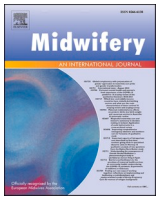
Midwifery 139 (2024) 104170

Contents lists available at ScienceDirect

Midwifery

journal homepage: www.elsevier.com/locate/midw



Antenatal education incorporating complementary medicine techniques for labour and birth to reduce the rates of epidural in primiparous women: A randomised control trial

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ARTICLE INFO

Keywords:
Antenatal education
Complementary therapies
Childbirth preparation
Epidural
RCT

ABSTRACT

Problem: Globally medical management of labour and birth has significantly increased, with epidurals attributed to the cascade of interventions.
Background: There are few randomised control trials that evaluate the effectiveness of antenatal education programs. A previous trial at two Australian hospitals found an antenatal program of integrative complementary therapies significantly reduced rates of interventions for low-risk primiparous women.
Aim: To reduce rates of intervention in labour and birth, with a primary outcome of decreased epidural use during labour.
Methods: Low to moderate risk primiparous women were randomised at 24–36 weeks' gestation to the intervention group and standard care, or standard care alone. Clinical and psychological measures were analysed by intention-to-treat. Trial registration ACTRN12618001353280
Findings: In total, 178 women participated (n = 88 intervention, n = 90 Standard care), demographic characteristics were similar between groups, almost half (49 %) reported a pre-existing medical condition, and well-being scores fell within the average range. Epidural use was lower in the intervention group (47.7% vs 56.7 %) with higher rates of vaginal birth (52.3% vs 42.2 %), however, no statistical differences for birth outcomes were found between groups. Attitude to childbirth scores were statistically higher for women who attended the intervention (59.1 vs 54.3 p00.001).
Discussion: Higher psychometric scores demonstrated women in the intervention group felt an increased sense of coping and control. Antenatal education that includes complementary therapies can reduce fear and improve attitudes about childbirth.
Conclusions: Replicating study protocols enabled the generalisability of findings to a more diverse group of women, and data will contribute to a larger meta-analysis design to detect smaller treatment effects for operative birth.

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https://doi.org/10.1016/j.midw.2024.104170
Received 4 June 2024; Received in revised form 21 August 2024; Accepted 28 August 2024
Available online 30 August 2024

Statements of Significance

Problem or Issue

Globally medical management of labour and birth has significantly increased, as has rates of epidural and caesarean sections.

What is Already Known

Strategies to address unnecessary birth interventions suggest antenatal education that includes complementary therapies for labour and birth may reduce epidural rates in low-risk primiparous women and contribute to self-efficacy.

What this Paper Adds

This RCT provides data to support generalisability of antenatal education inclusive of complementary therapies for low to moderate risk women. Further, attitude to childbirth scores were statistically higher for women who attended the antenatal education intervention. This finding is significant as increased fear of childbirth is associated with increased rates of caesarean section.

Introduction

Pregnancy, labour and birth are normal physiological life events for the majority of women (Council of Australian Governments, 2019). In Australia birth predominately occurs in a hospital setting, and the mortality rates are among the lowest in the world (AIHW, 2020, 2023). However, with hospital-based births the occurrence of medical management for physiological labour has increased significantly, as has the rates of epidural use and unnecessary caesarean section (Chen et al., 2018). In 2021, one third (33 %) of selected low-risk women giving birth for the first time in Australia had a caesarean section birth, a rate which has steadily increased from 24.5 % in 2004 (AIHW, 2023). Management of labour more commonly includes induction, pharmacological pain relief, augmentation of labour, continuous fetal monitoring, episiotomy, active management to birth the placenta and operative interventions to birth the newborn (Fox et al., 2021). While the intentions of medical interventions are to improve maternal and neonatal birth outcomes they can be associated with increased risks of adverse effects, particularly when applied in the case of physiological labour which may outweigh the benefits (Akyildiz et al., 2021; Calik et al., 2018).

Epidural anaesthesia for labour pain management is an example of one intervention that has been identified as a mediator for a cascade of other interventions, disrupting the normal physiological processes of birth (Fox et al., 2021). While modern techniques of epidural administration have been suggested to negate the additional risk of operative birth, few clinical trials report on the potential serious effects of this form of analgesia (Anim-Somuah et al., 2018).

In Australia, most maternity services including those within public health systems offer expectant parents structured antenatal classes that may cover a range of topics such as preparation for labour and birth (Department of Health, 2020). Antenatal education is most commonly offered face to face as group sessions, or held one to one, and more recently via online platforms (Levett et al., 2023; Whitworth et al., 2023). However, the delivery and content are often highly variable and dependent upon the educator and facility where the classes are offered (Department of Health, 2020). Private antenatal courses to assist women to prepare for a physiological labour and birth have increased in popularity in Australia but are not routinely available for the general population (Levett et al., 2016a). Research suggests that antenatal education that incorporates behavioural and coping strategies such as complementary medicine techniques and mindfulness/deep relaxation interventions (Fumagalli et al., 2022; Smith et al., 2018) have demonstrated improved maternal psychosocial outcomes (Lonnberg et al., 2020; Shorey et al., 2019), and may reduce caesarean section and increase spontaneous vaginal birth rates (Chen et al., 2018).

