THE COMPLETE BIRTH STUDY

EFFECTIVENESS OF A COMPLEX ANTEMNATAL EDUCATION PROGRAM INCORPORATING COMPLEMENTARY MEDICINE TECHNIQUES FOR PAIN RELIEF IN LABOUR AND BIRTH FOR FIRST-TIME MOTHERS: A MIXED METHODS STUDY

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A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy, National Institute of Complementary Medicine, School of Science and Health, University of Western Sydney.

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DECLARATION

I, Katherine Levett declare that this thesis, submitted in fulfilment of the requirements of the award of PhD, in the National Institute of Complementary Medicine, in the School of Science and Health, University of Western Sydney, is wholly my work unless otherwise referenced or acknowledged. This document has not been submitted, either wholly or in part, to any other educational institution.

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DATE:

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Glossary of terms

ATBQ  Attitude Towards Birth Questionnaire
CAM  Complementary and alternative medicine
CM  Complementary medicine
Complete Birth  The Complete Birth Study: Evidence-based CM techniques combined to form study workshop. Based on She Births® program. Acupressure component based on Acupressure for labour and birth protocol (Betts 2005).
CS  Caesarean section
EA  Electro-acupuncture
EDB  Epidural block
EPDS  Edinburgh Postnatal Depression Scale
HKH  Hornsby Ku-ring-gai Hospital
LAS  Labour Agentry Scale
TCM  Traditional Chinese medicine
MA  Manual acupuncture
MMR  Mixed methods research
PPH  Post-partum haemorrhage
Primipara  A women pregnant for the first time (over 20 weeks’ gestation)
Primiparous  A first pregnancy (over 20 weeks’ gestation)
RCT  Randomised controlled trial
Abstract:

Background: Reviews of maternity services in Australia have called for a reduction in interventions and an increase in education and support to increase rates of normal birth. Evidence suggests that selected complementary therapies (CM) are effective during labour to assist with the management of pain, and in decreasing interventions. Antenatal education, in the Australian maternity context, has shifted from its original focus of birth preparation, to a broader focus on overall pregnancy, birth and parenting information. The aim of this study was to evaluate the effectiveness of a complementary therapies antenatal education package: The ‘Complete Birth Study’, to reduce rates of epidural block (EDB) and other outcomes in low-risk first-time mothers (primiparas). Additionally, we explored the experiences of women, partners and midwives in the use and preferences of complementary therapies during birth.

Method: This mixed methods study was implemented in two public hospitals in Sydney Australia, reflecting two diverse socio-economic areas. One hundred and seventy one low-risk primiparous women were recruited to the study, and were randomised to receive the Complete Birth Study package plus usual care, or to usual care alone. An RCT of the intervention was conducted, and comprised six CM techniques including: acupressure; yoga; massage; visualisation/relaxation; breathing techniques; continuous partner support; as well as education about normal birth physiology, plus standard antenatal care and compared this with standard antenatal care alone. Birth outcome data were obtained from hospital birth summaries, and women’s sense of control was evaluated using the Labour Agentry Scale and Attitude Toward Birth Questionnaires. Data were analysed using an intention to treat analysis. To examine the selective use, rehearsal and preferences of women and partners in using CM techniques, in-depth interviews were conducted with a sub-group of study participants, 13 women and 7 partners, at six weeks’ post-partum. To examine midwives use and preference for CM techniques, a focus group with 12 midwives at the higher recruiting study hospital was conducted following completion of recruitment. Thematic analysis was used to analyse the transcribed in-depth interview and focus group data.
Results: Birth outcome data showed a significant reduction in rates of EDB as the primary outcome measure. An absolute reduction of 45%, and a relative reduction of 65% (RR=0.35 [95% C.I.: 0.23-0.52], p<0.001) in the EDB rate was demonstrated in the study group compared with the control group. The Complete Birth Study was also effective in significantly reducing secondary outcomes, such as rates of augmentation, length of second stage labour, CS and resuscitation of the newborn, and showing a trend towards reducing instrumental vaginal births and major perineal trauma. This study also provides evidence for an increase in positive attitude towards birth in the antenatal period and increased feelings of agency of control during labour and birth. In characterising the effectiveness of the program and its components through in-depth interviews with women and partners and a focus group with midwives, the overarching theme identified was ‘making sense of labour and birth’. In examining how women, partners and midwives used the CM techniques to make sense of the labour and birth, three major themes were identified: ‘working for normal’, ‘having a toolkit’, and ‘finding what works’. Women and partners identified acupressure, breathing techniques and yoga as the most useful therapies.

Conclusions: This mixed methods study provides evidence that antenatal education using CM techniques is an effective and viable method of managing pain during labour, increasing personal control for women, enabling partners and midwives to provide appropriate support, and thereby reducing some medical interventions and increasing the normal birth rate. These significant results demonstrate the effectiveness of providing an independent educational program, using evidence-based practices, and incorporating midwifery and CM philosophies, through the public hospital system. This research provides us with an opportunity to contribute a valuable dialogue to inform evidence-based policy decision-making addressing the specific challenges of current antenatal education and maternity care in NSW.

Abstract
Chapter 1 – OVERVIEW AND CHAPTER OUTLINE

1.1 Thesis title

The Complete Birth Study: Effectiveness of a complex antenatal education program incorporating complementary medicine techniques for pain relief in labour and birth for first-time mothers: a mixed methods study.

1.2 Statement of the problem

In contemporary Western maternity settings, most births now occur in hospitals, and with this change of birthplace from home to hospital, labour and birth have increasingly become medicalised. Currently in Australia, more than 96% of women who give birth do so in a hospital (Li, Zeki, Hilder, & Sullivan, 2013), with maternity care being predominantly provided through medical-led models of care (Bertran, Merialdi, & Lauer, 2007; Gibbons et al., 2010). With this move from home to hospital, birth, which was once largely social, is now largely medical (Dahlen, Homer, Leap, & Tracy, 2011) and women are no longer exposed to the birthing practices and social supports that were present in the past (Pitcock & Clark, 1992). As obstetricians increasingly manage labour and birth, interventions previously reserved for high-risk pregnant women, such as routine induction of labour and administration of an epidural block (EDB) for pain relief, have become more commonly used and even considered standard management for low-risk women (American College of Obstetricians and Gynecologists & Society for Maternal-Fetal Medicine, 2014b; Anderson, 2004; Benoit, Zadoroznyj, Hallgrimsdottir, Treloar, & Taylor, 2010; Lauer, Betrán, Merialdi, & Wojdyla, 2010). This is especially the case with women having their first baby (Dahlen et al., 2012; Roberts, Tracy, & Peat,
The routine use of EDBs for pain relief in labour has been identified as a major contributing factor to resulting intervention in birth, such as rising rates of assisted vaginal births and caesarean section (CS) (Dahlen, Schmied, Dennis, & Thornton, 2013; Green & Baston, 2007; Roberts, Tracy, & Peat, 2000b). For this reason, investigating methods to reduce rates of EDB use has become a priority, and maternity services reviews are calling for a decrease in these interventions and for the promotion of more normal birth (NSW Department of Health, 2010).

Childbirth education has also seen a shift, from being independent of the hospital system and primarily a woman-centred program for the preparation of natural birth (Zwelling, 2000, 2010) to being embedded within the hospital system and focusing on parent education. Medical management of labour and birth are now part of the teaching curriculum and accepted as part of normal birth (Ferguson, Davis, & Browne, 2013; Lothian, 2007, 2008a; Walker, Visger, & Rossie, 2009).

Complementary medicine (CM) may offer increased options for pain relief in physiological birth (Smith, Collins, Cyna, & Crowther, 2006) and may be effective within the hospital antenatal education framework and maternity setting. CM’s philosophical framework is supportive of a holistic approach to women’s needs and traditional concepts of midwifery. It is also independent from current maternity hospital systems. However, the evidence for CM is controversial and inconsistent (Levett, Smith, Dahlen, & Bensoussan, 2014; Verhoef et al., 2005; Walach, Falkenberg, Fonnebo, Lewith, & Jonas, 2006; Witt, 2011) and further research is needed to guide women and their healthcare providers’ decisions to use these modalities.
1.3 Background

1.3.1 Rising rates of medical interventions

With increasing medical management of all aspects of labour and birth, a concerning rise in rates of intervention has been seen in most developed countries (Gibbons et al., 2010). In Australia, most births occur in hospitals with highly trained obstetricians, midwives and allied health professionals. Thus the dominant system of medical-led care has assumed management of labour and birth (Green & Baston, 2007). Today, the priorities of obstetric practice are the safety of the mother and newborn, and pain relief in labour (Simkin, 1996), and these priorities have become embedded in our sociological view of birth (Pincus, 2013; Pitcock & Clark, 1992). There is a high incidence of surgical and technological interventions during birth, and a low threshold for giving pharmacological pain relief. The maternal and neonatal mortality rates in Australia are among the lowest in the world (Bryant, 2009). However, mortality rates have plateaued, and the intervention rates during birth are rising and are well above OECD (Organisation for Economic Co-operation and Development) averages (Bryant, 2009). As interventions such as routine use of EDBs increase, so does the rate of instrumental births and associated medical interventions (Dahlen, Schmied, et al., 2013; Green & Baston, 2007; King, 1997; Roberts et al., 2000a).

Rates of EDB use in New South Wales (NSW) hospitals have shown a rapid rise over the past decade. The 2012 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 (Centre for Epidemiology and Evidence, 2012). Additionally, these rates differed considerably between the public and private systems (Dahlen et
al., 2012). Rates of CS have also seen a rapid rise. The 2013 Australian CS rate was 32.2% compared with an OECD average of 26.9% (OECD, 2013). However, wide variability also exists across regions, states and institutions (Dahlen et al., 2012; Senate Committee, 1999). This level of intervention is considered high, and there is increasing recognition of the associated morbidities being seen in Australian women as a result (NSW Department of Health, 2010; Roxon, 2008).

Reduction of medical interventions and the reorientation of birth as a normal physiological event have been recurrent themes for 30 years. In 1985 the World Health Organization (WHO) stated that there was no justification for CS rates to exceed 10–15% of births in developed nations, due to the increasing risk of morbidity without commensurate benefits (WHO, 1985). In 2015, WHO restated that there is no increased benefit from a CS rate that exceeds 10–15%, and CS should only be used where medically necessary (WHO & HRP, 2015). In spite of this recommendation, the CS rate in Australia continues to rise (Australian Bureau of Statistics, 2012; Centre for Epidemiology and Evidence, 2012). In a follow-up report of the 1985 recommendations, WHO reported that rising CS rates in developed nations are associated with three factors: increased income per capita (demand); increased ability to provide the service, with increasing care given by obstetricians (supply); and, most significantly, the healthcare system itself. The healthcare system relates to the legal framework in which the decisions for health care are made (Lauer et al., 2010).

Since the Sherman report in 1989 (NSW Health Department, 1989a), which called for the reorientation of birth as a normal event, repeated calls for the reduction of unnecessary interventions and the provision of low-risk normal birthing options for
women have been made by Australian state and federal reviews of maternity services (Bryant, 2009; NSW Department of Health, 2010; Roxon, 2008; Senate Committee, 1999).

