme design by Svennson *et al* follows a general format of six sessions, each lasting for 2 hours, the following subjects (from programme design by Svennson *et al*) may overlap with the study programme:

- Labour and birth: 20 min;
- Education first stage: 10 min;
- Preparing for labour: 25 min;
- Labour stations (active demonstration and practice): 15 min.

Participant timeline

Patient and public involvement

In keeping with Standard 2 of the Australian Commission for Safety and Quality in Healthcare,[86] a community and consumer lead with the necessary skills and experience will be appointed to take on the Stakeholder Relations Liaison role which will provide input into all aspects of the project including the design, outcome choice, analyses, interpretation of findings and implementation of the findings into practice and policy.

Data analysis

Analysis will be of all women ever randomised to the included trials and will be based on intention-to-treat. Baseline and service characteristics of participants (including age, ethnicity, parity, education level, SES, BMI, model-of-care) will be summarised by trial and overall by treatment group, reporting frequency and percentage for categorical variables and mean and SD (or median and IQR) for continuous variables. Hospital characteristics (public/private, hospital capability level, SCN/NICU level) will also be summarised.

Univariable analysis will be undertaken to identify predictors (maternal factors, hospital factors, models of care) of CS and key secondary outcomes including epidural rates, mode of birth (normal vaginal birth, instrumental, CS), length of labour (latent, first, second stage) and key safety measures including PPH (<500, >500–1000, >1000–1500, >1500 mL) and requirement for resuscitation of the newborn. Relative risk (RR) and 95% CIs will be estimated using log-binomial regression. Predictors of CM use will also be assessed using this method.

Primary outcome

For the primary analysis, the effectiveness of the programme on CS rates will be assessed in nulliparous women. Results will be reported for individual trials and then combined in a meta-analysis using a fixed-effect log-binomial one-stage regression model and treatment effects will be reported as an RR and 95% CI. This model will adjust for potential confounders including maternal age, onset of labour (spontaneous, induced), augmentation (yes, no); epidural (yes, no) and other predictors identified from the univariable analysis. The level of heterogeneity will be assessed using the I^2 statistic. If heterogeneity is high (I^2 >30%), a random-effects model will be used for a sensitivity analysis.

Additional outcomes

Secondary analyses will be performed to assess the impact of the programme on additional maternal outcomes

(including epidural rates, mode of birth, length of labour) using the same methods outlined above.

Planned subgroup analyses

The effect of the intervention (comprehensive CBE vs comparator) may vary due to certain characteristics of either the woman, or the way the intervention was delivered. This will be examined using a random-effects model and χ^2 tests for interaction will be performed to test for statistically significant differences ($p<0.05$) in the treatment effect between subgroups. The following subgroup analyses will be performed (see below for definitions):

Participant baseline characteristics

- Parity (nulliparous/multiparous);
- Model of care (standard midwifery/group practice midwifery/doctors);
- Maternal risk status (low risk/high risk);
- Maternal education (minimum completed secondary/postsecondary education);
- Maternal SES** (low SES/high SES).

Intervention characteristics

- Mode of intervention delivery (face-to-face/online);
- Intensity (number of sessions<4/≥4);
- Provider of intervention (hospital-based employee/independent educator);
- Individual components in programme (number of CMs included=3/≥3).

Subgroup analyses definitions

Maternal risk status definition:

- Low risk: singleton, term, vertex pregnancies and the absence of any other medical, obstetric or surgical conditions
- High risk: not low risk.[87]

***Maternal SES*: using SES classifications within each trial (eg, local regional definitions) to define group as high or low SES.

Component: include evidence-based techniques used for management of labour as described in introduction/rationale.

Number of sessions: a complete lesson contained within the programme. For example, one complete 2-day course may be divided into four complete lessons or sessions.

For EPDS or other scale, an analysis of covariance analysis will be conducted to assess difference in score by treatment group, adjusting for baseline score.

Sensitivity analysis

To assess whether results are robust to different methods of analysis and trial quality, the following sensitivity analyses will be conducted:

- If outcomes show high level of unexplained heterogeneity, a random-effects models will be run.
- If found, trials at high risk of bias[67] will be excluded.

Data monitoring procedures

Each trial will include its own Data and Safety Monitoring Committee. Trials will contribute their de-identified data after reporting their own trial analysis via publication.

Project management

Membership of the AEDUCATE Collaboration includes representative(s) from each of the trials contributing data to the project. A Steering Group has been established with a project Secretariat, which includes member of the Cochrane PMA/IPD Methods groups, representatives of the collaborating trials and other related experts as required. Project coordination and data management/analysis are coordinated from the University of Notre Dame, School of Medicine and the NHMRC Clinical Trials Centre, University of Sydney, Australia.