BirthCourse™ was developed to provide education and instruction regarding complementary medicine components of care that have been established individually in the literature (Levett et al., 2016b). Until more recently research into complementary medicine techniques for labour and birth has been limited (Levett et al., 2016a). The concept of delivering a complementary medicine package of care via an antenatal education model is novel in the Australian public hospital context. Data to date regarding complementary medicine suggest that there is a potential to reduce rates of epidural use and the cascade of interventions, and that antenatal education is highly acceptable and accessed by the majority of first-time mothers in Australia (Levett et al., 2016b). However there is a need for randomised controlled trials (RCTs) to be undertaken in different settings, with diverse populations to evaluate the effectiveness of complementary antenatal programs, as well as to provide data for future prospective analysis. This randomised controlled trial of MyBirth Course, a context specific adaption of BirthCourse™ examines the effectiveness of this intervention program to reduce medical interventions in labour and birth.

Methods

The primary objective of this study

To evaluate the effectiveness of a complementary medicine antenatal education program (MyBirth Course) for pain management in labour, delivered to women and their birth partners (plus standard care), compared with women receiving standard care alone, to reduce the incidence of epidural use during labour.

Study design: A single site, non-blinded Randomised Controlled Trial (RCT) of the MyBirth Course (integrated complementary therapy program) as an antenatal package of care, compared with standard care for low to moderate risk primiparous women. Data from this study will contribute to a prospective meta-analysis study (to be reported separately), (Levett et al., 2020) with the aim to detect a smaller clinically relevant effect of a 5 % reduction in caesarean section rates.

Primary outcome: The incidence of epidural use.

Secondary maternal outcomes: Onset of labour (spontaneous or induction), other pharmacological pain relief for labour, augmentation of labour, mode of birth (vaginal birth, instrumental, or caesarean), perineal trauma (first, second, third and fourth degree tear [severe perineal trauma]), and episiotomy, postpartum haemorrhage (PPH), length of labour (first stage, second stage, third stage, total length), gestational age at birth, duration of hospital stay. Validated psychosocial instruments were used to assess aspects of the woman's attitude and wellbeing around childbirth. These were: Prenatal Attitudes to Childbirth, Post-birth Labour Agentry Scale, Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) and Capture My Mood (CMM). The CMM wellbeing tool and WEMBS were implemented to assess for correlation between these two tools.

Secondary neonatal outcomes: Apgar scores at 5 min, resuscitation at birth, respiratory distress, admission to neonatal intensive care (NICU) or special care nursery (SCN), duration of stay in NICU/SCN, birth weight.

Intervention: MyBirth Course is an antenatal education package utilising the resources from BirthCourse™(https://www.birthcourse.com.au) for the management of women's pain in labour and birth. The workshops involve interactive education and practice sessions to develop CT techniques (Table 1), led by one of three (LM, JF, JW) experienced antenatal educator following a scripted program. The following concepts and techniques are introduced to the woman and their chosen birth support person during the course: Concepts; the physiology of birth, the fear-pain-tension cycle, working with pain, the relaxation response. Techniques; guided visualization and relaxation, active birth- movement, yoga and positions for birth, acupressure, breathing (Diaphragmatic breathing referred to as belly breathing and

Table 1
My birth course program overview.

Modules	Content	Duration
Module 1: Mind & body – working together	■ Preparing for birth ■ What does the evidence say? ■ How fear can affect birth ■ The uterus and how it works ■ Building a positive belief system – language, positive reinforcement ■ Relaxation ■ Healthy habits ■ Support team	Day 1 or session 1
Module 2: Evidence-based support tools	■ Our toolkit ■ Breathing techniques (working with our body) ■ Guided visualisations ■ Relaxation techniques ■ Acupressure techniques for labour and birth ■ Birth environment – keeping things calm	Day 1 or session 2
Module 3: Birthing with confidence – tools & knowledge	■ Movement & yoga ■ Upright positioning for labour and birth ■ Working towards physiological birth ■ Special circumstances ■ Building knowledge – decision making tools ■ Massage (light, moderate and strong) ■ Other non-pharmacological pain relief for labour ■ Letting go – releasing fears (practical session)	Day 2 or session 3
Module 4: Happy birthing day!	■ Pathway to a healthy birth ■ Making sense of labour and birth ■ Progression – how to tell, how to help ■ Medicine as backup ■ Meeting baby (plus birthing placenta & breastfeeding) ■ Practical exercise – birth rehearsal/visualization	Day 2 or session 4

Adapted from BirthCourse https://www.birthcourse.com.au.

birth breathing referred to as J-breathing techniques), and massage techniques (Levett et al., 2020). The intervention aimed to increase women's confidence and feeling of personal control.

Duration of intervention: Participation in the course involved the completion of four modules in either a 2-day weekend or a series of (4 × 2.5 h) evening workshops. Participants chose which scheduled workshops (weekend or evening) they wished to attend. Participants were asked to complete a practice workbook outlining the tools and techniques (when/where/with whom) and had access to online resources that included videos demonstrating techniques, handouts and revision sheets (https://www.birthcourse.com.au). Participants were encouraged to practice the techniques in preparation for labour and birth but were not prescribed any specific duration or frequency of time to practice.

Standard care/Control: The Preparing for Birth and Parenting - antenatal classes offered to all women at the tertiary maternity hospital were held in the evenings or on weekends. Pregnant women and their support partner booked at 20–24 weeks gestation to attend classes. The classes commenced at approximately 30 weeks of pregnancy.

