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The Complete Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour

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Keywords: Epidural, complementary medicine, antenatal education, normal birth, caesarean section randomised controlled trial.

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ABSTRACT:

Objective: To evaluate the effect of an antenatal integrative medicine education program, in addition to usual care, for nulliparous women on intrapartum epidural use.

Design: Open label, assessor blind, randomised controlled trial **(**RCT).

Setting: Two public hospitals in Sydney, Australia.

Population: 176 nulliparous women with low-risk pregnancies, attending hospital-based antenatal clinics.

Methods and Intervention: Randomisation at 24-36 weeks' gestation to the Complete Birth Study, a two-day integrative medicine antenatal education program, plus standard care, compared with standard care alone.

Main outcome measures: Rate of epidural use. Secondary: onset of labour, augmentation, mode of birth, newborn outcomes.

Results: There was a significant difference in epidural use between the two groups: study group (23.9%) standard care (68.7%) (risk ratio (RR): 0.37 [95% C.I.: 0.25, 0.55], p=<0.001). The study group participants reported a reduced rate of augmentation (RR=0.54 [95% C.I.: 0.38-0.77], p<0.0001); caesarean section (RR=0.52, [95% C.I.:0.31-0.87], p=0.017); length of second stage (MD= -0.32, [95% C.I.:-0.64, 0.002] p=0.05); any perineal trauma (0.88 [0.78-0.98] P=0.02); and resuscitation of the newborn (RR=0.47 [95% C.I.:0.25-0.87] p=<0.015).

There were no statistically significant differences found in spontaneous onset of labour, pethidine use, rate of post-partum haemorrhage (PPH), major perineal trauma (3rd and 4th degree tears), or admission to special care nursery/neonatal intensive care unit (SCN/NICU) (p=0.25).

Conclusion: The Complete Birth antenatal education program, which incorporates evidence-based complementary medicine (CM) techniques, acupressure, relaxation, massage and yoga techniques, significantly reduced epidural use and caesarean section. This study provides evidence for integrative medicine as an effective adjunct to antenatal education and contributes to the body of best practice evidence.

Trial registry: Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

Article summary

Strengths and limitations of this study

- This is the first RCT in Australia that has investigated the effectiveness of a birth preparation course, integrating multiple CM techniques, for the support of natural birth for first time mothers. This suggests a reorientation of antenatal education towards normal birth and reflects current outcome measures in reports of maternity services policy directives.
- The study used self-administered, evidence-based, CM techniques, and blinded analysis to test an a priori hypothesis; and implemented a pragmatic design where participants were free to use any of the techniques with no prescriptions or time limitations for use, allowing women and partners to have control and agency in their birth process and use information and CM tools to manage their own labours.

- The primary outcome measure of EDB was used, rather than frequently used pain scores, as the objective measure of EDB has been identified as a mediating factor in labour interventions and mode of birth, described as the cascade of interventions.
- Limitations of this study include higher enrolment of relatively wealthy, well-educated women, and relatively fewer participants from the area identified as lower socio-economic status. This is in line with previously CM research, but it is worth considering that the highest rates of epidural use and caesarean section, is also amongst this more advantaged population.
- Wider national and international implementation of this study is recommended to confirm results in a broader population and examine issues of generalisability.

INTRODUCTION:

There has been a rise in rates of intervention during labour and birth in most developed countries,[1 2], and the intervention rates in Australia during birth are well above the Organisation for Economic Cooperation and Development (OECD) averages,[3]. As these interventions increase, such as routine use of epidural block (EDB), so does the rate of instrumental births and associated medical interventions,[4-8]. Epidural rates in New South Wales (NSW) hospitals have shown a rapid rise over the past decade. In 2012, the state average for EDB use was 46.5%, however, there was broad variation within the state, ranging from 15% to 82.7% depending on region and hospital,[9 10]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of augmentation, assisted vaginal births and caesarean section (CS),[4 6-8 11].

Childbirth education has also seen a shift away from birth preparation,[12 13], to a curriculum broadly centred on overall parent education,[14]. Findings from a systematic review on childbirth education reports that the effectiveness of antenatal education for childbirth or parenthood supports the idea that educational interventions have a role in increasing feelings of self-confidence and agency, but demonstrates little impact on reducing interventions and associated morbidity in labour,[15 16].

Integrative medicine approaches, and complementary medicine (CM) in particular, may offer increased options for pain relief in birth,[17], and may be effective within the hospital antenatal education framework. The term integrative medicine is used when referring to incorporating CM or complementary therapies (CT) into mainstream health care,[18]. Recent Australian data suggest that 74.4% of women used some form of CM during pregnancy, and 66.7% of these women also

used non-pharmacological pain relief in labour,[19]. The Cochrane Systematic Review on pain management for labour finds some evidence to suggest that acupuncture, relaxation, massage, and water immersion may assist in the management of labour with few side effects, however more research is needed to establish efficacy of these techniques,[20].

In response to the need to establish the evidence base for CM interventions for pain management in labour we undertook a randomised controlled trial (RCT) to test the hypothesis that nulliparous women who undergo a CM antenatal education course, in addition to usual antenatal care would use less EDB than nulliparous women who receive usual antenatal care alone. Trials of complex interventions are difficult to conduct, and do not have linear models, and require a pragmatic approach to implementation,[21 22].

Methods

The study was an assessor-blinded, open-label pragmatic randomised controlled trial, called the *Complete Birth Study* (Complementary Therapies for Labour and Birth Study). The Complete Birth Study protocol was developed using an already established private birth preparation course, 'She Births®', and the 'Acupressure techniques for use during childbirth and pregnancy' protocol,[23]. The creators of these courses gave permission to use their work as the basis of the study. The Complete Birth course was adapted to reflect the evidence base for the CM techniques that were incorporated,[22 24-26].

From April 2012 to August 2013, women and their birth partners were recruited to the Complete Birth Study, a two-arm study consisting of a study group, who received the Complete Birth Study course in addition to usual care, and a control group, who received usual care alone.

Participants

Women were eligible to enter the trial if they had a singleton pregnancy with a cephalic presentation, were low risk (no pre-existing medical complications or existing obstetric complications), were first time mothers (nulliparous), and had sufficient English to participate in a workshop. Women were excluded from entering the trial if they had pre-identified risk factors, were enrolled, or intending to enrol, in a 'continuity of care' midwifery program or in a private birth preparation course, were unable to attend a weekend workshop, or had insufficient English for participation. Recruitment was undertaken at two public hospitals in Sydney Australia that reflected diverse socio-economic areas (see supplementary file S1). Recruitment was also conducted through the affiliated Western Sydney University (WSU) in response to newspaper and magazine advertisements. Participants who were recruited through WSU attended the workshops at either of the two hospital study sites.

Randomisation

We used a computer generated randomisation sequence prepared centrally via the 'Sealed Envelope' website (https://www.sealedenvelope.com), and concealed centrally. Stratification occurred for hospital site, yielding three randomisation lists: 'Site H, 'Site N', and 'WSU'. Women were randomly allocated to either the Complete Birth antenatal education programme in addition to usual care, or usual care alone. Randomisation occurred on a 1:1 allocation ratio to ensure equal numbers in each group at each hospital.

Intervention

Two-day workshops (see supplementary file 2) were conducted over a weekend at one of the two hospital venues on a fortnightly to monthly basis over a 15 month period from May 2012 to

August 2013. A total of 20 workshops were conducted during this time. Participants attended with a birth partner, and there was a maximum of 12 couples and a minimum of two couples at each workshop, with an average of eight couples per workshop. The study investigator (KL) ran each workshop.

The philosophy and techniques included the intervention program were designed to support a woman during her pregnancy and labour by introducing techniques to enhance a natural state of relaxation (visualisation, breathing, massage, yoga) and provide tools to facilitate labour progression (yoga, acupressure) and pain relief (breathing, acupressure, visualisation). The program introduces concepts of birth as a natural physiological process, and the idea of 'working with pain',[27] using evidence based CM tools by which the birth process can be managed,[20]. Women and partners received education about the physiology of normal birth.

The tools used were:

1. Visualisation,[25] - four guided visualisations rehearsed through the workshops and given to participants on a CD to practice at home
2. Yoga postures,[28] – the six postures practiced encouraged relaxation, physiological position for labour, opening of the pelvis and downward descent of the baby
3. Breathing techniques,[20] - four breathing techniques were introduced: soft sleep (SS) breaths for relaxation between contractions; blissful belly (BB) breaths which were used during contractions for pain relief; cleansing calming (CC) breaths used following contractions during the transition period of labour; and the 'J' breath which was for use during the second stage of labour and encouraged descent of the baby avoiding active pushing

4. Massage,[26] – two techniques were shown to partners; the endorphin massage used between contractions, which is a soft technique and encourages endorphin release; and the strong massage which is used during contractions for pain relief and focuses on squeezing the pelvic bones from the outside
5. Acupressure,[22 24], which uses six main points for use during labour selected from a previously published protocol,[23]. These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea, and positioning of baby
6. Facilitated partner support,[29-31], uses the concept of working with pain,[27] and instructs partners regarding actions and techniques which may be supportive for the birthing woman, and gives time for discussion and rehearsal by couples during the course.

Usual care consisted of the hospital based antenatal education course routinely available at each hospital. Antenatal education classes in Australia currently take a general descriptive approach to labour preparation, and emphasise parenting and post-partum issues as the main focus,[14]. Classes generally run weekly over six to seven weeks, or over 1-2 weekends, and include topics such as: pregnancy changes, exercise and back care during pregnancy, signs of labour, unexpected outcomes in labour and birth, pharmacological pain management, managing labour and birth, newborn care and breastfeeding, parenthood and baby's first weeks.

Blinding

Women, partners and the chief investigator (KL) were not blinded to group allocation. Group allocated was subsequently coded, and outcome measures were assessed and analysed blind to study group allocation. Midwives and doctors at each of the two main study hospitals and other sites were aware of the study, but delivery suit personnel were blinded to study participants' group allocation. Study course content was not disclosed to midwives to avoid any change in

practice that may occur. Group allocation and data was linked by identification codes allowing the analysis to be undertaken blind.

A priori outcome measures

Primary outcome: Epidural use for pain relief.

Secondary outcomes: other pharmacological pain relief during labour; induction of labour; augmentation of labour; length of labour; instrumental delivery; caesarean section, post-partum haemorrhage (PPH) perineal trauma; Apgar scores <7 at 5 minutes; resuscitation; admission to special care nursery/neonatal intensive care unit (NICU/SCN). Other outcomes included attitude towards birth and personal sense of control.

Questionnaires

For sense of personal control measures we used the Labour Agentry Scale (LAS),[32]. Within 72 hours following birth the LAS was administered to all women. Clinical outcomes were collected from hospital birth records, and the NSW Hospitals' birth summaries, which were accessed from the hospitals where the participant had given birth.

Analysis

An intention-to-treat analysis was used for the primary and secondary outcome data. Chi square and t-tests were used for univariate analysis of categorical and continuous data respectively. Significance was set at an alpha of 0.05, reporting on relative risk with a 95% confidence interval. Group allocation was coded by an independent researcher, and the investigator undertook the analysis blind to group allocation. Data was analysed using SPSS version 22,[33].

Sample size and power

The trial was designed to demonstrate an absolute reduction of 20% in epidural use from 46% in those women managed with usual care to 26% in those women who were randomised to the Complete Birth antenatal education program. The rate of use of EDB was determined by published data for the two study hospitals in 2011 NSW Mothers and Babies Report,[34]. This required a total sample size of 170 women for an 80% power at a significance level of $p<0.05$. Recruitment continued until 176 women had been enrolled, and those randomised to the treatment group had either completed the course or were known to have missed their course, with 171 completing the study. A 20% attrition rate was included in the sample size calculation. A low drop-out rate (<3%) was observed for the overall study population, and separately for each arm of the study (<5%),[35]. Primary outcome data was available for all consenting participants.

Results

We assessed 315 women for eligibility to participate in the study, of whom, 176 were randomised and 171 were included in the final analysis (Figure 1). Women were randomised to the Study Group, n=89, or the Control Group, n=87. From the 315 women screened, 139 were excluded for the following reasons: 105 declined to participate, and 34 did not meet inclusion criteria (insufficient English (n=7), attending private birth preparation course (n=12), continuity of care model (n=6), mod-high risk: GDM (n=5), breech presentation (n=4).

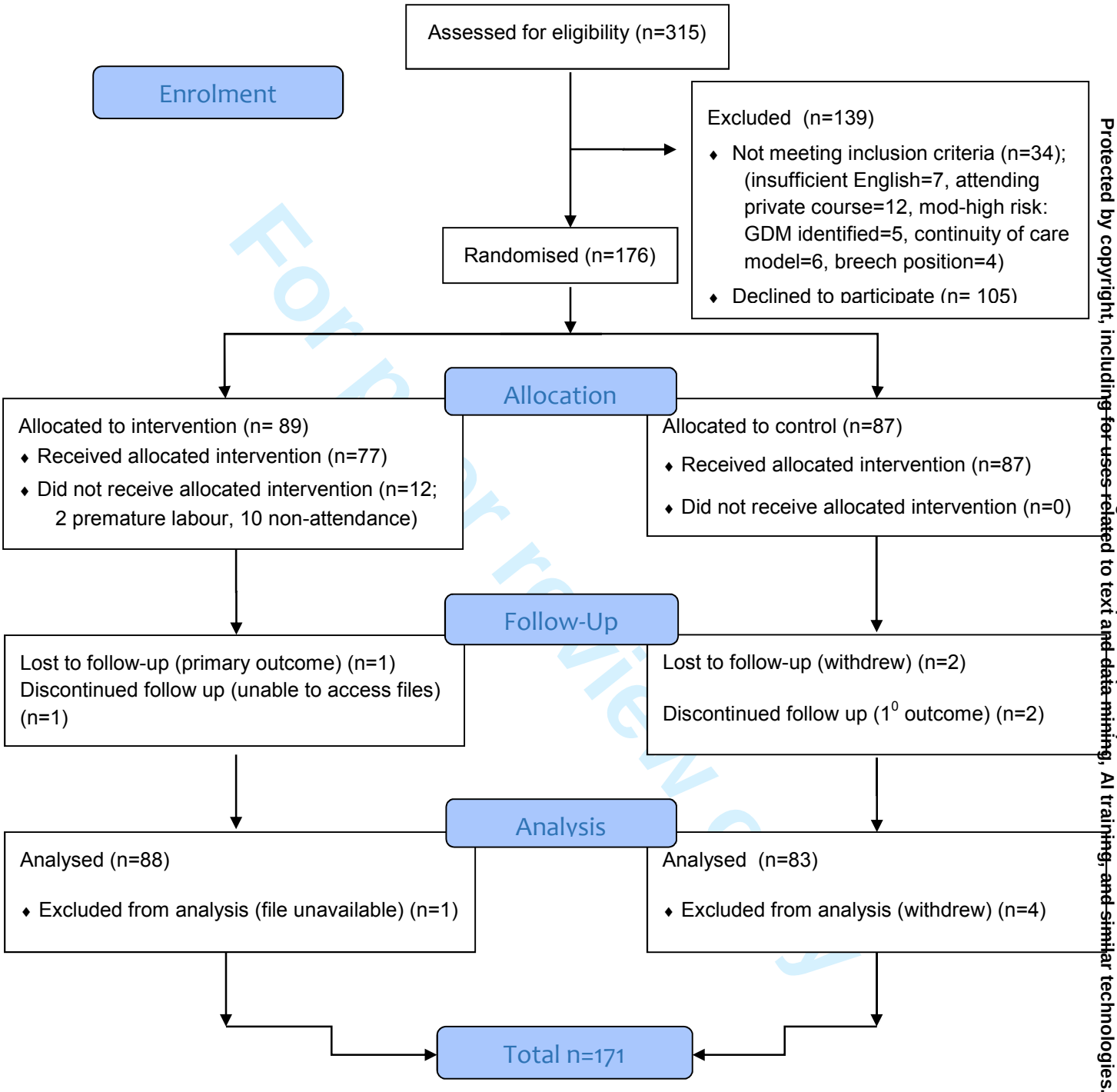

Figure 1: CONSORT Flowchart of Complete Birth Study

All women completed the trial entry form at baseline including demographic information. Not all women answered each question in the trial entry form (Table 1). Following birth, the LAS was completed by 72 of the 88 women (82%) in the study group, and 52 of the 83 (62%) women in the control group.

Participants did not significantly differ from each other in terms of their age, body mass index (BMI), cultural background, level of education, income, hospital status, or model of care (Table 1). Babies were not different in terms of average gestational age, or weight at birth.

Table 1: Participant baseline demographics

Demographic Characteristics	Study Group *n* = 87	Control Group *n* = 85	Difference statistic, p-value
Mean Age (years, ± SD)	30.41 (± 4.99)	28.87 (± 5.24)	p=0.06
BMI (mean ±SD)	22.66 (±4.47)	23.35 (±3.93)	P=0.35
Cultural Background:	***n* = 79 (%)**	***n* = 61 (%)**	χ^2 (2)=0.124 p=0.77
Caucasian	58 (73.4)	44 (72.1)	
Asian	10 (12.7)	11 (18.0)	
Other	11 (13.9)	6 (9.9)	
Income	***n* = 78 (%)**	***n* = 61 (%)**	χ^2 (2)=5.393 p=0.25
<60	12 (15.4)	12 (19.7)	
60-80K	7 (9.0)	10 (16.4)	
80-100K	17 (21.8)	10 (16.4)	
>100K	42 (53.5)	29 (47.5)	
Total	**78**	**61**	
Education	***n* = 81 (%)**	***n* = 60 (%)**	χ^2 (2)=0.220 p=0.64
High School/Vocational	24 (29.6)	20 (33.3)	
University/Post Grad	57 (70.4)	40 (66.7)	
Hospital status	***n* = 87 (%)**	***n* = 85 (%)**	χ^2 (2)=0.124 p=0.77
Public status	82 (94.3)	79 (92.9)	
Private Status	5 (5.7)	6 (7.1)	
Model of Care:	***n* = 87 (%)**	***n* = 85 (%)**	χ^2 (2)=3.232 p=0.20
Midwifery	67 (82.7)	64 (85.3)	
Doctors Care	4 (4.9)	7 (9.3)	
Shared Care	10 (12.3)	4 (5.3)	

Primary outcome

A statistically and clinically significant reduction in epidural rate was found for the intervention group compared with the control group. The rate of EDB in the control group was 68.7%, and 23.9% in the study group (risk ratio (RR) = 0.37 [95% C.I.: 0.25, 0.55] p=<0.0001), (Table 2). Using a true intention to treat analysis (ITT), we examined the data including data points for the five women who had dropped out, withdrawn or were lost to follow-up. There were four in the control group, and one in the study group. Using a best-case–worst-case scenario, we included the five cases with missing data for the primary outcome. If the four control group women did not have an EDB and the one study group woman did have an EDB (worst case), the results were still highly statistically significant with a risk ratio of: 0.40 [95% C.I.: 0.27, 0.59] p=<0.0001.

