Can antenatal education improve maternity outcomes?

The AEDUCATE Collaboration – protocol for a large prospective meta-analysis of comprehensive antenatal education programs

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Current project – NHMRC funded fellowship grant

- AEDUCATE Collaboration:
  - Antenatal Education Using Comprehensive AnTenatal Education to reduce interventions in labour and birth
- Grant Title:
  - Novel approach to childbirth education program to reduce rates of caesarean section for first time mothers
- Study design – Prospective Meta Analysis (PMA)

What is a prospective meta-analysis?

- **PMA:**
  - A PMA is a meta-analysis of studies (usually RCTs) that are identified, evaluated and determined to be eligible for the meta-analysis before the results of any of those studies became known.
  - Agree on outcome measures and collection of data

Aims

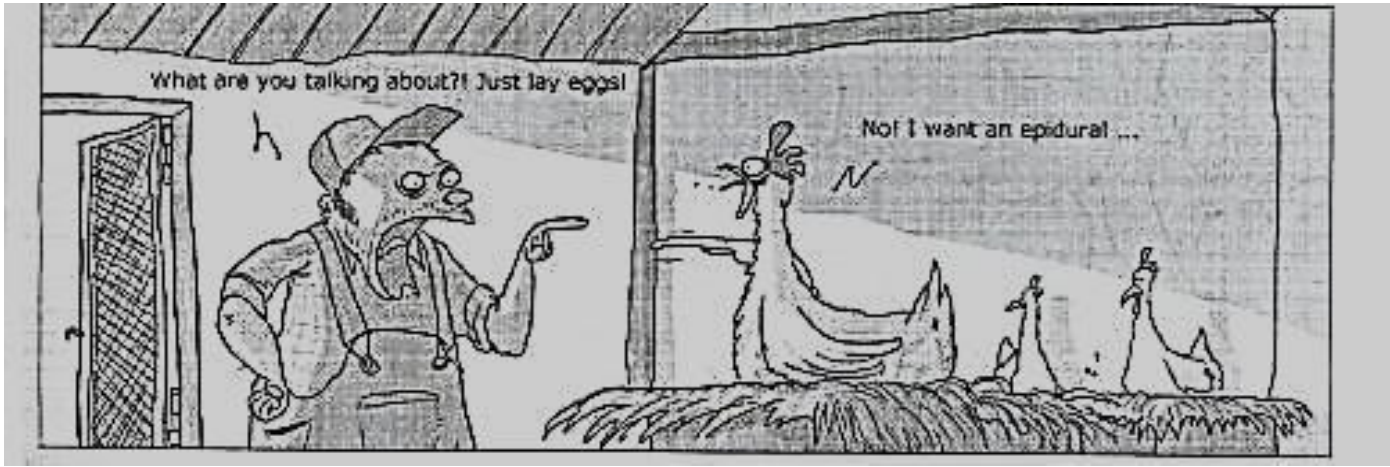
- **This project aims to:**
  - Evaluate the effectiveness and cost-effectiveness of implementing a comprehensive antenatal education program into routine care settings
  - Explore facilitators and barriers that may influence implementation of the program in diverse populations and hospital settings

Why are we doing this study?

- Giving birth - commonest acute overnight hospital admission
- Rates of intervention critically high
- Consumes substantial proportion of the health budget.
- 300,000(AUS), 650,000(UK) babies born each year
- Over 98% of women use maternity care services (public or private) = 1 million patient days in hospital (AUS)
- Development of a cost effective program to reduce rates of unnecessary medical interventions - expected to have substantial maternal and neonatal health benefits
- Assist in the development and implementation of novel models of care that address national and international gaps in antenatal education.

Background

- Rates of medical interventions in normal labour and birth are increasing significantly, in particular - rates of CS
- Medical interventions becoming routine
- 2018 WHO and Lancet series warned against excessive use of obstetric interventions such as CS
- Unnecessary CS contributes to morbidity and mortality
- Reviews of maternity services repeatedly call for reductions to these rates
- But how to reduce?



Antenatal education
What do we know?