Standard care classes covered the following four topics. Topic One: Caring for your new baby and early parenting (2 h); Topic Two: Labour and active birth (2 h); Topic Three: Birth intervention (2 h); Topic four: Practical skills for labour/refresher course (2 h). Topic four included info on massage, relaxation, positioning, breath awareness, physical recovery from the birth and getting back into shape. The Preparing for Birth and Parenting program was designed and run by educators from the Hospital.

Sample size and statistical power: The sample size calculation was undertaken to achieve an 80 % power to detect the primary outcome of a 20 % reduction in epidural rate, as observed in the original study by Levett et al. (2016b). The calculation determined that $n = 190$ women (95 in each group) would be needed to achieve a statistical significance at a p-value of (alpha) of 0.05, with a type II error rate (β) of 0.2. Anticipating possible participant losses, the recruitment target was set to ensure at least 105 were in each group.

Randomisation: Once eligibility was confirmed women who consented to participate, were randomised. Randomisation was undertaken via the Sealed Envelope service (https://www.sealedenvelope.com) with computer generated sequence allocation using random block design. Allocation assignments were placed and sealed in opaque sealed envelopes by a person not involved in the conduct of the trial and securely held in the area where randomization occurred. Researchers were blinded to allocation with envelopes only opened after participant details were recorded.

Ethical Statement: Ethics approval was obtained from the University of South Australia Human Ethics Committee application 201,343 and the Women's & Children's Hospital Network Human Research Ethics Committee HREC/18/WCHN/19 and 2020/HRE01521.

Study setting: Recruitment was conducted at the largest tertiary maternity hospital in Adelaide, South Australia with an approximate birth rate of 5000 births per year. The intervention (MyBirth course) was conducted off site at the University of South Australia, Health and Medical Clinic (City West Campus).

Participants: Primiparous women between 24 and 36 weeks gestation, not considered high risk for obstetric or medical disorders as defined by the ACM National guidelines for consultation and referral (ACM, 2014), and who were booked to attend antenatal classes and receive standard care at the tertiary hospital were eligible to participate.

Recruitment: Following ethics approval, recruitment was undertaken between 19th August 2018 and 9th August 2021.

COVID-19 restrictions prevented the recruitment of participants during the months of March 2020 and September 2020. The trial was suspended for this seven-month period. In addition, the standard care arm of the trial was modified following this period as the hospital suspended face to face antenatal education from April 2020 until April 2021. In this time women were offered access to online modules with a 2-hour online session facilitated by a midwife educator.

All women that booked into the tertiary hospital's antenatal classes were provided with information for the study and those who showed an interest and were eligible received a participant information sheet and consent form. The study was publicised to midwives and doctors who worked in the outpatient antenatal clinics. In addition, study flyers were located in the outpatient clinics, and near amenities within the clinic area.

Due to COVID-19 between September 2020 and July 2021 (when face-to-face recruitment was not permitted), women who booked into the hospital's antenatal classes were provided a link to the study website as part of their confirmation email that detailed options for additional antenatal classes. Women who were interested where then able to access a participant information sheet and consent form from the site or contact the principal researcher for more information.

Inclusion criteria

- Between 24 and 36 weeks of completed pregnancy
- Primiparous
- Singleton pregnancies
- Low to moderate risk as defined by Australian College of Midwives National Midwifery Guidelines for consultation and referral (ACM, 2014).
- Sufficient standard of English language and writing for participation in the workshops

Exclusion criteria

- High risk pregnancies
- Congenital abnormalities
- Participation in similar program of complementary antenatal education (such as 'Calm Birth', 'Hypnobirthing', 'Active Birthing' etc.)
- Participation in midwifery group practice (1:1 Midwifery continuity of care model)
- Age <18 years
- Multiple births

Data collection tools

The study approach and data collection tools used at the different time points can be seen in Fig. 1.

Attitude to Childbirth Questionnaire: All women were asked to complete the Attitude to Birth Questionnaire (Humenick and Bugen, 1981), a validated instrument used in birth studies. The purpose of the attitude to birth scale was to assess the change in feelings and attitudes regarding the forthcoming birth, as measured by the scale, at trial entry and following women's respective completion of the antenatal program (whether intervention or standard care alone).

Capture My Mood & Warwick Edinburgh Mental Wellbeing Scale (WEMWBS): Participants from both groups were asked to complete the Capture My Mood (CMM) tool and the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) following their respective completion of the antenatal program. The CMM is a 5-point visual scale for women to self-monitor their wellbeing which align with the five core concepts of the WEMWBS (McKellar et al., 2017). The WEMWBS is a 14-item scale with 5 response categories, summed to provide a single score ranging from 14 to 70 (Stewart-Brown et al., 2009). The WEMWBS has been validated as a reliable tool to measure mental wellbeing among people and takes approximately 5 min to complete.

Labour Agentry Scale: All women were asked to complete the Labour Agentry Scale post-birth, a validated and reliable instrument that measures expectancies, confidence and experiences of personal control during childbirth (Hodnett and Simmons-Tropea, 1987). The Labour Agentry Scale contained 10 questions using a 7-point Likert scale for response.