Table 2: Primary and secondary outcomes measures:

OUTCOMES	Study Group (n=88) %	Control Group (n=83) %	Risk Ratio
Epidural analgesia	21 (23.9)	57 (68.7)	0.37 [0.25-0.55] P<0.0001**
Spontaneous Onset Labour	62 (70.5)	54 (65.1)	1.13 [0.82-1.57] P=0.51
Augmentation	25 (28.4)	48 (57.8)	0.54 [0.38-0.77] P<0.0001**
Mode of Birth: NVB	60 (68.2)	39 (47.0)	1.56 [1.12-2.17] P=<0.01**
Mode of Birth: CS	16 (18.2)	27 (32.5)	0.52 [0.31-0.87] P=0.017*
Mode of Birth: Instrumental	12 (13.6)	17 (20.5)	0.57 [0.30-1.09] P=0.09
Nitrous Oxide (Gas)	40 (45.5)	49 (59.0)	0.77 [0.57-1.03] P=0.092
Pethidine	19 (20.5)	15 (19.3)	1.11 [0.78-1.56] P=0.70
Any perineal trauma ^(Trauma/NVB)	61/72 (84.7)^	54/56 (96.4)^	0.88 [0.78-0.98] P=0.02*
Major Perineal Trauma ^(Trauma/NVB)	49/72 (68.1)^	37/56 (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
Resuscitation (Suction +/- O_2)	12 (13.6)	24 (28.9)	0.47 [0.25-0.87] P=0.015*
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

* <0.05 ** <0.01

^ percentage is from total vaginal births: denominator = 72 in study group and 56 in control group. Major perineal trauma is defined as 3rd or 4th degree tear and episiotomy.

Secondary clinical outcomes

Women in the study group were statistically more likely to experience a normal vaginal birth RR=1.56 [1.12-2.17], p=<0.01, and were less likely to have medical or surgical augmentation during labour (RR=0.50 [95% CI: 0.35-0.73], p<0.001), birth by caesarean section (RR=0.52 [0.31-0.87], p=0.01) or any perineal trauma (RR=0.88 [95% C.I.: 0.78-0.98], p=0.02). We also found a reduced length of second stage of labour (MD= -0.32 [95% CI: -0.64, 0.002], p=0.05) in the study group (Table 2). Babies of women in the study group were also less likely to require resuscitation by suction or with oxygen (bag and mask) (RR=0.3 [95% C.I.:0.2-0.8], p=<0.01). There were no differences in the rare outcomes of intubation or cardiac massage required at birth. Only one baby in the study group required intubation. Although not statistically significant there were some non-significant trends toward the study group having less likelihood of an instrumental vaginal birth (RR=0.57 [95% C.I.: 0.30-1.09], p=0.09), and nitrous oxide (gas) for pain management (RR= 0.77 [95% C.I.: 0.58-1.03], p=0.08).

No significant differences were found in the secondary outcome measures of spontaneous onset of labour (RR=1.09 [95% CI:0.90-1.34), p=0.38), pethidine use (RR=1.19 [95% CI: 0.65-2.2]), p=0.56), rates of post-partum haemorrhage (PPH) (RR=0.95 [95% CI: 0.57-1.55], p=0.81), or major perineal trauma (second/third/fourth degree tear or episiotomy) (RR=0.82 [95% CI: 0.41-1.61], p=0.56). No significant differences were found in Apgar scores (RR=0.99 [95% CI:0.95-1.03], p=1.0), or admission to the SCN/NICU (RR=0.59 [95% CI:0.24-1.46], p=0.2).

The length of the second stage of labour was 1 hour for the study group and1 hour 32 minutes for the control group giving a statistically significant mean difference of 32 minutes (p=0.05). There were no significant differences between the groups for the first stage of labour or the total length of labour (see Table 3).

Table 3: Length of labour

OUTCOMES Length of Labour	Study Group (n=86) Mean (SD)	Control Group (n=83) Mean (SD)	Difference Statistic MD [95% CI] p-value
1st stage	6.12 (3.95)	6.53 (3.90)	MD= -0.41 [-1.79, 0.98] p=0.56
2nd stage	1.00 (0.87)	1.32 (0.98)	MD= -0.32 [-0.64, 0.002] p=0.05*
Total length of labour	7.43 (4.13)	8.20 (4.37)	MD= -0.77 [-2.26, 0.72] P=0.31

* p=0.05

The LAS questionnaire examined whether the course had any impact on attitudes and feelings about birth and women's feelings of agentry. The LAS was completed by 72 of the 88 women in the study group (82%), with an average score of 164.97 (SD=27.06). In the control group 52 of the 83 women (62%) completed the form, and had an average score of 150.92 (SD=30.03). We found a statistically significant difference between the two groups for this score (MD=14.05, 95% C.I.: 3.84-24.26, $p < 0.01$).

Given that a large number of women did not complete this form, there is the possibility of reporting bias in the results, we used a Levene's test for equality of variance, and found the variance between the two groups was not significantly different (p=0.59).

Analysis of patterns of CM use in labour reveal women in the study group used an average of 3.94 (SD=1.4) techniques during labour, and in the antenatal period practised various techniques for an average total of 12.94 (SD=9.7) times per week. Women in the control group did not report antenatal practice of techniques, but some (<5%) did report using techniques such as breathing or visualisation during the labour. No individual CM technique, nor amount of

rehearsal in the antenatal period, was associated with reduced likelihood of EDB use in the study group, indicating an overall effect of the program. Belly Breaths, visualisation and acupressure were identified as being the more utilised techniques, and yoga, massage and J breaths being less utilised by women.

Discussion

Main findings

The RCT demonstrated the effectiveness of this antenatal education program for first time mothers, showing an absolute reduction of 45% and a relative reduction of 63% (RR=0.37, p<0.001) in epidural rate in the study group compared with controls. The study also showed increased rates of normal vaginal birth without surgical or mechanical assistance, and found reduced rates of augmentation in labour, length of second stage of labour, perineal trauma, caesarean section, and the need for resuscitation of the newborn. Univariate results for secondary outcomes should be interpreted with caution however, as these are likely to be related to the primary outcomes of EDB, which has been shown to mediate the effect these secondary outcomes,[36 37].

Current antenatal education has undergone a distinct shift towards normalising all births and preparing parents for parenthood. However, specific preparation for normal labour appears to have been de-emphasised in classes,[38-40]. Anecdotally, the majority of women attend routine antenatal education classes, but there is no current literature to provide accurate numbers,[41 42]. The results from the Cochrane Systematic Review suggest that while antenatal education aims to prepare women and partners for childbirth and early parenting, studies to date have shown a lack of high-quality evidence and a high variability of outcome measures. Therefore, the effects of

antenatal education are still largely unknown,[15]. Studies exploring the use of antenatal education interventions, antenatal mindfulness training and self-hypnosis training have failed to demonstrate any reduction in the use of analgesia during labour and birth or on CS rates,[15 43-48]. Some commentators suggest that the impact of antenatal education in routine care may in fact be reinforcing medical management of labour and birth, and therefore not addressing the rising rates of medical pain relief and the associated complications,[7 38 40 49 50].

In this study we emphasised the importance of reorienting the concept of normal birth using an antenatal education framework and a variety of evidence-based integrative CM techniques to help women manage pain in labour and birth. One of the recently voiced concerns of using alternative birth positions, such as yoga postures and upright positions, is the potential for increased risk of perineal trauma,[51]. The data from our research showed a statistically significant reduction in perineal trauma for women. Among those women who had vaginal births, 84.7% of the study group compared with 96.4% of the control group sustained some kind of perineal trauma during birth (RR=0.88, p=0.02).

The study provides evidence that antenatal education integrating CM techniques is an effective and viable method of managing pain, decreasing medical interventions, and increasing personal control for women. These clinically and statistically significant results are important in establishing an evidence base for the use and effectiveness of antenatal education programs incorporating CM techniques for the management of pain during childbirth as an adjunct to parent education offered as usual care. This program has the potential to provide a cost effective method of antenatal education. A costing and economic analysis of this program will be undertaken and reported elsewhere, providing a measure of relative benefit for outcomes saved. Reorienting antenatal education classes towards supporting normal birth and providing

techniques to help women manage pain is an important contribution to reducing inventions in labour and birth.

Interpretation

Our study helps to address the question of whether antenatal education using CM techniques are effective in reducing rates of EDB in first time mothers. This finding, and other secondary findings of increased normal vaginal births, augmentation, perineal trauma, and CS, support some of the CM literature which show a reduction in rates of pharmacological pain relief, and some interventions during labour,[22 24-26]. These findings are in contrast to the parent education literature, hypnosis and psychoprophylaxis training literature for reduction of EDB during labour,[15 43 46 48 60-62]. The outcome of increase in positive attitude towards birth in the antenatal period and increased feelings of agency during labour and birth are supportive of the antenatal education literature,[15 16 38 45 60].

It remains important that methods used during labour are suitable for women's individual requirements and circumstances, and also account for conditions that may arise in the woman or infant during labour,[20]. This study demonstrates the capacity for a novel integrative antenatal education programme using CM techniques to reduce interventions in normal labour.

Future research

Policy initiatives supporting normal birth require novel solutions, and this study provides good evidence for such an initiative, including the potential for a revision to clinical practice in antenatal education. Future health services research should include translation of study outcomes into clinical practice, involving a-priori cost effectiveness analysis, exploring key stakeholders views about changing practice and undertake a multi-centred international study to assess the

impact of the study in a broader context and beyond Australia. This article reports on the first implementation of this antenatal education course, and evaluates feasibility of conduct. Wider implementation and generalisability of results can be established with a larger trial of this intervention.

Conclusion

The rise in interventions rates in labour and birth need to be addressed as a matter of priority as outlined by reviews of maternity services,[3 11] and international reports,[1 2]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of interventions including caesarean section,[4 6-8 20]. This study highlights the effectiveness of an integrated antenatal education approach, incorporating evidence-based CM techniques to reduce rates of EDB, leading to a reduction in other interventions in labour and birth, including caesarean section.

The re-orientation of antenatal education and the promotion of birth as a normal physiological event is critical if we are to reduce interventions in birth. This shift requires education and support to help women manage the challenges of labour and birth. The results from this study demonstrate the effectiveness of the Complete Birth course to provide an individualised, evidence-based, woman-centred, integrated approach to care, that reduces medical interventions and morbidity in labour.

Trial Registrations and ethics approvals

The study was approved by the Western Sydney University ethics committee (H9579), Northern Sydney Local Health District (NSLHD) ethics committee (1111-476M, NEAF: HREC/11/H/268), and has site specific approval at the Western Sydney LHD (WSLDH) ethics committee (SSA/12/N/58), and was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

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Competing Interests

No, there are no competing interests

Contributorship Statement

KL, as the PhD student, was the main contributor to the development and design of the trial, the conduct of the trial, and drafting of the manuscript. CAS is the primary supervisor, and HGD the second supervisor, and each assisted with the research design, review of data and manuscript drafts. AB is the third supervisor and assisted with research design, and review of manuscript drafts.

Data Sharing Statement

The unpublished data may be available upon request.

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. WHO. Caesarean sections should only be performed when medically necessary. Executive summary. In: WHO, editor. Geneva: WHO, 2015:8.
3. Bryant R. Improving maternity services in Australia: The report of the maternity services review. In: Australia Co, editor. Canberra: Commonwealth of Australia, 2009.
4. Anim-Somuah M, Smyth RM, Jones L. Epidural versus non-epidural or no analgesia in labour. *The Cochrane database of Systematic Reviews* 2011(12):CD000331.
5. King T. Epidural anesthesia in labor benefits versus risks. *Journal of Nurse-Midwifery* 1997;42(5):377-88.
6. Dahlen H, Schmied V, Dennis CL, et al. Rates of obstetric intervention during birth and selected maternal and neonatal outcomes for low risk women born in Australia compared to those born overseas. *BMC Pregnancy and Childbirth* 2013;13(1):100.
7. 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(1):6-13.
8. Roberts CL, Tracy S, Peat B. Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *Brit Med J* 2000;321(7254):137-41.
9. Centre for Epidemiology and Evidence. New South Wales Mothers and Babies 2010. In: Evidence CfEa, editor. Sydney: NSW Ministry of Health. , 2012.
10. 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(5).
11. NSW Department of Health. Maternity - Towards Normal Birth in NSW. In: Health N, editor. *Policy Directive*. Sydney: NSW Health, 2010.
12. Zwelling E. The history of Lamaze continues: an interview with Elisabeth Bing. *Journal of Perinatal Education* 2000;9(1):15-21.
13. Zwelling E. Down memory lane: recollections of Lamaze International's First 50 Years. *Journal of Perinatal Education* 2010;19(3):11-16.
14. Svennson J, Barclay L, Cooke M. Effective Antenatal Education: Strategies Recommended by Expectant and New Parents. *Journal of Perinatal Education* 2008;17:33-42.
15. Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database of Systematic Reviews* 2007(3).
16. Jaddoe VW. Antenatal education programmes: do they work? *The Lancet* 2009;374(9693):863-64.
17. Smith CA, Collins CT, Cyna AM, et al. Complementary and alternative therapies for pain management in labour. *Cochrane Database of Systematic Reviews* 2006(4):CD003521.
18. National Institute of Health. National Center for Complemenary and Integrative Health. In: NIH, editor. *NCCIH*. Bethesda, Maryland: NIH, 2015:National Center.

19. Steel A, Adams J, Sibbritt D, et al. The influence of complementary and alternative medicine use in pregnancy on labor pain management choices: results from a nationally representative sample of 1,835 women. *J Altern Complement Med* 2014;20(2):87-97.
20. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. *Cochrane Database of Systematic Reviews* 2012;3:CD009234.
21. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ : British Medical Journal* 2008;337:a1655.
22. 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(0).
23. Betts D. Acupressure techniques for use during childbirth and pregnancy. *Childbirth solutions Online. Available at: VRL: http://www. Accessed 2015*. 2005.
24. Smith CA, Collins CT, Crowther CA, et al. Acupuncture or acupressure for pain management in labour. *Cochrane Database of Systematic Reviews* 2011(7):CD009232.
25. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. *Cochrane Database Syst Rev* 2011(12):CD009514.
26. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database of Systematic Reviews* 2012;2:CD009290.
27. Leap N, Dodwell M, Newburn M. Working with pain in labour. An overview of the evidence. *New Digest* 2010;49:22-26.
28. Field T. Yoga clinical research review. *Complementary therapies in clinical practice* 2011;17(1):1-8.
29. Copstick SM, Taylor KE, Hayes R, et al. Partner support and the use of coping techniques in labour. *Journal of psychosomatic research* 1986;30(4):497-503.
30. Leap N, Sandall J, Buckland S, et al. Journey to confidence: women's experiences of pain in labour and relational continuity of care. *Journal of Midwifery & Women's Health* 2010;55(3):234-42.
31. May C, Fletcher R. Preparing fathers for the transition to parenthood: Recommendations for the content of antenatal education. *Midwifery* 2013;29(5):474-78.
32. Hodnett ED, Simmons-Tropea DA. The labour agentry scale: Psychometric properties of an instrument measuring control during childbirth. *Research in Nursing & Health* 1987;10(5):301-10.
33. IBM SPSS Statistics for Windows, Version 22.0 [program]. Armonk, KY: IBM Corp, 2013.
34. Li Z, Zeki R, Hilder L, et al. Australia's mothers and babies 2011. In: AIHW, editor. *Perinatal statistics series no. 28. Cat. no. PER 59.* Canberra: AIHW National Perinatal Epidemiology and Statistics Unit, 2013.
35. Fewtrell MS, Kennedy K, Singhal A, et al. How much loss to follow-up is acceptable in long-term randomised trials and prospective studies? *Arch Dis Child* 2008;93(6):458-61.
36. 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(1):70-78.

37. Tracy SK, Tracy MB. Costing the cascade: estimating the cost of increased obstetric intervention in childbirth using population data. *BJOG: An International Journal of Obstetrics & Gynaecology* 2003;110(8):717-24.
38. Ferguson S, Davis D, Browne J. Does antenatal education affect labour and birth? A structured review of the literature. *Women Birth* 2013;26(1):e5-e8.
39. Murphy Tighe S. An exploration of the attitudes of attenders and non-attenders towards antenatal education. *Midwifery* 2010;26(3):294-303.
40. Walker DS, Visger JM, Rossie D. Contemporary Childbirth Education Models. *The Journal of Midwifery & Women's Health* 2009;54(6):469-76.
41. Lumley J, Brown S. Attenders and Nonattenders at Childbirth Education Classes in Australia: How Do They and Their Births Differ? *Birth* 1993;20(3):123-30.
42. Shearman R, Bennett C. Maternity services in New South Wales--childbirth moves toward the 21st century. *Med J Aust* 1989;150(12):673-6.
43. 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 : an international journal of obstetrics and gynaecology* 2015.
44. Bergström M, Kieler H, Waldenström U. Natural childbirth vs antenatal education. *Midwives* 2009;12(4):21-21.
45. Byrne J, Hauck Y, Fisher C, et al. Effectiveness of a Mindfulness-Based Childbirth Education Pilot Study on Maternal Self-Efficacy and Fear of Childbirth. *Journal of Midwifery & Women's Health* 2014;59(2):192-97.
46. Cyna AM, Crowther CA, Robinson JS, et al. Hypnosis Antenatal Training for Childbirth: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2013;120(10):1248-59.
47. Koehn ML. Childbirth education outcomes: an integrative review of the literature. *J Perinat Educ* 2002;11(3):10-19.
48. Madden K, Middleton P, Cyna AM, et al. Hypnosis for pain management during labour and childbirth. *Cochrane Database of Systematic Reviews*: John Wiley & Sons, Ltd, 2012.
49. Lothian JA. Listening to mothers II: knowledge, decision-making, and attendance at childbirth education classes. *Journal of Perinatal Education* 2007;16(4):62-67.
50. Lothian JA. Childbirth education at the crossroads. *J Perinat Educ* 2008;17(2):45-9.
51. Gupta JK, Hofmeyr GJ. Position for women during second stage of labour. *Cochrane Database of Systematic Reviews* 2004(1):CD002006.
52. Tracy SK, Sullivan E, Wang YA, et al. Birth outcomes associated with interventions in labour amongst low risk women: A population-based study. *Women and Birth* 2007;20(2):41-48.
53. Adams J, Easthope G, Sibbritt D. Exploring the relationship between women's health and the use of complementary and alternative medicine. *Complement Ther Med* 2003;11(3):156-58.
54. Adams J, Lui CW, Sibbritt D, et al. Women's Use of Complementary and Alternative Medicine During Pregnancy: A Critical Review of the Literature. *Birth* 2009;36(3):237-45.
55. MacLennan AH, Wilson DH, Taylor AW. The escalating cost and prevalence of alternative medicine. *Prev Med* 2002;35(2):166-73.

56. Australian Bureau of Statistics. Australian Health Survey. Canberra, ACT: ABS, 2012.
57. Australian Bureau of Statistics. Census of population and housing: Socio-economic indexes for Areas (SEIFA). Canberra: ABS, 2008.
58. Adams J, Sibbritt D, Lui CW. The Use of Complementary and Alternative Medicine During Pregnancy: A Longitudinal Study of Australian Women. *Birth* 2011;38(3):200-06.
59. Adams J, Sibbritt DW, Easthope G, et al. The profile of women who consult alternative health practitioners in Australia. *Med J Australia* 2003;179(6):297-300.
60. Bergström M, Kieler H, Waldenström U. Effects of natural childbirth preparation versus standard antenatal education on epidural rates, experience of childbirth and parental stress in mothers and fathers: a randomised controlled multicentre trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2009;116(9):1167-76.
61. Bergström M, Kieler H, Waldenström U. A randomised controlled multicentre trial of women's and men's satisfaction with two models of antenatal education. *Midwifery* 2011;27(6):e195-e200.
62. Cyna AM, McAuliffe GL, Andrew MI. Hypnosis for pain relief in labour and childbirth: a systematic review. *Brit J Anaesth* 2004;93(4):505-11.