1.3.2 The medicalised birth

Childbirth and the management of pain in childbirth has undergone a fundamental change from a paradigm where birth is a normal physiological event, managed with strong social and emotional supports, to a medical paradigm primarily managed by pharmacological methods (Kennedy, Grant, Walton, Shaw-Battista, & Sandall, 2010; NHS, 2007; NSW Department of Health, 2010; Romano & Lothian, 2008). The belief that pain is not necessary to the childbirth process and can be medically managed is prevalent in current thinking (Green & Baston, 2007). The drivers for medicalised birth and pharmacological management of pain are numerous, with many contributing factors, such as: characteristics of the hospital setting, workforce practices, financial and legal constraints and pressures, maternal characteristics and cultural norms (Cameron, Roberts, & Peat, 2004; Green & Baston, 2007; Johanson, Newburn, & Macfarlane, 2002; McCarthy, Rigg, Cady, & Cullinane, 2007). The consequence of routinely using medical management previously reserved for high-risk women is that it is now considered part of a ‘normal’ birth (Johanson et al., 2002). Routine interventions include induction and augmentation of labour, continuous electronic monitoring, routine vaginal examination, EDB, instrumental delivery, episiotomy and CS (NSW Department of Health, 2010). Such interventions are expensive, often unnecessary (Dahlen, Downe, Duff, & Gyte, 2013), and can contribute to morbidity, dissatisfaction and loss of autonomy for many women (Declercq, Sakala, Corry, Applebaum, & Herrlich, 2014; Goodman, Mackey, & Tavakoli, 2004; Green & Baston, 2003).
Additionally, with increasing interventions, the idea of what constitutes a normal or a high-risk birth is changing. Interventions once associated with high-risk deliveries, such as active management with augmentation of labour, are now commonly seen in low-risk labours. The advent of ‘active management of labour’ (O’Driscoll & Stronge, 1973), with augmentation of labour and other interventions, was intended to reduce complications from very long labours, traditionally more than 24 hours. With this active management, the average length of labour shortened, and what was previously considered a normal length of labour accordingly altered. This changed parameter consequently drove further interventions to meet the new standards, and the cycle continued (Dahlen, Downe, et al., 2013; Selin, Almstrom, Wallin, & Berg, 2009). The morbidity associated with these interventions, both physical and emotional, is now also becoming commonplace (Christiaens & Bracke, 2007; Goodman et al., 2004; Hidaka & Callister, 2012; Hodnett, 2002; Johanson et al., 2002; Kitzinger et al., 2006). Recently, the Lancet series on midwifery care has identified that increasing midwifery-led care, refocusing birth as a normal physiological process, and shifting away from medicalised frameworks would be effective in reducing morbidity and mortality for mothers and babies (Homer et al., 2014; Renfrew et al., 2014; ten Hoope-Bender et al., 2014; ten Hoope-Bender & Renfrew, 2014; Van Lerberghe et al., 2014).

1.3.3 Models of care

In the Australian maternity care system, there are options for public and private hospital care. In 2011, 29% of women chose to deliver in a private hospital, with a private obstetrician on a fee-for-service basis. However, the majority of women, 71%, delivered in the public system, with little or no cost associated with care (Li et al., 2013). The provision of most public sector maternity services in antenatal clinics
is medical-led, via a fragmented model, where women see different healthcare
providers during their pregnancy, labour and postnatal care (Homer et al., 2001).
Often women in fragmented care will not know the midwife or doctor who will
attend them in birth (Sandall, Soltani, Gates, Shennan, & Devane, 2013).

Australian and international research has demonstrated clear links between provision
of care by a private obstetrician in a private hospital and higher intervention rates;
links that cannot be attributed to differences in risk status among women (Dahlen et
al., 2012; King, 2000; Roberts et al., 2000a; Shorten & Shorten, 2004). Research
shows that low-risk primiparous women who have birth in a private hospital
compared with a public hospital were more likely to have an intervention in birth
than not (Dahlen et al., 2012).

In the public system, women also have limited access to continuity of care midwifery
models, sometimes called midwifery group practice, team midwifery or caseload
midwifery (Sandall, Hatem, Devane, Soltani, & Gates, 2009). The focus is on
continuous supportive care for normal physiological processes and normal birth
(Homer et al., 2001; Sandall et al., 2013; ten Hoope-Bender & Renfrew, 2014; Walsh
& Devane, 2012). Continuity of care programs enable women to have the same
primary midwife or group of midwives through their pregnancy and birth. Research
into continuity of care programs have demonstrated improved outcomes such as
reduced EDB use, increased likelihood of spontaneous onset of labour, fewer
episiotomies and instrumental deliveries, reduced CS prior to labour, and a 23%
reduction in preterm birth (Commonwealth of Australia, 2008, 2009; Homer et al.,
2001; McLachlan et al., 2008; NHS, 2007; Roberts, Algert, Douglas, Tracy, & Peat,
2002; Ryan, Revill, Devane, & Normand, 2013; Sutcliffe et al., 2012; ten Hoope-
Bender & Renfrew, 2014; Tracy et al., 2013; Walsh & Devane, 2012). Additionally, research demonstrates the cost-effectiveness of continuity of care programs (Ryan et al., 2013; Tracy et al., 2013).

1.3.4 Promotion of normal birth
Childbearing is one of the most common reasons for accessing health services in Australia (Australian Bureau of Statistics, 2010; Hodnett, 2002), and it consumes a large proportion of the health budget (Australian Bureau of Statistics, 2010). Therefore, consideration of methods to reduce rates of intervention would seem appropriate and relevant to all healthcare providers.

In the UK, there is a concerted effort to reorient birth as normal (Kennedy et al., 2010; NHS, 2007), and in 2012 the Royal College of Midwives released a document for the Normal Birth Campaign (Royal College of Midwives, 2012). In Australia, the NSW government released a policy directive in 2010: *Towards Normal Birth in NSW*. The focus of this directive is an increase in support for the promotion of ‘normal’ birth (NSW Department of Health, 2010).

1.3.5 Antenatal education
Antenatal education as a formal structure was first introduced in Australia and the US in the 1960s (Ferguson et al., 2013; Walker et al., 2009). This was in response to increasing occurrence of hospital-based births and the accompanying loss of women’s social support (Ferguson et al., 2013; Murphy-Tighe, 2010). As hospital births became more common, and obstetric practitioners became more involved in birth, the use of drugs to manage labour pain became more widespread (Zwelling, 2000, 2010). Women were also requesting pain relief options from their obstetricians without awareness of the side effects from these drugs (Pitcock & Clark, 1992;
Zwelling, 2000). In the 40s and 50s in developed nations, there was an increase in the practice of isolating women, anaesthetising them for birth, and administering a cocktail of amnesiac and sedating drugs known as ‘twilight sleep’ (Pitcock & Clark, 1992). This created a situation where women were out of control during their labours and many had no memory of the birth (Zwelling, 2000). Advocates for women’s birthing rights mounted a backlash to these interventionist practices, and childbirth education was born (Lothian, 2008a).

Childbirth classes in the 1960s were based on the work of Grantly Dick-Read in the UK, Elisabeth Bing and Marjorie Karmel in the US, and Frederick Lamaze in France (Dick-Read, 1957; Lothian, 2008a). The classes focused on giving women support and preparation for natural childbirth using relaxation, breathing and psychological preparation (now termed phychoprophylaxis) (Ferguson et al., 2013; Murphy-Tighe, 2010; Nolan & Hicks, 1997; Walker et al., 2009). Such classes are now a routine part of antenatal care in most developed nations (Jaddoe, 2009). However, the focus has shifted away from natural birth preparation and towards preparation for hospital births and medical interventions, promoting the idea that all births are normal and equal (Lothian, 2008a; Walker et al., 2009). There is concern that these classes also function to induct prospective parents into the medical policies and practices of the institution in which they occur (Ferguson et al., 2013; Walker et al., 2009). Based on current consumer needs, these classes now encompass education about pregnancy, newborn care and early parenting with a focus on the involvement of the father (Svensson, 2005; Walker et al., 2009).

Attendance at antenatal education classes is beginning to decline; at the same time, intervention rates are increasing (Lothian, 2008a). It is also becoming apparent that
women and practitioners are becoming more accepting of medical management as a normal part of labour (Ferguson et al., 2013). Advocates for women’s birthing rights are again beginning to mount a backlash against normalising the interventionist practices and are calling for changes to maternity care and antenatal education (Dahlen, Schmied, et al., 2013; Lothian, 2008a, 2008b; NSW Department of Health, 2010).

1.3.6 Natural birth courses and complementary medicine

Private antenatal courses for natural birth preparation are increasing in popularity in Australia. These courses are conducted outside the formal antenatal education system and generally have not been formally evaluated for their effectiveness in reducing medical interventions. Two of these programs: ‘She Births®’ and ‘Acupressure for birth preparation’ (Betts, 2005) provide support and education for natural birth preparation and are based on CM philosophies. The She Births® program includes five different CM practices and has its base in the Ayurveda tradition. Acupressure for birth preparation is based in the philosophies of traditional Chinese medicine (TCM). There is a growing evidence base to support the effectiveness of the individual CM techniques incorporated in these programs (Jones et al., 2012).

CM is becoming more commonly used in maternity to support various aspects of pregnancy and birth (Adams, Lui, et al., 2011; Adams et al., 2009; Allaire, Moos, & Wells, 2000; Betts, Smith, & Dahlen, 2012; Bishop, Yardley, & Lewith, 2010; Chuntharapat, Petpichetchian, & Hatthakit, 2008; Cyna, McAuliffe, & Andrew, 2004; Smith et al., 2006). The philosophies and practices of CM promote women’s use of natural physiological processes to increase the likelihood of having a normal
birth. This philosophical viewpoint is supportive of CM use in the maternity setting (Adams, 2006; Adams, Lui, et al., 2011; Allaire et al., 2000).

Trials and systematic reviews have been conducted on elements of CM such as: yoga (Chuntharapat et al., 2008; Field, 2011; Narendran, Nagarathna, Narendran, Gunasheela, & Nagendra, 2005); manual therapies including massage (Field, Hernandez-Reif, Taylor, Quintino, & Burman, 1997; McNabb, Kimber, Haines, & McCourt, 2006; Smith, Levett, Collins, & Jones, 2012); relaxation (Smith, Levett, Collins, & Crowther, 2011; Syrjala, Donaldson, Davis, Kippes, & Carr, 1995); and partner support (Copstick, Taylor, Hayes, & Morris, 1986). However, the most substantial body of work has been in the investigation of acupuncture and acupressure for the purpose of assisting and managing pain in childbirth (Díaz Espinosa & Ángel Macías, 2013; Hamidzadeh, Shahpourian, Orak, Montazeri, & Khosravi, 2012; Hantoushzadeh, Alhusseini, & Lebaschi, 2007; Hjelmstedt et al., 2010; Hyodo & Gega, 1977; Kashanian & Shahali, 2010; Ma et al., 2011; Mårtensson, Stener-Victorin, & Wallin, 2008; Münstedt et al., 2011; Nesheim et al., 2003; Qu & Zhou, 2007; Rammerö, Hanson, & Kihlgren, 2002; Skilnand, Fossen, & Heiberg, 2002; Zhou, 2007; Ziaei & Hajipour, 2006). Systematic reviews have been conducted (Cho, Lee, & Ernst, 2010; Lee & Ernst, 2004; Smith, Collins, Crowther, & Levett, 2011), and critiques of these systematic reviews have followed (Citkovitz, Schnyder, & Hoskins, 2011; Levett et al.).

1.3.7 The Complete Birth Course

The Complete Birth Study is a multifaceted and complex package of care. Modifications have been made to two existing courses, She Births® and Acupressure for labour and birth (Betts, 2005), to more accurately reflect the CM evidence base.
and to increase appropriateness in a public hospital antenatal education context. This process of review of the evidence is described further in chapters two and three, where the evidence for the effectiveness of antenatal education and individual complementary therapies is examined. These reviews of the evidence influenced what was included in the course, whereby components that did not have a sufficient evidence base were removed from the final study course, and those that demonstrated evidence of effectiveness were included. These antenatal education courses, or similar private ones, have generally not been subject to rigorous evaluation in Australia. We used a mixed methods research (MMR) approach, integrating both qualitative and quantitative methods to understand the effect of the complex Complete Birth intervention as a whole, as well as the effect of the individual components.

The concept of delivering a CM package of care via an antenatal education model is novel in the Australian public hospital context. Data to date suggest that CM therapies have the potential to reduce EDB rates and thereby reduce other interventions downstream in the birthing process (Jones et al., 2012). Antenatal education is a routine part of maternity care, and has long been used in Australia, particularly by first-time mothers (Ferguson et al., 2013; Jaddoe, 2009; Lumley & Brown, 1993; Schneider, 2001; Svennson, Barclay, & Cooke, 2008; Walker et al., 2009).