Demographic and lifestyle questions: Data known to influence intervention rates in labour were collected at trial entry such as model of care, cultural background, educational level, maternal age, gestational age, smoking status, pre-pregnancy weight, household income, obstetric risk status, and comorbidities (Levett et al., 2020).

MyBirth course evaluation form (intervention group only): Women in the intervention group completed a questionnaire upon completing the MyBirth course and again within 6 weeks post-birth. Program evaluation included participants identifying practices covered in the course, what techniques they liked the most, techniques they liked the least, intention to practice and an open text for any other feedback. Post-birth questionnaire required participants to confirm techniques practiced and how often within each week, complementary therapies (CT) used for pain relief for labour and birth, what CT was most used, what CT was least used and an opportunity to provide any additional information they wished to share.

Data Analysis: Analysis was by intention to treat (ITT) for primary and secondary outcome data. Risk ratios and 95 % confidence intervals were used to compare main effect outcomes between the two groups. T-test with 95 % confidence intervals were used to assess mean score differences between pre and post-test scores by allocation for attitude to childbirth measures. Analyses were performed in STATA v 16.1 and SPSS V28.

Results

During the study period 823 women were screened for eligibility, and 181 consented to participate in the trial (Fig. 2). Following randomisation 89 women were allocated to the intervention group and 92 women to standard care. Three women withdrew after randomisation, and 21 (11.8 %) did not receive the intervention. Data were analysed as intension to treat. Fig. 2 (CONSORT diagram) indicates the reason(s) for not receiving allocated intervention.

In total, 178 women (88 intervention, 90 standard care) were included in the final analysis. All women completed the demographic information at trial entry although not all women answered every question (Table 2). Twenty-seven women (14 intervention, 13 standard care) were lost to follow up and did not complete post-birth questionnaires.

The demographic characteristics of participants were similar between groups, with a mean age of 31 years. The majority of women identified as Australian, with a combined household income of more than $80,000 and had completed a higher degree of education (undergraduate or postgraduate level). Almost half (49 %) of all women recruited self-reported a pre-existing medical condition such as asthma, hypothyroidism, gestational diabetes, hypertension and/or endometriosis and received antenatal care provided by a doctor (Table 2).

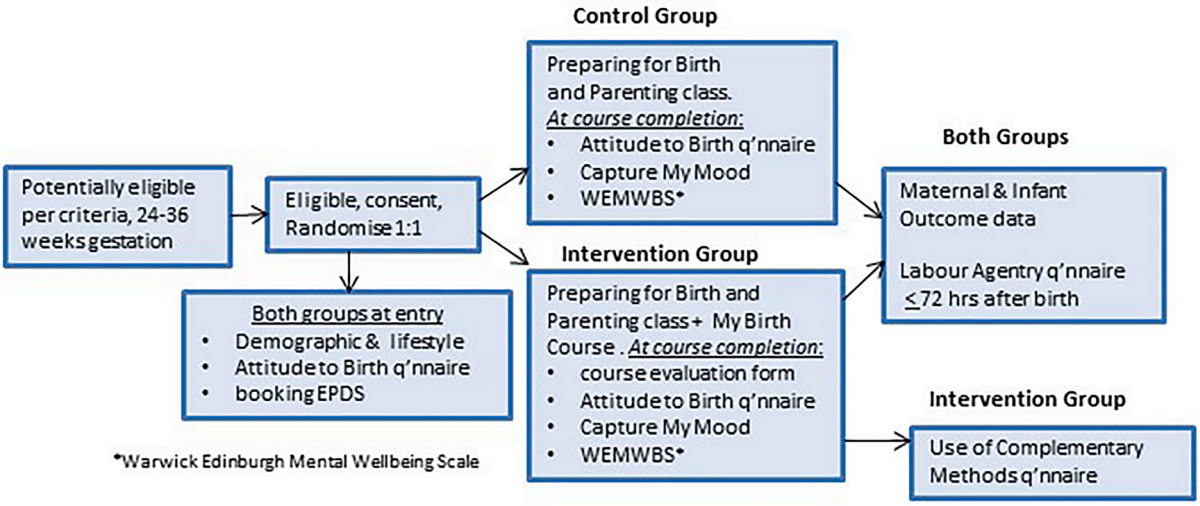

Fig. 1. Study approach here.