- Current models of antenatal education demonstrate little change in obstetric outcomes.
  - CSR: “the effects of general antenatal education for childbirth or parenthood, or both, remain largely unknown”[1]
  - In Australia, competency standards developed by CAPEA, but no requirement for implementation or evaluation
  - Lack of evaluation or examination as to outcomes or effectiveness
  - Limited integration of evidence into practice

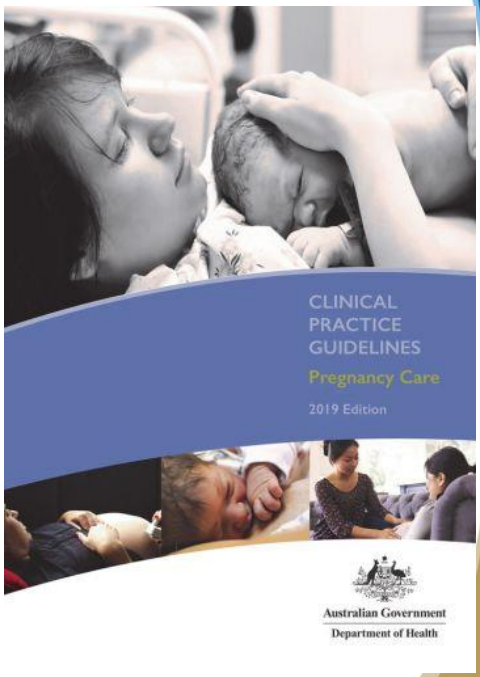
1. Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. Cochrane Database of Systematic Reviews 2007; (3)

Aims of antenatal education?

- Department of Health, Pregnancy Care Guidelines states:

Antenatal education aims to:

- Develop networks for social support
- Influence health behaviours
- Reduce perinatal morbidity and mortality
- Prepare women and partners for childbirth, by:
  - Building women's confidence in their ability to labour and give birth
  - Prepare women for the pain of labour
  - Support their ability to give birth without pain relief



What do we see in classes?

- Focus shifted to parent education rather than birth preparation
- Birth is viewed as “just a day in your life”
- Introduction to hospital policies and procedures?
- Adjusting expectation of couples to probable interventions in labour (evoking fear and anxiety)
- Normalising medical pain management
- Lack of options

ACOG recommendations

Safer Care Recommendations: Highlights

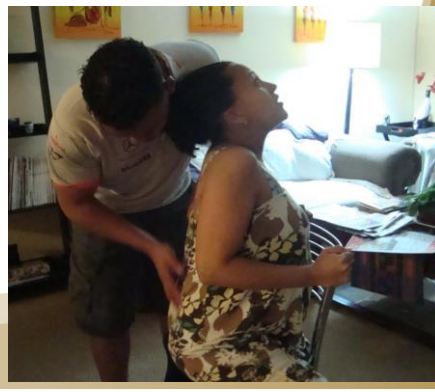
The Committee Opinion notes, "Many common obstetric practices are of limited benefit for low-risk women in spontaneous labor." For such women, ACOG encourages individualized care and use of the following alternatives (listed on the right side of the table), instead of the common obstetric practices listed on the left side:

Instead of...	Many women can benefit from...
Being admitted early to the birth facility	Going to the birth facility once in "active" labor (about 6 centi-meters dilation)
Using continuous electronic fetal monitoring (EFM) during labor	Listening to the baby's heart tones at intervals with a handheld device (Doppler or fetal stethoscope)
Laboring without continuous support	Having continuous labor support, e.g., from a doula
Using IV lines, with no fluids by mouth	Drinking clear liquids
Using a procedure to break membranes	Leaving membranes intact, to break on their own
Laboring while lying down in bed	Staying upright and moving around in labor
Using epidural and other pain medication	Using various drug-free pain relief measures
Pushing and giving birth while lying on her back	Giving birth in most comfortable position
Pushing when 10 centimeters dilation is reached	Resting while baby moves down and waiting for the urge to push
Following staff-directed coaching to push	Pushing in her preferred, most effective way