The ‘CompleTe Birth’ (Complementary Therapies) Study (Complete Birth) was developed in direct response to the Towards Normal Birth in NSW policy directive (NSW Department of Health, 2010) in order to support women to have a normal birth. The founders of the two programs on which the study is based, Nadine
Richardson (She Births®) and Dr Debra Betts (Acupressure for pain relief in labour), have given permission for their programs to be used in this study. The evaluation of Complete Birth for the management of natural labour and birth has the potential to make an important contribution to the evidence base for CM and birth education research.

1.4 Aims

This research aims to examine the use of complementary therapies for the support and management of labour and birth for first-time mothers and their birth partners the role that complementary therapies may play in the facilitation of natural birth. The research has three main objectives:

1. To examine the effectiveness of an antenatal education package of CM therapies (Complete Birth Study) in addition to standard care, to reduce EDB rates in primiparous women, compared with standard care alone.

2. To examine how women and their partners, who participate in the Complete Birth Study, characterise the effectiveness of the program and its components.

3. To examine how midwives perceive the use of the Complete Birth Study techniques for women and their partners and what they see as the potential facilitators and inhibitors in the public hospital system.

1.5 Thesis approach

The Complete Birth Study incorporates the philosophies of maternal wellbeing, CM and childbirth education. To assess this complex intervention, the thesis is presented in the following way: Chapter 1, this introduction, presents the statement of the
problem and the overview of the issues to be examined. Following this, Chapter 2 explores the background issues that have influenced the introduction and evolution of antenatal education in Australia and internationally. This chapter also investigates other background issues, such as drivers for use of pain relief, particularly EDBs, and looks at this issue within the context of modern maternity care and the delivery of antenatal education. This chapter then examines the evidence for antenatal education with the focus on measures of effectiveness for these classes. Chapter 3 then assesses the evidence for CM therapies and their effectiveness for pain relief in labour and birth. This chapter discusses the research framework applied to CM therapies and the potential for differing interpretations of the data. The methods chapter (Chapter 4), which describes the methodological rationale for the study and its philosophical underpinnings, follows this. The methods chapter discusses the appropriateness of the MMR approach for this study. Chapter 5 outlines the results from the randomised controlled trial, and examines and analyses the quantitative data. This is followed by Chapter 6, which presents the integrated qualitative data results from the in-depth interviews with women and partners, and the focus group with midwives. The final chapter (Chapter 7) presents the integration of the qualitative and quantitative findings using the triangulation method and the discussion of these findings in the context of the literature. Strengths and limitations are addressed, as well as suggestions for application of these findings into practice.

1.5.1 Research approach

The Complete Birth Study was developed by the researcher, with modifications made to the two existing courses on which it was based to more accurately reflect the CM evidence base and to increase appropriateness in a public hospital antenatal education context. These courses, or similar private ones, have generally not been
subject to rigorous evaluation in Australia. We used a mixed methods research (MMR) approach, integrating both qualitative and quantitative methods to understand the complexity of the Complete Birth intervention as a whole, and the effect of the individual components.

To evaluate the effectiveness of this complex intervention, a randomised controlled trial (RCT) was considered the most appropriate method for the main study (Concato, Shah, & Horwitz, 2000), and the primary outcome measure was rate of EDB use. Secondary outcome measures included other maternal and neonatal outcomes that will be described further in the methods chapter (Chapter 4).

The main aim of RCTs is to reduce bias and allow direct comparison of two groups with regard to effectiveness as evidenced by specific outcomes. However, this design alone cannot address questions regarding how and why the study has an effect on the use of pharmacological pain relief. RCTs also do not address some of the pragmatic aspects of implementation for complex interventions. Questionnaires were used to determine if the study produced a change in attitude, or had a transformative effect on the way women approached and coped with labour. We also investigated the role of rehearsal of the CM techniques on the outcome of interest. A questionnaire following the birth was used to determine if the amount of rehearsal, or specific individual components, or the package as a whole was of most value. To understand how the program may operate effectively in the future, teasing apart which aspects were of use is essential.

To determine the effectiveness and acceptability of the Complete Birth program and the way in which it was used by participants, it was also necessary to undertake
qualitative research into both the participants’ experiences of the course and the midwifery staff’s opinion of the program.

To understand the acceptability of the program to women and partners, in-depth interviews with participants is required. We explored women’s reasoning in using the CM techniques in a particular way during labour through a series of interviews with a subset of women participating in the treatment arm of the RCT. We interviewed women and partners until thematic saturation occurred. Thematic analysis was used to analyse the data.

Following identification and analysis of the main themes that emerged from the in-depth interviews, a focus group with midwives was undertaken. We invited midwives from the main study hospital, Hornsby Ku-ring-gai Hospital (HKH) to participate in a focus group. We explored their views on the effectiveness of CM techniques and their roles in working with couples in the study. We asked about the pragmatic approaches required to implement CM techniques into clinical practice.

A mixed methods approach was therefore chosen for this study and conducted in a sequential design. Integration of data occurred in the analysis stage of the study. Integration is the term used to describe the points during the research process at which mixing of qualitative and quantitative data occurred, and in this study it occurs at multiple points throughout the data collection and analysis process (Andrew & Halcomb, 2009). The process of integration comprised the blending of themes common to the analysis of data from each stage and brought together, compared and contrasted, and then discussed in an integrated way. The findings from the interviews with women were used to inform the questions in the focus groups with midwives. The method used for this thesis is triangulation, where different data sources are used
to triangulate or validate findings on a particular question or theme (O'Cathain, Murphy, & Nicholl, 2010).

1.6 Significance

Evidence-based strategies are required to address the high rate of medical interventions during labour and birth. The NSW Health policy directive: Towards Normal Birth in NSW has set benchmarks for hospitals to increase the normal vaginal birth rate in NSW hospitals. This policy directive is set to end in 2015 with little evidence to date of any significant downward turn in overall intervention rates across the state of NSW. This research is in direct response to the Towards Normal Birth in NSW policy and addresses some of its primary aims. The study evaluates the evidence for an antenatal education course incorporating CM techniques for managing pain during labour and birth. Findings from this study will help to establish an evidence base for the use and effectiveness of CM techniques for labour and birth via a hospital-based antenatal education program (Complete Birth), and its findings have the potential to influence current policy development.
Chapter 2 – Setting the Scene: Antenatal Education

Background and Literature Review

2.1 Introduction

The first part of this chapter examines the background and changing landscape of contemporary childbirth, and the influences of Western maternity systems on the medicalisation of labour and birth. The second part explores the dynamic nature of labour pain perception and the use and effects of EDBs. The third part examines the influences on the shifting focus of childbirth education towards parent education, and the final section is a literature review that examines the outcomes of antenatal education with particular focus on outcomes for the management of pain in labour and birth. These issues are critical in shaping current content of antenatal education programs, and therefore have a bearing on current outcome measures and evaluation of effectiveness. The term ‘antenatal education’ is used in this thesis to generally describe the classes that occur in the antenatal period, unless the specific focus of one kind of class is relevant.

2.2 Setting the scene – the changing landscape of childbirth

2.2.1 Medicalisation of birth

Giving birth in established medical institutions has led to decreased maternal and neonatal mortality, which is an important factor for women and babies (Senate Committee, 1999). While some authors argue that this claim is overstated (Hinote & Wasserman, 2012; Kitzinger et al., 2006), the issue remains that with increasing hospital births, there has been a commensurate rise in the medicalisation of births in these institutions, and that rates of declining mortality have plateaued (Bryant, 2009).
The drivers for increasing medicalisation are complex. Research suggests that some of the drivers for women to accept medical interventions during labour and birth include: society's trust in a high technology approach and expectations of perfection in pregnancy (no risk to the baby); practitioners' fear of litigation; increased demand for monitoring and documentation; and an emphasis of science over humanism (Green & Baston, 2007; Johanson et al., 2002; Kitzinger et al., 2006; Zwelling, 2008).

New guidelines from the American College of Obstetrics and Gynecology (ACOG) and the Society for Maternal-Fetal Medicine (SMFM), support revising definitions of normal labour, and cite evidence showing that labour progress is significantly longer than was previously taught (Caughey, Cahill, Guise, & Rouse, 2014). ACOG and SMFM guidelines recognise that non-medical interventions such as continuous support reduces the incidence of interventions leading to caesarean deliveries (American College of Obstetricians and Gynecologists & Society for Maternal-Fetal Medicine, 2014a, 2014b).

This increased medicalisation has raised concern over the associated increase in morbidities and disempowerment seen in labouring women (Senate Committee, 1999). Controversy over the significant rise in intervention rates in low-risk normal births, and the cascade of further interventions that occurs as a result, is at the forefront of commentary and debate, and has been highlighted in reviews and research (Allen, O'Connell, Liston, & Baskett, 2003; Benoit et al., 2010; Bewley & Cockburn, 2002; Bryant, 2009; Buckley, 2015; Burrows, Meyn, & Weber, 2004; Clark, Carr, Loyd, Cook, & Spinnato, 1998; Dahlen et al., 2014; Dickinson, Paech, McDonald, & Evans, 2002; Green & Baston, 2007; Heinze & Sleigh, 2003; Hodnett,
2.2.2 Changing attitudes of women

Research has demonstrated that over the past decade there has been a measurable shift in women’s attitudes towards a greater acceptance of medical interventions as part of normal birth (Green & Baston, 2007; McIntyre, Francis, & Chapman, 2011a, 2011b, 2012). In the UK, Green and Baston’s (2007) research found that higher ‘acceptance of medical intervention’ scores were significantly associated with CS and instrumental modes of birth, and that use of EDB is the factor most associated with these modes of birth (Green & Baston, 2007).

In Australia, as elsewhere, acceptance of pain relief in labour has become culturally embedded; at the same time, the benefits and purpose of natural physiological birth have become subordinated to risk management of labour (Ferguson et al., 2013; Madden, Turnbull, Cyna, Adelson, & Wilkinson, 2013). Walker et al. (2009) suggests that women come to birth having been only exposed to the medicalised idea of birth, which serves to reinforce the idea that childbirth is risky (Walker et al., 2009). This is called by Dahlen (2010) the 0.1% doctrine, where the 1:1000 risks are emphasised, rather than framing the safety of 999:1000 (Dahlen, 2010). The fact that there is an ongoing campaign aimed at reorienting childbirth to a more ‘normal’ framework by professional colleges representing midwives and governments, speaks about the pervasive risk orientation that exists (NSW Department of Health, 2010; Royal College of Midwives, 2012).
2.2.3 Fear, control and decision-making

The literature reports that more women have become fearful of childbirth, and there are increasing numbers of interventions designed to decrease fear (Green & Baston, 2003; Guszkowska, 2014; Hotelling, 2013; Johnson & Slade, 2003; Lindgren, Brink, & Klinberg-Allvin, 2011; Sinclair & Stockdale, 2011; Sjögren, 1997; Sjogren & Thomassen, 1997), and that fear is thought to be associated with complications for up to 20% of pregnancies in developed nations. (Gamble & Creedy, 2001; Saisto & Halmesmaki, 2003), including increased pain, prolonged labour and CS (Johnson & Slade, 2003). The potential for reducing fear and pain in childbirth, as well as increasing satisfaction, has been identified in measures to increase self-efficacy and control in labour (Attanasio, McPherson, & Kozhimannil, 2014; Crowe & von Baeyer, 1989; Hodnett, 2002; Larsen & Plog, 2012). Women’s self-confidence in their ability to cope with labour has also been found to be predictive of use of pharmacological pain relief (Howarth, Swain, & Treharne, 2011; Simkin & O'Hara, 2002).

