BMJ Open

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

Kate M Levett ,[1,2] Sarah J Lord ,[1,3] Hannah G Dahlen,[4] Caroline A Smith,[2,5] Federico Girosi ,[6,7] Soo Downe,[8] Kenneth William Finlayson,[8] Julie Fleet,[9] Mary Steen,[9] Mary-Ann Davey,[10] Elizabeth Newnham,[11] Anette Werner,[12] Leslie Arnott,[13] Kerry Sutcliffe,[1] Anna Lene Seidler ,[14] Kylie Elizabeth Hunter ,[14] Lisa Askie[14]

To cite: Levett KM, Lord SJ, Dahlen HG, *et al*. 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. *BMJ Open* 2020;**10**:e037175. doi:10.1136/bmjopen-2020-037175

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-037175).

Received 28 January 2020
Revised 09 July 2020
Accepted 14 August 2020

For numbered affiliations see end of article.

Correspondence to
Dr Kate M Levett;
kate.levett@nd.edu.au

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.
Trial registration number CRD42020103857.

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]

Author affiliations
[1]School of Medicine Sydney, University of Notre Dame Australia, Darlinghurst, New South Wales, Australia
[2]NICM Health Research Institute, University of Western Sydney, Penrith South, New South Wales, Australia
[3]NHMRC Clinical Trials Centre, Camperdown, New South Wales, Australia
[4]School of Nursing and Midwifery, University of Western Sydney, Parramatta, New South Wales, Australia
[5]Graduate Research School, University of Western Sydney, Kingswood, New South Wales, Australia
[6]Translational Health Research Institute, Western Sydney University, Penrith, New South Wales, Australia
[7]Capital Markets CRC, New South Wales, Australia, Sydney, New South Wales, Australia
[8]School of Midwifery and Community Health, University of Central Lancashire, Preston, UK

[9]School of Nursing and Midwifery, University of South Australia, Adelaide, South Australia, Australia
[10]Obstetrics & Gynaecology, Monash Health, Monash University Central Clinical School, Melbourne, Victoria, Australia
[11]School of Nursing & Midwifery, Griffith University, Medowbrook, Queensland, Australia
[12]Department of Clinical Research, University of Southern Denmark, Odense, Denmark
[13]The B.E.A.R. Program, Lamaze Australia, Melbourne, Victoria, Australia
[14]NHMRC Clinical Trials Centre, The University of Sydney, Camperdown, New South Wales, Australia

Twitter Kate M Levett @LevettKate, Hannah G Dahlen @hannahdahlen, Julie Fleet @DrJulieFleet and Anna Lene Seidler @LeneSeidler

Contributors The protocol was drafted by KML, SJL with significant review and editing review by M-AD, HGD, SD, JF, KWF. Review of methods, analysis and overview of manuscript by LAs, ALS, KEH. Economic analysis advice by FG and reviewed and edited by LAr, LN, CAS, MS, KS, AW. All members of this group were sent draft versions and invited to comment and contribute changes. All authors read and approved the final manuscript. KML guarantees this review.

Funding This study was supported by NHMRC (GNT1166247).

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

ORCID iDs
Kate M Levett http://orcid.org/0000-0003-3784-4648
Sarah J Lord http://orcid.org/0000-0003-2763-5949
Federico Girosi http://orcid.org/0000-0003-3937-2285
Anna Lene Seidler http://orcid.org/0000-0002-0027-1623
Kylie Elizabeth Hunter http://orcid.org/0000-0002-2796-9220