THE STORY
SO FAR

Comprehensive childbirth education package – background study 2011-15

- Developed a comprehensive package of childbirth education – **RCT**:
  - 1. intervention + usual care
  - 2. usual care alone
- Intervention:
  - 2 day workshop for women and their birth partners
  - Incl: Nulliparas, low risk, not in continuity of care
- Intervention includes:
  - **Knowledge**
    - Physiology of birth (hormones, principles, triggers)
  - **Support**
    - Partner support techniques
  - **Tools**
    - Acupressure and point selection
    - Upright and active postures and positions, yoga
    - Guided visualisation (x4)
    - Breathing techniques (x4)
    - Massage techniques (x2)



Study publications

Open Access Research

BMJ Open Complementary therapies for labour and birth study: a randomised controlled trial of antenatal integrative medicine for pain management in labour

Kate M Levett,[1] C A Smith,[1] A Bensoussan,[1] H G Dahlen[2]

Open Access Research

BMJ Open Cost analysis of the CTLB Study, a multitherapy antenatal education programme to reduce routine interventions in labour

Kate M Levett,[1,2] Hannah G Dahlen,[3] Caroline A Smith,[2] Kenneth William Finlayson,[4] Soo Downe,[4] Federico Girosi[5,6]

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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

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Altmetric 17

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Article Info | CrossMark

Results

OUTCOMES	Treatment Group (n=88) %	Control Group (n=83) %	Risk Ratio
Epidural analgesia	21 (23.9%)	57 (68.7%)	0.35 [0.23-0.52] P<0.0001**
Mode of birth NVB	60 (68.2%)	39 (47.0%)	1.56 [1.12-2.17] P<0.01**
Augmentation	25 (28.4%)	48 (57.8%)	0.50 [0.35-0.73] P<0.0001**
Mode of birth CS	16 (18.2%)	27 (32.5%)	0.52 [0.31-0.87] P=0.017*
Mode Birth NVB/Instrumental	12 (13.6%)	17 (20.5%)	0.57 [0.30-1.05] P=0.09
Resuscitation (Suction +/- O2)	12 (13.6%)	24 (28.9%)	0.47 [0.25-0.87] P=0.01**

Results

OUTCOMES	Treatment Group (n=88) %	Control Group (n=83) %	Risk Ratio
Spontaneous Onset Labour	62 (70.5%)	54 (65.1%)	1.09 [0.90-1.34] P=0.38
Pethidine	19 (21.6%)	15 (18.1%)	1.19 [0.65-2.2] P=0.56
Nitrous Oxide (Gas)	40 (45.5%)	49 (59.0%)	77 [0.58-1.03] P=0.09
Perineal Trauma (NVB=72, 56)^	61 (84.7%)^	54 (96.4%)^	0.88 [0.78-0.98] P=0.02*
Major Perineal Trauma (NVB=72, 56)^	49 (68.1%)^	37 (66.1%)^	0.94 [0.57-1.55] P=0.85
PPH	13 (14.8%)	15 (18.1%)	0.82 [0.41-1.61] P=0.68
APGAR < 7 (5 min)	3 (3.4%)	4 (4.8%)	0.99 [0.95-1.03] P=1.0
NICU/SCN admit	7 (8.0%)	11 (13.2%)	0.59 [0.24-1.46] P=0.25

Qualitative results
Interviews & focus groups

Overarching theme from interviews:

- ***'Making sense of labour'***

Midwifery focus groups:

- ***'Following women in labour'***

Cost analysis

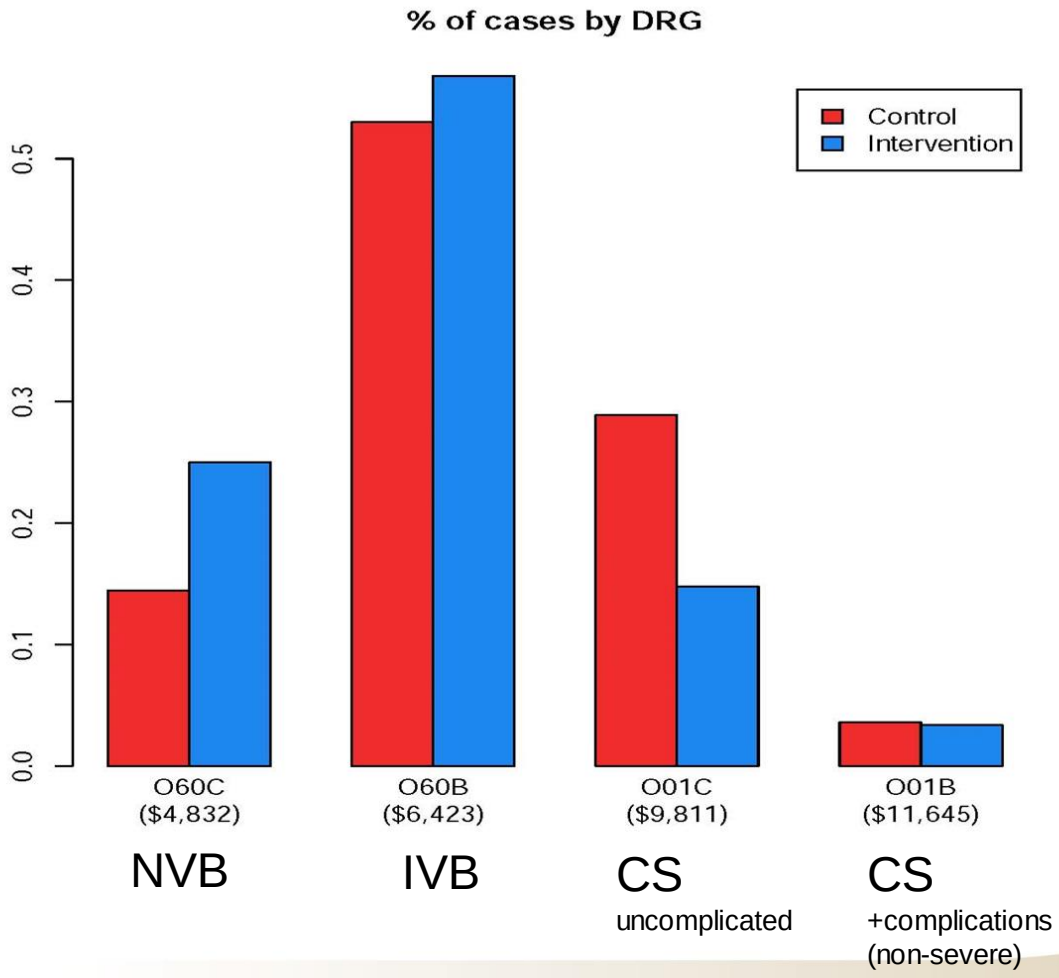
Australian Refined Diagnosis Related Groups (AR-DRGs)

Australian Refined Diagnosis Related Groups

- Single outcome for labour and birth – AR-DRG codes.
- based on highest level of intervention during labour and birth.
- AR-DRG codes - group together hospital admissions of the same clinical type that utilise similar amounts of hospital resources.

Outcomes (± neonatal)	Code	AR-DRG associated cost	Study group	Total cost per birth	Control group	Total cost per birth
NVB uncomplicated	O60C	$4,832	22	$106,304	12	$57,984
NVB + complications not severe/catastrophic	O60B	$6,423	50	$321,150	44	$282,612
NVB + complications severe/catastrophic	O60 A	$9,393	0	0	0	0
CS uncomplicated	O01C	$9,811	13	$127,543	24	$235,464
CS + complications not severe/catastrophic	O01B	$11,645	3	$34,962	3	$34,962
CS + complications severe/catastrophic	O01 A	$16,646	0	0	0	0
TOTAL			**88**	**$609,854**	**83**	**$642,301**
Av. cost per woman				**$6,930**		**$7,739**
Av. cost saved from intervention - Cost of implementing				**$141**	**-cost**	**$808** **$667**