There has also been substantial literature to suggest that control in childbirth and decision-making are essential for satisfaction with the birth experience (Hodnett, 2002; Hodnett & Simmons-Tropea, 1987; Hollins Martin & Robb, 2013; Hotelling, 2013; Howarth, Swain, & Treharne, 2010; Kannan, Jamison, & Datta, 2001). Research consistently finds that personal control during labour and birth, self-efficacy and involvement in decision-making are important factors in satisfaction (Christiaens & Bracke, 2007; Crowe & von Baeyer, 1989; Escott, Spiby, Slade, & Fraser, 2004; Goodman et al., 2004; Morgan, Bulpitt, Clifton, & Lewis, 1982). However, the link between informed decision-making and control in labour depends on the supportive care provided by medical and midwifery staff and the
dominant messages they give about childbirth: medical event versus natural occurrence (Hodnett, 2002; Walsh, 2006).

In a systematic review, Hodnett (2002) described four key factors that were crucial for women’s satisfaction with the childbirth experience. These were personal expectations, the amount of support from caregivers, the quality of the caregiver–patient relationship, and involvement in decision-making (Hodnett, 2002). Hollins Martin also describes contemporary health care as one where choice and informed decision-making are now well embedded in policy. Midwives perceive their role as providing choice and information, but see it as the woman’s role to decide what opportunities she will take up (Hollins Martin & Robb, 2013).

The concept that antenatal care is capable of enabling women to make informed choices for their health care may be well established in the literature (Ahldén, Ahlehagen, Dahlgren, & Josefsson, 2012; Gagnon & Sandall, 2007; Hildingsson, Dalén, Sarenfelt, & Ransjö-Arvidson, 2013; Hinote & Wasserman, 2012; Hollins Martin & Robb, 2013); however, an alternative and consistent theme is that women are not sufficiently informed about the risks from medical management in childbirth to make a properly informed decision (Goldberg & Shorten, 2014). The literature describes a potentially coercive approach used in some hospitals to encourage compliance with institutional rules and guidelines, which may render women’s control over their childbirth as less likely (Ferguson et al., 2013; Henry & Nand, 2004; Hinote & Wasserman, 2012; Howarth et al., 2010; Lothian, 2008b; Walker et al., 2009). Kitzinger et al. (2006) states that women are often anxious that if they go against the medical system or medical advice, they, or their babies, will be neglected or punished in some way (Kitzinger et al., 2006). This is reiterated by Lothian
(2008a), whose research suggests that in large teaching institutions in particular, women and childbirth educators are pressured to not ‘rock the boat’ (Lothian, 2008a). This establishes the context where women are vulnerable and may be influenced by the dominant institutional messages provided (Ferguson et al., 2013).

In a study of first-time mothers in New Zealand, researchers found that self-efficacy in taking personal responsibility for one’s health was a core theme. Participants who described taking personal responsibility were more likely to be well informed and well prepared for any birth experience, and they felt more confident that they would be able to work with whatever labour and birth event eventuated. This neoliberal idea of personal responsibility reflects the choices women make in relation to being in control of and accountable for their own birth processes. Benoit et al. (2010) and McIntyre et al. (2012) also discuss this idea in relation to market- or consumer-driven changes, where changes to maternity services are influenced by women’s choices, and reflect the loosening of control of medical dominance (Benoit et al., 2010; McIntyre et al., 2012).

2.3 Influences on labour pain

The influences on perception and management of labour pain are complex, and fundamental to the premise of management of pain in childbirth and childbirth education.

Labour is facilitated by hormonal processes, which can potentially be disrupted by stress and fear (Buckley, 2002, 2015). Moderating or alleviating stress can have an enhancing effect on labour hormones for efficient and natural birth (Buckley, 2015;

Buckley (2002, 2015) proposes that a cycle of fear, tension and pain have a considerable influence on labour (Fear-Tension-Pain Cycle) (Buckley, 2002, 2015). She states that fear in childbirth leads to muscular and emotional tension, which influences the stress hormones, and that this leads to increased pain (the influence of EDBs on these hormones is discussed in section 2.3.7). The research suggests that practices that affect stress hormones, such as continuous labour support and manual techniques, are beneficial for reduction of stress, anxiety, tension and therefore pain during labour and birth (Buckley, 2002, 2015; Hodnett, 2002).

### 2.3.1 Attitudes to pain

Kitzinger and colleagues (2006) point to our modern attitudes towards pain influencing our attitudes towards acceptance of medical intervention. The expectation that we should not feel pain, and that we can pop a pill to fix it, is prevalent in our lives. Where it concerns childbirth, Kitzinger and her colleagues (2006) suggest that this attitude creates a situation where women are less likely to have developed personal coping strategies for pain, and therefore rely on medical supports for labour (Kitzinger et al., 2006). Supporting this idea of unacceptable pain, Lothian (2008a) believes that our childbirth education encourages informed decision-making about pain relief based on the efficacy of institutionally available medical choices (Lothian, 2008a). Choices are not about whether to use pharmacological pain relief, but which pain relief to use.
2.3.2 Perception of labour pain

The perception of labour pain is very different for each individual (Wesselmann, 2008), and subjective reporting of pain scores as an outcome measure for labour interventions has been controversial (Citkovitz et al., 2011; Levett et al., 2014). Evidence shows that pain intensity is perceived differently to pain unpleasantness, suggesting that it is the relationship to pain that may be important. The research indicates a complex interplay of emotional states, attention, and sensory inputs that can alter pain perception (Rainville, Bao, & Chrétien, 2005; Villemure & Bushnell, 2002; Villemure & Schweinhardt, 2010).

Vullemure and colleagues’ 2002 and 2010 research indicate that both our attentional and emotional states alter the way we perceive pain, and that the underlying mechanisms that are responsible for pain modulation implicate different brain circuits that are activated when either the sensory (intensity) or affective (unpleasantness) perception of pain occurs (Villemure & Bushnell, 2002; Villemure & Schweinhardt, 2010).

Experimental pain research using a visual analogue scale (VAS) conducted in the 1980s found that labouring women, rated their degree of unpleasantness (VAS affective) lower than their level of pain sensation intensity (VAS sensory). Affective VAS, but not sensory VAS ratings of pain were considerably reduced when women in labour focused on the birth of the child compared with focusing on their pain. The results suggest the importance of distinguishing between measures of the sensory intensity versus the unpleasantness of pain, and that psychological and contextual factors modulate the experience (Price, Harkins, & Baker, 1987). This has
implications for the appropriateness of overall pain scales being used to assess the efficacy of interventions in labour.

Evidence from neuroimaging also suggests that within the context of pain, there are a variety of brain networks that have been implicated in the experience of pain (Bassett & Bullmore, 2009; Davis, 2011; Legrain, Iannetti, Plaghki, & Mouraux, 2011). Additionally, recent studies have demonstrated that brain structure and function undergo plasticity in chronic pain conditions, and that network dynamics are altered (Baliki, Schnitzer, Bauer, & Apkarian, 2011; Davis, 2011; Moayedi, Massieh, & Karen, 2013; Seifert & Maihofner, 2011).

2.3.3 The neuromatrix theory and brain plasticity

The neuromatrix theory, which is a popularly cited pain theory (Moayedi et al.; Trout, 2004), states that an individual’s perception of pain is mediated by multiple simultaneous influences. These include physical, psychological, cultural and experiential influences interpreted by the mind and body (Melzack, 2001). This has been confirmed by later research in the area (Rainville et al., 2005; Seifert & Maihofner, 2011; Trout, 2004; Villemure & Schweinhardt, 2010). Melzack (2001) characterises pain perception as a dynamic and complex system operating in the whole being, influenced by past memories and experiences. These patterns, initially laid down genetically, are characteristic to the individual, and develop over time. Subsequently, they are overlaid by experiences and sensory inputs to form what is termed a ‘neurosignature’, unique for that person (Melzack, 2001). The neurosignature can perpetuate itself, or can be altered by changing one or more stimuli that contribute to the overall pattern (Trout, 2004). This indicates the brain’s ‘neuroplasticity’, which characterises the dynamic, changeable brain that can
accommodate and adapt to changes when introduced (Melzack, Coderre, Katz, & Vaccarino, 2001). The theory takes into account the influences of past psychosomatic experiences and affective components to pain (Melzack & Wall, 1965).

2.3.4 The neuromatrix and influences on labour pain

Labour pain is a complex and subjective experience, mediated by neural pathways (Madden et al., 2013; Trout, 2004; Wesselmann, 2008), and can be influenced by environmental factors, learned values and attitudes to the perception and expression of acute pain (Madden et al., 2013; Melzack, Kinch, Dobkin, Lebrun, & Taenzer, 1984). Pain behaviour and satisfaction with the birth experience are linked to these influences (Morgan et al., 1982; Trout, 2004; Wesselmann, 2008) and to goals and expectations for pain relief (Rainville et al., 2005).

The neuromatrix theory of pain has been utilised by Trout (2004) as an organising principle for the analysis of influences on labour pain (Trout, 2004). The theory recognises the multiple and simultaneous influences on pain, including past experiences, emotions, cognitive input, cultural factors, as well as stress regulation capacity, immune system and other sensory inputs such as aroma. In perceiving pain, three networks work in parallel to process pain. These are sensory-discriminative (somatosensory components), affective-motivational (limbic system components), and evaluative-cognitive (thalamocortical components). Recognised within the model are contributions from the stress response system, immune system variables, and the autonomic nervous system (Melzack et al., 2001; Melzack et al., 1984; Trout, 2004). Melzack (1984) found a wide variability in labouring women’s pain scores on the McGill pain questionnaire, which takes into account not only the severity of pain, but also the quality of pain, noting ‘striking individual differences’ in labouring
women’s pain scores, with some women reporting severe pain and some women reporting almost no pain at all. His observations included that severity of pain was noted to be lower in women who had received prepared childbirth classes (Melzack et al., 1984).

Trout (2004) also describes that for some women, experiencing intense pain during labour helped them cope subsequently, with women reporting an enhanced ability to cope with other painful or stressful experiences in their lives. This may imply the contribution of past recognition of labour as pain having a positive affective component, and reorganising the plastic neural networks for relative pain (Trout, 2004).

In an overview of the evidence, researchers Leap and colleagues (Leap, Sandall, Buckland, & Huber, 2010) discuss the ‘working with pain’ approach to labour support. This is distinguished from the commonly held ‘pain relief’ paradigm that exists in maternity systems. The research suggests that when labour is progressing normally, and there is normal pain, women can be supported through labour by creating an appropriate environment with supportive care, encouraging women to successfully cope with labour. By providing a supportive environment, the release of women’s own natural hormones is enhanced, and women can be encouraged to work with the pain. Additionally, by following labour’s natural progression and observing women’s behaviour during labour, caregivers are able to monitor whether labour is progressing normally or assistance is required.

### 2.3.5 Influence of caregivers

In Hodnett’s (2002) review of pain and women’s satisfaction with the childbirth experience, the research concludes that the attitudes and behaviours of the caregivers
are as influential on subsequent satisfaction as pain, pain relief, and medical interventions (Hodnett, 2002). The four factors found to be most important were personal expectations, the amount of support from caregivers, the quality of the caregiver-patient relationship, and involvement in decision-making. These have been discussed previously; however, it is important in the context of pain perception to note that these factors were found to be so important that they overrode other indicators of pain in perceiving the childbirth experience as positive.

2.3.6 Pain and satisfaction with birth

Birth satisfaction is a commonly used outcome measure for interventions in labour and birth. The assessment of birth satisfaction is highly complex, with different psychosocial factors influencing perceived satisfaction, as discussed above (Hodnett, 2002; Hollins Martin & Robb, 2013; Howarth et al., 2010; Humenick & Bugen, 1981; Kannan et al., 2001; Martin & Fleming, 2011). These factors also appear to be cross-cultural (Christiaens & Bracke, 2007).

In 1989, Crowe identified several variables that had been traditionally associated with positive experiences, and found that psychological variables predictive of positive childbirth include personal control, confidence in preparation from childbirth classes, and levels of anxiety. Measures of confidence and ability to cope were associated with knowledge of practical skills for labour, and expectations for labour being met (Crowe & von Baeyer, 1989).