REFERENCES

1 Gibbons L, Belizán JM, Lauer JA, *et al*. The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. *World health report* 2010;30:1–31.
2 World Health Organization. WHO statement on caesarean section rates. Geneva WHO; 2015.
3 Betran AP, Torloni MR, Zhang JJ, *et al*. WHO statement on caesarean section rates. *BJOG* 2016;123:667–70.
4 Visser GHA, Ayres-de-Campos D, Barnea ER, *et al*. FIGO position paper: how to stop the caesarean section epidemic. *Lancet* 2018;392:1286–7.
5 WHO. WHO recommendations: intrapartum care for a positive childbirth experience. Geneva World Health Organization; 2018.
6 Bryant R. Improving maternity services in Australia: the report of the maternity services review. Canberra Commonwealth of Australia; 2009.
7 Centre for Epidemiology and Evidence. *New South Wales mothers and babies 2016*. Sydney: NSW Ministry of Health, 2016.
8 Anim-Somuah M, Smyth RMD, Jones L, *et al*. Epidural versus non-epidural or no analgesia in labour. *Cochrane Database Syst Rev* 2011;177:CD000331.
9 King T. Epidural anesthesia in labor. benefits versus risks. *J Nurse Midwifery* 1997;42:377–88.
10 Dahlen HG, Schmied V, Dennis C-L, *et al*. Rates of obstetric intervention during birth and selected maternal and perinatal outcomes for low risk women born in Australia compared to those born overseas. *BMC Pregnancy Childbirth* 2013;13:100.
11 Green JM, Baston HA. Have women become more willing to accept obstetric interventions and does this relate to mode of birth? data from a prospective study. *Birth* 2007;34:6–13.
12 Roberts CL, Tracy S, Peat B. Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *BMJ* 2000;321:137–41.
13 Polidano C, Zhu A, Bornstein JC. The relation between cesarean birth and child cognitive development. *Sci Rep* 2017;7:11483.
14 Althabe F, Sosa C, Belizán JM, *et al*. Cesarean section rates and maternal and neonatal mortality in low-, medium-, and high-income countries: an ecological study. *Birth* 2006;33:270–7.
15 Blustein J, Liu J. Time to consider the risks of caesarean delivery for long term child health. *BMJ* 2015;350:h2410.
16 Davey M-A, King J. Caesarean section following induction of labour in uncomplicated first births- a population-based cross-sectional analysis of 42,950 births. *BMC Pregnancy Childbirth* 2016;16:92.
17 Souza JP, Gülmezoglu A, Lumbiganon P, *et al*. Caesarean section without medical indications is associated with an increased risk of adverse short-term maternal outcomes: the 2004-2008 WHO global survey on maternal and perinatal health. *BMC Med* 2010;8:71.
18 NSW Department of Health. Maternity - Towards Normal Birth in NSW. Sydney Policy Directive; 2010: 27.
19 ACOG. *Approaches to limit intervention during labor and birth*. Washington DC: The American College of Obstetricians and Gynecologists, 2017: e20–8.
20 ACOG & SMFM. Nation's Ob-Gyns take aim at preventing cesareans. In: *The American College of obstetricians and Gynecologists atSfM-FM*. Washington, DC, 2014.
21 ACOG & SMFM. Safe prevention of the primary cesarean delivery. obstetric care consensus No. 1. *Obstetrics & Gynecology* 2014;123:693–711.
22 Betrán AP, Ye J, Moller A-B, *et al*. The increasing trend in caesarean section rates: global, regional and national estimates: 1990-2014. *PLoS One* 2016;11:e0148343.
23 Roberts CL, Algert CS, Ford JB, *et al*. Pathways to a rising caesarean section rate: a population-based cohort study. *BMJ Open* 2012;2:e001725.
24 Spong CY, Berghella V, Wenstrom KD, *et al*. Preventing the first cesarean delivery: summary of a joint Eunice Kennedy Shriver National Institute of child health and human development, Society for Maternal-Fetal medicine, and American College of obstetricians and Gynecologists workshop. *Obstet Gynecol* 2012;120:1181–93.
25 Redman S, Oak S, Booth P, *et al*. Evaluation of an antenatal education programme: characteristics of attenders, changes in knowledge and satisfaction of participants. *Aust N Z J Obstet Gynaecol* 1991;31:310–6.
26 Nolan M. Effectiveness of antenatal education. *Br J Midwifery* 1994;2:534–8.
27 Nolan ML, Hicks C. Aims, processes and problems of antenatal education as identified by three groups of childbirth teachers. *Midwifery* 1997;13:179–88.
28 Spiby H, Henderson B, Slade P, *et al*. Strategies for coping with labour: does antenatal education translate into practice? *J Adv Nurs* 1999;29:388–94.
29 Ferguson S, Davis D, Browne J. Does antenatal education affect labour and birth? A structured review of the literature. *Women Birth* 2013;26:e5–8.
30 Walker DS, Visger JM, Rossie D. Contemporary childbirth education models. *J Midwifery Womens Health* 2009;54:469–76.
31 Murphy Tighe S. An exploration of the attitudes of attenders and non-attenders towards antenatal education. *Midwifery* 2010;26:294–303.
32 Jaddoe VWV. Antenatal education programmes: do they work? *Lancet* 2009;374:863–4.
33 Svensson J, Barclay L, Cooke M. Effective antenatal education: strategies recommended by expectant and new parents. *J Perinat Educ* 2008;17:33–42.
34 Gagnon AJ, Sandall J, Cochrane Pregnancy and Childbirth Group. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database Syst Rev* 2007;6.
35 Artieta-Pinedo I, Paz-Pascual C, Grandes G, *et al*. The benefits of antenatal education for the childbirth process in Spain. *Nurs Res* 2010;59:194–202.
36 Simkin P. Should ACOG support childbirth education as another means to improve obstetric outcomes? Response to ACOG Committee opinion # 687: approaches to limit intervention during labor and birth. *Birth* 2017;44:293–7.
37 Levett K, Dahlen HG. Perspective: childbirth education in Australia: have we lost our way? *Women Birth* 2019;32:291–3.
38 Department of Health. *Clinical practice guidelines: pregnancy care*. Canberra: Australian Government, Department of Health, 2018.
39 Tracy SK, Sullivan E, Wang YA, *et al*. Birth outcomes associated with interventions in labour amongst low risk women: a population-based study. *Women Birth* 2007;20:41–8.