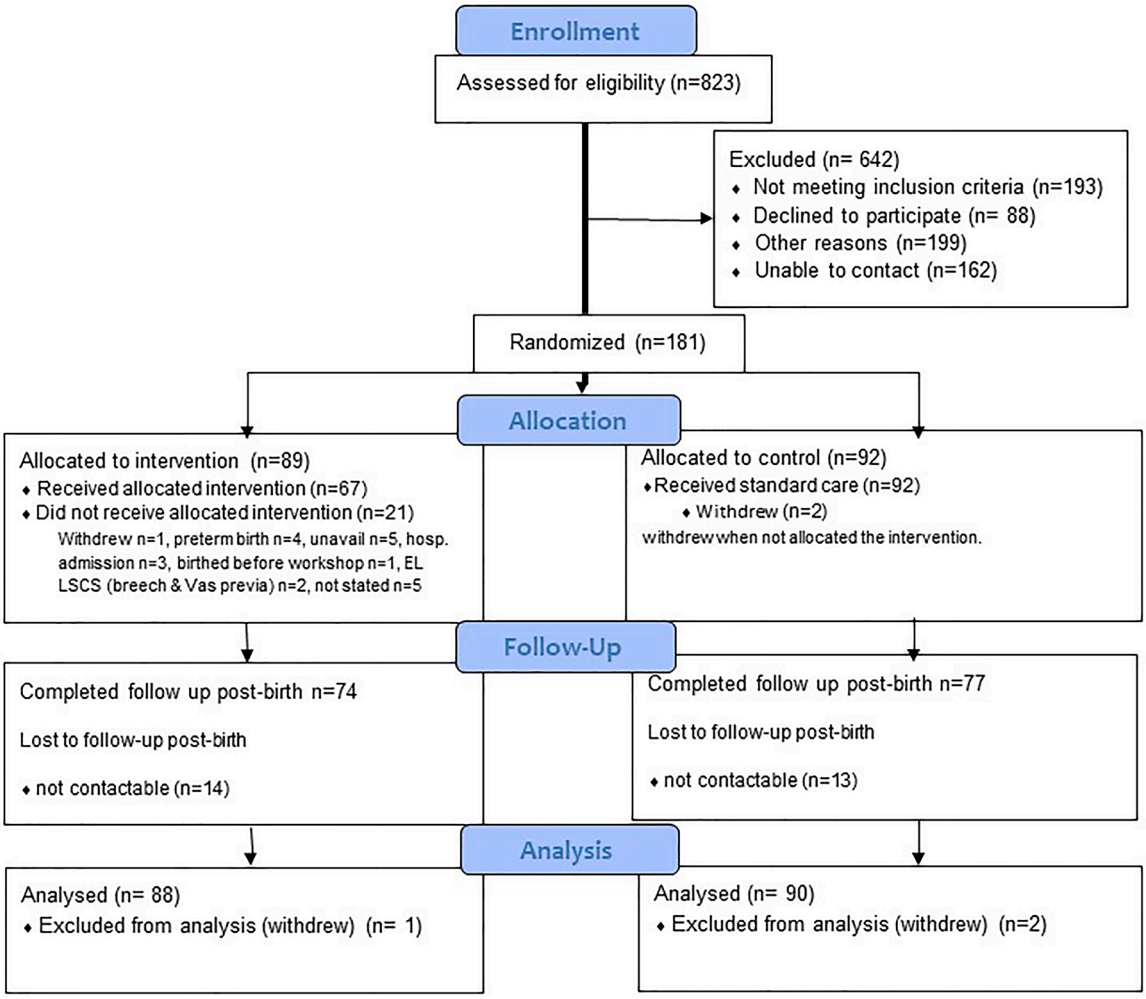

Fig. 2. CONSORT flow diagram.

Primary and secondary outcomes

For the primary outcome, women allocated to the intervention group were less likely to use an epidural (47.7 % compared to 56.7 %, $p = 0.23$) and nitrous (52.3% vs 65.6 %, $p = 0.04$), more likely to have a spontaneous onset of labour (59.1% vs 52.2 %, $p = 0.36$), and achieve a vaginal birth (52.3% vs 42.2 %, $p = 0.18$). They were also less likely to have their baby admitted to neonatal nursery, when compared to standard care (Table 3). While these findings (with the exception of nitrous use) did not reach statistical significance, women in the intervention group had a 0.84 relative risk reduction (16 % reduction in risk) of having an epidural and 0.85 times the risk (15 % reduction in risk) of having a caesarean birth. All other secondary birth outcome measures including postpartum blood loss, major perineal trauma (two women in each group sustained severe perineal trauma), and neonatal outcomes were comparable (Table 3).

For the secondary psychosocial measures, there was a statistically significant difference ($p = 0.000$) in mean pre-post course score on the Attitude to Childbirth questionnaire for women in the intervention group, with an increase of score from 50.5 (pre-course) to 59.1 (post-course). An increase in score was also observed for the standard care group from 52.0 (pre-course) to 54.3 (post-course), however this did not reach statistical significance ($p = 0.09$) (Table 4). Similarly, results of the post-birth LAS scores demonstrated a higher mean score for women in the intervention group but this was not statistically significant (Table 4).

A total of 134 participants completed both the CMM and the WEMWBS. The Pearson correlation coefficient, ($r = 0.8179$ with a statistically significance level at $p < 0.01$) confirmed a positive correlation between the two tools (Table 4).

Of the women ($n = 88$) in the intervention group, 58 women completed the post-birth follow up on CT used for labour and birth. The majority (87.7 %, $n = 50/57$) reported they had practiced the CT techniques learnt in the course in the lead up until labour (time ranged from 1 to 7 times per week). The most practiced CT therapies included acupressure 75.4 % ($n = 43/57$), belly breathing 85.9 % ($n = 49/57$), j-breathing 87.7 % ($n = 50/57$), yoga 77.2 % ($n = 44/57$), and massage 84.2 % ($n = 48/57$). Additionally, the vast majority of women (98.3 %, $n = 57/58$) reported they used the CT techniques during labour to assist with pain management. Participants reported they had used most techniques at some stage of labour. When asked what combination of CT was used for pain relief the responses included yoga 64.8 % ($n = 57/88$), belly and J-breathing 64.8 % ($n = 57/88$), massage 52.3 % ($n = 46/88$) and acupressure 40.9 % ($n = 36/88$). When asked what was most used, participants responses varied, the majority relied on breathing techniques - J-breathing (59.1 %, $n = 52/88$) and Belly breathing (29.5 %, $n = 26/88$), massage (29.5 % $n = 26/88$), yoga (19.3 %, $n = 17/88$) and then acupressure (27.3 % $n = 24/88$).