Supplementary information

The Complete Birth Study consisted of a two-day workshop (no cost to participants) to be held at either Site H or Site N on a nominated weekend. The workshop consisted of the following programme:

Complete Birth protocol –the programme, philosophy and techniques are designed to support a woman during her pregnancy and labour by introducing techniques to enhance a natural state of relaxation for the optimal birth experience,[1]. The program introduces concepts of birth as a natural physiological process, and evidence-based CM techniques by which the normal birth process can be managed,[2]. These are described below.

'Acupressure for pain relief in labour' protocol– Acupressure consists of applying moderate pressure to acu-points using locations described in Traditional Chinese Medicine (TCM) texts. The location and uses of a variety of acupressure points for the purpose of assisting the physiological processes of labour, as well as the emotional support for the woman were taught to the woman and her birth partner. A booklet accompanied this session to facilitate review and home practice, with suggestions for most appropriate uses of certain points and point combinations,[3].

Participants were advised to practice at home from 37 weeks' gestation, practicing once a week for five minutes at 37 weeks, followed by two to three times a week for 7-10 minutes at 38 weeks, four to five times a week for 10-15 minutes at 39 weeks, and after 40 weeks' gestation, they could use the induction combination of points every two hours to assist in bringing on labour.

Six main points used:

Sp-6 (Sanyinjiao) for induction and augmentation of labour

L.I.-4 (Hegu) for pain relief

G.B.-21 (Jianjing) has a descending action to aid the first and second stages of labour and can stimulate uterine contractions. Also useful for bleeding following birth.

Bl-32 (Ciliao) for pain relief

Ki-1 (Yongquan) for relaxation and calming effect, especially during transition

Bl-60 (Kunlun) used during first stage of labour, promotes the descent of the baby during labour

Other useful points

Pc-6 (Neiguan) for nausea and vomiting during labour, and can be especially useful if epidural analgesia used

Bl-67 (Zhiyin) for malposition of the baby prior to labour

Point combinations

Sp-6 + L.I.-4 + Bl-32 for induction of labour

Bl-60 + L.I.-4 for posterior presentation during labour

Sp-6 + L.I.-4 for unestablished labour or failure to progress

Sp-6 + Bl-32 for swollen cervical lip at full dilation

G.B.-21 + L.I.-4 for failure to progress during second stage

Outline of the labour process in terms of the anatomy and physiology of birth – a description of what happens physically to the body during 'normal' labour and birth. The couples are taught about the anatomical structure of the uterus and the function of the three layers of the uterus in facilitating birth. The stages of labour are described and what the contractions may feel like and how long they are likely to last. The sympathetic and parasympathetic nervous systems are described and the reactions of the body when each are activated, and its effect during labour. Having an optimal mindset for the labour was also discussed. How participants could mentally approach labour as if they were training for an athletic event, and to have the right frame of mind to prepare for it. From a basis of knowledge and understanding of the stages of labour and the body's response, then further concepts can be introduced.

The hormonal cycle during birth - Hormones that are produced during the birth process were described and their effect on the body during stressed and relaxed states. The hormones discussed were oxytocin, relaxin, beta-endorphins, adrenalin and prolactin, and the natural cascade of these hormones that occur during an uninterrupted labour. Additionally, the effect on these hormones when pharmacological pain relief, or synthetic oxytocin (syntocinin) for induction and augmentation is introduced, was also described.

Techniques:

Breathing: Mindfulness of breath or conscious breathing combined with relaxation are powerful tools for labour [4]. There are three types of breathing techniques taught in Complete Birth: Blissful Belly (BB) breaths. Participants were instructed to breathe in through the nose to the count of 10, and then slow release to the count of 10. The goal was three breaths in one minute, but practice was required for most people to achieve this. Partners were instructed how to count their partner in, and how to use this technique during a

contraction. This was rehearsed numerous times during the course. The second technique was the Soft Sleep (SS) breaths that were to be used in between contractions and are the soft relaxed breathing that occurs when going to sleep. This was to re-focus the women between each contraction and conserve energy. The third technique is the J breath, and is used to assist the descent of the baby during the second stage of labour. This technique is an alternative to active pushing during the second stage, and both techniques are practiced by the women to demonstrate the difference in focus. For the J breath, the focus in on keeping the jaw loose, pressure on the out breath from the top of the abdominal muscles and the pelvis tilted slightly forward. In this way the perineum is also kept relaxed.

Relaxation and visualisation: a description of the relaxation response when the parasympathetic nervous system is activated was given to the participants. The relaxation techniques comprise of four guided relaxation exercises on a CD. These are practiced during the course and then given to women and partners for home practice as often as they wanted to do it. The four exercises included progressive relaxation, lotus flower, count down, visualisation of the ligaments and muscles of the pelvis. Included in the relaxation CDs were visualisations including seeing the baby coming into an optimal position; visualisation of the optimal birth experience; and visualisation of your special place in nature where you feel completely safe and relaxed.

Movement and yoga positions: Using positions with hips wide open, using gravity and your alignment to assist with labour's progress. Standing, leaning, using furniture, fit balls, partner support to aid the baby's descent. Movement should be effortless and meditative. Yoga positions will be taught that aid labour and can be performed by women in labour,[4]. There were five yoga postures taught:

Baddha Konassana (cobbler pose): which is a resting pose for between contractions. Spiralling movements can be added for pain relief or focusing concentration

Balasana (child's pose): which is also a resting pose for between contractions, and for regaining energy when tired. This position is also helpful when pain relief is sought from acupressure or massage techniques

Upavishta Konassana (legs wide stretch): for opening hips before labour, during pre-labour and in the first stage while comfortable

Marjaryasana (cat pose or stretch): for pain relief during and after contractions to stretch out the stomach muscles

Malasana (squat pose): used for upright positioning for pain relief and the descent of the baby during second stage. This can be modified with the use of chairs or cushions for a seated squat, or on the knees or with the support of the partner. This pose is practiced after 20 weeks and until 37 weeks' gestation for shorter periods of time, and can be held longer to assist with induction following 37 weeks. This posture is contraindicated if there is any pubic symphysitis present, or the placenta is low lying.

Massage: Massage techniques are useful during birth for pain relief,[5]. Two techniques were taught, and home practice was encouraged as often as the couples liked. The techniques were:

Strong massage technique is used to 'meet' the contraction where the woman is feeling the strongest sensation. The partner uses the heel of his/her hand and squeezes and rotates at the points on the buttocks during the contraction.

Endorphin technique is a soft technique used during the time between contractions to increase the release of natural opiates. Skin contact and soft rhythmic movements up and around the back, shoulders and arms is instructed.

Supplementary Table 1: CM therapies used during labour

Complementary Therapy Used	No EDA n=67 (%)	Yes EDA n=21 (%)	Risk ratio P value
Acupressure	29 (43.3%)	12 (57.1%)	0.78 [0.61-0.98] P=0.11
Breathing technique: Belly Breaths (first stage)	42 (62.7%)	11 (52.4%)	1.1 [0.23-2.04] p=0.68
Breathing technique 2: 'J' Breaths (second stage)	23 (34.3%)	8 (38.1%)	0.91 [0.7-1.2] p=0.56
Yoga	29 (43.3%)	11 (52.4%)	0.83 [0.65-6.79] p=0.22
Massage	30 (44.8%)	10 (47.6%)	0.91 [0.70-1.2] p=0.55
Visualisation	38 (56.7%)	11 (52.4%)	0.99 [0.72-1.35] p=1.0

References:

1. Buckley S. Undisturbed birth. Nature's blueprint for ease and ecstasy. Midwifery today with international midwife 2002(63):19-24
2. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. Cochrane Database of Systematic Reviews 2012;**3**:CD009234 doi: 10.1002/14651858.CD009234.pub2[published Online First: Epub Date]|.
3. Betts D. Acupressure techniques for use during childbirth and pregnancy. Childbirth solutions Online Available at: VRL: http://www Accessed 2015 2005
4. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. Cochrane Database Syst Rev 2011(12):CD009514 doi: 10.1002/14651858.CD009514[published Online First: Epub Date]|.
5. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. Cochrane Database of Systematic Reviews 2012;**2**:CD009290 doi: 10.1002/14651858.CD009290.pub2[published Online First: Epub Date]|.

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	1-2
Introduction				
Background	2	Scientific background and explanation of rationale		5
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	7
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	7-9
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	8-9
	4B		Details of how the interventions were standardized	8-9
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	8
Objectives	5	Specific objectives and hypotheses		
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		10
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	11

Randomization–sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	7
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	9
	11B		If blinded, method of blinding and description of the similarity of interventions†	10
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	12
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	7-9
Recruitment	14	Dates defining the periods of recruitment and follow-up		
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	13-14

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		15
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		16-18
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		18
Adverse events	19	All important adverse events or side effects in each intervention group		17
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	19
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	21-22
Overall evidence	22	General interpretation of the results in the context of current evidence		22

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.

BMJ Open

The Complementary Therapies for Labour and Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour

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The Complementary Therapies for Labour and Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour

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Keywords: Epidural, complementary medicine, antenatal education, normal birth, caesarean section, randomised controlled trial.

Word count:

ABSTRACT:

Objective: To evaluate the effect of an antenatal integrative medicine education program in addition to usual care for nulliparous women on intrapartum epidural use.

Design: Open label, assessor blind, randomised controlled trial **(**RCT).

Setting: Two public hospitals in Sydney, Australia.

Population: 176 nulliparous women with low-risk pregnancies, attending hospital-based antenatal clinics.

Methods and Intervention: The Complementary Therapies for Labour and Birth protocol, based on the She Births® and Acupressure for labour and birth courses, incorporated six evidence-based complementary medicine (CM) techniques; acupressure, visualisation and relaxation, breathing, massage, yoga techniques and facilitated partner support. Randomisation occurred at 24-36 weeks' gestation, and participants attended a two-day antenatal education program, plus standard care, or standard care alone.

Main outcome measures: Rate of analgesic epidural use. Secondary: onset of labour, augmentation, mode of birth, newborn outcomes.

Results: There was a significant difference in epidural use between the two groups: study group (23.9%) standard care (68.7%) (risk ratio (RR): 0.37 [95% C.I.: 0.25, 0.55], p=<0.001). The study group participants reported a reduced rate of augmentation (RR=0.54 [95% C.I.: 0.38-0.77], p<0.0001); caesarean section (RR=0.52, [95% C.I.:0.31-0.87], p=0.017); length of second stage (MD= -0.32, [95% C.I.:-0.64, 0.002] p=0.05); any perineal trauma (0.88 [0.78-0.98] P=0.02); and resuscitation of the newborn (RR=0.47 [95% C.I.:0.25-0.87] p=<0.015).

There were no statistically significant differences found in spontaneous onset of labour, pethidine use, rate of post-partum haemorrhage (PPH), major perineal trauma (3rd and 4th degree tears/episiotomy), or admission to special care nursery/neonatal intensive care unit (SCN/NICU) (p=0.25).

Conclusion: The complementary therapies for labour and birth study protocol significantly reduced epidural use and caesarean section. This study provides evidence for integrative medicine as an effective adjunct to antenatal education and contributes to the body of best practice evidence.

Trial registry: Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

Article summary

Strengths and limitations of this study

- This is the first RCT in Australia that has investigated the effectiveness of a birth preparation course, integrating multiple complementary medicine (CM) techniques, for the support of natural birth for first time mothers. This suggests a reorientation of antenatal education towards normal birth and reflects current outcome measures in reports of maternity services policy directives.
- The study used self-administered, evidence-based, CM techniques, and blinded analysis to test and a priori hypothesis; and implemented a pragmatic design where participants

were free to use any of the techniques with no prescriptions or time limitations for use, allowing women and partners to have control and agency in their birth process and use information and CM tools to manage their own labours.

- The primary outcome measure of epidural block (EDB) was used, rather than frequently used pain scores, as the objective measure of EDB has been identified as a mediating factor in labour interventions and mode of birth, described as the cascade of interventions.
- Limitations of this study include higher enrolment of relatively wealthy, well-educated women, and relatively fewer participants from the area identified as lower socio-economic status. This is in line with previous CM research, but it is worth considering that the highest rates of epidural use and caesarean section, is also amongst this more advantaged population.
- Wider national and international implementation of this study is recommended to confirm results in a broader population and examine issues of generalisability.

INTRODUCTION:

There has been a rise in rates of intervention during labour and birth in most developed countries,[1 2], and the intervention rates in Australia during birth are well above the Organisation for Economic Cooperation and Development (OECD) averages,[3]. As these interventions increase, such as routine use of epidural block (EDB), so does the rate of instrumental births and associated medical interventions,[4-8]. Epidural rates in New South Wales (NSW) hospitals have shown a rapid rise over the past decade. In 2012, the state average for EDB use was 46.5%, however, there was broad variation within the state, ranging from 15% to 82.7% depending on region and hospital,[9 10]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of augmentation, assisted vaginal births and caesarean section (CS),[4 6-8 11].

Childbirth education has also seen a shift away from birth preparation,[12 13], to a curriculum broadly centred on overall parent education,[14]. Findings from a systematic review on childbirth education reports that the effectiveness of antenatal education for childbirth or parenthood supports the idea that educational interventions have a role in increasing feelings of self-confidence and agency, but demonstrates little impact on reducing interventions and associated morbidity in labour,[15 16].

Integrative medicine approaches, and complementary medicine (CM) in particular, may offer increased options for pain relief in birth,[17], and may be effective within the hospital antenatal education framework. The term integrative medicine is used when referring to incorporating CM or complementary therapies (CT) into mainstream health care,[18]. Recent Australian data suggest that 74.4% of women used some form of CM during pregnancy, and 66.7% of these women also

used non-pharmacological pain relief in labour,[19]. The Cochrane Systematic Review on pain management for labour finds some evidence to suggest that acupuncture, relaxation, massage, and water immersion may assist in the management of labour with few side effects, however more research is needed to establish efficacy of these techniques,[20].

In response to the need to establish the evidence base for CM interventions for pain management in labour we undertook a randomised controlled trial (RCT) to test the hypothesis that nulliparous women who undergo a CM antenatal education course, in addition to usual antenatal care would use less EDB than nulliparous women who receive usual antenatal care alone. Trials of complex interventions are difficult to conduct, and do not have linear models, and require a pragmatic approach to implementation,[21 22].

Methods

The Complementary Therapies for Labour and Birth (CTLB) study protocol included the existing She Births® Antenatal Education Program, with an acupressure component 'Acupressure techniques for use during childbirth and pregnancy' protocol,[23]. The study protocol was further adapted to reflect the evidence base for the CM techniques that were incorporated,[22 24-26].

From April 2012 to August 2013, women and their birth partners were recruited to a two-arm study consisting of a study group, who received the CTLB protocol in addition to usual care, and a control group, who received usual care alone. The study was an assessor-blinded, open-label pragmatic randomised controlled trial.

Participants

Women attending antenatal clinic were eligible to participate in the study from 24 to 34 weeks' gestation. They were provided with a participant information sheet for themselves and their birth partner. If they were interested and eligible to participate, women and partners signed individual consent forms. Women were eligible to enter the trial if they had a singleton pregnancy with a cephalic presentation, were low risk (no pre-existing medical complications or existing obstetric complications), were first time mothers (nulliparous), and had sufficient English to participate in a course. Women were excluded from entering the trial if they had pre-identified risk factors, were enrolled, or intending to enrol, in a 'continuity of care' midwifery program or in a private birth preparation course, were unable to attend a weekend course, had insufficient English for participation, or had been previously randomised to the trial. Recruitment was undertaken at two public hospitals in Sydney Australia that reflected diverse socio-economic areas. Recruitment was also conducted through the affiliated Western Sydney University (WSU) in response to newspaper and magazine advertisements. Participants who were recruited through WSU attended the courses at either of the two hospital study sites. All eligible women were approached in the antenatal clinic at site 1, as this was a smaller unit, individual contact was possible, and all clinics were attended regularly by the researcher. At site 2, the hospital was much larger, and more diverse with regard to structure of the clinics. Different clinics were attended, and eligible women at those clinics were approached. It was not possible to attend all clinics at this larger unit, and a range of clinics were selected on different weeks to achieve a representative sample of women. For site 3, where flyers and newspaper advertisements were used for recruitment, the response rate was quite low. All eligible women who contacted us through these means were

randomised to the study. We do not have data on the women who were not eligible to participate. The randomisation target was achieved quite quickly, and participation was popular.

Randomisation

We used a web-based computer generated randomisation sequence prepared centrally via the 'Sealed Envelope' website (https://www.sealedenvelope.com), and concealed centrally. Stratification occurred for hospital site, yielding three randomisation lists: 'Site H, 'Site N', and 'WSU'. Women were randomly allocated to either the study group or usual care alone. Randomisation occurred on a 1:1 allocation ratio to ensure equal numbers in each group at each hospital. All randomisations were entered by the investigator KL.

Intervention

Two-day courses (see supplementary file 1) were conducted over a weekend at one of the two hospital venues on a fortnightly to monthly basis over a 15 month period from May 2012 to August 2013. A total of 20 courses were conducted during this time. Participants attended prior to 36 weeks' gestation with a birth partner, and there was a maximum of 12 couples and a minimum of two couples at each course, with an average of eight couples per course. The study investigator (KL) ran each course.

The underlying philosophy and specific techniques included in the intervention program were designed to support a woman during her pregnancy and labour by introducing tools to enhance a natural state of relaxation (visualisation, breathing, massage, yoga) and facilitate labour progression (yoga, acupressure) and pain relief (breathing, acupressure, visualisation). The CTLB protocol introduces concepts of birth as a natural physiological process, and the idea of

'working with pain',[27] using evidence based CM tools by which the birth process can be managed,[20]. Women and partners received education about the physiology of normal birth.

The tools used were:

1. Visualisation,[25] - four guided visualisations rehearsed through the courses and given to participants on a CD to practice at home
2. Yoga postures,[28] – five postures and movements practiced to encourage relaxation, physiological position for labour, opening of the pelvis and downward descent of the baby
3. Breathing techniques,[20] - four breathing techniques were introduced: Soft Sleep Breaths (SS) for relaxation between contractions; Blissful Belly Breaths(BB) which were used during contractions for pain relief; Cleansing Calming Breaths(CC) used following contractions during the transition period of labour; and the Gentle Birthing Breath(GB) which was for use during the second stage of labour and encouraged descent of the baby avoiding active pushing and protection of the pelvic floor
4. Massage,[26] – two techniques were shown to partners; the endorphin massage used between contractions, which is a soft technique and encourages endorphin release; and the stronger massage which is used during contractions for pain relief and focuses on squeezing the buttock, especially the piriformis muscle to interrupt pain perception
5. Acupressure,[22 24], which uses six main points for use during labour selected from a previously published protocol,[23]. These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea, and positioning of baby
6. Facilitated partner support,[29-31], uses the concept of working with pain,[27] and instructs partners to advocate for the labouring woman, promoting her oxytocin levels and

minimising her stress with actions and techniques which are supportive for the birthing woman, and gives time for facilitated discussion and rehearsal by couples during the course.