In Australia, Dickinson (2003) reported overall satisfaction scores for labour and delivery were high regardless of analgesic approach, which reflected the multiple issues other than pain relief that are involved in the childbirth experience (Dickinson, Paech, McDonald, & Evans, 2003). The recent Cochrane Review of EDB versus...
non-EDB or no analgesia found no difference in maternal satisfaction with the childbirth experience (RR=0.95 [95% C.I.: 0.87, 1.03]) or maternal satisfaction with type of pain relief (RR=0.10 [95% C.I.: -0.49, 0.70]) (Anim-Somuah, Smyth, & Jones, 2011).

Perception and influences on labour pain are complex, and our modern attitudes towards pain being avoidable and unacceptable have resulted in women being less likely to have developed personal coping strategies for pain, and more likely to rely on medical pain relief (Kitzinger et al., 2006). Diverse perceptions and modifiable influences on the subjective experience of pain and birth satisfaction have implications for reliable and comparable outcome measures in research. Influences on pain, pain perception and pain management are potentially modifiable through education, and while the use of antenatal education has been linked with increased satisfaction with birth, its links with changes to birth outcomes, such as decreased use of pharmacological pain relief, CS, and instrumental vaginal births, are less clear. The use of EDBs in particular has been linked with an increased likelihood of assisted and surgical births (Buckley, 2015; Dahlen, Schmied, et al., 2013; Roberts et al., 2000a; Tracy, Sullivan, Wang, Black, & Tracy, 2007); these issues will now be discussed.

2.3.7 Epidural block
The increasing use of EDBs in normal birth reflects not only the current climate of birth in developed nations, but also has been identified as the main mediating factor in the cascade of interventions seen in labour and birth (Dahlen et al., 2012; Green & Baston, 2007; Tracy & Tracy, 2003). In a review of the evidence, Buckley (Buckley, 2015) has highlighted the effects of an EDB on normal birth, which has now long
been recognised (Abboud et al., 1983; Homer et al., 2014; Jouppila, Jouppila, Moilanen, & Pakarinen, 1980). Initially, the use of an EDB during labour reduces maternal oxytocin, probably by blocking or numbing the feedback loop that promotes oxytocin release centrally. Oxytocin has a widespread effect on the body and brain, and by activating the parasympathetic nervous system, reduces stress (Mendelson, 2009). Oxytocin is responsible for the onset of labour, rhythmic and regular uterine contractions during labour, and calming and adapting effects of the mother–baby dyad (Kosfeld, Heinrichs, Zak, Fischbacher, & Fehr, 2005; Odent, 2013). Consequently, when an EDB is used, oxytocin decreases and labour slows, and there is then a requirement for augmentation with synthetic oxytocin (Syntocinon) (Rossignol, Chaillet, Boughrassa, & Moutquin, 2014). Further, there is a reduction of the beta-endorphin and epinephrine levels during labour. This may have the effect of disrupting hormonally-mediated maternal adaptation and attachment with the newborn (due to reduction of oxytocin and beta-endorphins), may cause hypotension (due to the reduction of epinephrine), and over time reduce uterine contractions (due to the reduction of epinephrine and oxytocin), which may result in a prolonged second stage and potentially the use of forceps or vacuum (Rossignol et al., 2014). Additionally, there is a consequent increase in fetal hypoxia, stress hormones and the risk of CS for labour complications. Following labour, prolactin levels are reduced in the presence of increased stress hormones. Prolactin is responsible for adaptations of maternal physiology to breastfeeding and infant bonding (Jouppila et al., 1980).

Research has further highlighted that EDBs are a significant mediating factor in the cascade of interventions leading to increased risk of mechanical and operative births (Buckley, 2015; Dahlen et al., 2012; Roberts et al., 2000b; Rossignol et al., 2014;
Tracy & Tracy, 2003). The literature suggests that more women are now having EDBs for routine pain relief in normal birth (Dahlen et al., 2012; Goldberg, Cohen, & Lieberman, 1999; Green & Baston, 2007; Heinze & Sleigh, 2003; Hidaka & Callister, 2012; Lothian, 2008a 2670). While the average varies between institutions and across the public and private sector, in 2012 more than 46% of parturient women in NSW had an EDB (Centre for Epidemiology and Evidence, 2012).

Women who use an EDB in labour have been shown to be statistically more likely to proceed to other interventions, such as requiring augmentation of labour with synthetic oxytocin, to manage the effects of the EDB (Clark et al., 1998; Dahlen et al., 2012; Goldberg et al., 1999; Jepsen & Keller, 2014; Jones et al., 2012; King, 1997; Lieberman & O'Donoghue, 2002; Roberts et al., 2000a).

The mediating effect of EDBs on subsequent interventions has been demonstrated by Australian research investigating NSW birth data for rates of obstetric intervention between public and private patients (Dahlen, et al., 2014). Dahlen et al. (2014) and Roberts et al. (2000b), found that while birth outcomes were strongly associated with models of care, having an EDB during labour significantly increased the likelihood of having an instrumental birth, especially in private patients (Dahlen et al., 2014; Roberts et al., 2000a). These researchers identified that having an EDB began a cascade of interventions leading to operative births, particularly instrumental vaginal births, and a low probability of a normal vaginal birth (Dahlen et al., 2014; Roberts et al., 2000a). Research by Green (2007) found that an EDB increased the odds of an operative birth by almost sixfold [Odds Ratio (OR): 5.93 CI 3.88-9.05] and primiparas were five times more likely than multiparas [OR: 5.13 CI 3.57-7.01] to have an EDB (Green & Baston, 2007).
These findings are largely consistent with trial evidence from a 2011 Cochrane Review (Anim-Somuah et al., 2011) of unintended effects of EDBs. This review reported on 23 trials (7,935 women), and stated that there was sufficient evidence that EDBs were associated with: higher rates of instrumental births (Risk ratio (RR) 1.42, 95% CI 1.28 to 1.57, 23 trials, 7935 women); extended second stage of labour (Mean difference (MD) 13.66 minutes, 95% CI 6.67 to 20.66, 13 trials, 4233 women); increased oxytocin augmentation (RR 1.19, 95% CI 1.03 to 1.39, 13 trials, 5815 women); maternal hypotension (RR 18.23, 95% CI 5.09 to 65.35, eight trials, 2789 women); motor-blockade (RR 31.67, 95% CI 4.33 to 231.51, three trials, 322 women); a greater likelihood of intrapartum fever (RR 3.34, 95% CI 2.63 to 4.23, six trials, 2741 women); urinary retention (RR 17.05, 95% CI 4.82 to 60.39, three trials, 283 women); and an increased risk of CS for fetal distress (RR 1.43, 95% CI 1.03 to 1.97, 11 trials, 4816 women).

Women have come to rely increasingly on medical-led care and technology to support normal labour and birth (Johnson & Slade, 2003; Lindgren et al., 2011; Sjögren, 1997; Sjogren & Thomassen, 1997), and are being managed with interventions traditionally reserved for more high-risk cases, particularly with routine use of EDBs (Johanson et al., 2002). Current reviews and guidelines reflect the growing concern from medical groups about rising rates of interventions and CS (American College of Obstetricians and Gynecologists & Society for Maternal-Fetal Medicine, 2014b; Buckley, 2015; Caughey et al., 2014; NSW Department of Health, 2010). Clinical practice in Australia and other developed countries such as the US does not yet reflect the recommendations in reviews, or current guidelines, and indicates the need for re-education of women and practitioners about the benefits of natural labour and birth.
2.4 Birth education

In 2004, it was estimated that around 85% of first-time mothers and their partners attended antenatal education classes in Australia (Henry & Nand, 2004; Lumley & Brown, 1993). This finding is now more than 10 years old and may be significantly out of date; however no current literature for Australian is available. In the UK a more recent national survey found 62.6% of primiparous women reported attending antenatal education classes (Redshaw & Heikkila, 2010). Data suggest that attendance at antenatal education is declining in the UK (Lothian, 2008a) and the US (Walker et al., 2009). In the Listening to Mothers survey in the US, the number of women who indicated that they would attend antenatal education classes declined from 70% in the 2002 survey to just 59% in the 2013 survey (Declercq, Sakala, Corry, & Applebaum, 2007; Declercq et al., 2014). While current data are not available, Ferguson (2013) suggests that this decline, reported internationally, very likely reflects the situation in Australia (Ferguson et al., 2013).

Traditionally, the aim of these classes was preparation for a natural labour and birth. Antenatal education as a formal structure was first introduced in Australia and the US in the 1960s (Ferguson et al., 2013; Walker et al., 2009). This followed an era where social support was lost as a result of births occurring more frequently in hospitals, and medical management of labour pain was widespread. Consequently, women had little accompanying knowledge of physiological childbirth practices.

Within hospitals in the US from the early 1900s, a practice of highly medicalised drug interventions emerged for pain management in labour. These practices included the use of full anaesthesia and a cocktail of drugs known as ‘twilight sleep’ (Pitcock & Clark, 1992; Zwelling, 2000). This cocktail included scopolamine to induce
amnesia and meperidine (pethidine), a narcotic, to induce sedation (Simkin, 1996). It became apparent that a subsequent increased demand for twilight sleep was being driven by consumers, with women seeking pain relief in labour with what was perceived as modern medical techniques, and practitioners acquiescing to their requests despite adverse effects (Pitcock & Clark, 1992). During twilight sleep, the woman was often unconscious for labour and birth, or the drugs had a hallucinogenic effect causing great distress and confusion. Consequently, a labouring woman may have been subjected to tethering and deprivation of liberties to cope with the effects of the twilight sleep, and often with no memory of the event (Pitcock & Clark, 1992; Zwelling, 2000). As these adverse effects became more evident, the women’s movement began advocating for natural birth options, less dominance of medicine over women’s birth, and increased awareness and education for women. They advocated for women to be awake, aware, and able to participate in their own birth (Broome & Koehler, 1986). It was on this platform of raised awareness and information to counter the unintended negative effects of medical management of birth, that childbirth education was born (Pitcock & Clark, 1992; Simkin, 1996).

2.4.1 Childbirth education: a revolution

Childbirth classes in the 1960s were based on the work of Grantly Dick-Read in the UK in the 1930s and 40s (Dick-Read, 1933, 1957). Elisabeth Bing and Marjorie Karmel in the US had adapted the work of Dick-Read, and over time incorporated the techniques taught by Frederick Lamaze in France (Bing, 1967; Bing, Karmel, & Tanz, 1961; Karmel, 1959; Lamaze, 1970; Lothian, 2008a; Zwelling, 2000). The classes focused on giving women support and preparation for natural childbirth using the Lamaze method for relaxation, breathing and psychological preparation, and was termed psychoprophylaxis (Ferguson et al., 2013; Murphy-Tighe, 2010; Nolan &
Hicks, 1997; Walker et al., 2009). Bing and Karmel founded the American Society for Psychoprophylaxis in Obstetrics (ASPO), now called Lamaze International (Zwelling, 2000).

The classes became very popular with women and practitioners over time, as there was little accessible information for women, and practitioners were becoming concerned about the level of drug overuse for labouring women. As Elisabeth Bing describes it, ‘the atmosphere was right’ (Zwelling, 2000). The classes were founded from grassroots advocacy, and were small and conducted independently of the hospital. Educators were also independent of the maternity system and advocated for the promotion of natural birth and a change to the system. They provided women with the skills for natural birth, who then led consumer-driven change to the system (Lothian, 2008a).

The Leboyer method has also been influential in the philosophical approaches to birth education. Introduced from France during the 1970s, *Birth Without Violence* (Leboyer, 1978) provides information regarding the most peaceful and least violent way for babies to be born into the world. Leboyer’s focus was on the peaceful transition of the baby from the womb to the world and how mothers and healthcare providers can best facilitate this, rather than using practices that had become common, such as smacking the baby to stimulate its first breath, and bright lights in the ‘delivery room’. Instead, practices such as dim lights, a quiet room, placing the baby straight on to the mother’s abdomen, delayed cord cutting and gentle touch including immersion in warm water were advocated to allow the baby to get used to life gently.
Michel Odent’s teachings and writings have also influenced the approach to birth education by focusing on developing women’s self-confidence, trust and faith in an innate ability to give birth (Bailey, Crane, & Nugent, 2008).