Funding

Funding for the AEDUCATE Collaboration has been received from the National Health and Medical Research Council of Australia (GNT1166247), with each individual trial receiving funding from their own respective funding bodies.

Expected completion date for the study is December 2024.

Publication policy

Individual datasets remain the property of trialists, and can be published in relevant journals. The overall data for meta-analysis will be held, analysed and published by the collaborative group, led by the Cochrane PMA group. Each of the participating trials will be able to publish their main individual trial results prior to publication of the final PMA results. Each of the participating trials will seek to include reference to the AEDUCATE Collaboration in the published abstract and, if possible, in the text of their main individual trial publication. The main manuscript will be prepared by the AEDUCATE Steering Group, before circulation to the full Collaborative Group for comment and revision. Publications using these data will be authored on behalf of the AEDUCATE Collaboration, either with specific named authors, or on behalf of the Collaboration as a whole, as agreed by the Steering Group.

Ethical considerations

Data ownership and confidentiality

Participants in the individual trials have previously consented to participation in their respective trial. The data are available through an agreement between all Chief Investigators of the included trials and ethical approval for each of the trials has been given by their respective Human Research Ethics Committees. The trialists remain the custodians of their own data and retain the right to withdraw their data from the analysis at any time. Data will be de-identified before being shared with the AEDUCATE Collaboration data management team. Data are provided on the stipulation that all trials have received ethical clearances from their relevant bodies.

Study registration

This protocol has been registered with PROSPERO (103857), and has the Universal Trial Number

Table 3 Characteristics of studies included to date

Trial acronym Registration number	BirthCourse	My BirthCourse
Planned sample size	400 first-time mothers	276 first-time mothers
Country/State of recruitment	NSW, Australia (UNDA)	SA, Australia (UniSA)
Intervention	Programme includes education on physiology, and five CM techniques: acupressure, massage, yoga, visualisation, breathing techniques. Plus usual care.	Programme includes education on physiology, and five CM techniques: acupressure, massage, yoga, visualisation, breathing techniques. Plus usual care.
Comparator	Usual care	Usual care
Gestational age at inclusion	24–36^{+6} weeks' gestation	24–36^{+6} weeks' gestation
Risk status	Mixed risk	Low and moderate risk
Duration of trial	2 days, or 4 sessions (4 modules, each 2.5 hours)	2 days, or 4 sessions (4 modules, each 2.5 hours)
Duration of follow-up	6 weeks post partum	6 weeks post partum
Primary outcome	Caesarean section	Epidural analgesia
Caesarean section outcome included	Yes	Yes
Qualitative study	Included	Not included
Funding	NHMRC ECR Fellowship	UniSA grant
Registry trial number	ANZCTR 12619000830190	ANZCTR 12618001353280

CM, complementary medicine; NSW, New South Wales.

(U1111-1216-4512). Individual trialists will register their trials on a clinical trials registry, such as ANZCTR or other.

Protocol amendments

All protocol amendments, numbered sequentially and dated, will be sent directly to the principal investigators, whose responsibility it will be to submit to the relevant ethical review boards as soon as possible.

Current eligible trials

There are currently two trials that are eligible for inclusion in this PMA (see table 3). They are both located in Australia, one in NSW (BirthCourse) and one in South Australia (My BirthCourse), and use a common individual trial protocol.

Significance

This study will extend the findings of the original RCT,[46] which demonstrated significant reductions in medical interventions, including epidural analgesia and CS, during labour and birth for low-risk first-time mothers, to other populations to test its generalisability. The unique contribution of this proposal is to extend the generalisability of the findings by recruiting a more diverse group of women from different hospitals and areas, and to determine the real-world effectiveness of programmes of comprehensive CBE programmes when delivered through a range of maternity units in Australia and internationally. It will use an IPD, prospective meta-analysis design, which is novel in this setting, to account for individual variation that exists within maternity systems, and will assess clinical effectiveness, quantify resource use and cost-effectiveness that will affect sustainability.

How will the project contribute to the health of the Australian and international communities?

The project will build on the evidence base for the effectiveness of comprehensive CBE programmes in addition to hospital-based parent education programmes, and how these can best support women and their partners in labour and birth. The results from this study will inform national and international models of antenatal and labour care for the management of normal labour and birth, and the prevention of morbidity in maternity healthcare settings. Additionally, the reduction in rates of CS will contribute to the reduction of lifetime risk of morbidity becoming evident in the literature for post-CS follow-up of women and babies.[88 89]

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