Usual care consisted of the hospital based antenatal education course routinely available at each hospital. Antenatal education classes in Australia currently take a general descriptive approach to labour preparation, and emphasise parenting and post-partum issues as the main focus,[14]. Classes generally run weekly over six to seven weeks, or over 1-2 weekends, and include topics such as: pregnancy changes, exercise and back care during pregnancy, signs of labour, unexpected outcomes in labour and birth, pharmacological pain management, managing labour and birth, newborn care and breastfeeding, parenthood and baby's first weeks.

Blinding

Women, partners and the chief investigator (KL) were not blinded to group allocation. Group allocated was subsequently coded, and outcome measures were assessed and analysed blind to study group allocation. Midwives and doctors at each of the two main study hospitals and other sites were aware of the study, but delivery suite personnel were blinded to study participants' group allocation. Study course content was not disclosed to midwives to avoid any change in practice that may occur. Group allocation and data was linked by identification codes allowing the analysis to be undertaken blind.

A priori outcome measures

Primary outcome: Epidural use for pain relief.

Secondary outcomes: other pharmacological pain relief during labour; induction of labour; augmentation of labour; length of labour; instrumental delivery; caesarean section, post-partum

haemorrhage (PPH) (greater than 500ml blood loss); perineal trauma ($1^{st}/2^{nd}/3^{rd}/4^{th}$ degree tear/episiotomy); major or severe perineal trauma ($3^{rd}/4^{th}$ degree tear/episiotomy); Apgar scores <7 at 5 minutes; resuscitation of the newborn (with oxygen, suction, bag and mask, intubation, cardiac massage); admission to special care nursery/neonatal intensive care unit (NICU/SCN). Other outcomes included attitude towards birth and personal sense of control, as well as post-natal depression at 6 weeks, measured by the Edinburgh Post-Natal Depression Scale (EPDS) [32].

Questionnaires

For sense of personal control measures we used the Labour Agentry Scale (LAS),[33]. Within 72 hours following birth the LAS was administered to all women (see Supplementary file 2). The LAS contains 29 questions with a 7 point Likert-scale ranging from '1= almost always', to '7= rarely'. Therefore, scores could theoretically range from 29, indicating the most agency possible, to a high score of 203 indicating the lowest agency possible.Clinical outcomes were collected from hospital birth records, and the NSW Hospitals' birth summaries, which were accessed from the hospitals where the participant had given birth.

Analysis

An intention-to-treat analysis was used for the primary and secondary outcome data. Chi square and t-tests were used for univariate analysis of categorical and continuous data respectively. Significance was set at an alpha of 0.05, reporting on relative risk with a 95% confidence interval. Group allocation was coded by an independent researcher, and the investigator undertook the analysis blind to group allocation. Data was analysed using SPSS version 22,[34].

Sample size and power

The trial was designed to demonstrate an absolute reduction of 20% in epidural use from 46% in those women managed with usual care to 26% in those women who were randomised to the study. The rate of use of EDB was determined by published data for the two study hospitals in 2011 NSW Mothers and Babies Report,[35]. This required a total sample size of 170 women for an 80% power at a significance level of $p<0.05$. Recruitment continued until at least 170 women had been enrolled, and those randomised to the treatment group had either completed the course or were known to have missed their course, with 176 randomised and 171 completing the study. A low drop-out rate (<3%) was observed for the overall study population, and separately for each arm of the study (<5%),[36]. Primary outcome data was available for all consenting participants.

Results

We assessed 315 women for eligibility to participate in the study, of whom, 176 were randomised and 171 were included in the final analysis (Figure 1). Five women were lost to follow up. Women were randomised to the Study Group, n=89, or the Control Group, n=87. From the 315 women screened, 139 were excluded for the following reasons: 105 declined to participate, and 34 did not meet inclusion criteria (insufficient English (n=7), attending private birth preparation course (n=12), continuity of care model (n=6), mod-high risk: GDM (n=5), breech presentation (n=4). In the final analysis, there were 101 women included from site 1, 30 women from site 2, and 40 women from site 3.

INSERT FIGURE 1 HERE

All women completed the trial entry form at baseline including demographic information. Not all women answered each question in the trial entry form (Table 1). Following birth, the LAS was completed by 72 of the 88 women (82%) in the study group, and 52 of the 83 (62%) women in the control group.

Participants in the intervention group did not significantly differ from those in the control group in terms of their age, body mass index (BMI), cultural background, level of education, income, hospital status, or model of care (Table 1). Babies were not different in terms of average gestational age or weight at birth.

Table 1: Participant baseline demographics

Demographic Characteristics	Study Group *n* = 87	Control Group *n* = 85
Mean Age (years, ± SD)	30.41 (± 4.99)	28.87 (± 5.24)
BMI (mean ±SD)	22.66 (±4.47)	23.35 (±3.93)
Cultural Background:	***n* = 79 (%)**	***n* = 61 (%)**
Caucasian	58 (73.4)	44 (72.1)
Asian	10 (12.7)	11 (18.0)
Other	11 (13.9)	6 (9.9)
Income	***n* = 78 (%)**	***n* = 61 (%)**
<60	12 (15.4)	12 (19.7)
60-80K	7 (9.0)	10 (16.4)
80-100K	17 (21.8)	10 (16.4)
>100K	42 (53.5)	29 (47.5)
Total	**78**	**61**
Education	***n* = 81 (%)**	***n* = 60 (%)**
High School/Vocational	24 (29.6)	20 (33.3)
University/Post Grad	57 (70.4)	40 (66.7)
Hospital status	***n* = 87 (%)**	***n* = 85 (%)**
Public status	82 (94.3)	79 (92.9)
Private Status	5 (5.7)	6 (7.1)
Model of Care:	***n* = 87 (%)**	***n* = 85 (%)**
Midwifery	67 (82.7)	64 (85.3)
Doctors Care	4 (4.9)	7 (9.3)
Shared Care	10 (12.3)	4 (5.3)

Primary outcome

A statistically and clinically significant reduction in epidural rate was found for the intervention group compared with the control group. The overall unadjusted rate of EDB in the control group was 68.7%, and 23.9% in the study group (risk ratio (RR) = 0.35 [0.23-0.52] p=<0.0001), (Table 2). In addition to stratification of randomisation by site, a post-hoc analysis was performed for each site. The risk ratios were similar to the primary analysis (RR1=0.27 [0.12-0.60], RR2=0.31 [0.11-0.90], RR3=0.39 [0.23-0.65]). Using a true intention to treat analysis (ITT), we examined the data including data points for the five women who had dropped out, withdrawn or were lost to follow-up. There were four in the control group, and one in the study group. Using a best-case–worst-case scenario, we included the five cases with missing data for the primary outcome. If the four control group women did not have an EDB and the one study group woman did have an EDB (worst case), the results were still highly statistically significant with a risk ratio of: 0.40 [95% C.I.: 0.27, 0.59] p=<0.0001.

Table 2: Unadjusted primary and secondary outcomes measures:

OUTCOMES	Study 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**
Spontaneous Onset Labour	62 (70.5)	54 (65.1)	1.13 [0.82-1.57] p=0.51
Augmentation	25 (28.4)	48 (57.8)	0.54 [0.38-0.77] p<0.0001**
Mode of Birth: NVB	60 (68.2)	39 (47.0)	1.56 [1.12-2.17] p=<0.01**
Mode of Birth: CS	16 (18.2)	27 (32.5)	0.52 [0.31-0.87] p=0.017*
Mode of Birth: Instrumental	12 (13.6)	17 (20.5)	0.57 [0.30-1.09] p=0.09
Nitrous Oxide (Gas)	40 (45.5)	49 (59.0)	0.77 [0.57-1.03] p=0.092
Pethidine	19 (20.5)	15 (19.3)	1.11 [0.78-1.56] p=0.70
Any perineal trauma ^(Trauma/VB)	61/72 (84.7)^	54/56 (96.4)^	0.88 [0.78-0.98] p=0.02*
Major Perineal Trauma ^(Trauma/VB)	49/72 (68.1)^	37/56 (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
Resuscitation (Suction +/- O_2 / bag and mask)	12 (13.6)	24 (28.9)	0.47 [0.25-0.87] p=0.015*
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

* <0.05 ** <0.01

^ percentage is from all vaginal births: denominator = 72 in study group and 56 in control group. Major perineal trauma is defined as 3rd or 4th degree tear and episiotomy.

Secondary clinical outcomes

Women in the study group were more likely to experience a normal vaginal birth RR=1.56 [1.12-2.17], p=<0.01, and were less likely to have medical or surgical augmentation during labour (RR=0.54 [95% CI: 0.38-0.77], p<0.001), birth by caesarean section (RR=0.52 [0.31-0.87], p=0.01) or any perineal trauma (RR=0.88 [95% C.I.: 0.78-0.98], p=0.02). We also found a reduced length of second stage of labour (MD= -0.32 [95% CI: -0.64, 0.002], p=0.05) in the study group (Table 2). Babies of women in the study group were also less likely to require resuscitation by suction (plus or minus oxygen) or with bag and mask (RR=0.47 [95% C.I.:0.25-0.87], p=0.015). There were no differences in the rare outcomes of intubation or cardiac massage required at birth. Only one baby in the study group required intubation. Although not statistically significant there were some non-significant trends toward the study group having less likelihood of an instrumental vaginal birth (RR=0.57 [95% C.I.: 0.30-1.09], p=0.09), and nitrous oxide (gas) for pain management (RR= 0.77 [95% C.I.: 0.57-1.03], p=0.09).

No significant differences were found in the secondary outcome measures of spontaneous onset of labour (RR=1.13 [95% CI:0.82-1.57), p=0.51), pethidine use (RR=1.11 [95% CI: 0.65-2.2]), p=0.56), rates of post-partum haemorrhage (PPH) (RR=0.82 [95% CI: 0.41-1.61], p=0.85) or major perineal trauma (third/fourth degree tear or episiotomy), (RR=0.94 [95% CI: 0.57-1.55], p=0.85). No significant differences were found in Apgar scores (RR=0.99 [95% CI:0.95-1.03], p=1.0), or admission to the SCN/NICU (RR=0.59 [95% CI:0.24-1.46], p=0.25).

The length of the second stage of labour was 1 hour for the study group and1 hour 32 minutes for the control group giving a mean difference of 32 minutes (p=0.05). There were no significant differences between the groups for the first stage of labour or the total length of labour (see Table 3).

Table 3: Length of labour

OUTCOMES Length of Labour	Study Group (n=86) Mean (SD)	Control Group (n=83) Mean (SD)	Difference Statistic MD [95% CI] p-value
1st stage	6.12 (3.95)	6.53 (3.90)	MD= -0.41 [-1.79, 0.98] p=0.56
2nd stage	1.00 (0.87)	1.32 (0.98)	MD= -0.32 [-0.64, 0.002] p=0.05*
Total length of labour	7.43 (4.13)	8.20 (4.37)	MD= -0.77 [-2.26, 0.72] P=0.31

* p=0.05

The LAS questionnaire examined whether the course had any impact on attitudes and feelings about birth and women's feelings of agentry. The LAS was completed by 72 of the 88 women in the study group (82%), with an average score of 164.97 (SD=27.06). In the control group 52 of the 83 women (62%) completed the form, and had an average score of 150.92 (SD=30.03). We found a statistically significant difference between the two groups for this score (MD=14.05, 95% C.I.: 3.84-24.26, $p < 0.01$).

Given that a large number of women did not complete this form, there is the possibility of reporting bias in the results, we used a Levene's test for equality of variance, and found the variance between the two groups was not significantly different (p=0.59). Additionally, we did a post-hoc analysis to determine if any differences were present between the study group and the control group for baseline characteristics, controlling for responders vs non-responders. No differences were found between groups.

Six weeks following the birth, participants completed an EPDS questionnaire. However, there was a high rate of non-compliance with this form: 27 women in the study group and 41 women in the control group did not complete this form. There was no statistically significant difference between groups at 6-week follow-up for this cohort of women (see Table 4).

Table 4: Six-week post-partum: Edinburgh Postnatal Depression Scale

EDPS Postnatal	**Study Group *n* = 61 Mean (SD)**	**Control Group *n* = 42 Mean (SD)**	**Mean Difference 95% CI p-value**
Postnatal EPDS	4.49 (3.44)	4.07 (3.93)	MD= 0.42, [-1.03, 1.87] p=0.57

CI: Confidence interval; EPDS: Edinburgh Postnatal Depression Scale; MD: Mean difference

Analysis of patterns of CM use in labour reveal women in the study group used an average of 3.94 (SD=1.4) techniques during labour, and in the antenatal period practised various techniques for an average total of 12.94 (SD=9.7) times per week. Women in the control group did not report antenatal practice of techniques, but some (<5%) did report using techniques such as breathing or visualisation during the labour. No individual CM technique, nor amount of rehearsal in the antenatal period, was associated with reduced likelihood of EDB use in the study group, indicating an overall effect of the program.

To examine if there was any preference for therapies used during labour, we asked women in the study group (n=88) what specific CM therapies they used during labour. On average, women used 3.94 (SD=1.4) techniques over the duration of their labour, and in order of frequency used, Blissful Belly Breaths were used most frequently, by 60.2% of women; visualisation was used by

55.7%; acupressure by 46.6%; yoga and massage each by 45.5% of women; and Gentle Birthing Breaths were used by 35.2% of women during labour.

Discussion

Main findings

The RCT demonstrated the effectiveness of the CTLB study, based on the She Births® Antenatal Education Program and acupressure for labour protocol[37] for first time mothers, showing an absolute reduction of 45% and a relative reduction of 63% (RR=0.37, p<0.001) in epidural rate in the study group compared with controls. The study also showed increased rates of normal vaginal birth without surgical or mechanical assistance, and found reduced rates of augmentation in labour, length of second stage of labour, perineal trauma, caesarean section, and the need for resuscitation of the newborn. Univariate results for secondary outcomes should be interpreted with caution however, as these are likely to be related to the primary outcomes of EDB, which has been shown to mediate the effect these secondary outcomes,[38 39]. Additionally, where response rates for secondary analyses are low, results should be interpreted with caution.

We note that women in the control group experienced a higher than average rate of EDB use, augmentation and instrumental vaginal birth, which is consistent with data showing higher rates of intervention for nulliparous women compared with multiparous women [10]. The data for EDB use in this study are consistent with rates for women who are identified as being anxious [40 41]. Further research is needed to identify if women who are anxious are more likely to participate in antenatal education programs, and whether these women may benefit more from this type of intervention.

Current antenatal education has undergone a distinct shift towards normalising all births and preparing parents for parenthood. However, specific preparation for normal labour appears to have been de-emphasised in classes,[42-44]. Anecdotally, the majority of women attend routine antenatal education classes, but there is no current literature to provide accurate numbers,[45 46]. The results from the Cochrane Systematic Review suggest that while antenatal education aims to prepare women and partners for childbirth and early parenting, studies to date have shown a lack of high-quality evidence and a high variability of outcome measures. Therefore, the effects of antenatal education are still largely unknown,[15]. Studies exploring the use of antenatal education interventions, antenatal mindfulness training and self-hypnosis training have failed to demonstrate any reduction in the use of analgesia during labour and birth or on CS rates,[15 47-52].

Some commentators suggest that the impact of antenatal education in routine care may in fact be reinforcing medical management of labour and birth, and therefore not addressing the rising rates of medical pain relief and the associated complications,[7 42 44 53 54]. In this study, we assessed if women from the control group used CM techniques, as demonstration of cross over. However, less than five percent of women reported using these techniques during their labour, and this is unlikely to introduce any contamination to the results.

In this study we emphasised the importance of reorienting the concept of normal birth using an antenatal education framework and a variety of evidence-based integrative CM techniques to help women manage pain in labour and birth. One of the recently voiced concerns of using alternative birth positions, such as yoga postures and upright positions, is the potential for increased risk of perineal trauma,[55]. The data from our research showed a statistically significant reduction in perineal trauma for women. Among those women who had vaginal births, 84.7% of the study group compared with 96.4% of the control group sustained some kind of perineal

trauma during birth (RR=0.88, p=0.02). Techniques were rehearsed in the antenatal period with some acupressure for induction techniques practiced lightly from 37 weeks as per the published literature,[37]. This is reported to work with the hormones that are naturally present in the woman's body, but do not artificially induce contractions. This is an important safety outcome, and there were no differences in gestational age at birth.

The study provides evidence that antenatal education integrating CM techniques is an effective and viable method of managing pain, decreasing medical interventions, and increasing personal control for women. These clinically and statistically significant results are important in establishing an evidence base for the use and effectiveness of antenatal education programs incorporating CM techniques for the management of pain during childbirth as an adjunct to parent education offered as usual care. This program has the potential to provide a cost effective method of antenatal education. A costing and economic analysis of this program will be undertaken and reported elsewhere, providing a measure of relative benefit for outcomes saved. Reorienting antenatal education classes towards supporting normal birth and providing techniques to help women manage pain is an important contribution to reducing interventions in labour and birth.

Interpretation

Our study helps to address the question of whether antenatal education using CM techniques are effective in reducing rates of EDB in first time mothers. This finding, and other secondary findings of increased normal vaginal births, and reduced augmentation, perineal trauma, and CS, support some of the CM literature which show a reduction in rates of pharmacological pain

relief, and some interventions during labour,[22 24-26]. These findings are in contrast to the parent education literature, hypnosis and psychoprophylaxis training literature for reduction of EDB during labour,[15 47 50 52 56-58]. The outcome of increase in positive attitude towards birth in the antenatal period and increased feelings of agency during labour and birth are supportive of the antenatal education literature,[15 16 42 49 56]. The finding that no individual technique was associated with reduced rates of EDB highlights the concept that these techniques form a 'toolkit' of techniques and represent an overall holistic approach toward labour and birth. The combination of active birth techniques with relaxation techniques is unique to this program.

The primary outcome measure of EDB was used for this study, rather than pain scores which are frequently used in other CM studies [22]. The objective measure of EDB has been identified as a mediating factor shown to influence labour interventions and mode of birth, which is described in the literature as the cascade of interventions [7 8 10 39 59]. The literature highlights the mechanism whereby an initial intervention during labour triggers subsequent interventions to manage the effects of the prior intervention. EDB has been shown to mediate this effect and is associated with outcomes such as augmentation during labour, instrumental vaginal birth, and CS [38]. This study demonstrates an impact on rates of EDB, as well as on rates of augmentation, perineal trauma and CS, and therefore may have an effect on the cascade of interventions. Therefore, caution is required when interpreting secondary outcome measures.

It remains important that methods used during labour are suitable for women's individual requirements and circumstances, and also account for conditions that may arise in the woman or infant during labour,[20]. This study demonstrates the capacity for a novel integrative antenatal education program using CM techniques to reduce interventions in normal labour.