Cost analysis



Summary

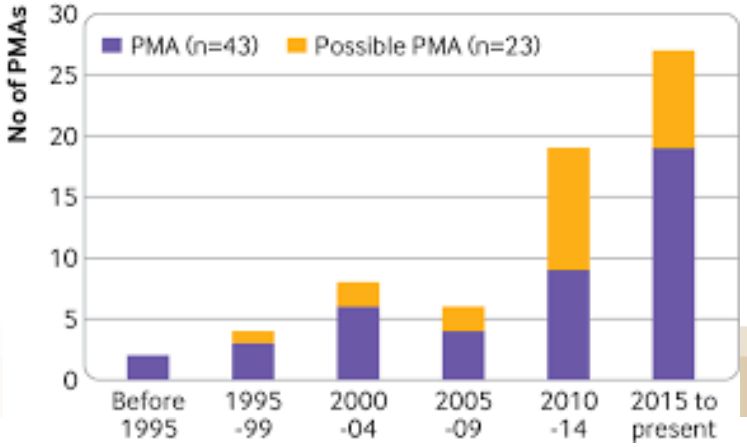
- Quantitative
  - Significant reduction in rates of
    - caesarean section
    - epidural
    - perineal trauma,
    - newborn resuscitation rates,
    - shorter second stage of labour.
- Qualitative themes
  - Primary/secondary
    - Making sense of labour and birth
    - Having a toolkit
    - Following women in labour
- Cost analysis
  - Saved an average of $AUD808 per woman
  - cost $AUD141 per woman to implement

Summary previous trial

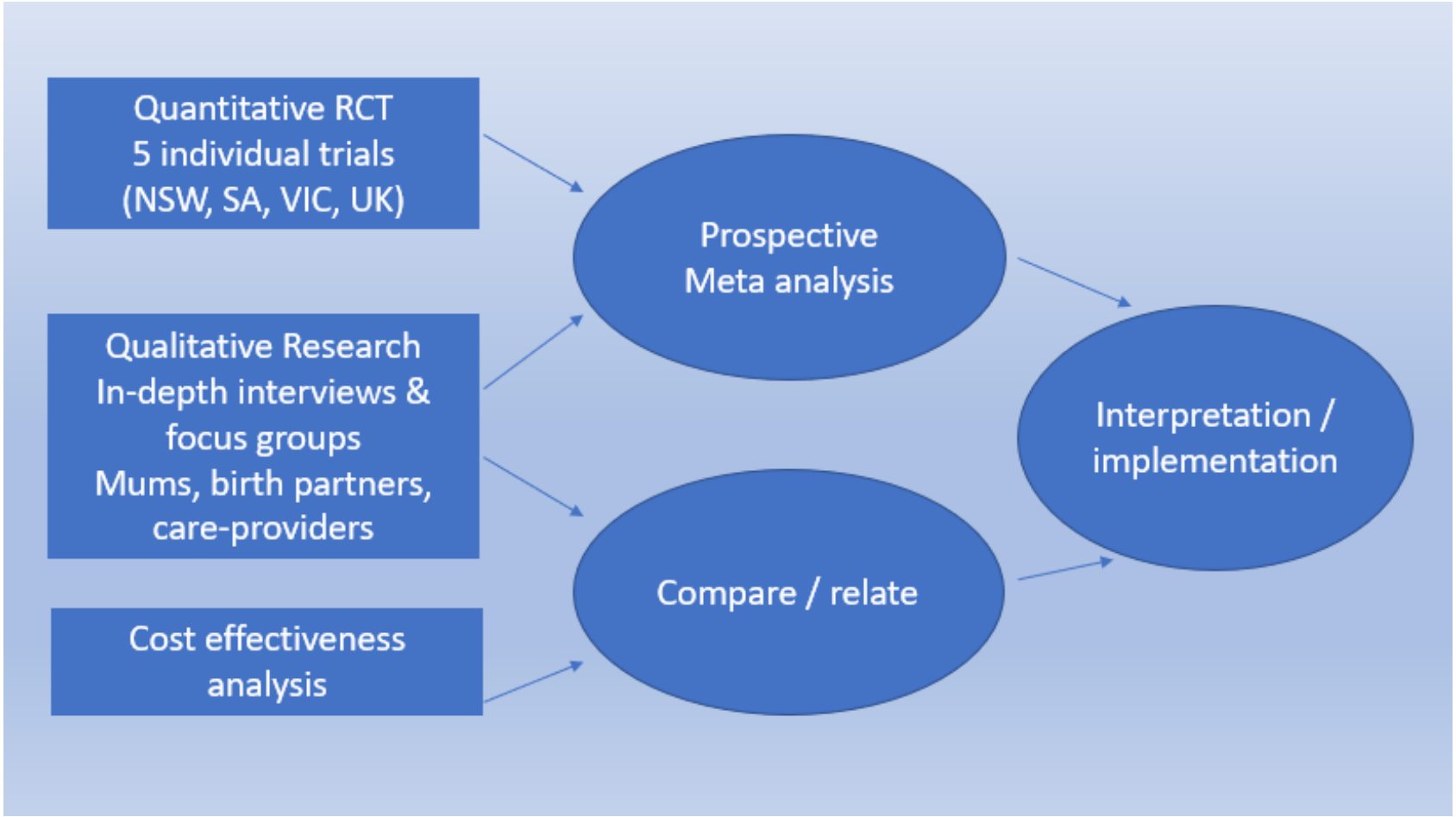
- Comprehensive antenatal education course **supports normal** labour and birth
- Value of ***independent*** childbirth education
- Lowering rates of intervention saves **money** for funders (governments / hospitals / individuals)
- Main cost savings from ***reduced CS***
- AR-DRG codes provide **uniform assessment** for Australian trials and is internationally transferrable (underestimates true cost)
- Economic analysis should be embedded in all perinatal trials
- **Implementation** of evidence into practice is vital