40 Delgado Nunes V, Gholitabar M, Sims JM, *et al*. Intrapartum care of healthy women and their babies: summary of updated NICE guidance. *BMJ* 2014;349:g6886–g86.
41 Buckley S. Undisturbed birth. Nature's blueprint for ease and ecstasy. *Midwifery Today Int Midwife* 2002;63:19–24.
42 Buckley SJ. Executive Summary. In: *Hormonal physiology of childbearing: evidence and implications for women, babies, and maternity care*. Washington, D.C.: Childbirth Connection Programs, National Partnership for Women & Families, 2015.
43 Dixon L, Skinner J, Foureur M. The emotional and hormonal pathways of labour and birth: integrating mind, body and behaviour. *New Zealand College of Midwives Journal* 2013;48:15–23.
44 Downe S, Finlayson K, Melvin C, *et al*. Self-Hypnosis for intrapartum pain management in pregnant nulliparous women: a randomised controlled trial of clinical effectiveness. *BJOG* 2015;122:1226–34.
45 Finlayson K, Downe S, Hinder S, *et al*. Unexpected consequences: women's experiences of a self-hypnosis intervention to help with pain relief during labour. *BMC Pregnancy Childbirth* 2015;15:229.
46 Levett KM, Smith CA, Bensoussan A, *et al*. Complementary therapies for labour and birth study: a randomised controlled trial of antenatal integrative medicine for pain management in labour. *BMJ Open* 2016;6:e010691.
47 Levett KM, Smith CA, Bensoussan A, *et al*. The Complementary Therapies for Labour and Birth Study making sense of labour and birth - Experiences of women, partners and midwives of a complementary medicine antenatal education course. *Midwifery* 2016b;40:124–31.
48 Jones L, Othman M, Dowswell T, *et al*. Pain management for women in labour: an overview of systematic reviews. *Cochrane Database Syst Rev* 2012;3:CD009234.
49 de Jonge A, van Diem MT, Scheepers PLH, *et al*. Increased blood loss in upright birthing positions originates from perineal damage. *BJOG* 2007;114:349–55.
50 Kibuka M, Thornton JG, Cochrane Pregnancy and Childbirth Group. Position in the second stage of labour for women with epidural anaesthesia. *Cochrane Database Syst Rev* 2017;20.
51 Levett KM, Smith CA, Bensoussan A, *et al*. Complementary therapies for labour and birth study: a randomised controlled trial of antenatal integrative medicine for pain management in labour. *BMJ Open* 2016;6:e010691.
52 Levett KM, Dahlen HG, Smith CA, *et al*. Cost analysis of the CTLB study, a multitherapy antenatal education programme to reduce routine interventions in labour. *BMJ Open* 2018;8:e017333.
53 Seidler AL, Hunter KE, Cheyne S, *et al*. A guide to prospective meta-analysis. *BMJ* 2019;367:l5342.
54 Sandall J, Soltani H, Gates S, *et al*. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Syst Rev* 2016;4:CD004667.
55 Tracy SK, Hartz DL, Tracy MB, *et al*. Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* 2013;382:1723–32.
56 McLachlan HL, Forster DA, Davey MA, *et al*. Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. *BJOG* 2012;119:1483–92.
57 Dahlen HG, Tracy S, Tracy M, *et al*. Rates of obstetric intervention among low-risk women giving birth in private and public hospitals in NSW: a population-based descriptive study. *BMJ Open* 2012;2. doi:10.1136/bmjopen-2012-001723. [Epub ahead of print: 10 09 2012].
58 Dahlen HG, Tracy S, Tracy M, *et al*. Rates of obstetric intervention and associated perinatal mortality and morbidity among low-risk women giving birth in private and public hospitals in NSW (2000-2008): a linked data population-based cohort study. *BMJ Open* 2014;4:e004551.
59 Athukorala C, Rumbold AR, Willson KJ, *et al*. The risk of adverse pregnancy outcomes in women who are overweight or obese. *BMC Pregnancy Childbirth* 2010;10:56.
60 Shaw D, Guise J-M, Shah N, *et al*. Drivers of maternity care in high-income countries: can health systems support woman-centred care? *Lancet* 2016;388:2282–95.
61 Rossignol M, Chaillet N, Boughrassa F, *et al*. Interrelations between four antepartum obstetric interventions and cesarean delivery in women at low risk: a systematic review and modeling of the cascade of interventions. *Birth* 2014;41:70–8.
62 Lumley J, Brown S. Attenders and nonattenders at childbirth education classes in Australia: how do they and their births differ? *Birth* 1993;20:123–30.