Future research

Policy initiatives supporting normal birth require novel solutions, and this study provides good evidence for such an initiative, including the potential for a revision of clinical practice in antenatal education. Future health services research should include translation of study outcomes into clinical practice, involving a-priori cost effectiveness analysis, exploring key stakeholders' views about changing practice and undertake a multi-centred international study to assess the impact of the study in a broader context and beyond Australia. This article reports on the first implementation of this antenatal education program, and evaluates feasibility of conduct. We are seeking to establish a larger trial in a broader national and international setting whereby issues of implementation and generalisability may be addressed. As a first stage, these results are promising and further investigation is warranted.

Conclusion

The rise in interventions rates in labour and birth need to be addressed as a matter of priority as outlined by reviews of maternity services,[3 11] and international reports,[1 2]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of interventions including caesarean section,[4 6-8 20]. This study highlights the effectiveness of a novel integrated antenatal education approach, incorporating evidence-based CM techniques to reduce rates of EDB, leading to a reduction in other interventions in labour and birth, including caesarean section. This program is novel in its approach and forms a unique toolkit for women and partners to use in their labour and birth.

The re-orientation of antenatal education and the promotion of birth as a normal physiological event is critical if we are to reduce interventions in birth. This shift requires education and

support to help women manage the challenges of labour and birth. The results from this study demonstrate the potential effectiveness of the complementary therapies for labour and birth in providing an individualised, evidence-based, woman-centred, integrated approach to care, that reduces medical interventions and morbidity in labour.

Trial Registrations and ethics approvals

The study was approved by the Western Sydney University ethics committee (H9579), Northern Sydney Local Health District (NSLHD) ethics committee (1111-476M, NEAF: HREC/11/H/268), and has site specific approval at the Western Sydney LHD (WSLDH) ethics committee (SSA/12/N/58), and was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

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Contribution of authorship

KL, as the PhD student, was the main contributor to the development and design of the study, the conduct of the study, and drafting of the manuscript. CAS was the primary supervisor, and HGD was the second supervisor, and each assisted with the research design, review of data and manuscript drafts. AB is the third supervisor and assisted with research design, and review of manuscript.

Competing Interests

None to declare

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Data sharing statement

Extra data may be available upon request by emailing K.Levett@westernsydney.edu.au

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. WHO. Caesarean sections should only be performed when medically necessary. Executive summary. In: WHO, editor. Geneva: WHO, 2015:8.
3. Bryant R. Improving maternity services in Australia: The report of the maternity services review. In: Australia Co, editor. Canberra: Commonwealth of Australia, 2009.
4. Anim-Somuah M, Smyth RM, Jones L. Epidural versus non-epidural or no analgesia in labour. *The Cochrane database of Systematic Reviews* 2011(12):CD000331.
5. King T. Epidural anesthesia in labor benefits versus risks. *Journal of Nurse-Midwifery* 1997;42(5):377-88.
6. Dahlen H, Schmied V, Dennis CL, et al. Rates of obstetric intervention during birth and selected maternal and neonatal outcomes for low risk women born in Australia compared to those born overseas. *BMC Pregnancy and Childbirth* 2013;13(1):100.
7. 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(1):6-13.
8. Roberts CL, Tracy S, Peat B. Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *Brit Med J* 2000;321(7254):137-41.
9. Centre for Epidemiology and Evidence. New South Wales Mothers and Babies 2010. In: Evidence CfEa, editor. Sydney: NSW Ministry of Health. , 2012.
10. 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(5).
11. NSW Department of Health. Maternity - Towards Normal Birth in NSW. In: Health N, editor. *Policy Directive*. Sydney: NSW Health, 2010.
12. Zwelling E. The history of Lamaze continues: an interview with Elisabeth Bing. *Journal of Perinatal Education* 2000;9(1):15-21.
13. Zwelling E. Down memory lane: recollections of Lamaze International's First 50 Years. *Journal of Perinatal Education* 2010;19(3):11-16.
14. Svennson J, Barclay L, Cooke M. Effective Antenatal Education: Strategies Recommended by Expectant and New Parents. *Journal of Perinatal Education* 2008;17:33-42.
15. Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database of Systematic Reviews* 2007(3).
16. Jaddoe VW. Antenatal education programmes: do they work? *The Lancet* 2009;374(9693):863-64.
17. Smith CA, Collins CT, Cyna AM, et al. Complementary and alternative therapies for pain management in labour. *Cochrane Database of Systematic Reviews* 2006(4):CD003521.
18. National Institute of Health. National Center for Complemenary and Integrative Health. In: NIH, editor. *NCCIH*. Bethesda, Maryland: NIH, 2015:National Center.

19. Steel A, Adams J, Sibbritt D, et al. The influence of complementary and alternative medicine use in pregnancy on labor pain management choices: results from a nationally representative sample of 1,835 women. *J Altern Complement Med* 2014;20(2):87-97.
20. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. *Cochrane Database of Systematic Reviews* 2012;3:CD009234.
21. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ : British Medical Journal* 2008;337:a1655.
22. 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(0).
23. Betts D. Acupressure techniques for use during childbirth and pregnancy. *Childbirth solutions Online. Available at: VRL: http://www. Accessed 2015*. 2005.
24. Smith CA, Collins CT, Crowther CA, et al. Acupuncture or acupressure for pain management in labour. *Cochrane Database of Systematic Reviews* 2011(7):CD009232.
25. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. *Cochrane Database Syst Rev* 2011(12):CD009514.
26. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database of Systematic Reviews* 2012;2:CD009290.
27. Leap N, Dodwell M, Newburn M. Working with pain in labour. An overview of the evidence. *New Digest* 2010;49:22-26.
28. Field T. Yoga clinical research review. *Complementary therapies in clinical practice* 2011;17(1):1-8.
29. Copstick SM, Taylor KE, Hayes R, et al. Partner support and the use of coping techniques in labour. *Journal of psychosomatic research* 1986;30(4):497-503.
30. Leap N, Sandall J, Buckland S, et al. Journey to confidence: women's experiences of pain in labour and relational continuity of care. *Journal of Midwifery & Women's Health* 2010;55(3):234-42.
31. May C, Fletcher R. Preparing fathers for the transition to parenthood: Recommendations for the content of antenatal education. *Midwifery* 2013;29(5):474-78.
32. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *The British Journal Of Psychiatry: The Journal Of Mental Science* 1987;150:782-86.
33. Hodnett ED, Simmons-Tropea DA. The labour agentry scale: Psychometric properties of an instrument measuring control during childbirth. *Research in Nursing & Health* 1987;10(5):301-10.
34. IBM SPSS Statistics for Windows, Version 22.0 [program]. Armonk, KY: IBM Corp, 2013.
35. Li Z, Zeki R, Hilder L, et al. Australia's mothers and babies 2011. In: AIHW, editor. *Perinatal statistics series no. 28. Cat. no. PER 59*. Canberra: AIHW National Perinatal Epidemiology and Statistics Unit, 2013.
36. Fewtrell MS, Kennedy K, Singhal A, et al. How much loss to follow-up is acceptable in long-term randomised trials and prospective studies? *Arch Dis Child* 2008;93(6):458-61.

37. Betts D. The use of acupuncture as a routine pre-birth treatment. *Journal of Chinese Medicine - Hove* 2004:5-8.
38. 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(1):70-78.
39. Tracy SK, Tracy MB. Costing the cascade: estimating the cost of increased obstetric intervention in childbirth using population data. *BJOG: An International Journal of Obstetrics & Gynaecology* 2003;110(8):717-24.
40. Rouhe H, Salmela-Aro K, Toivanen R, et al. Obstetric outcome after intervention for severe fear of childbirth in nulliparous women - randomised trial. *BJOG* 2013;120(1):75-84.
41. Sjogren B, Thomassen P. Obstetric outcome in 100 women with severe anxiety over childbirth. *Acta obstetricia et gynecologica Scandinavica* 1997;76(10):948-52.
42. Ferguson S, Davis D, Browne J. Does antenatal education affect labour and birth? A structured review of the literature. *Women Birth* 2013;26(1):e5-e8.
43. Murphy Tighe S. An exploration of the attitudes of attenders and non-attenders towards antenatal education. *Midwifery* 2010;26(3):294-303.
44. Walker DS, Visger JM, Rossie D. Contemporary Childbirth Education Models. *The Journal of Midwifery & Women's Health* 2009;54(6):469-76.
45. Lumley J, Brown S. Attenders and Nonattenders at Childbirth Education Classes in Australia: How Do They and Their Births Differ? *Birth* 1993;20(3):123-30.
46. Shearman R, Bennett C. Maternity services in New South Wales--childbirth moves toward the 21st century. *Med J Aust* 1989;150(12):673-6.
47. 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 : an international journal of obstetrics and gynaecology* 2015.
48. Bergström M, Kieler H, Waldenström U. Natural childbirth vs antenatal education. *Midwives* 2009;12(4):21-21.
49. Byrne J, Hauck Y, Fisher C, et al. Effectiveness of a Mindfulness-Based Childbirth Education Pilot Study on Maternal Self-Efficacy and Fear of Childbirth. *Journal of Midwifery & Women's Health* 2014;59(2):192-97.
50. Cyna AM, Crowther CA, Robinson JS, et al. Hypnosis Antenatal Training for Childbirth: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2013;120(10):1248-59.
51. Koehn ML. Childbirth education outcomes: an integrative review of the literature. *J Perinat Educ* 2002;11(3):10-19.
52. Madden K, Middleton P, Cyna AM, et al. Hypnosis for pain management during labour and childbirth. *Cochrane Database of Systematic Reviews*: John Wiley & Sons, Ltd, 2012.
53. Lothian JA. Listening to mothers II: knowledge, decision-making, and attendance at childbirth education classes. *Journal of Perinatal Education* 2007;16(4):62-67.
54. Lothian JA. Childbirth education at the crossroads. *J Perinat Educ* 2008;17(2):45-9.
55. Gupta JK, Hofmeyr GJ. Position for women during second stage of labour. *Cochrane Database of Systematic Reviews* 2004(1):CD002006.

56. Bergström M, Kieler H, Waldenström U. Effects of natural childbirth preparation versus standard antenatal education on epidural rates, experience of childbirth and parental stress in mothers and fathers: a randomised controlled multicentre trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2009;116(9):1167-76.

57. Bergström M, Kieler H, Waldenström U. A randomised controlled multicentre trial of women's and men's satisfaction with two models of antenatal education. *Midwifery* 2011;27(6):e195-e200.

58. Cyna AM, McAuliffe GL, Andrew MI. Hypnosis for pain relief in labour and childbirth: a systematic review. *Brit J Anaesth* 2004;93(4):505-11.

59. Tracy SK, Sullivan E, Wang YA, et al. Birth outcomes associated with interventions in labour amongst low risk women: A population-based study. *Women and Birth* 2007;20(2):41-48.

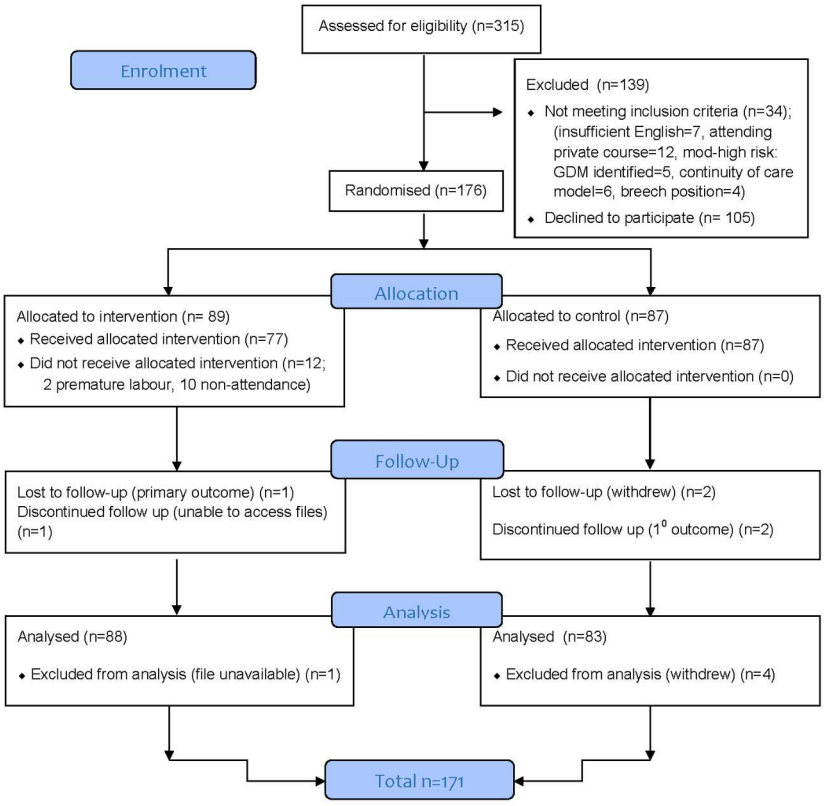

Figure 1: CONSORT Flowchart of CTLB Study

143x186mm (300 x 300 DPI)

Supplementary information

The Complementary Therapies for Labour and Birth study protocol, based on the She Births® course and the acupressure for labour and birth protocol,[1], consisted of a two-day course (no cost to participants) to be held at either Site H or Site N on a nominated weekend. The course consisted of the following program:

Complementary Therapies for Labour and Birth protocol –the program, philosophy and techniques, are designed to support a woman during her pregnancy and labour by introducing techniques to enhance a natural state of relaxation for the optimal birth experience,[2]. The program introduces concepts of birth as a natural physiological process, and evidence-based CM techniques by which the normal birth process can be managed,[3]. These are described below.

'Acupressure for pain relief in labour' protocol– Acupressure consists of applying moderate pressure to acu-points using locations described in Traditional Chinese Medicine (TCM) texts. The location and uses of a variety of acupressure points for the purpose of assisting the physiological processes of labour, as well as the emotional support for the woman were taught to the woman and her birth partner. A booklet accompanied this session to facilitate review and home practice, with suggestions for most appropriate uses of certain points and point combinations,[1].

Participants were advised to practice at home from 37 weeks' gestation, practicing once a week for five minutes at 37 weeks, followed by two to three times a week for 7-10 minutes at 38 weeks, four to five times a week for 10-15 minutes at 39 weeks, and after 40 weeks' gestation, they could use the induction combination of points every two hours to assist in bringing on labour.

Six main points used:

Sp-6 (Sanyinjiao) for induction and augmentation of labour

L.I.-4 (Hegu) for pain relief

G.B.-21 (Jianjing) has a descending action to aid the first and second stages of labour and can stimulate uterine contractions. Also useful for bleeding following birth.

Bl-32 (Ciliao) for pain relief

Ki-1 (Yongquan) for relaxation and calming effect, especially during transition

Bl-60 (Kunlun) used during first stage of labour, promotes the descent of the baby during labour

Other useful points

Pc-6 (Neiguan) for nausea and vomiting during labour, and can be especially useful if epidural analgesia used

Bl-67 (Zhiyin) for malposition of the baby prior to labour

St-44 (Neiting) for reflux

Point combinations

Sp-6 + L.I.-4 + Bl-32 for induction of labour

Bl-60 + L.I.-4 for posterior presentation during labour

Sp-6 + L.I.-4 for unestablished labour or failure to progress

Sp-6 + Bl-32 for swollen cervical lip at full dilation

G.B.-21 + L.I.-4 for failure to progress during second stage

Outline of the labour process in terms of the anatomy and physiology of birth – a description of what happens physically to the body during 'normal' labour and birth. The couples are taught about the anatomical structure of the uterus and the function of the three layers of the uterus in facilitating birth. The stages of labour are described and what the contractions may feel like and how long they are likely to last. The sympathetic and parasympathetic nervous systems are described and the reactions of the body when each are activated, and its effect during labour. Having an optimal mindset for the labour was also discussed. How participants could mentally approach labour as if they were training for an athletic event, and to have the right frame of mind to prepare for it. From a basis of knowledge and understanding of the stages of labour and the body's response, then further concepts can be introduced.

The hormonal cycle during birth - Hormones that are produced during the birth process were described and their effect on the body during stressed and relaxed states. The hormones discussed were oxytocin, relaxin, beta-endorphins, adrenalin and prolactin, and the natural cascade of these hormones that occur during an uninterrupted labour. Additionally, the effect on these hormones when pharmacological pain relief, or synthetic oxytocin (syntocinin) for induction and augmentation is introduced, was also described.

Techniques:

Breathing: Mindfulness of breath or conscious breathing combined with relaxation are powerful tools for labour [4]. There are three types of breathing techniques taught in Complete Birth: Blissful Belly (BB) breaths. Participants were instructed to breathe in through the nose to the count of 10, and then slow release to the count of 10. The goal was three breaths in one minute, but practice was required for most people to achieve this. Partners were instructed how to count their partner in, and how to use this technique during a contraction. This was

rehearsed numerous times during the course. The second technique was the Soft Sleep (SS) breaths that were to be used in between contractions and are the soft relaxed breathing that occurs when going to sleep. This was to re-focus the women between each contraction and conserve energy. The third technique is the Gentle Birthing (GB) breath, and is used to assist the descent of the baby during the second stage of labour. This technique is an alternative to active pushing during the second stage, and both techniques are practiced by the women to demonstrate the difference in focus. For the GB breath, the focus in on keeping the jaw loose, pressure on the out breath from the top of the abdominal muscles and the pelvis tilted slightly forward. In this way the perineum is also kept relaxed.

Relaxation and visualisation: a description of the relaxation response when the parasympathetic nervous system is activated was given to the participants. The relaxation techniques comprise of four guided relaxation exercises on a CD. These are practiced during the course and then given to women and partners for home practice as often as they wanted to do it. The four exercises included progressive relaxation, lotus flower, count down, visualisation of the ligaments and muscles of the pelvis. Included in the relaxation CDs were visualisations including seeing the baby coming into an optimal position; visualisation of the optimal birth experience; and visualisation of your special place in nature where you feel completely safe and relaxed.

Movement and yoga positions: Using positions with hips wide open, using gravity and your alignment to assist with labour's progress. Standing, leaning, using furniture, fit balls, partner support to aid the baby's descent. Movement should be effortless and meditative. Yoga positions encouraged relaxation, physiological positioning for labour, opening of the pelvis and downward descent of the baby, and can be performed by women in labour,[4]. There were five yoga postures taught:

Baddha Konassana (cobbler pose): which is a resting pose for between contractions. Spiralling movements can be added for pain relief or focusing concentration

Balasana (child's pose): which is also a resting pose for between contractions, and for regaining energy when tired. This position is also helpful when pain relief is sought from acupressure or massage techniques

Upavishta Konassana (legs wide stretch): for opening hips before labour, during pre-labour and in the first stage while comfortable

Marjaryasana (cat pose or stretch): for pain relief during and after contractions to stretch out the stomach muscles

Malasana (squat pose): used for upright positioning for pain relief and the descent of the baby during second stage. This can be modified with the use of chairs or cushions for a seated squat, or on the knees or with the support of the partner. This pose is practiced after 20 weeks and until 37 weeks' gestation for shorter periods of time, and can be held longer to assist with induction following 37 weeks. This posture is contraindicated if there is any pubic symphysitis present, or the placenta is low lying.

Massage: Massage techniques are useful during birth for pain relief,[5]. Two techniques were taught, and home practice was encouraged as often as the couples liked. The techniques were:

Strong massage technique is used to 'meet' the contraction where the woman is feeling the strongest sensation. The partner uses the heel of his/her hand and squeezes and rotates at the points on the buttocks, especially the piriformis muscle to interrupt pain perception during the contraction.