The 1960s and 70s was an era of great change for women and the promotion of women’s rights, women’s liberation movement and freedom to choose. This revolutionary notion of active participation was supported and enhanced by the childbirth classes of the day (Zwelling, 2000, 2010).

2.4.2 Parent education: an evolution

In the 1980s women were entering the workforce in greater numbers than ever before, and family structures were changing (Shearman & Bennett, 1989). With an increased focus on gaining professional standing, women now had to navigate new demands balancing work and home (Zwelling, 2010). It was also becoming more common to see fathers in the birth rooms, along with a greater expectation around the father’s role in parenting. Simultaneously, technology and medical interventions were rapidly advancing and were seen as symbolic of affluence and development (Zwelling, 2008, 2010). Kitzinger also pointed out the influence of ‘male’ thinking in driving the acceptance of more technology, as ‘doing something’ is more aligned with the male mindset. Technology allowed male partners to be an active participant in the birth process and have more control over ostensibly hidden indicators of labour progress (Kitzinger et al., 2006).

The goals of parents attending birth education classes were subsequently changing over this time. The idea of ‘parent’ education for early newborn life, rather than birth education, was extending the parameters of the classes. Parents were gaining a greater acceptance of technology around birth, and with it a passivity around the
need for birth advocacy (Zwelling, 2008). Parent education was gaining momentum, and technological advances were becoming more revered and valued as a mechanism of safety (Zwelling, 2010).

In 1989, the most comprehensive review of obstetric services in NSW till that date, the Shearman report, was released (NSW Health Department, 1989b). Shearman identified that outcomes for mothers and babies are widely used as important indicators of the health and health care of communities. The report proposed important changes to improve services at the time, including expansion of birth centres and the management of low risk births by midwifery-led models of care. The report stated concern from consumers and maternity care providers that unnecessary interventions in birth were increasing and that policies of routine use of interventions, including EDBs, based on outdated or unproven theories, should be reviewed. The rising CS rate was highlighted as being of particular concern with a 0.9% increase per annum in NSW, from 4.2% in the 1970s to 15.3% in 1986.

The report also emphasised the value of parent education, and viewed education for prospective parents as part of a continuum of care. This continuum included education about: healthy pre-conception; early pregnancy; late pregnancy, including labour preparation and newborn care; and postnatal life, including the development of parent-craft skills. The report suggested that the term ‘parenting education’ be adopted to describe this continuum; however, the phases were separate in terms of provision of services. Classes for childbirth preparation, offered in later pregnancy, were seen to be particularly useful for first-time mothers and the expectation was that around 90% of primigravid women would attend where classes were offered. The authors commented that evaluation of effectiveness of classes was relatively scarce at
the time and hampered by a lack of common outcome measures (NSW Health Department, 1989b). However, they cited evidence from a review conducted in 1980 by Cogan, that suggested that while more ‘advantaged’ women were likely to attend classes, the outcomes included reduced medication use, reduced pain, less frequent use of forceps and a more positive attitude towards labour and birth (Cogan, 1980). Evidence also cited from Lumley (1982) suggested that the benefits of classes included social support, improved pregnancy experience, skills for relaxation and posture enhancement, and increasing women’s ability to be more assertive and critical in managing their healthcare options and providers (Shearman & Bennett, 1989).

The Shearman report emphasised women’s satisfaction and choice in maternity care, and the orientation of birth as a normal physiological event. Birth preparation classes were seen as occurring within the continuum of classes for parenting preparation, not as a choice between the two. The report warned against increasing use of routine monitoring and interventions without sufficient evidence for the benefits. This was due to the increased risks posed to normal birth and loss of autonomy for women (Shearman & Bennett, 1989). Similar recommendations are still being given in current reviews of maternity services (Bryant, 2009; NSW Department of Health, 2010).

Despite these recommendations, EDBs and technology in birth became more prevalent through the 1990s and 2000s. At the same time, fewer women were reported to be attending childbirth education classes (Declercq et al., 2007; Declercq et al., 2014; Lothian, 2007). As women and men developed an increasing reliance on medical technology to support their labour and birth, commentators have observed
that this corresponds to a reduced belief in the capacity, or indeed the necessity, of education to empower and support them in natural birth practices (Pitcock & Clark, 1992; Zwelling, 2008).

2.4.3 Antenatal education: incorporating all births as normal

Current antenatal education classes are a routine part of antenatal care in most developed nations (Jaddoe, 2009). They have now long been used in Australia for the purposes of providing information about the normal expectations and range of experiences for birthing women and new parents (Ferguson et al., 2013; Handfield & Bell, 1995; Lumley & Brown, 1993).

The scope of childbirth education has expanded to incorporate all aspects of pregnancy, birth and parenting. The educators presenting the classes aim to provide a balanced and unbiased view of all possible outcomes during labour and what can be expected if problems arise (Handfield & Bell, 1995). Current consumer demand has become less concerned with learning skills to cope with labour, and more concerned with preparation for all types of birth and the management of parenthood (Ferguson et al., 2013; Lothian, 2008a; Svennson et al., 2008; Svensson, 2005; Walker et al., 2009). Based on current consumer needs, these classes now encompass education about pregnancy, newborn care and early parenting with a focus on the involvement of the father (Svensson, 2005; Walker et al., 2009).

Consequently, the goals and purpose of childbirth education have shifted to meet public expectations. Prospective parents now want information across the whole antenatal period including parent education (Svensson, 2005). They want support in making sense of the vast amount of media information (Lothian, 2008b), and
decision-making about choices for birth, where the safety of the baby is the dominant feature (Zwelling, 2008).

Thus, childbirth education evolved into parent education, and while parent education is routinely provided in maternity services, there is little consensus as to the aims and objectives of the classes or data to demonstrate effectiveness or common outcome measures. This will now be discussed.

2.5 Literature review

2.5.1 Effectiveness of antenatal education

The aims of antenatal education are to assist prospective parents to prepare for pregnancy, birth and early parenthood. Attendees seek information regarding decision-making for labour and birth, skills for coping with labour and labour pain, information on pain relief options, and breastfeeding and early parenting (Gagnon & Sandall, 2007). The literature suggests that educational programs are as varied as the outcomes they seek to produce, and reviews of antenatal education highlight this diversity.

2.5.2 Methodology

A search of the MEDLINE, CINAHL, PUBMED, EMBASE and Cochrane databases was performed in June 2013, January 2014, and December 2014 using the keywords ‘childbirth’, ‘birth’, ‘antenatal’, ‘maternal’, ‘maternity’, ‘parent’, ‘labo*r’, and ‘delivery’ cross-referenced with ‘classes’, ‘education’, ‘preparation’ and ‘satisfaction’, and were not limited in methodology. Qualitative studies, qualitative reviews, RCTs and systematic reviews were examined for relevance to the topic.
2.5.3 Systematic and literature reviews

Four reviews of antenatal education were located through the search methods described above, three literature reviews and one systematic review (Broome & Koehler, 1986; Ferguson et al., 2013; Gagnon & Sandall, 2007; Koehn, 2002). These reviews have a broad range of scope. The earliest literature review evaluated studies mainly of psychoprophylaxis from the 1960s to early 80s (Broome & Koehler, 1986). A second literature review focused on studies of efficacy of broader social outcomes through the 1990s (Koehn, 2002). A Cochrane systematic review then looked at any structured educational class given to pregnant women (Gagnon & Sandall, 2007), and the latest literature review evaluated current antenatal education programs’ effect on normal birth outcomes from 2000 to 2012 (Ferguson et al., 2013). Some individual studies and commentaries not included in these reviews are also highlighted.

In the early literature review by Broome (Broome & Koehler, 1986), authors focused on the effects of psychoprophylaxis taught in antenatal education classes from the 1960s to 80s. The review summarised the evidence and suggested that women who attended prepared childbirth classes used less medication during labour, experienced less pain, and were more positive about birth, compared to non-attendees. One study (Nelson, 1982) examined working-class women who were randomised to receive prepared childbirth classes or usual care, and were shown to have better outcomes than unprepared working-class women, dispelling the notion that the disparity in outcomes was due to socio-economic status. This study found that prepared women were more likely to favour a natural birth, and less likely to express a desire to use pain medication than working-class women who did not attend classes. During the birth, prepared women were more active and experienced less medical interventions.
than unprepared women. This did not hold for middle-class women indicating there may be some difference for educational status.

The review overall reported some evidence for fewer maternal and fetal complications, and there was inconsistent evidence for length of labour (Broome & Koehler, 1986). However, the ability for studies to control for other variables in the childbirth experience was cited as a potential confounding factor. The authors discuss other factors that account for much of the discrepancy, and are unrelated to childbirth preparation, such as different reporting and definitions of complications, physician support and practices, medication use during labour and hospital policy. Aspects of the setting and care providers were reported to be influential in childbirth outcomes.

In a literature review by Koehn (Koehn, 2002), 12 studies, reporting on 1,219 women, were examined. The studies, conducted from 1995 to 2000, broadened the evaluation of childbirth education’s contribution beyond that of natural birth outcomes. This review highlights that care providers, their philosophical position, and the institutions in which the childbirth education classes occur had a profound influence on what couples could apply during birth. The educational interventions reviewed were substantially heterogeneous and the authors proposed a systematised approach to evaluation. Outcome measures of interest that were suggested included additional health and wellness focused outcomes, such as self-care, health promoting behaviours, quality of life, care received and symptom management beyond the birth experience. The studies were evaluated according to these proposed categories, and for the category of health promoting behaviours, the authors found that, where reported, a positive change was suggested in areas of self-actualisation, health
responsibility, exercise, nutrition and interpersonal support (3 studies). Notable flaws were described for some studies with regard to sample selection and unsystematic approaches, but the overall outcomes suggested that health promotion outcomes were positively influenced by childbirth education classes. Women reported that they believed themselves to be prepared for natural birth, but not prepared for unexpected events. Again, the authors state that influences of care providers or services of the institution were difficult to distinguish from that of the classes.

For the category of perceptions related to birth, outcomes were difficult to compare due to heterogeneous designs, but overall there were no differences between women of higher and lower income with regard to perceived control, satisfaction, pain perception and use of pain medication. The main finding in this category was that despite the stated purpose of childbirth classes to prepare women to manage labour confidently, the tools developed to measure such outcomes, such as labour agentry scales, were rarely used. Additionally, the physical tools women used to cope with labour, such as breathing, postural change and relaxation, were also rarely evaluated.

In evaluation of class curriculum, significant differences were found in the priorities of the educators and prospective parents, with more parenting education requested by participants. Finally, when reviewing the impact on coping, one study found that childbirth classes significantly reduced anxiety post-intervention, and that anxiety was not linked to measures of confidence.

In the Cochrane systematic review and meta-analysis of antenatal education, nine trials reporting on 2,284 women found that interventions varied enormously, and there were as many outcome measures as there were ways of providing antenatal education (Gagnon & Sandall, 2007). Some may be more effective; however, there
was no consistent measure on which to compare. Seven of the nine studies were from the US from 1987 to 2001, one from Canada and US in 1997, and the most recent study from Iran in 2005. Three small randomised studies (n<25) were predominantly white American women, and evaluated breastfeeding, attachment and maternal adaptation (Carter-Jessop, 1981; Davis & Akridge, 1987; Hamilton-Dodd, Kawamoto, Clark, Burke, & Fanchiang, 1989). One randomised study of men and women evaluated parenting skills post-partum (Corwin, 1999), and two randomised studies of men evaluated paternal adaptation, sensitivity and empathy in high-risk and low-risk individuals (Pfannenstiel & Honig, 1995; Westney, Cole, & Munford, 1988). One placebo-controlled study looked at African-American women who were at high social risk (Klerman et al., 2001). The study investigated using ‘augmented’ antenatal care, where antenatal education was one of 16 interventions provided. A large multi-centre RCT from Canada (11 sites) and the US (1 site) reporting on 1,275 women examined vaginal birth rates following a previous CS (Fraser, Maunsell, Hodnett, & Moutquin, 1997). This was the only study judged by the authors to be at low risk of bias. The final study from Iran reported on 200 women who were randomised to attend seven 90-minute antenatal education classes divided into three sections. The first section gave information on baby care, stages of labour, and diet; the second provided counselling; and the third introduced and practised neuro-muscular exercises for labour. The outcomes of interest focused on labour and birth measures, and some early post-partum health indicators. This study reported a significant reduction in pelvic pain, back pain and headache during pregnancy, and a significant reduction in dystocia and CS during labour and birth (Mehdizadeh, Roosta, Chaichian, & Alaghehbandan, 2005). This trial was considered to be at some
risk of bias as no information was given regarding randomisation procedure or control group.