63 Fabian HM, Rådestad IJ, Waldenström U. Characteristics of Swedish women who do not attend childbirth and parenthood education classes during pregnancy. *Midwifery* 2004;20:226–35.
64 Ghersi D, Berlin J, Askie L. Chapter 19: Prospective meta-analysis. In: JPT H, G S, eds. *Cochrane Handbook for systematic reviews of interventions: the Cochrane collaboration*, 2011.
65 Review Manager (RevMan) [program]. 5.3 version. Copenhagen; 2014.
66 World Medical Association. World Medical association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191–4.
67 Higgins JPT, Green S, Cochrane Collaboration. *Cochrane Handbook for systematic reviews of interventions*. Chichester, England ; Hoboken, NJ: Wiley-Blackwell, 2008.
68 AIHW. *National core maternity indicators 2017*. 22. Canberra, Australia: AIHW, 2019.
69 Tennant R, Hiller L, Fishwick R, *et al*. The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007;5:63.
70 McKellar L, Steen M, Lorensuhewa N. Capture my mood: a feasibility study to develop a visual scale for women to self-monitor their mental wellbeing following birth. *Evidence Based Midwifery* 2017;15:54–9.
71 Vedam S, Stoll K, Martin K, *et al*. The mother's autonomy in decision making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. *PLoS One* 2017;12:e0171804.
72 Vedam S, Stoll K, Rubashkin N, *et al*. The mothers on respect (MOR) index: measuring quality, safety, and human rights in childbirth. *SSM Popul Health* 2017;3:201–10.
73 Benson H, Klipper M. *The relaxation response*. New York: Harper Collins, 1992.
74 Smith CA, Levett KM, Collins CT, *et al*. Relaxation techniques for pain management in labour. *Cochrane Database Syst Rev* 2018;3:CD009514.
75 Lovas J. Evidence-Based relaxation therapy: physiological and psychological benefits. *Journal of the Australian Traditional-Medicine Society* 2015;21:105–6.
76 Lovas JG, Lovas DA. Rapid relaxation--practical management of preoperative anxiety. *J Can Dent Assoc* 2007;73:437–40.
77 Betts D. Acupressure techniques for use during childbirth and pregnancy; 2005.
78 Levett KM, Smith CA, Dahlen HG, *et al*. Acupuncture and acupressure for pain management in labour and birth: a critical narrative review of current systematic review evidence. *Complement Ther Med* 2014;22:523–40.
79 Gupta JK, Hofmeyr GJ. Position for women during second stage of labour. *Cochrane Database Syst Rev* 2004:CD002006.
80 Guszkowska M. The effect of exercise and childbirth classes on fear of childbirth and locus of labor pain control. *Anxiety Stress Coping* 2014;27:176–89.
81 Smith CA, Levett KM, Collins CT, *et al*. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database Syst Rev* 2012:CD009290.
82 Uvnäs-Moberg K, Handlin L, Petersson M. Self-soothing behaviors with particular reference to oxytocin release induced by non-noxious sensory stimulation. *Front Psychol* 2014;5:1529.
83 Simkin PP, O'hara M. Nonpharmacologic relief of pain during labor: systematic reviews of five methods. *Am J Obstet Gynecol* 2002;186:S131–59.
84 Field T, Hernandez-Reif M, Taylor S, *et al*. Labor pain is reduced by massage therapy. *J Psychosom Obstet Gynaecol* 1997;18:286–91.
85 Nabb MTM, Kimber L, Haines A, *et al*. Does regular massage from late pregnancy to birth decrease maternal pain perception during labour and birth?--A feasibility study to investigate a programme of massage, controlled breathing and visualization, from 36 weeks of pregnancy until birth. *Complement Ther Clin Pract* 2006;12:222–31.
86 Australian Commission on Safety and Quality in Health Care. National safety and quality health service standards. Sydney; 2017.
87 National Research Council BoCYaFIoM. An update on research issues in the assessment of birth settings: workshop summary. assessment of risk in pregnancy. Washington DC National Academies Press (US); 2013.
88 Liu S, Liston RM, Joseph KS, *et al*. Maternal mortality and severe morbidity associated with low-risk planned cesarean delivery versus planned vaginal delivery at term. *CMAJ* 2007;176:455–60.
89 Smith GCS, Pell JP, Dobbie R. Caesarean section and risk of unexplained stillbirth in subsequent pregnancy. *Lancet* 2003;362:1779–84.