Endorphin technique is a soft technique used during the time between contractions to increase the release of natural opiates. Skin contact and soft rhythmic movements up and around the back, shoulders and arms is instructed.

Supplementary Table 1: CM therapies used during labour

Complementary Therapy Used	No EDA n=67 (%)	Yes EDA n=21 (%)	Risk ratio P value
Acupressure	29 (43.3%)	12 (57.1%)	0.78 [0.61-0.98] P=0.11
Breathing technique: Belly Breaths (first stage)	42 (62.7%)	11 (52.4%)	1.1 [0.23-2.04] p=0.68
Breathing technique 2: Gentle Birthing Breaths (second stage)	23 (34.3%)	8 (38.1%)	0.91 [0.7-1.2] p=0.56
Yoga	29 (43.3%)	11 (52.4%)	0.83 [0.65-6.79] p=0.22
Massage	30 (44.8%)	10 (47.6%)	0.91 [0.70-1.2] p=0.55
Visualisation	38 (56.7%)	11 (52.4%)	0.99 [0.72-1.35] p=1.0

References:

1. Betts D. Acupressure techniques for use during childbirth and pregnancy. Childbirth solutions Online Available at: VRL: http://www Accessed 2015 2005.
2. Buckley S. Undisturbed birth. Nature's blueprint for ease and ecstasy. Midwifery today with international midwife 2002(63):19-24.
3. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. Cochrane Database of Systematic Reviews 2012;**3**:CD009234.
4. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. Cochrane Database Syst Rev 2011(12):CD009514.
5. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. Cochrane Database of Systematic Reviews 2012;**2**:CD009290.

Complementary Therapies for Labour and Birth Study

POST PARTUM QUESTIONNAIRE: Labour Agentry Scale

PATIENT INITIALS: ___ ___ ___ MRN: __ __ __ __ __ __ __ __ __ __ Version 1:10/10/11

FEELINGS DURING CHILDBIRTH SCALE:

Please answer each question reflecting how you felt during your childbirth

1. I felt confident	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
2. I felt defeated	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
3. I felt important	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
4. I felt tense	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
5. I had a sense of understanding of what was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
6. I felt insecure	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
7. I felt relaxed	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
8. I felt competent	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
9. Someone or something else was in charge of my labour	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
10. I felt inadequate	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

11. I experienced a sense of distress	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
12. Everything seemed unclear and unreal	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
13. I was completely aware of everything that was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
14. I felt panicked	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
15. I felt like I was falling to pieces	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
16. I had a feeling of constriction and of being confined	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
17. I was in control	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
18. I experienced a sense of being with others who care	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
19. Everything made sense	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
20. I felt like I was dying	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
21. I felt like I was doing everything I should have been doing	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
22. I felt helpless	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
23. Everything seemed calm and peaceful	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

24. I experienced a sense of success	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
25. I felt powerless	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
26. I experienced a sense of failure	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
27. I was accepting of what was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
28. I felt capable	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
29. I felt bad about my behaviour during labour	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	1-2
Introduction				
Background	2	Scientific background and explanation of rationale		5
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	7
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	7-9
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	8-9
	4B		Details of how the interventions were standardized	8-9
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	8
Objectives	5	Specific objectives and hypotheses		
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		10
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	11

Randomization–sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	7
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	9
	11B		If blinded, method of blinding and description of the similarity of interventions†	10
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	12
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	7-9
Recruitment	14	Dates defining the periods of recruitment and follow-up		
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	13-14

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		15
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		16-18
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		18
Adverse events	19	All important adverse events or side effects in each intervention group		17
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	19
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	21-22
Overall evidence	22	General interpretation of the results in the context of current evidence		22

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.

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The Complementary Therapies for Labour and Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour

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The Complementary Therapies for Labour and Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour

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ABSTRACT:

Objective: To evaluate the effect of an antenatal integrative medicine education program in addition to usual care for nulliparous women on intrapartum epidural use.

Design: Open label, assessor blind, randomised controlled trial **(**RCT).

Setting: Two public hospitals in Sydney, Australia.

Population: 176 nulliparous women with low-risk pregnancies, attending hospital-based antenatal clinics.

Methods and Intervention: The Complementary Therapies for Labour and Birth protocol, based on the She Births® and Acupressure for labour and birth courses, incorporated six evidence-based complementary medicine (CM) techniques; acupressure, visualisation and relaxation, breathing, massage, yoga techniques and facilitated partner support. Randomisation occurred at 24-36 weeks' gestation, and participants attended a two-day antenatal education program, plus standard care, or standard care alone.

Main outcome measures: Rate of analgesic epidural use. Secondary: onset of labour, augmentation, mode of birth, newborn outcomes.

Results: There was a significant difference in epidural use between the two groups: study group (23.9%) standard care (68.7%) (risk ratio (RR): 0.37 [95% C.I.: 0.25, 0.55], p=<0.001). The study group participants reported a reduced rate of augmentation (RR=0.54 [95% C.I.: 0.38-0.77], p<0.0001); caesarean section (RR=0.52, [95% C.I.:0.31-0.87], p=0.017); length of second stage (MD= -0.32, [95% C.I.:-0.64, 0.002] p=0.05); any perineal trauma (0.88 [0.78-0.98] P=0.02); and resuscitation of the newborn (RR=0.47 [95% C.I.:0.25-0.87] p=<0.015).

There were no statistically significant differences found in spontaneous onset of labour, pethidine use, rate of post-partum haemorrhage (PPH), major perineal trauma (3rd and 4th degree tears/episiotomy), or admission to special care nursery/neonatal intensive care unit (SCN/NICU) (p=0.25).

Conclusion: The complementary therapies for labour and birth study protocol significantly reduced epidural use and caesarean section. This study provides evidence for integrative medicine as an effective adjunct to antenatal education and contributes to the body of best practice evidence.

Trial registry: Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

Article summary

Strengths and limitations of this study

- This is the first RCT in Australia that has investigated the effectiveness of a birth preparation course, integrating multiple complementary medicine (CM) techniques, for the support of natural birth for first time mothers. This suggests a reorientation of antenatal education towards normal birth and reflects current outcome measures in reports of maternity services policy directives.
- The study used self-administered, evidence-based, CM techniques, and blinded analysis to test an a priori hypothesis; and implemented a pragmatic design where participants

were free to use any of the techniques with no prescriptions or time limitations for use, allowing women and partners to have control and agency in their birth process and use information and CM tools to manage their own labours.

- The primary outcome measure of epidural block (EDB) was used, rather than frequently used pain scores, as the objective measure of EDB has been identified as a mediating factor in labour interventions and mode of birth, described as the cascade of interventions.
- Limitations of this study include higher enrolment of relatively wealthy, well-educated women, and relatively fewer participants from the area identified as lower socio-economic status. This is in line with previous CM research, but it is worth considering that the highest rates of epidural use and caesarean section, are also amongst this more advantaged population.
- Wider national and international implementation of this study is recommended to confirm results in a broader population and examine issues of generalisability.

INTRODUCTION:

There has been a rise in rates of intervention during labour and birth in most developed countries,[1 2], and the intervention rates in Australia during birth are well above the Organisation for Economic Cooperation and Development (OECD) averages,[3]. As these interventions increase, such as routine use of epidural block (EDB), so does the rate of instrumental births and associated medical interventions,[4-8]. Epidural rates in New South Wales (NSW) hospitals have shown a rapid rise over the past decade. In 2012, the state average for EDB use was 46.5%, however, there was broad variation within the state, ranging from 15% to 82.7% depending on region and hospital,[9 10]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of augmentation, assisted vaginal births and caesarean section (CS),[4 6-8 11].

Childbirth education has also seen a shift away from birth preparation,[12 13], to a curriculum broadly centred on overall parent education,[14]. Findings from a systematic review on childbirth education reports that the effectiveness of antenatal education for childbirth or parenthood supports the idea that educational interventions have a role in increasing feelings of self-confidence and agency, but demonstrates little impact on reducing interventions and associated morbidity in labour,[15 16].

Integrative medicine approaches, and complementary medicine (CM) in particular, may offer increased options for pain relief in birth,[17], and may be effective within the hospital antenatal education framework. The term integrative medicine is used when referring to incorporating CM or complementary therapies (CT) into mainstream health care,[18]. Recent Australian data suggest that 74.4% of women used some form of CM during pregnancy, and 66.7% of these women also

used non-pharmacological pain relief in labour,[19]. The Cochrane Systematic Review on pain management for labour finds some evidence to suggest that acupuncture, relaxation, massage, and water immersion may assist in the management of labour with few side effects, however more research is needed to establish efficacy of these techniques,[20].

In response to the need to establish the evidence base for CM interventions for pain management in labour we undertook a randomised controlled trial (RCT) to test the hypothesis that nulliparous women who undergo a CM antenatal education course, in addition to usual antenatal care would use less EDB than nulliparous women who receive usual antenatal care alone. Trials of complex interventions are difficult to conduct, and do not have linear models, and require a pragmatic approach to implementation,[21 22].

Methods

The Complementary Therapies for Labour and Birth (CTLB) study protocol included the existing She Births® Antenatal Education Program, with an acupressure component 'Acupressure techniques for use during childbirth and pregnancy' protocol,[23]. The study protocol was further adapted to reflect the evidence base for the CM techniques that were incorporated,[22 24-26].

From April 2012 to August 2013, women and their birth partners were recruited to a two-arm study consisting of a study group, who received the CTLB protocol in addition to usual care, and a control group, who received usual care alone. The study was an assessor-blinded, open-label pragmatic randomised controlled trial.

Participants

Women attending antenatal clinic were eligible to participate in the study from 24 to 34 weeks' gestation. They were provided with a participant information sheet for themselves and their birth partner. If they were interested and eligible to participate, women and partners signed individual consent forms. Women were eligible to enter the trial if they had a singleton pregnancy with a cephalic presentation, were low risk (no pre-existing medical complications or existing obstetric complications), were first time mothers (nulliparous), and had sufficient English to participate in a course. Women were excluded from entering the trial if they had pre-identified risk factors, were enrolled, or intending to enrol, in a 'continuity of care' midwifery program or in a private birth preparation course, were unable to attend a weekend course, had insufficient English for participation, or had been previously randomised to the trial. Recruitment was undertaken at two public hospitals in Sydney Australia that reflected diverse socio-economic areas. Recruitment was also conducted through the affiliated Western Sydney University (WSU) in response to newspaper and magazine advertisements. Participants who were recruited through WSU attended the courses at either of the two hospital study sites. All eligible women were approached in the antenatal clinic at site 1, as this was a smaller unit, individual contact was possible, and all clinics were attended regularly by the researcher. At site 2, the hospital was much larger, and more diverse with regard to structure of the clinics. Different clinics were attended, and eligible women at those clinics were approached. It was not possible to attend all clinics at this larger unit, and a range of clinics were selected on different weeks to achieve a representative sample of women. For site 3, where flyers and newspaper advertisements were used for recruitment, the response rate was quite low. All eligible women who contacted us through these means were

randomised to the study. We do not have data on the women who were not eligible to participate. The randomisation target was achieved quite quickly, and participation was popular.

Randomisation

We used a web-based computer generated randomisation sequence prepared centrally via the 'Sealed Envelope' website (https://www.sealedenvelope.com), and concealed centrally. Stratification occurred for hospital site, yielding three randomisation lists: 'Site H, 'Site N', and 'WSU'. Women were randomly allocated to either the study group or usual care alone. Randomisation occurred on a 1:1 allocation ratio to ensure equal numbers in each group at each hospital. All randomisations were entered by the investigator KL.

Intervention

Two-day courses (see supplementary file 1) were conducted over a weekend at one of the two hospital venues on a fortnightly to monthly basis over a 15 month period from May 2012 to August 2013. A total of 20 courses were conducted during this time. Participants attended prior to 36 weeks' gestation with a birth partner, and there was a maximum of 12 couples and a minimum of two couples at each course, with an average of eight couples per course. The study investigator (KL) ran each course.

The underlying philosophy and specific techniques included in the intervention program were designed to support a woman during her pregnancy and labour by introducing tools to enhance a natural state of relaxation (visualisation, breathing, massage, yoga) and facilitate labour progression (yoga, acupressure) and pain relief (breathing, acupressure, visualisation). The CTLB protocol introduces concepts of birth as a natural physiological process, and the idea of

'working with pain',[27] using evidence based CM tools by which the birth process can be managed,[20]. Women and partners received education about the physiology of normal birth.

The tools used were:

1. Visualisation,[25] - four guided visualisations rehearsed through the courses and given to participants on a CD to practice at home
2. Yoga postures,[28] – five postures and movements practiced to encourage relaxation, physiological position for labour, opening of the pelvis and downward descent of the baby
3. Breathing techniques,[20] - four breathing techniques were introduced: Soft Sleep Breaths (SS) for relaxation between contractions; Blissful Belly Breaths(BB) which were used during contractions for pain relief; Cleansing Calming Breaths(CC) used following contractions during the transition period of labour; and the Gentle Birthing Breath(GB) which was for use during the second stage of labour and encouraged descent of the baby avoiding active pushing and protection of the pelvic floor
4. Massage,[26] – two techniques were shown to partners; the endorphin massage used between contractions, which is a soft technique and encourages endorphin release; and the stronger massage which is used during contractions for pain relief and focuses on squeezing the buttock, especially the piriformis muscle to interrupt pain perception
5. Acupressure,[22 24], which uses six main points for use during labour selected from a previously published protocol,[23]. These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea, and positioning of baby
6. Facilitated partner support,[29-31], uses the concept of working with pain,[27] and instructs partners to advocate for the labouring woman, promoting her oxytocin levels and

minimising her stress with actions and techniques which are supportive for the birthing woman, and gives time for facilitated discussion and rehearsal by couples during the course.

Usual care consisted of the hospital based antenatal education course routinely available at each hospital. Antenatal education classes in Australia currently take a general descriptive approach to labour preparation, and emphasise parenting and post-partum issues as the main focus,[14]. Classes generally run weekly over six to seven weeks, or over 1-2 weekends, and include topics such as: pregnancy changes, exercise and back care during pregnancy, signs of labour, unexpected outcomes in labour and birth, pharmacological pain management, managing labour and birth, newborn care and breastfeeding, parenthood and baby's first weeks.

Blinding

Women, partners and the chief investigator (KL) were not blinded to group allocation. Group allocated was subsequently coded, and outcome measures were assessed and analysed blind to study group allocation. Midwives and doctors at each of the two main study hospitals and other sites were aware of the study, but delivery suite personnel were blinded to study participants' group allocation. Study course content was not disclosed to midwives to avoid any change in practice that may occur. Group allocation and data was linked by identification codes allowing the analysis to be undertaken blind.

A priori outcome measures

Primary outcome: Epidural use for pain relief.

Secondary outcomes: other pharmacological pain relief during labour; induction of labour; augmentation of labour; length of labour; instrumental delivery; caesarean section, post-partum

haemorrhage (PPH) (greater than 500ml blood loss); perineal trauma ($1^{st}/2^{nd}/3^{rd}/4^{th}$ degree tear/episiotomy); major or severe perineal trauma ($3^{rd}/4^{th}$ degree tear/episiotomy); Apgar scores <7 at 5 minutes; resuscitation of the newborn (with oxygen, suction, bag and mask, intubation, cardiac massage); admission to special care nursery/neonatal intensive care unit (NICU/SCN). Other outcomes included attitude towards birth and personal sense of control, as well as post-natal depression at 6 weeks, measured by the Edinburgh Post-Natal Depression Scale (EPDS) [32].

Questionnaires

For sense of personal control measures we used the Labour Agentry Scale (LAS),[33]. Within 72 hours following birth the LAS was administered to all women (see Supplementary file 2). The LAS contains 29 questions with a 7 point Likert-scale ranging from '1= almost always', to '7= rarely'. Therefore, scores could theoretically range from 29, indicating the most agency possible, to a high score of 203 indicating the lowest agency possible.Clinical outcomes were collected from hospital birth records, and the NSW Hospitals' birth summaries, which were accessed from the hospitals where the participant had given birth.

Analysis

An intention-to-treat analysis was used for the primary and secondary outcome data. Chi square and t-tests were used for univariate analysis of categorical and continuous data respectively. Significance was set at an alpha of 0.05, reporting on relative risk with a 95% confidence interval. Group allocation was coded by an independent researcher, and the investigator undertook the analysis blind to group allocation. Data was analysed using SPSS version 22,[34].

Sample size and power

The trial was designed to demonstrate an absolute reduction of 20% in epidural use from 46% in those women managed with usual care to 26% in those women who were randomised to the study. The rate of use of EDB was determined by published data for the two study hospitals in 2011 NSW Mothers and Babies Report,[35]. This required a total sample size of 170 women for an 80% power at a significance level of $p<0.05$. Recruitment continued until at least 170 women had been enrolled, and those randomised to the treatment group had either completed the course or were known to have missed their course, with 176 randomised and 171 completing the study. A low drop-out rate (<3%) was observed for the overall study population, and separately for each arm of the study (<5%),[36]. Primary outcome data was available for all consenting participants.

Results

We assessed 315 women for eligibility to participate in the study, of whom, 176 were randomised and 171 were included in the final analysis (Figure 1). Five women were lost to follow up. Women were randomised to the Study Group, n=89, or the Control Group, n=87. From the 315 women screened, 139 were excluded for the following reasons: 105 declined to participate, and 34 did not meet inclusion criteria (insufficient English (n=7), attending private birth preparation course (n=12), continuity of care model (n=6), mod-high risk: GDM (n=5), breech presentation (n=4). In the final analysis, there were 101 women included from site 1, 30 women from site 2, and 40 women from site 3.

INSERT FIGURE 1 HERE

All women completed the trial entry form at baseline including demographic information. Not all women answered each question in the trial entry form (Table 1). Following birth, the LAS was completed by 72 of the 88 women (82%) in the study group, and 52 of the 83 (62%) women in the control group.

Participants in the intervention group did not significantly differ from those in the control group in terms of their age, body mass index (BMI), cultural background, level of education, income, hospital status, or model of care (Table 1). Babies were not different in terms of average gestational age or weight at birth.