Discussion

Findings from this study suggest that targeted CT education provided through the MyBirth Course reduced the primary outcome of epidural, and secondary outcomes related to intervention rates for primiparous

Table 2
Participant demographics.

Characteristics	*n*=	My Birth Group *n* = 88	n=	Control n = 90	*n*=
Age (years, mean±SD)	178	31.8 (3.8)	88	31.4 (4.2)	90
Body mass index (mean±SD)	172	23.8 (4.5)	86	25.1 (5.2)	86
Ethnicity/Cultural identify (%)	178		88		90
Australian		*n* = 61 (69.3 %)		*n* = 65 (72.2 %)	
Asian		*n* = 2 (2.3 %)		*n* = 0 (0.0 %)	
Indian		*n* = 3 (3.4 %)		*n* = 4 (4.4 %)	
Chinese		*n* = 6 (6.8 %)		*n* = 2 (2.2 %)	
Vietnamese		*n* = 1 (1.1 %)		*n* = 1 (1.1 %)	
Other		*n* = 10 (11.4 %)		*n* = 14 (15.6 %)	
Income (%)	175		88		90
<$40,000		*n* = 9 (10.2 %)		*n* = 5 (5.6 %)	
$40,000 - $60,000		*n* = 3 (3.4 %)		*n* = 6 (6.7 %)	
$60, 000 - $80,000		*n* = 10 (11.4 %)		*n* = 5 (5.6 %)	
$80,000 - $100,000		*n* = 16 (18.2 %)		*n* = 12 (13.4 %)	
> $100,000		*n* = 47 (53.4 %)		*n* = 52 (57.8 %)	
did not wish to answer		*n* = 2 (2.3 %)		*n* = 8 (8.9 %)	
Education (%)	177		88		90
Year 10 or School Certificate		*n* = 0 (0.0 %)		*n* = 3 (3.3 %)	
Year 12 or Higher School Certificate		*n* = 4 (4.5 %)		*n* = 7 (7.8 %)	
TAFE, Certificate, Diploma or equivalent		*n* = 15 (17.0 %)		*n* = 14 (15.6 %)	
Undergraduate or university qualification		*n* = 39 (44.3 %)		*n* = 41 (45.6 %)	
Post Graduate qualification		*n* = 30 (34.1 %)		*n* = 24 (26.7 %)	
Model of care (%)	178		88		90
Midwifery clinic		*n* = 45 (51.1 %)		*n* = 41 (45.6 %)	
Doctors clinic		*n* = 24 (27.3 %)		*n* = 24 (26.7 %)	
Shared care		*n* = 19 (21.6 %)		*n* = 25 (27.8 %)	
Pre-existing medical conditions (%)	177	*n* = 43 (48.9 %)	88	*n* = 44 (48.9 %)	90
Hospital admissions during this pregnancy	177	*n* = 10 (11.5 %)	87	*n* = 8 (8.9 %)	90
Alcohol in pregnancy (%)	172		88		89
nothing		*n* = 86 (97.7 %)		*n* = 86 (96.6 %)	
1 – 2 glasses per week		*n* = 2 (2.3 %)		*n* = 3 (3.4 %)	
3 – 7 glasses per week		*n* = 0 (0.0 %)		*n* = 0 (0.0 %)	
> 7 glasses per week		*n* = 0 (0.0 %)		*n* = 0 (0.0 %)	
Smoking in pregnancy (%)	177		88		90
non-smoker		*n* = 86 (97.7 %)		*n* = 86 (96.6 %)	
stopped smoking when pregnant		*n* = 1 (1.1 %)		*n* = 3 (3.4 %)	
current smoker		*n* = 1 (1.1 %)		*n* = 0 (0.0 %)	

Table 3
Primary and secondary outcomes.

Intervention	My Birth Group *n* = 88 (%)	Control *n* = 90 (%)	Risk ratio (95 % CI)
Epidural use	42 (47.7 %)	51 (56.7 %)	RR 0.84 (0.63 to 1.12) $p = 0.233$
Spontaneous labour onset	52 (59.1 %)	47 (52.2 %)	RR 0.86 (0.62 to 1.19) $p = 0.358$
Vaginal birth	46 (52.3 %)	38 (42.2 %)	RR 0.83 (0.62 to 1.09) $p = 0.183$
Caesarean	20 (22.7 %)	24 (26.7 %)	RR 0.85 (0.51 to 1.43) $p = 0.543$
Instrumental birth	22 (25.0 %)	28 (31.1 %)	RR 0.80 (0.51 to 1.27) $p = 0.349$
Fentanyl (denominator 161)	18 (22.2 %)	16 (20.0 %)	RR=1.11 (0.61 to 2.02) $p = 0.730$
Nitrous (denominator 81 each group)	46 (52.27 %)	59 (65.6 %)	RR 0.78 (0.62 to 0.98) $p = 0.035$*
Any perineal trauma[a]	60/68 (88.2 %)	60/66 (90.9 %)	RR 0.97 (0.86 to 1.10) $p = 0.613$
Major perineal trauma[b]	29/68 (42.6 %)	35/66 (53.0 %)	RR=0.84 (0.60 to 1.18) $p = 0.318$
Apgar <7 (5 min)	2/84 (2.3 %)	1/87 (1.1 %)	RR=2.07 (0.19 to 22.42) $p = 0.549$
Neonatal resuscitation	9/85 (10.6 %)	13/88 (14.8 %)	RR=0.72 (0.32 to 1.59) $p = 0.412$
Nursery admission	19/84 (10.6 %)	27/87 (14.8 %)	RR=0.73 (0.44 to 1.21) $p = 0.22$