Current study – PMA!

- Comprehensive CBE requires assessment on a larger scale
- Diverse populations and settings
- Informs broader implementation
- Assess the factors that modify the effectiveness of CBE:
  - different models of care, demographics including insurance status, parity, obstetric-risk, socio-economic status, cultural background, and co-morbid conditions.
- National and International input
- Prospective meta-analysis (PMA) study design



PMA


Quantitative RCT
5 individual trials
(NSW, SA, VIC, UK)
Qualitative Research
In-depth interviews &
focus groups
Mums, birth partners,
care-providers
Cost effectiveness
analysis
Prospective
Meta analysis
Compare / relate
Interpretation /
implementation

Study questions and PICO

- **Primary study question**:
  - Does the addition of a comprehensive multi-component antenatal education (ANC) birth preparation program reduce caesarean section (CS) in nulliparous women, compared to standard hospital care.
- **Secondary study question**:
  - Do participant, intervention components or hospital characteristics modify the effectiveness of the program?
- **Population**:
  - Women with singleton vertex pregnancies, and no indication for planned CS or epidural.
- **Intervention:** Comprehensive CBE
- **Comparator:** Usual care
- **Outcomes**: **Primary**: caesarean section.
  - **Secondary**: epidural analgesia, perineal trauma, post-partum haemorrhage, newborn resuscitation, psychosocial wellbeing.
  - **Subgroup analysis**: parity, model of care, maternal risk status, maternal education, maternal socio-economic status, intervention components.

Study design PMA

- Study design:
  - An individual participant data (IPD) prospective meta-analysis (PMA) of randomised controlled trials (including cluster design).
  - The Antenatal AEDUCATE collaboration has been formed with investigators from each of the eligible randomised controlled trial, proposed trials and other relevant personnel.
  - Each trial will be conducted independently but share core protocol elements to contribute data to the PMA.
  - Each of the trials that will be included are deemed eligible for the PMA if their results are not yet known to anyone outside their Data Monitoring Committees.

Intervention: Comprehensive childbirth education

- Components:
  - ***Knowledge and understanding*** - providing education about normal labour physiological and hormonal processes for women and partners to understand how the body works in labour.
  - ***Positive mindset*** - positive psychological focus on women's ability and capacity for normal birth;
  - ***Tools and techniques (≥3)*** 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 - yoga, acupressure and massage;
      - relaxation techniques - breathing, visualisation;
      - range of positions - movement, upright, forward, side lying or comfort positions enabling women to listen and respond to bodily cues during labour.