Table 1: Participant baseline demographics

Demographic Characteristics	Study Group *n* = 87	Control Group *n* = 85
Mean Age (years, ± SD)	30.41 (± 4.99)	28.87 (± 5.24)
BMI (mean ±SD)	22.66 (±4.47)	23.35 (±3.93)
Cultural Background:	***n* = 79 (%)**	***n* = 61 (%)**
Caucasian	58 (73.4)	44 (72.1)
Asian	10 (12.7)	11 (18.0)
Other	11 (13.9)	6 (9.9)
Income	***n* = 78 (%)**	***n* = 61 (%)**
<60	12 (15.4)	12 (19.7)
60-80K	7 (9.0)	10 (16.4)
80-100K	17 (21.8)	10 (16.4)
>100K	42 (53.5)	29 (47.5)
Total	**78**	**61**
Education	***n* = 81 (%)**	***n* = 60 (%)**
High School/Vocational	24 (29.6)	20 (33.3)
University/Post Grad	57 (70.4)	40 (66.7)
Hospital status	***n* = 87 (%)**	***n* = 85 (%)**
Public status	82 (94.3)	79 (92.9)
Private Status	5 (5.7)	6 (7.1)
Model of Care:	***n* = 87 (%)**	***n* = 85 (%)**
Midwifery	67 (82.7)	64 (85.3)
Doctors Care	4 (4.9)	7 (9.3)
Shared Care	10 (12.3)	4 (5.3)

Primary outcome

A statistically and clinically significant reduction in epidural rate was found for the intervention group compared with the control group. The overall unadjusted rate of EDB in the control group was 68.7%, and 23.9% in the study group (risk ratio (RR) = 0.35 [0.23-0.52] p=<0.0001), (Table 2). In addition to stratification of randomisation by site, a post-hoc analysis was performed for each site. The risk ratios were similar to the primary analysis (RR1=0.27 [0.12-0.60], RR2=0.31 [0.11-0.90], RR3=0.39 [0.23-0.65]). Using a true intention to treat analysis (ITT), we examined the data including data points for the five women who had dropped out, withdrawn or were lost to follow-up. There were four in the control group, and one in the study group. Using a best-case–worst-case scenario, we included the five cases with missing data for the primary outcome. If the four control group women did not have an EDB and the one study group woman did have an EDB (worst case), the results were still highly statistically significant with a risk ratio of: 0.40 [95% C.I.: 0.27, 0.59] p=<0.0001.

Table 2: Unadjusted primary and secondary outcomes measures:

OUTCOMES	Study 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**
Spontaneous Onset Labour	62 (70.5)	54 (65.1)	1.13 [0.82-1.57] p=0.51
Augmentation	25 (28.4)	48 (57.8)	0.54 [0.38-0.77] p<0.0001**
Mode of Birth: NVB	60 (68.2)	39 (47.0)	1.56 [1.12-2.17] p=<0.01**
Mode of Birth: CS	16 (18.2)	27 (32.5)	0.52 [0.31-0.87] p=0.017*
Mode of Birth: Instrumental	12 (13.6)	17 (20.5)	0.57 [0.30-1.09] p=0.09
Nitrous Oxide (Gas)	40 (45.5)	49 (59.0)	0.77 [0.57-1.03] p=0.092
Pethidine	19 (20.5)	15 (19.3)	1.11 [0.78-1.56] p=0.70
Any perineal trauma ^(Trauma/VB)	61/72 (84.7)^	54/56 (96.4)^	0.88 [0.78-0.98] p=0.02*
Major Perineal Trauma ^(Trauma/VB)	49/72 (68.1)^	37/56 (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
Resuscitation (Suction +/- O_2 / bag and mask)	12 (13.6)	24 (28.9)	0.47 [0.25-0.87] p=0.015*
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

* <0.05 ** <0.01

^ percentage is from all vaginal births: denominator = 72 in study group and 56 in control group. Major perineal trauma is defined as 3rd or 4th degree tear and episiotomy.

Secondary clinical outcomes

Women in the study group were more likely to experience a normal vaginal birth RR=1.56 [1.12-2.17], p=<0.01, and were less likely to have medical or surgical augmentation during labour (RR=0.54 [95% CI: 0.38-0.77], p<0.001), birth by caesarean section (RR=0.52 [0.31-0.87], p=0.01) or any perineal trauma (RR=0.88 [95% C.I.: 0.78-0.98], p=0.02). We also found a reduced length of second stage of labour (MD= -0.32 [95% CI: -0.64, 0.002], p=0.05) in the study group (Table 2). Babies of women in the study group were also less likely to require resuscitation by suction (plus or minus oxygen) or with bag and mask (RR=0.47 [95% C.I.:0.25-0.87], p=0.015). There were no differences in the rare outcomes of intubation or cardiac massage required at birth. Only one baby in the study group required intubation. Although not statistically significant there were some non-significant trends toward the study group having less likelihood of an instrumental vaginal birth (RR=0.57 [95% C.I.: 0.30-1.09], p=0.09), and nitrous oxide (gas) for pain management (RR= 0.77 [95% C.I.: 0.57-1.03], p=0.09).

No significant differences were found in the secondary outcome measures of spontaneous onset of labour (RR=1.13 [95% CI:0.82-1.57), p=0.51), pethidine use (RR=1.11 [95% CI: 0.65-2.2]), p=0.56), rates of post-partum haemorrhage (PPH) (RR=0.82 [95% CI: 0.41-1.61], p=0.85) or major perineal trauma (third/fourth degree tear or episiotomy), (RR=0.94 [95% CI: 0.57-1.55], p=0.85). No significant differences were found in Apgar scores (RR=0.99 [95% CI:0.95-1.03], p=1.0), or admission to the SCN/NICU (RR=0.59 [95% CI:0.24-1.46], p=0.25).

The length of the second stage of labour was 1 hour for the study group and1 hour 32 minutes for the control group giving a mean difference of 32 minutes (p=0.05). There were no significant differences between the groups for the first stage of labour or the total length of labour (see Table 3).

Table 3: Length of labour

OUTCOMES Length of Labour	Study Group (n=86) Mean (SD)	Control Group (n=83) Mean (SD)	Difference Statistic MD [95% CI] p-value
1st stage	6.12 (3.95)	6.53 (3.90)	MD= -0.41 [-1.79, 0.98] p=0.56
2nd stage	1.00 (0.87)	1.32 (0.98)	MD= -0.32 [-0.64, 0.002] p=0.05*
Total length of labour	7.43 (4.13)	8.20 (4.37)	MD= -0.77 [-2.26, 0.72] P=0.31

* p=0.05

The LAS questionnaire examined whether the course had any impact on attitudes and feelings about birth and women's feelings of agentry. The LAS was completed by 72 of the 88 women in the study group (82%), with an average score of 164.97 (SD=27.06). In the control group 52 of the 83 women (62%) completed the form, and had an average score of 150.92 (SD=30.03). We found a statistically significant difference between the two groups for this score (MD=14.05, 95% C.I.: 3.84-24.26, $p < 0.01$).

Given that a large number of women did not complete this form, there is the possibility of reporting bias in the results, we used a Levene's test for equality of variance, and found the variance between the two groups was not significantly different (p=0.59). Additionally, we did a post-hoc analysis to determine if any differences were present between the study group and the control group for baseline characteristics, controlling for responders vs non-responders. No differences were found between groups.

Six weeks following the birth, participants completed an EPDS questionnaire. However, there was a high rate of non-compliance with this form: 27 women in the study group and 41 women in the control group did not complete this form. There was no statistically significant difference between groups at 6-week follow-up for this cohort of women (see Table 4).

Table 4: Six-week post-partum: Edinburgh Postnatal Depression Scale

EDPS Postnatal	**Study Group *n* = 61 Mean (SD)**	**Control Group *n* = 42 Mean (SD)**	**Mean Difference 95% CI p-value**
Postnatal EPDS	4.49 (3.44)	4.07 (3.93)	MD= 0.42, [-1.03, 1.87] p=0.57

CI: Confidence interval; EPDS: Edinburgh Postnatal Depression Scale; MD: Mean difference

Analysis of patterns of CM use in labour reveal women in the study group used an average of 3.94 (SD=1.4) techniques during labour, and in the antenatal period practised various techniques for an average total of 12.94 (SD=9.7) times per week. Women in the control group did not report antenatal practice of techniques, but some (<5%) did report using techniques such as breathing or visualisation during the labour. No individual CM technique, nor amount of rehearsal in the antenatal period, was associated with reduced likelihood of EDB use in the study group, indicating an overall effect of the program.

To examine if there was any preference for therapies used during labour, we asked women in the study group (n=88) what specific CM therapies they used during labour. On average, women used 3.94 (SD=1.4) techniques over the duration of their labour, and in order of frequency used, Blissful Belly Breaths were used most frequently, by 60.2% of women; visualisation was used by

55.7%; acupressure by 46.6%; yoga and massage each by 45.5% of women; and Gentle Birthing Breaths were used by 35.2% of women during labour.

Discussion

Main findings

The RCT demonstrated the effectiveness of the CTLB study, based on the She Births® Antenatal Education Program and acupressure for labour protocol[37] for first time mothers, showing an absolute reduction of 45% and a relative reduction of 63% (RR=0.37, p<0.001) in epidural rate in the study group compared with controls. The study also showed increased rates of normal vaginal birth without surgical or mechanical assistance, and found reduced rates of augmentation in labour, length of second stage of labour, perineal trauma, caesarean section, and the need for resuscitation of the newborn. Univariate results for secondary outcomes should be interpreted with caution however, as these are likely to be related to the primary outcomes of EDB, which has been shown to mediate the effect these secondary outcomes,[38 39]. Additionally, where response rates for secondary analyses are low, results should be interpreted with caution.

We note that women in the control group experienced a higher than average rate of EDB use, augmentation and instrumental vaginal birth, which is consistent with data showing higher rates of intervention for nulliparous women compared with multiparous women [10]. The data for EDB use in this study are consistent with rates for women who are identified as being anxious [40 41]. Further research is needed to identify if women who are anxious are more likely to participate in antenatal education programs, and whether these women may benefit more from this type of intervention.

Current antenatal education has undergone a distinct shift towards normalising all births and preparing parents for parenthood. However, specific preparation for normal labour appears to have been de-emphasised in classes,[42-44]. Anecdotally, the majority of women attend routine antenatal education classes, but there is no current literature to provide accurate numbers,[45 46]. The results from the Cochrane Systematic Review suggest that while antenatal education aims to prepare women and partners for childbirth and early parenting, studies to date have shown a lack of high-quality evidence and a high variability of outcome measures. Therefore, the effects of antenatal education are still largely unknown,[15]. Studies exploring the use of antenatal education interventions, antenatal mindfulness training and self-hypnosis training have failed to demonstrate any reduction in the use of analgesia during labour and birth or on CS rates,[15 47-52].

Some commentators suggest that the impact of antenatal education in routine care may in fact be reinforcing medical management of labour and birth, and therefore not addressing the rising rates of medical pain relief and the associated complications,[7 42 44 53 54]. In this study, we assessed if women from the control group used CM techniques, as demonstration of cross over. However, less than five percent of women reported using these techniques during their labour, and this is unlikely to introduce any contamination to the results.

In this study we emphasised the importance of reorienting the concept of normal birth using an antenatal education framework and a variety of evidence-based integrative CM techniques to help women manage pain in labour and birth. One of the recently voiced concerns of using alternative birth positions, such as yoga postures and upright positions, is the potential for increased risk of perineal trauma,[55]. The data from our research showed a statistically significant reduction in perineal trauma for women. Among those women who had vaginal births, 84.7% of the study group compared with 96.4% of the control group sustained some kind of perineal

trauma during birth (RR=0.88, p=0.02). Techniques were rehearsed in the antenatal period with some acupressure for induction techniques practiced lightly from 37 weeks as per the published literature,[37]. This is reported to work with the hormones that are naturally present in the woman's body, but do not artificially induce contractions. This is an important safety outcome, and there were no differences in gestational age at birth.

The study provides evidence that antenatal education integrating CM techniques is an effective and viable method of managing pain, decreasing medical interventions, and increasing personal control for women. These clinically and statistically significant results are important in establishing an evidence base for the use and effectiveness of antenatal education programs incorporating CM techniques for the management of pain during childbirth as an adjunct to parent education offered as usual care. This program has the potential to provide a cost effective method of antenatal education. A costing and economic analysis of this program will be undertaken and reported elsewhere, providing a measure of relative benefit for outcomes saved. Reorienting antenatal education classes towards supporting normal birth and providing techniques to help women manage pain is an important contribution to reducing interventions in labour and birth.

Interpretation

Our study helps to address the question of whether antenatal education using CM techniques are effective in reducing rates of EDB in first time mothers. This finding, and other secondary findings of increased normal vaginal births, and reduced augmentation, perineal trauma, and CS, support some of the CM literature which show a reduction in rates of pharmacological pain

relief, and some interventions during labour,[22 24-26]. These findings are in contrast to the parent education literature, hypnosis and psychoprophylaxis training literature for reduction of EDB during labour,[15 47 50 52 56-58]. The outcome of increase in positive attitude towards birth in the antenatal period and increased feelings of agency during labour and birth are supportive of the antenatal education literature,[15 16 42 49 56]. The finding that no individual technique was associated with reduced rates of EDB highlights the concept that these techniques form a 'toolkit' of techniques and represent an overall holistic approach toward labour and birth. The combination of active birth techniques with relaxation techniques is unique to this program.

The primary outcome measure of EDB was used for this study, rather than pain scores which are frequently used in other CM studies [22]. The objective measure of EDB has been identified as a mediating factor shown to influence labour interventions and mode of birth, which is described in the literature as the cascade of interventions [7 8 10 39 59]. The literature highlights the mechanism whereby an initial intervention during labour triggers subsequent interventions to manage the effects of the prior intervention. EDB has been shown to mediate this effect and is associated with outcomes such as augmentation during labour, instrumental vaginal birth, and CS [38]. This study demonstrates an impact on rates of EDB, as well as on rates of augmentation, perineal trauma and CS, and therefore may have an effect on the cascade of interventions. Therefore, caution is required when interpreting secondary outcome measures.

It remains important that methods used during labour are suitable for women's individual requirements and circumstances, and also account for conditions that may arise in the woman or infant during labour,[20]. This study demonstrates the capacity for a novel integrative antenatal education program using CM techniques to reduce interventions in normal labour.

Future research

Policy initiatives supporting normal birth require novel solutions, and this study provides good evidence for such an initiative, including the potential for a revision of clinical practice in antenatal education. Future health services research should include translation of study outcomes into clinical practice, involving a-priori cost effectiveness analysis, exploring key stakeholders' views about changing practice and undertake a multi-centred international study to assess the impact of the study in a broader context and beyond Australia. This article reports on the first implementation of this antenatal education program, and evaluates feasibility of conduct. We are seeking to establish a larger trial in a broader national and international setting whereby issues of implementation and generalisability may be addressed. As a first stage, these results are promising and further investigation is warranted.

Conclusion

The rise in interventions rates in labour and birth need to be addressed as a matter of priority as outlined by reviews of maternity services,[3 11] and international reports,[1 2]. The high use of EDB for pain relief in labour has been identified as a contributing factor in rising rates of interventions including caesarean section,[4 6-8 20]. This study highlights the effectiveness of a novel integrated antenatal education approach, incorporating evidence-based CM techniques to reduce rates of EDB, leading to a reduction in other interventions in labour and birth, including caesarean section. This program is novel in its approach and forms a unique toolkit for women and partners to use in their labour and birth.

The re-orientation of antenatal education and the promotion of birth as a normal physiological event is critical if we are to reduce interventions in birth. This shift requires education and

support to help women manage the challenges of labour and birth. The results from this study demonstrate the potential effectiveness of the complementary therapies for labour and birth in providing an individualised, evidence-based, woman-centred, integrated approach to care, that reduces medical interventions and morbidity in labour.

Trial Registrations and ethics approvals

The study was approved by the Western Sydney University ethics committee (H9579), Northern Sydney Local Health District (NSLHD) ethics committee (1111-476M, NEAF: HREC/11/H/268), and has site specific approval at the Western Sydney LHD (WSLDH) ethics committee (SSA/12/N/58), and was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: **ACTRN12611001126909**).

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Contribution of authorship

KL, as the PhD student, was the main contributor to the development and design of the study, the conduct of the study, and drafting of the manuscript. CAS was the primary supervisor, and HGD was the second supervisor, and each assisted with the research design, review of data and manuscript drafts. AB is the third supervisor and assisted with research design, and review of manuscript.

Competing Interests

None to declare

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Data sharing statement

Extra data may be available upon request by emailing K.Levett@westernsydney.edu.au

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. WHO. Caesarean sections should only be performed when medically necessary. Executive summary. In: WHO, editor. Geneva: WHO, 2015:8.
3. Bryant R. Improving maternity services in Australia: The report of the maternity services review. In: Australia Co, editor. Canberra: Commonwealth of Australia, 2009.
4. Anim-Somuah M, Smyth RM, Jones L. Epidural versus non-epidural or no analgesia in labour. *The Cochrane database of Systematic Reviews* 2011(12):CD000331.
5. King T. Epidural anesthesia in labor benefits versus risks. *Journal of Nurse-Midwifery* 1997;42(5):377-88.
6. Dahlen H, Schmied V, Dennis CL, et al. Rates of obstetric intervention during birth and selected maternal and neonatal outcomes for low risk women born in Australia compared to those born overseas. *BMC Pregnancy and Childbirth* 2013;13(1):100.
7. 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(1):6-13.
8. Roberts CL, Tracy S, Peat B. Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *Brit Med J* 2000;321(7254):137-41.
9. Centre for Epidemiology and Evidence. New South Wales Mothers and Babies 2010. In: Evidence CfEa, editor. Sydney: NSW Ministry of Health. , 2012.
10. 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(5).
11. NSW Department of Health. Maternity - Towards Normal Birth in NSW. In: Health N, editor. *Policy Directive*. Sydney: NSW Health, 2010.
12. Zwelling E. The history of Lamaze continues: an interview with Elisabeth Bing. *Journal of Perinatal Education* 2000;9(1):15-21.
13. Zwelling E. Down memory lane: recollections of Lamaze International's First 50 Years. *Journal of Perinatal Education* 2010;19(3):11-16.
14. Svennson J, Barclay L, Cooke M. Effective Antenatal Education: Strategies Recommended by Expectant and New Parents. *Journal of Perinatal Education* 2008;17:33-42.
15. Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database of Systematic Reviews* 2007(3).
16. Jaddoe VW. Antenatal education programmes: do they work? *The Lancet* 2009;374(9693):863-64.
17. Smith CA, Collins CT, Cyna AM, et al. Complementary and alternative therapies for pain management in labour. *Cochrane Database of Systematic Reviews* 2006(4):CD003521.
18. National Institute of Health. National Center for Complemenary and Integrative Health. In: NIH, editor. *NCCIH*. Bethesda, Maryland: NIH, 2015:National Center.

19. Steel A, Adams J, Sibbritt D, et al. The influence of complementary and alternative medicine use in pregnancy on labor pain management choices: results from a nationally representative sample of 1,835 women. *J Altern Complement Med* 2014;20(2):87-97.
20. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. *Cochrane Database of Systematic Reviews* 2012;3:CD009234.
21. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ : British Medical Journal* 2008;337:a1655.
22. 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(0).
23. Betts D. Acupressure techniques for use during childbirth and pregnancy. *Childbirth solutions Online. Available at: VRL: http://www. Accessed 2015*. 2005.
24. Smith CA, Collins CT, Crowther CA, et al. Acupuncture or acupressure for pain management in labour. *Cochrane Database of Systematic Reviews* 2011(7):CD009232.
25. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. *Cochrane Database Syst Rev* 2011(12):CD009514.
26. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database of Systematic Reviews* 2012;2:CD009290.
27. Leap N, Dodwell M, Newburn M. Working with pain in labour. An overview of the evidence. *New Digest* 2010;49:22-26.
28. Field T. Yoga clinical research review. *Complementary therapies in clinical practice* 2011;17(1):1-8.
29. Copstick SM, Taylor KE, Hayes R, et al. Partner support and the use of coping techniques in labour. *Journal of psychosomatic research* 1986;30(4):497-503.
30. Leap N, Sandall J, Buckland S, et al. Journey to confidence: women's experiences of pain in labour and relational continuity of care. *Journal of Midwifery & Women's Health* 2010;55(3):234-42.
31. May C, Fletcher R. Preparing fathers for the transition to parenthood: Recommendations for the content of antenatal education. *Midwifery* 2013;29(5):474-78.
32. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *The British Journal Of Psychiatry: The Journal Of Mental Science* 1987;150:782-86.
33. Hodnett ED, Simmons-Tropea DA. The labour agentry scale: Psychometric properties of an instrument measuring control during childbirth. *Research in Nursing & Health* 1987;10(5):301-10.
34. IBM SPSS Statistics for Windows, Version 22.0 [program]. Armonk, KY: IBM Corp, 2013.
35. Li Z, Zeki R, Hilder L, et al. Australia's mothers and babies 2011. In: AIHW, editor. *Perinatal statistics series no. 28. Cat. no. PER 59*. Canberra: AIHW National Perinatal Epidemiology and Statistics Unit, 2013.
36. Fewtrell MS, Kennedy K, Singhal A, et al. How much loss to follow-up is acceptable in long-term randomised trials and prospective studies? *Arch Dis Child* 2008;93(6):458-61.