* Statistically significant.
[a] Denominator all vaginal births for each group.
[b] Major perineal trauma defined as severe perineal trauma and/or, episiotomy.

Table 4
Validated psychosocial scale scores.

Scale	My Birth Group		Control		p value
	n=	Mean Score, SD (95 % CI)	n=	Mean Score, SD (95 % CI)	
Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)	63	52.9, 7.2 (51.1 to 54.7)	76	53.4, 7.0	0.699
Capture My Mood	59	19.2, 3.0 (18.4 to 19.9)	75	19.3, 2.7 (18.7 to 19.9)	0.870
Labour Agentry Scale	74	55.3, 8.8 (53.2 to 57.3)	77	52.8, 9.7 (50.6 to 55.0)	0.09
Attitude to Childbirth Questionnaire pre-course	78	50.5, 6.3 (49.1 to 52.0)	76	52.0, 7.4 (50.3 to 53.7)	–
Attitude to Childbirth Questionnaire post-course	64	59.1, 6.8 (57.4 to 60.8)*	78	54.3, 9.0 (52.2 to 56.3)**	–

* $p = 0.000$ difference in mean pre-post course score for Attitude to Childbirth questionnaire.
** $p = 0.096$ difference in mean pre-post course score for Attitude to Childbirth questionnaire.

women who presented with low to moderate risk factors. While epidural rates did not show a statistically significant difference, there was a reduced use of epidural pain relief in the intervention group and a statistically significant reduction of nitrous oxide use. Additionally, fewer women in the intervention group required medical intervention including caesarean sections, although the study was not powered to demonstrate a significance in this outcome. The MyBirth Course intentionally provided education to women and their partners that addressed the physiology of birth and how to 'work' with pain, this included using guided visualization and relaxation techniques, movement, yoga, acupressure and massage. A systematic review (Fumagalli et al., 2022) suggested strategies used to cope with labour pain positively influence birth outcomes. For example, this review included studies that reported a decrease in the level of pain experienced during labour, women stayed at home longer and there was an associated decrease in the duration of first and second stages of labour (Fumagalli et al., 2022). While our study did not examine level of pain in labour, participants in the intervention group reported positive experiences with implementing the CT strategies.

Globally, high rates of medical interventions including induction, epidural use and caesarean section are concerning (Boerma et al., 2018). The World Health Organization (WHO) recommended non-clinical interventions to reduce unnecessary caesarean sections that include three focuses; women, health practitioners, and health organisations (WHO, 2018). Many women have a fear of childbirth and for these women, they are more likely to have medical interventions (O'Connell et al., 2021). In a recent Cochrane review on non-pharmacological interventions for fear of childbirth, it was noted that effective treatments helped women to

have confidence in their ability to give birth, utilise ways to cope with labour, and empower their decision-making during pregnancy and the birth process (O'Connell et al., 2021).

A key finding from this study is that the women in the intervention group had higher scores for attitude to childbirth than the standard care group. The score showed a statistically significant difference from pre- to post-test for the intervention group, suggesting that the antenatal classes and the associated coping strategies positively influenced their attitude to birth. One of the constructs within the attitude to birth questionnaire is a sense of control in childbirth (Humenick and Bugen, 1981). A recent scoping review that explored women's experience of birth trauma (Watson et al., 2021)[p420], identified the significance of the 'women's sense of knowing and control'. Women identified that fear developed during pregnancy alongside a lack of knowledge, was compounded if they faced unexpected experiences during labour and birth (Watson et al., 2021). It was suggested that increasing knowledge and preparing women for possible experiences during birth promoted self-efficacy, a sense of control, and ultimately reduced fear and anxiety. Midwives play an important role in advocating a positive birth experience for women and that this begins during pregnancy, most effectively through building and trusting relationship but also by a commitment to inform and encourage women in their own capacity to give birth, and provide tools to respond to situations that may arise during the birth process (Karlström et al., 2015).

Our findings support those seen in previous studies, which suggest that preparing women antenatally can enhance their birth experience by assisting them to develop confidence in their ability and coping strategies (Kacperczyk-Bartnik et al., 2019; Karabulut et al., 2015). In a cross-sectional study that explored the impact of antenatal classes on levels of fear and perception of pain, women who attended the antenatal classes were calmer at birth regardless of perception of pain (Kacperczyk-Bartnik et al., 2019). This finding was believed to be due to increased feelings of control and being informed and prepared for labour and birth, and also the possibility of unexpected circumstances (Kacperczyk-Bartnik et al., 2019). Likewise, levels of fear significantly decreased following antenatal education (Kacperczyk-Bartnik et al., 2019) and these studies concluded that antenatal classes should be recommended particularly because of the capacity to influence the level of fear associated with childbirth (Kacperczyk-Bartnik et al., 2019; Karabulut et al., 2015).