There was a lack of high-quality evidence from trials and so the effects of antenatal education were difficult to assess, and most did not assess birth outcomes. The majority of studies had variable quality of design and outcome measures, and with the exception of the Mehdizadeh et al. (Mehdizadeh et al., 2005) study, were all conducted in the 1980s–90s. The study by Fraser et al. (Fraser et al., 1997), which was judged to be high quality, assessed the outcomes for vaginal birth after caesarean (VBAC). The study assessed 1,275 women with a previous CS providing expanded education about VBAC. The experimental group (n=641) were given individualised prenatal education and support from a specialist research nurse. No differences were found for the primary outcome measure of vaginal birth achieved, or for the other outcome measures including proportion attempting vaginal birth, CS and maternal and neonatal morbidity. The review authors recommend further research to ensure effective ways of meeting the needs of parents and their newborn infants, and helping health professionals support pregnant women and their partners in preparing for birth and parenting, with effective resource use (Gagnon & Sandall, 2007).

In the final literature review, by Ferguson et al. (2013), studies from 2000 to 2012 were examined and categorised according to positive physical effects and positive emotional effects on normal birth outcomes (Ferguson et al., 2013). Overall, the review found a decrease in false labour admissions following enhanced antenatal education; however, this did not lead to an increase in normal birth rates. Some positive emotional effects from class attendance, such as decreased anxiety and increased partner involvement, were reported, but again no links to increased normal
birth rate were demonstrated. There were contradictory findings for birth outcomes, such as rates of vaginal birth, induction of labour, and EDB. The review identified studies that showed an increase and a decrease in rates for each of the outcomes.

### 2.5.4 Commentary and literature not included in reviews

In reviewing other literature not included in these previous reviews, a study of 228 postnatal women in the UK, participating in qualitative interviews, found that there was a variable response from women as to the perceived value of childbirth education, and their capacity to prepare women for birth and parenthood. Some women valued the classes, and others felt they were unnecessary (Hollins Martin & Robb, 2013). Birth outcomes were not linked to this qualitative study, so it is not possible to know what bearing these attitudes have on birth. However, they reported that women used a variety of sources to access information about pregnancy and childbirth options, including the internet, which has implications for reliability and accuracy of these sources. One of the main themes identified in their study was ‘in labour nothing goes to plan’ (Hollins Martin & Robb, 2013). This is relevant to women’s increasing acceptance of medical management identified by Green (Green & Baston, 2007), indicating the pervasive message that women should not plan too much or get their hopes up, as the outcomes are always unanticipated and not within their control. The researchers conclude that opportunities for education should be made available for women, with women in control of uptake, as when women are cognisant of the critical nature of the outcomes at stake they may perceive more value in education (Hollins Martin & Robb, 2013). This however draws attention to the pervasive messages of the dominant medical paradigms, where women are informed of the unexpected nature of birth, and remain unaware of the need for reorienting ideas about normal birth to improve outcomes.
In a 2005 nationally representative study, 3,455 Swedish-speaking primiparous women (75% of all eligible women) were surveyed at three time points: early pregnancy, early post-partum period (2 months), and one year following birth (Fabian, Rådestad, & Waldenström, 2004). One study reported on the second survey in the early post-partum period (Fabian, Rådestad, & Waldenström, 2005), and results from 1,197 primiparas were included. This constituted a response rate of 82% of primiparas who consented to the main study. The results determined that antenatal education did not affect first-time mothers’ experience of childbirth and assessment of parental skills. Attendance did however increase their social network with other new parents. Most women (74%) reported that antenatal education helped them prepare for childbirth, 40% indicated it prepared them for early parenthood, and 58% had met with other class participants in the year following birth. However, there was no effect on birth outcomes such as mode of birth or experience of pain, and more women who attended the childbirth education classes used EDBs than non-attenders (50% vs 41%, RR=0.6, 95% CI:0.4–0.9, p<0.05) (Fabian et al., 2005). In a more recent 2013 survey (Hildingsson et al., 2013) of first-time Swedish women and partners, participants reported a lower satisfaction with antenatal education than the earlier 2005 survey (Fabian et al., 2005). In 2013, 56% of women and 62% of men felt the education was a positive experience, 68% of women and 63% of men found it useful for childbirth preparation, and 47% of women and 44% of men found it helpful for early parenthood. High level of participant education was the only variable found to be positively associated with satisfaction with antenatal education classes (Hildingsson et al., 2013). The respondents were primarily Swedish-born, excluding foreign-born women who may have different needs in the antenatal period and lower levels of education, which may have affected the results of the study.
In a large, high-quality RCT investigating the effects of psychoprophylaxis training for birth, two types of childbirth education classes in Sweden were compared (Bergström, Kieler, & Waldenström, 2009a). The two courses were compared based on the following outcome measures: EDB rates, birth experience, parental stress, satisfaction with education, satisfaction with childbirth preparation and satisfaction with parenthood education. The rationale for the study included consideration of the shifting focus of antenatal education over the past two decades in Sweden to one that incorporates parent education (Fabian et al., 2005; Hildingsson et al., 2013). The Swedish study recruited a total of 1,087 low-risk primiparous women and 1,064 of their partners to attend either classes focusing on psychoprophylaxis training or standard antenatal classes focusing on parent education. The two courses were compared using the following outcome measures: EDB rates, birth experience, parental stress, satisfaction with education, satisfaction with childbirth preparation and satisfaction with parenthood education. The primary outcome measure for the study was EDB rate. No differences were found between groups for EDB use (52% in both groups), birth experience, or parental stress. The study used an intention to treat analysis; however there was some crossover of treatment received, with 37% of women in the standard group also receiving psychoprophylaxis training. When these women were removed from the analysis, the principal result was the same. However, the awareness-raising aspect of the study may have influenced what was used in labour, with women accessing information from other sources. Women and men in the natural group (the prophylaxis group) were more satisfied with the education component and more satisfied with the childbirth preparation compared with women and men in the standard care group. While the overall satisfaction scores for parenthood education were low, more women and men from the standard group were
more satisfied than those from the natural group (Bergström et al., 2009a; Bergström, Kieler, & Waldenström, 2011). The lack of ability to blind the groups, and the simultaneous resurgence of psychoprophylaxis’ popularity in Sweden at the time may have influenced crossover, and more generalised changes in attitudes towards more natural births may have influenced the more equal outcomes of this trial.

Hypnosis for childbirth, which is a development and extension of psychoprophylaxis techniques, has been evaluated for efficacy in a number of antenatal settings. A 2012 Cochrane Review investigating hypnosis for pain management during labour and childbirth (Madden, Middleton, Cyna, Matthewson, & Jones, 2012) reviewed seven trials and reported on 1,213 women, including data later published as the HATCh (Hypnosis Antenatal Training for Childbirth) Trial (Cyna et al., 2013). Despite the inclusion of antenatal hypnotherapy in six of the trials, there was significant heterogeneity among the trials, mainly with regard to timing of intervention, length of intervention, rehearsal time and qualification of person administering the intervention. No significant difference was found between the groups for the primary outcome of pharmacological pain relief (RR=0.63 [95% CI: 0.39-1.01]), spontaneous vaginal birth (RR=1.35 [95% CI: 0.93-1.96]), or satisfaction with pain relief (RR=1.06 [95% CI: 0.94-1.20]) (Madden et al., 2012). In a recently published study, Downe and colleagues (2015) conducted a large multi-centre RCT of self-hypnosis plus usual care, versus usual care alone, and found that there was no significant difference between the groups for the primary outcome of epidural analgesia, or other secondary associated clinical outcomes, or in cost savings. Women’s fear and anxiety however, were significantly reduced in the study group (Downe et al., 2015).
Using a novel mindfulness meditation and a skills-based approach, a team from Western Australia investigated the effectiveness of Mindfulness-Based Childbirth Education for maternal mental health improvements (Byrne, Hauck, Fisher, Bayes, & Schutze, 2014). This small (n=18) single arm, pre- and post-intervention study found that women showed significant improvements for fear of childbirth (MD= -13.12, p=0.04) and anxiety score (DASS-21) (MD= -5.5, p<0.01) pre- and post-birth, and for childbirth self-efficacy (Cohen’s $d = -1.91$) pre- and post-intervention. This single-arm pilot study was not adequately powered to address other issues, and stated that they could not make any contribution towards pharmacological pain data. There were no significant differences found for other birth outcomes.

Jaddoe’s (2009) commentary summarises the issues faced by childbirth education; the nature of childbirth education is highly variable and there is a lack of consistent outcome measures. The commentary cites observations from small studies showing tendencies towards increasing parent knowledge, confidence and competence, but no change in birth outcomes (Jaddoe, 2009).

### 2.5.5 Evidence for the role of birth education

**Pain management decisions**
The idea of predetermined plans is of relevance when considering antenatal education and planning for labour and birth. There is evidence to support the notion that antenatal planning increases likelihood of successfully achieving a plan (Henry & Nand, 2004). Those who plan for natural childbirth, or who plan for an EDB, are statistically more likely to get it. Where there is crossover, more particularly from planning not to have an EDB to receiving an EDB, it is likely to occur significantly
later in the labour, reducing the likelihood of potential complications (Dickinson et al., 2002; Goldberg et al., 1999).

To investigate Australian women’s antenatal knowledge and plans regarding intrapartum pain management, a survey was conducted at a large Sydney tertiary hospital (Henry & Nand, 2004). The survey of 496 women had a 69% response rate, with 56% primiparas, and 61% being Australian-born. The results found that the majority of women (96%) accessed information regarding pain management, and most commonly through antenatal education classes (55%), multimedia (53%), friends and family (46%). Sixty percent of women felt they were very well informed about pain management in the antenatal period. Women were more likely to feel well informed if they were married/de facto (p<0.01), university educated (p=0.05), privately insured (p=0.05), or receiving birth centre care (p<0.01). The survey also found that 80% of women had a positive plan, that is, planned to use a specific type of pain relief, and 70% planned against a specific type of pain relief. Country of birth, language and education all significantly influenced women’s predetermined plans. Women who were university educated (p<0.01), or had an English-speaking background (p<0.01), were more likely to plan for ‘natural’ methods, whereas women who were Asian-born were less likely to plan for natural methods (p<0.01). Australian-born women were more likely to plan against pharmacological methods of pain relief (p<0.01). Predetermined plans affected actual use of pain management, with women planning to use natural methods being more likely to do so than women who do not plan to do so (74 vs. 26%, p<0.001), and women planning to use an EDB were also more likely to do so (64 vs. 36%, p<0.001). Having predetermined plans also affected timing of use, with women planning to use natural methods having a longer time prior to use (3.6 hr vs. 2.8 hr, p<0.001), as did women planning against
pharmacological methods (3.4 hr vs. 2.9 hr, p<0.001). This study, while it demonstrated a reasonable sample size, included mainly women from English-speaking backgrounds in a relatively privileged area of Sydney, which according to other research by Adams et al. (2011), would demonstrate a greater utilisation of natural methods and higher ability to access information (Adams, Sibbritt, & Lui, 2011). This study and other literature suggest that antenatal preparation and decision-making regarding methods of pain relief can influence what is actually received in labour (Goldberg et al., 1999; Heinze & Sleigh, 2003; Henry & Nand, 2004).