37. Betts D. The use of acupuncture as a routine pre-birth treatment. *Journal of Chinese Medicine - Hove* 2004:5-8.
38. 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(1):70-78.
39. Tracy SK, Tracy MB. Costing the cascade: estimating the cost of increased obstetric intervention in childbirth using population data. *BJOG: An International Journal of Obstetrics & Gynaecology* 2003;110(8):717-24.
40. Rouhe H, Salmela-Aro K, Toivanen R, et al. Obstetric outcome after intervention for severe fear of childbirth in nulliparous women - randomised trial. *BJOG* 2013;120(1):75-84.
41. Sjogren B, Thomassen P. Obstetric outcome in 100 women with severe anxiety over childbirth. *Acta obstetricia et gynecologica Scandinavica* 1997;76(10):948-52.
42. Ferguson S, Davis D, Browne J. Does antenatal education affect labour and birth? A structured review of the literature. *Women Birth* 2013;26(1):e5-e8.
43. Murphy Tighe S. An exploration of the attitudes of attenders and non-attenders towards antenatal education. *Midwifery* 2010;26(3):294-303.
44. Walker DS, Visger JM, Rossie D. Contemporary Childbirth Education Models. *The Journal of Midwifery & Women's Health* 2009;54(6):469-76.
45. Lumley J, Brown S. Attenders and Nonattenders at Childbirth Education Classes in Australia: How Do They and Their Births Differ? *Birth* 1993;20(3):123-30.
46. Shearman R, Bennett C. Maternity services in New South Wales--childbirth moves toward the 21st century. *Med J Aust* 1989;150(12):673-6.
47. 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 : an international journal of obstetrics and gynaecology* 2015.
48. Bergström M, Kieler H, Waldenström U. Natural childbirth vs antenatal education. *Midwives* 2009;12(4):21-21.
49. Byrne J, Hauck Y, Fisher C, et al. Effectiveness of a Mindfulness-Based Childbirth Education Pilot Study on Maternal Self-Efficacy and Fear of Childbirth. *Journal of Midwifery & Women's Health* 2014;59(2):192-97.
50. Cyna AM, Crowther CA, Robinson JS, et al. Hypnosis Antenatal Training for Childbirth: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2013;120(10):1248-59.
51. Koehn ML. Childbirth education outcomes: an integrative review of the literature. *J Perinat Educ* 2002;11(3):10-19.
52. Madden K, Middleton P, Cyna AM, et al. Hypnosis for pain management during labour and childbirth. *Cochrane Database of Systematic Reviews*: John Wiley & Sons, Ltd, 2012.
53. Lothian JA. Listening to mothers II: knowledge, decision-making, and attendance at childbirth education classes. *Journal of Perinatal Education* 2007;16(4):62-67.
54. Lothian JA. Childbirth education at the crossroads. *J Perinat Educ* 2008;17(2):45-9.
55. Gupta JK, Hofmeyr GJ. Position for women during second stage of labour. *Cochrane Database of Systematic Reviews* 2004(1):CD002006.

56. Bergström M, Kieler H, Waldenström U. Effects of natural childbirth preparation versus standard antenatal education on epidural rates, experience of childbirth and parental stress in mothers and fathers: a randomised controlled multicentre trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2009;116(9):1167-76.

57. Bergström M, Kieler H, Waldenström U. A randomised controlled multicentre trial of women's and men's satisfaction with two models of antenatal education. *Midwifery* 2011;27(6):e195-e200.

58. Cyna AM, McAuliffe GL, Andrew MI. Hypnosis for pain relief in labour and childbirth: a systematic review. *Brit J Anaesth* 2004;93(4):505-11.

59. Tracy SK, Sullivan E, Wang YA, et al. Birth outcomes associated with interventions in labour amongst low risk women: A population-based study. *Women and Birth* 2007;20(2):41-48.

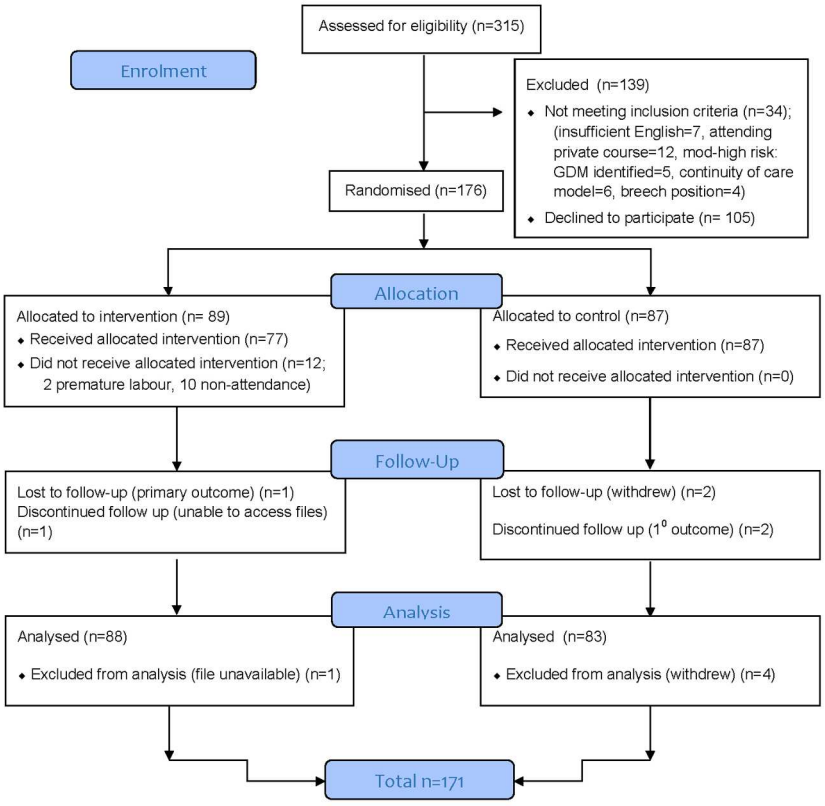

Figure 1: CONSORT Flowchart of CTLB Study

143x186mm (300 x 300 DPI)

Supplementary information

The Complementary Therapies for Labour and Birth study protocol, based on the She Births® course and the acupressure for labour and birth protocol,[1], consisted of a two-day course (no cost to participants) to be held at either Site H or Site N on a nominated weekend. The course consisted of the following program:

Complementary Therapies for Labour and Birth protocol –the program, philosophy and techniques, are designed to support a woman during her pregnancy and labour by introducing techniques to enhance a natural state of relaxation for the optimal birth experience,[2]. The program introduces concepts of birth as a natural physiological process, and evidence-based CM techniques by which the normal birth process can be managed,[3]. These are described below.

'Acupressure for pain relief in labour' protocol– Acupressure consists of applying moderate pressure to acu-points using locations described in Traditional Chinese Medicine (TCM) texts. The location and uses of a variety of acupressure points for the purpose of assisting the physiological processes of labour, as well as the emotional support for the woman were taught to the woman and her birth partner. A booklet accompanied this session to facilitate review and home practice, with suggestions for most appropriate uses of certain points and point combinations,[1].

Participants were advised to practice at home from 37 weeks' gestation, practicing once a week for five minutes at 37 weeks, followed by two to three times a week for 7-10 minutes at 38 weeks, four to five times a week for 10-15 minutes at 39 weeks, and after 40 weeks' gestation, they could use the induction combination of points every two hours to assist in bringing on labour.

Six main points used:

Sp-6 (Sanyinjiao) for induction and augmentation of labour

L.I.-4 (Hegu) for pain relief

G.B.-21 (Jianjing) has a descending action to aid the first and second stages of labour and can stimulate uterine contractions. Also useful for bleeding following birth.

Bl-32 (Ciliao) for pain relief

Ki-1 (Yongquan) for relaxation and calming effect, especially during transition

Bl-60 (Kunlun) used during first stage of labour, promotes the descent of the baby during labour

Other useful points

Pc-6 (Neiguan) for nausea and vomiting during labour, and can be especially useful if epidural analgesia used

Bl-67 (Zhiyin) for malposition of the baby prior to labour

St-44 (Neiting) for reflux

Point combinations

Sp-6 + L.I.-4 + Bl-32 for induction of labour

Bl-60 + L.I.-4 for posterior presentation during labour

Sp-6 + L.I.-4 for unestablished labour or failure to progress

Sp-6 + Bl-32 for swollen cervical lip at full dilation

G.B.-21 + L.I.-4 for failure to progress during second stage

Outline of the labour process in terms of the anatomy and physiology of birth – a description of what happens physically to the body during 'normal' labour and birth. The couples are taught about the anatomical structure of the uterus and the function of the three layers of the uterus in facilitating birth. The stages of labour are described and what the contractions may feel like and how long they are likely to last. The sympathetic and parasympathetic nervous systems are described and the reactions of the body when each are activated, and its effect during labour. Having an optimal mindset for the labour was also discussed. How participants could mentally approach labour as if they were training for an athletic event, and to have the right frame of mind to prepare for it. From a basis of knowledge and understanding of the stages of labour and the body's response, then further concepts can be introduced.

The hormonal cycle during birth - Hormones that are produced during the birth process were described and their effect on the body during stressed and relaxed states. The hormones discussed were oxytocin, relaxin, beta-endorphins, adrenalin and prolactin, and the natural cascade of these hormones that occur during an uninterrupted labour. Additionally, the effect on these hormones when pharmacological pain relief, or synthetic oxytocin (syntocinin) for induction and augmentation is introduced, was also described.

Techniques:

Breathing: Mindfulness of breath or conscious breathing combined with relaxation are powerful tools for labour [4]. There are three types of breathing techniques taught in Complete Birth: Blissful Belly (BB) breaths. Participants were instructed to breathe in through the nose to the count of 10, and then slow release to the count of 10. The goal was three breaths in one minute, but practice was required for most people to achieve this. Partners were instructed how to count their partner in, and how to use this technique during a contraction. This was

rehearsed numerous times during the course. The second technique was the Soft Sleep (SS) breaths that were to be used in between contractions and are the soft relaxed breathing that occurs when going to sleep. This was to re-focus the women between each contraction and conserve energy. The third technique is the Gentle Birthing (GB) breath, and is used to assist the descent of the baby during the second stage of labour. This technique is an alternative to active pushing during the second stage, and both techniques are practiced by the women to demonstrate the difference in focus. For the GB breath, the focus in on keeping the jaw loose, pressure on the out breath from the top of the abdominal muscles and the pelvis tilted slightly forward. In this way the perineum is also kept relaxed.

Relaxation and visualisation: a description of the relaxation response when the parasympathetic nervous system is activated was given to the participants. The relaxation techniques comprise of four guided relaxation exercises on a CD. These are practiced during the course and then given to women and partners for home practice as often as they wanted to do it. The four exercises included progressive relaxation, lotus flower, count down, visualisation of the ligaments and muscles of the pelvis. Included in the relaxation CDs were visualisations including seeing the baby coming into an optimal position; visualisation of the optimal birth experience; and visualisation of your special place in nature where you feel completely safe and relaxed.

Movement and yoga positions: Using positions with hips wide open, using gravity and your alignment to assist with labour's progress. Standing, leaning, using furniture, fit balls, partner support to aid the baby's descent. Movement should be effortless and meditative. Yoga positions encouraged relaxation, physiological positioning for labour, opening of the pelvis and downward descent of the baby, and can be performed by women in labour,[4]. There were five yoga postures taught:

Baddha Konassana (cobbler pose): which is a resting pose for between contractions. Spiralling movements can be added for pain relief or focusing concentration

Balasana (child's pose): which is also a resting pose for between contractions, and for regaining energy when tired. This position is also helpful when pain relief is sought from acupressure or massage techniques

Upavishta Konassana (legs wide stretch): for opening hips before labour, during pre-labour and in the first stage while comfortable

Marjaryasana (cat pose or stretch): for pain relief during and after contractions to stretch out the stomach muscles

Malasana (squat pose): used for upright positioning for pain relief and the descent of the baby during second stage. This can be modified with the use of chairs or cushions for a seated squat, or on the knees or with the support of the partner. This pose is practiced after 20 weeks and until 37 weeks' gestation for shorter periods of time, and can be held longer to assist with induction following 37 weeks. This posture is contraindicated if there is any pubic symphysitis present, or the placenta is low lying.

Massage: Massage techniques are useful during birth for pain relief,[5]. Two techniques were taught, and home practice was encouraged as often as the couples liked. The techniques were:

Strong massage technique is used to 'meet' the contraction where the woman is feeling the strongest sensation. The partner uses the heel of his/her hand and squeezes and rotates at the points on the buttocks, especially the piriformis muscle to interrupt pain perception during the contraction.

Endorphin technique is a soft technique used during the time between contractions to increase the release of natural opiates. Skin contact and soft rhythmic movements up and around the back, shoulders and arms is instructed.

Supplementary Table 1: CM therapies used during labour

Complementary Therapy Used	No EDA n=67 (%)	Yes EDA n=21 (%)	Risk ratio P value
Acupressure	29 (43.3%)	12 (57.1%)	0.78 [0.61-0.98] P=0.11
Breathing technique: Belly Breaths (first stage)	42 (62.7%)	11 (52.4%)	1.1 [0.23-2.04] p=0.68
Breathing technique 2: Gentle Birthing Breaths (second stage)	23 (34.3%)	8 (38.1%)	0.91 [0.7-1.2] p=0.56
Yoga	29 (43.3%)	11 (52.4%)	0.83 [0.65-6.79] p=0.22
Massage	30 (44.8%)	10 (47.6%)	0.91 [0.70-1.2] p=0.55
Visualisation	38 (56.7%)	11 (52.4%)	0.99 [0.72-1.35] p=1.0

References:

1. Betts D. Acupressure techniques for use during childbirth and pregnancy. Childbirth solutions Online Available at: VRL: http://www Accessed 2015 2005.
2. Buckley S. Undisturbed birth. Nature's blueprint for ease and ecstasy. Midwifery today with international midwife 2002(63):19-24.
3. Jones L, Othman M, Dowswell T, et al. Pain management for women in labour: an overview of systematic reviews. Cochrane Database of Systematic Reviews 2012;**3**:CD009234.
4. Smith CA, Levett KM, Collins CT, et al. Relaxation techniques for pain management in labour. Cochrane Database Syst Rev 2011(12):CD009514.
5. Smith CA, Levett KM, Collins CT, et al. Massage, reflexology and other manual methods for pain management in labour. Cochrane Database of Systematic Reviews 2012;**2**:CD009290.

Complementary Therapies for Labour and Birth Study

POST PARTUM QUESTIONNAIRE: Labour Agentry Scale

PATIENT INITIALS: ___ ___ ___ MRN: __ __ __ __ __ __ __ __ __ __ Version 1:10/10/11

FEELINGS DURING CHILDBIRTH SCALE:

Please answer each question reflecting how you felt during your childbirth

1. I felt confident	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
2. I felt defeated	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
3. I felt important	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
4. I felt tense	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
5. I had a sense of understanding of what was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
6. I felt insecure	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
7. I felt relaxed	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
8. I felt competent	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
9. Someone or something else was in charge of my labour	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
10. I felt inadequate	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

11. I experienced a sense of distress	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
12. Everything seemed unclear and unreal	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
13. I was completely aware of everything that was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
14. I felt panicked	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
15. I felt like I was falling to pieces	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
16. I had a feeling of constriction and of being confined	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
17. I was in control	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
18. I experienced a sense of being with others who care	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
19. Everything made sense	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
20. I felt like I was dying	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
21. I felt like I was doing everything I should have been doing	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
22. I felt helpless	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
23. Everything seemed calm and peaceful	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

24. I experienced a sense of success	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
25. I felt powerless	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
26. I experienced a sense of failure	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
27. I was accepting of what was happening	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
28. I felt capable	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**
29. I felt bad about my behaviour during labour	**Almost always**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	**Rarely**

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	1-2
Introduction				
Background	2	Scientific background and explanation of rationale		5
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	7
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	7-9
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	8-9
	4B		Details of how the interventions were standardized	8-9
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	8
Objectives	5	Specific objectives and hypotheses		
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		10
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	11

Randomization–sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	7
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	9
	11B		If blinded, method of blinding and description of the similarity of interventions†	10
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	12
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	7-9
Recruitment	14	Dates defining the periods of recruitment and follow-up		
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	13-14

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		15
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		16-18
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		18
Adverse events	19	All important adverse events or side effects in each intervention group		17
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	19
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	21-22
Overall evidence	22	General interpretation of the results in the context of current evidence		22

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.

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

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 and labour. *BMJ Open* 2016;6:e010691 doi:10.1136/bmjopen-2015-010691.

There are several amendments to this article:

Reference 23 should be Betts D. Acupressure techniques for use during childbirth and pregnancy. http://acupuncture.rhizome.net.nz (accessed 2015 2005).

The sentence: Acupressure,[22 24] which uses six main points for use during labour selected from a previously published protocol.[23] These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea and positioning of baby.

Should read: Acupressure, [22 24] which uses six main points for use during labour selected from a previously published protocol.[23] The participants were given DVDs of the acupressure protocol[23] to take home for practice. These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea and positioning of baby.

The sentence: The LAS contains 29 questions with a seven-point Likert scale ranging from '1=almost always', to'7=rarely'. Therefore, scores could theoretically range from 29, indicating the highest control possible, to a high score of 203 indicating the lowest agency possible.

Should read: The LAS contains 29 questions with a seven-point Likert scale ranging from '1=almost always', to'7=rarely'. Therefore, scores could theoretically range from 29, indicating the lowest control possible, to a high score of 203 indicating the highest agency possible.

The acknowledgements have been corrected to include: Dr Debra Betts provided the acupressure protocol for labour and birth and can be accessed at this address: https://acupuncture.rhizome.net.nz/). Dr Debra Betts (debra.betts@rhizome.net.nz) and Tom Kennedy (tzkennedy@hotmail.com) provided the DVD for the study participants. None were directly involved in this study.

Reference 1 in the supplementary data has been corrected to:

Reference 1: Betts D. Acupressure techniques for use during childbirth and pregnancy. http://acupuncture.rhizome.net.nz (accessed 2015 2005).

BMJ Open 2016;**6**:e010691corr1. doi:10.1136/bmjopen-2015-010691corr1