Two systematic reviews have also reported on the positive impact of childbirth education on the experience of childbirth, noting inclusion of CT (Moghaddam Hosseini et al., 2018; Taheri et al., 2018). The first was a systematic review and meta-analysis of prenatal and intrapartum interventions to create positive perceptions of childbirth that included several studies which specifically identified the promotion of relaxation during labour was effective for improving the childbirth experience (Taheri et al., 2018). Additionally, research demonstrated education based antenatal education was more effective than hypnosis alone on reducing fear (Moghaddam Hosseini et al., 2018) and coping strategies, such as breathing and visualisation, reduced fear and anxiety (Fumagalli et al., 2022). In this current study, the focus of the antenatal education included both knowledge on the physiology and process of labour and birth, that provided both education and time to practice the five CT (enabling participants additional tools/ strategies to use), as well as ways to approach decision making.

The intervention CT program was based on the BirthCourse™ which had previously been developed and piloted in a RCT involving two tertiary hospitals in Sydney, New South Wales (Levett et al., 2016b). However, there was a difference in the target population. The original study (Levett et al., 2016b) recruited only low-risk pregnant women (no pre-existing medical or obstetric complications), with the majority receiving midwifery care. This current study recruited low-moderate risk pregnant women receiving either midwifery or medical care, these factors may have influenced the primary and secondary outcome results. Even though this current and original study were conducted in Australia, they were piloted in different states. It may be that the standard care for antenatal classes in the two states differ and this needs to be considered (Shand et al., 2022). The standard care provided by the hospital in Adelaide, included some similar topics, however, CT techniques are not taught within the standard care classes. Therefore, having an opportunity to obtain additional information and learn how to utilise and practice CT techniques (not included in the standard care) may reinforce and enhance the standard care classes currently offered. Further research is required to address how information is provided and what mode of delivery is most preferred by expectant parents as this data was not collected as part of this trial. However, this study was able to demonstrate a trend towards a decrease in medical interventions, specifically epidural rates, that supports the findings of the original study (Levett et al., 2016b). It appears that women and their birth partners who were in the intervention group and received further education were more positive and confident for labour and birth and therefore, justifies further research and exploration.

Larger studies are required to adequately power secondary outcomes. Therefore, further plans are to include this current study with a collection of other studies and undertake a meta-analysis (Levett et al., 2020), results may then provide stronger evidence to demonstrate the influence and benefits of antenatal education that incorporates CT. Further research may also include interventions targeting healthcare providers and the inclusion of midwifery students in delivery of birth courses that incorporate CT. Understanding the attitudes, knowledge requirements and confidence to facilitate this form of antenatal education is important as is the inclusion of expectant parents to ensure modes of delivery and inclusion of resources meets their needs.

Strengths and limitations

The strength of this study is a randomised controlled trial powered for the primary outcome of epidural use. Key maternal characteristics were equivalent between the two groups. While it was not possible to blind participants to the intervention, data entry and analysis were undertaken independently by researchers not involved in the development of the intervention. This single site study followed the AEDUCATE Collaboration (Comprehensive antenatal education birth preparation programmes to reduce the rates of caesarean section in nulliparous women) protocol (Levett et al., 2020), where individual participant data can be used to contribute to a larger prospective meta-analysis, this is needed to provide more power to detect smaller treatment effects for outcomes such as caesarean section.

The trial was impacted by COVID-19 restrictions which prevented it from reaching the planned 95 participants per group. A post-hoc review by a statistician indicated that even if the recruitment target had been met, it would have been unlikely to achieve statistical significance for the primary outcome. This suggests the study may not have had sufficient power to detect the intended effect size. As a result, the findings should be interpreted with caution. Although the study did not meet its intended recruitment target, the study provides valuable data for a meta-analysis to combine results from similar trials. This will enhance overall statistical power, addressing the limitations of individual study size. Additionally, results for secondary psychosocial outcomes should be interpreted noting the smaller number of participants using some of these therapies and usage is based on self-reports. Intention to treat analysis was undertaken for the majority of data, however treatment effects for women who utilised the CT taught through the intervention could only be collected for treated participants. COVID interruption and change to standard care during the last few months of recruitment may have impacted how women felt about birthing during the uncertainty of the pandemic and restrictions may have impacted access to care and family support.

Conclusion

This study provides some evidence to support the original study of a reduction in epidural rates amongst women who participated in a CT program. Findings from this study will be used to inform a larger prospective meta-analysis design with the objective to assess effectiveness of CT programs plus standard care to reduce caesarean section rates in primiparous women. Education on CT may play a significant role in improving women's overall confidence towards childbirth, reducing stress and promote relaxation, which can result in positive birth outcomes for mother and baby.

CRediT authorship contribution statement

Julie-Anne Fleet: Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Conceptualization. **Pamela Adelson:** Writing – review & editing, Writing – original draft, Validation, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Lois McKellar:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Mary Steen:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to acknowledge Kate Levett for generously sharing protocols and resources from the original trial of the BirthCourse™, our research assistant Lisa Masters, childbirth educator Jen Watkins, and generosity of the women and support partners who participated. This project received funding through UniSA Sansom Institute seeding fund grant.

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