PMA requirements and opportunities

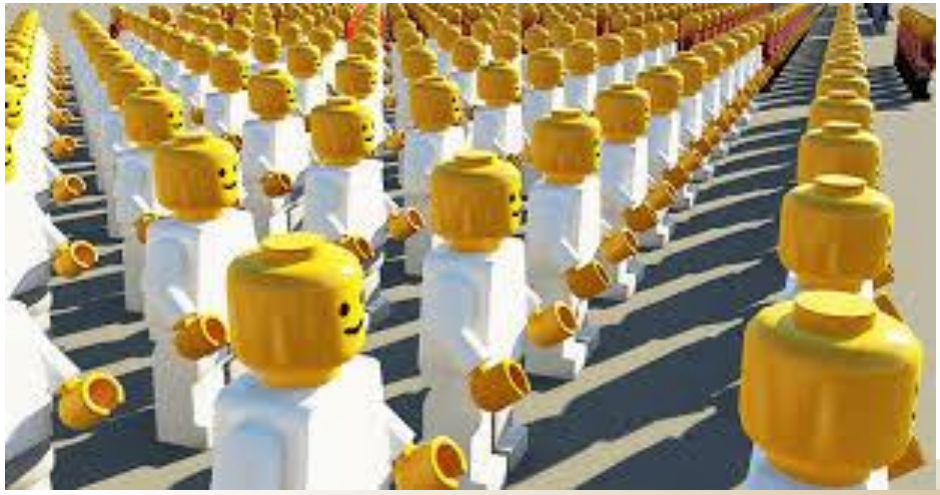
- Programs that include the three components, and are yet to be evaluated, are eligible to collaborate.
- No requirement for protocols to be identical - variety is desirable
- Accommodate different groups, settings and practices
- Identify if there is a particular group for whom most beneficial
- Define own entry criteria and outcome measures (incl. CS)
- Share the same core pre-specified protocol elements
- Opportunity to develop a standarised protocol in partnership with other trial groups, receive training in a program, but retain autonomy and responsibility for the conduct and design of trial

Trial level inclusion criteria

- Each trial has to be randomised
  - (including cluster randomisation) with an adequate level of allocation concealment.
- Intervention includes all three components
  - knowledge and understanding; positive mindset; and tools and techniques (including at least three individual evidence-based non-pharmacological techniques).
- Pregnant women
  - parity status recorded, model of care recorded, risk status recorded, enrolled some low risk women (trialist defined)
- Outcomes
  - includes CS.
- Comparator group
  - standard antenatal care available in their setting (different levels of background care).
- All participating trials to be registered
  - 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.

Sample size

- A total sample size of 2,500 - detect a clinically important 5% absolute difference in CS rates from 30% to 25%,
- 80% power and a significance level of $p<0.05$.
- Exploration of Rx interactions for specified secondary outcomes:
  - pharmacological pain relief (epidural), onset of labour, and instrumental vaginal birth.
- Relative effects of subgroups,
  - parity, risk status and model of care



Outcome measures

- Primary Outcome: Caesarean section
- Secondary Outcomes:
  - **Maternal**: onset of labour, indications for induction, failed induction, epidural block, 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 1st, 2nd, 3rd, 4th tear) and episiotomy, perineal suturing, commencement of skin to skin contact with baby (immediate, within first hour, first 2 hours), postnatal Edinburgh Post Natal Depression Score (EPDS) and key safety measures including PPH and readmission (see Appendix B for variable definitions). Plus one salutogenic scale. Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (Tennant et al., 2007).
  - **Newborn**: Apgar score at 5 mins, any resuscitation, birth weight, cord clamping, breastfeeding in first two 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: Clinical outcomes to classify into DRGs groups, or similar international code.
  - The DRG codes are mutually exclusive classifications
  - Analyse the cost of implementing the program compared with standard care
  - Codes for international classification of disease (ICD) and diagnosis related group (DRGs) (or equivalent) for each individual admission.

Intervention

- Included in the PMA will be individual trials of comprehensive antenatal education childbirth preparation programs,
- Include multiple components for birth preparation,
- designed to address the three objectives
    - 1. preparing women and their partners for childbirth through education on physiological/hormonal birth (knowledge and understanding);
    - 2. building women's confidence in their ability to labour and give birth, through psychological preparation for normal labour (positive mindset);
    - 3. support their ability to give birth without pain relief using evidence-based tools for birth preparation (tools and techniques).

Included evidence-based therapies

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:

1. Relaxation and guided visualisation
2. Acupressure
3. Breathing
4. Movement, yoga, labour and birth comfort position
5. Massage

Control group

- Control group
  - Usual care - including the standard antenatal education classes offered by the hospital,
  - should not include more than two components described above.
- Participation in any hospital-based program is patient 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 an exclusion criteria.

Data analysis

Data Analysis

- Intention-to-treat analysis
- Baseline and service characteristics of participants summarised by trial and overall by treatment group
- Hospital characteristics summarised.
- Univariable analysis undertaken to identify
  - predictors of CS
  - key secondary outcomes
  - predictors of CM use

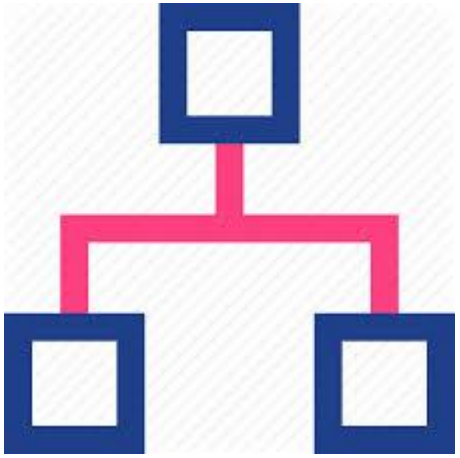
Data analysis PMA

- Primary analysis –
  - the effectiveness of the program on CS rates will be assessed in nulliparous women.
- Results will be reported for individual trials and then combined in a meta-analysis
  - fixed effect log-binomial one-stage regression model
- Model will adjust for potential confounders including
  - maternal age, onset of labour, augmentation, epidural, other predictors identified from the univariable analysis.

Subgroup analysis

- a. 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 secondary / post-secondary)
  - maternal socio-economic status (low SES / high SES)

- b. Intervention characteristics
  - mode of intervention delivery (face to face / online)
  - Intensity (number of sessions)
  - provider of intervention (hospital-based/independent)
  - individual components in program



Other details

- **Consumer engagement/advisor -** Standard 2 of the Australian Commission for Safety and Quality in Healthcare (ACSQHC)
- Data ownership
- Publication policy
- Funding
- Ethical considerations
- Common protocol
- Current studies

Current studies

Trial acronym **Registration number**	**BirthCourse**	**My BirthCourse**
Planned sample size	400 first time mothers	400 first time mothers
Country/State of recruitment	NSW Australia (UNDA)	SA Australia (UniSA)
Intervention	Program includes education on physiology, supportive care techniques, and 5 CM techniques: acupressure, massage, yoga, visualisation, breathing techniques. Plus usual care.	Program includes education on physiology, supportive care techniques, and 5 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 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	Caesarean section
Qualitative study	Included	Included
Funding	NHMRC ECR Fellowship	UniSA grant
Registry trial number	U1111-1216-4512 PROSPERO (under review)	ANZCTR

Significance

- Real world effectiveness (generalisability) – CBE delivery in diverse populations and settings
- PMA - novel design in this setting
- Assess clinical effectiveness, resource use and cost-effectiveness
- The project will build on the evidence base for the effectiveness of independent CBE programs
- Contribute understanding of how programs can best support women and their partners in labour and birth.
- Inform national and international models of antenatal and labour care for the management of normal labour and birth
- Prevention of morbidity in maternity health care settings
- Reduction in rates of caesarean section will contribute to the reduction of lifetime risk of morbidity becoming evident in the literature for post-CS follow up of women and babies