The role of rehearsal
For women to incorporate an idea or techniques about birth, rehearsal and practice is especially important (Spiby, Henderson, Slade, Escott, & Fraser, 1999). There needs to be sufficient time from introduction of techniques until the labour for practice and integration to occur (Heinze & Sleigh, 2003). The structure and support systems that exist in antenatal education classes allow for demonstration, feedback and rehearsal of techniques over a period of time, enabling women and their partners to practice what is learned in class and then ask any relevant questions to facilitate mastery of the technique (Henry & Nand, 2004). However, it is necessary to attach sufficient importance to the promotion of any technique, and its desired outcome, to promote a change of behaviour (Ferguson et al., 2013; Lothian, 2008a; Walker et al., 2009; Zwelling, 2008).

The resurgence of natural childbirth education
Women are beginning to recognise the importance of normal physiological birth and voicing their dissatisfaction with over-medicalised births. In Sweden, more women are using psychoprophylaxis training for their birth, and less than half (47%) stating
that they were satisfied with their current parent education (Bergström et al., 2009a).

In the most recent Listening to Mothers survey in the US, two thirds of women stated that they would consider a birthing centre for their next baby, 64% supported a woman’s right to choose a home birth, and 69% supported VBAC (Declercq et al., 2014). The survey enquired as to women’s interest in knowing about complications of specific interventions. Most mothers wanted to know about most/all complications prior to having an induction of labour (97.85%), CS (97.2%) or EDB (97.4%). Despite wanting to know about all or most of the complications of these interventions, women’s actual knowledge of complications after attending antenatal education was not significantly better than those women who had never attended antenatal education classes. Between 27% and 68% of women answered one or more questions relating to complications incorrectly (Lothian, 2007). Hinote and Wasserman (2012) note that an increasing vocal consumer base is having an influence on options available to women in birth (Hinote & Wasserman, 2012). They suggest that the power of medical dominance is contracting, and that the infectious disease oriented framework of the hospital institution is becoming outdated, and women’s choices and activism are changing contemporary birthing trends.

In Australia, 2004 research by Henry (Henry & Nand, 2004) also suggests that attitudes are changing with regard to awareness of the benefits of natural birth. The research found that 62% of women planned to use natural methods to support their labour and birth, and 47% were concerned about maternal side effects of interventions such as EDBs. While the literature suggests that while women are still accepting of medical intervention as a routine part of labour (Green & Baston, 2007; Henry & Nand, 2004; Hinote & Wasserman, 2012; Kitzinger et al., 2006), slowly, women are looking towards natural techniques to support labour, and are becoming
aware of the effects of medical intervention. The increasing popularity of private birth preparation courses available in Australia suggests that women’s knowledge and interest is increasing.

**Current natural birthing courses available in Australia**

Many privately run courses promoting natural birth are available in Australia and elsewhere, with courses such as ‘Hypnobirthing®, ‘Calmbirth®’, ‘Power Birth®’, ‘AcuBirth®’, ‘Yoni Yoga Birth®’, ‘Active Birth®’ and ‘She Births®’ available. Attendance at these classes is either instead of, or in addition to, standard hospital-based antenatal education classes. The main aim of these courses is to promote a naturalistic approach to birth where a woman’s psychological, physical and material resources are activated for the achievement of a natural birth where possible. The promotion of birth satisfaction as a valuable outcome in itself is included (Hodnett, 2002). The subtext to these classes is about women taking responsibility for their own education, body and birth experience (Howarth et al., 2011). Active planning for a natural birth in the context of the predominant biomedical models of care is an important component, as well as education about the potential consequences of medical interventions (Goodman et al., 2004; Green & Baston, 2003; Howarth et al., 2011; Kukla et al., 2009; Lothian, 2008a; Murphy-Tighe, 2010).

These courses offer a variety of techniques, with the central aim of providing instruction for reducing fear through education and training in calm-inducing routines for the management of labour, with the support of a partner. The basis for most of these modern courses is found in the two early approaches of Dick-Read (Dick-Read, 1933, 1957) and Lamaze (Lamaze, 1970). These were advocated by the early childbirth educators, Bing and Karmel, who founded the ASPO (Bing, 1967; Bing et al., 1961; Karmel, 1959). These early approaches emphasised physical fitness
and aimed to educate women about normal physiology of birth and the elimination of fear. This was done through relaxation and breathing, with continuous support by the father (Jaddoe, 2009). These techniques have been developed to form some of the modern classes, including She Births®, Hypnobirthing® and Calmbirth®. While there has been little evaluation of the efficacy of the current private classes, the psychoprophylaxis techniques have been the subject of some modern research. Hypnobirthing® has also been evaluated in a Cochrane Review (Madden et al., 2012), and more recently two large RCTs known as the HATCh Trial (Cyna et al., 2013), and the SHIP Trial {Downe, 2015 #3378}, where hypnosis and self-hypnosis were evaluated. Evidence suggests that these techniques do not change birth outcomes, but do show improvements in measures of maternal self-efficacy, anxiety and fear.

2.6 Summary

The effectiveness of antenatal education for childbirth or parenthood remains largely unknown, and research to date has not been of a sufficient quality to assess the many varied outcomes (Gagnon & Sandall, 2007; Hardie, Horsburgh, & Key, 2014; Koehn, 2002; Lothian, 2008b; Walker et al., 2009).

Childbirth education classes, established as an independent movement in the 1960s, were effective in countering the effects of increasing medicalisation and loss of social support seen through the first half of the 20th century. Using psychoprophylaxis techniques, physical fitness and the support of a partner, the focus was on preparation for natural labour and birth. Childbirth education became incorporated into the maternity system. However, through the 1980s and beyond, its
focus shifted with the changing needs of the consumer to encompass parent education.

Current evidence suggests that there is a shifting focus of antenatal education towards parent education and a decline in women attending classes. The varied outcomes reported for current antenatal education centre mainly on maternal satisfaction and self-efficacy measures. Measures for pharmacological pain relief and birth outcomes have not been shown to be affected positively by current alternative antenatal education programs, including psychoprophylaxis, hypnotherapy and mindfulness techniques for birth.

Using an EDB for pain management in labour has been identified as a mediating factor for other interventions that follow downstream, including mechanical vaginal births and CS, and has contributed to the medicalisation of childbirth (Buckley, 2015; Dickinson et al., 2002; Roberts et al., 2000a). Several maternity services reviews in Australia and internationally have highlighted increasing medical interventions in labour, including rising use of EDBs, as requiring attention and action for reduction (Bryant, 2009; NSW Department of Health, 2010; Roxon, 2008; Senate Committee, 1999).

A variety of private childbirth preparation classes are gaining popularity in Australia and internationally, and are centred on the idea of providing women with natural techniques for pain management. These classes are independent of the maternity system, are acceptable to women, and are in a unique position to provide messages about normal labour and birth. They have the framework to provide demonstration, rehearsal and feedback for the mastery of natural techniques to manage pain in
labour, with the purpose of reorienting women’s attitudes and reducing medical interventions.

Despite a decline, childbirth classes remain highly attended, and women continue to use classes to access information about pain relief. Research also suggests that antenatal planning significantly influences the type and timing of pain relief received (Henry & Nand, 2004), and that where preparation and practice has occurred prior to the event of childbirth, personal control and confidence is retained and optimised for a more satisfying experience of childbirth (Heinze & Sleigh, 2003; Henry & Nand, 2004; Morgan et al., 1982). Essentially, the promotion of birth as a normal physiological process which can be managed by the woman through a variety of techniques, supported by her birth partner and her caregivers, is the central theme of a woman-centred birth (Bryant, 2009; Buckley, 2002).

2.7 Conclusion

To date, evaluation of current antenatal education has found that the nature of childbirth education is highly variable and there is a lack of consistent outcome measures (Jaddoe, 2009). More recently, classes aimed at providing techniques for the management of natural labour and birth are emerging in Australia and internationally, as more women are seeking additional support with natural labour. However, the majority of these classes have not been evaluated for effectiveness in supporting natural birth, or have shown limited effectiveness.

CM practices for pregnancy and labour support are also gaining popularity with women (Adams, Sibbritt, et al., 2011; Steel et al., 2014) and some evidence-based CM practices for supporting natural labour and birth may be beneficial. Using an
established and acceptable antenatal education framework, the inclusion of CM therapies such as yoga, massage, acupressure and relaxation may provide women with effective tools for self-management of pain in labour. The next chapter examines the evidence for CM for pain management in labour and birth.
Chapter 3 – COMPLEMENTARY MEDICINE FOR PAIN
MANAGEMENT IN LABOUR AND BIRTH: A CRITICAL NARRATIVE
REVIEW OF CURRENT SYSTEMATIC REVIEW EVIDENCE

3.1 Introduction

CM refers to ‘a broad collection of therapeutic practices and products that are not considered part of conventional medicine’ (National Institute of Health, 2014). CM is growing in popularity in Australia (Xue, Zhang, Lin, Da Costa, & Story, 2007), particularly among pregnant women (Adams et al., 2009; Adams, Sibbritt, et al., 2011; Gaffney & Smith, 2004a; Skouteris et al., 2008; Steel et al., 2014), and is being used increasingly in the maternity setting by midwives (Hall, McKenna, & Griffiths, 2012, 2013; Harding & Foureur, 2009; Hope-Allan, Adams, Sibbritt, & Tracy, 2004; Huntley et al., 2004; Kalder, Knoblauch, Hrgovic, & Munstedt, 2011; Koehn, 2000). Birth is a complex cultural, social and physical event, and research suggests that CM is playing a greater role in managing pain in labour (Jones et al., 2012; Steel et al., 2014). However, methodological issues in the evaluation of CM are important to consider when reviewing the evidence (Citkovitz et al., 2011; Walach et al., 2006; Witt, 2011).

3.1.1 Complementary medicine use

Nationally representative survey data from Australia show that women are the highest users of CM in the general population (Adams, Sibbritt, Easthope, & Young, 2003; Steel et al., 2014), which is consistent with international data (Bishop & Lewith, 2010; Fugh-Berman & Kronenberg, 2003; Harris & Rees, 2000). These data also suggest that use of CM is associated with higher education and income (Adams,
Easthope, & Sibbritt, 2003; Adams, Sibbritt, et al., 2011; Bishop & Lewith, 2010; MacLennan, Wilson, & Taylor, 2002; Steel et al., 2014). Women commonly use CM during their reproductive age, and are increasingly using CM during their pregnancy and birth (Hope-Allan et al., 2004; Huntley et al., 2004; Kalder et al., 2011; Smith et al., 2006; Steel et al., 2014; Steel et al., 2012; Wiebelitz, Goecke, Brach, & Beer, 2009). Adams’s (2009) critical literature estimates that there is a wide variation in use of CM during pregnancy (between 1% and 87%), but for studies with a relatively large sample size (n ≥ 200), nine of these showed a prevalence of CM use ranging between 20% and 60% of pregnant women (Adams et al., 2009). Previous Australian data suggest CM usage to be between 39% and 87% of pregnant women, with data reflecting use of a broad range of herbal products and complementary therapies (Gaffney & Smith, 2004b; Pinn & Pallett, 2002). Skouteris’s (2008) survey data from Victoria suggest that 36.8% of pregnant women consulted with a CM practitioner during their pregnancy in the eight weeks prior to the survey, and that 24.3% were planning preparations for labour using natural therapies (Skouteris et al., 2008).

In line with their earlier research, Adams et al. (2003, 2009) report CM use in pregnancy to be associated with women who are older and have a higher education and income status (Adams, Easthope, et al., 2003; Adams et al., 2009). This finding is in contrast to that of Skouteris (2008) who shows no such difference between users and non-users of CM during pregnancy (Skouteris et al., 2008); however, both groups showed high educational and income status, which may reflect a self-selection bias in those who responded to the survey.

Adams et al. (2009) also reported in the literature factors that were associated with CM use during pregnancy including previous or habitual use of CM, primiparity,
planning for a natural birth and being a non-smoker (Adams et al., 2009). Data from recent national surveys in Australia also reveal that women who consulted more frequently with their midwives were more likely to use acupuncture during their pregnancy (Steel et al., 2012), and CM generally for labour support (Steel et al., 2014). Midwives have been shown to have a positive view of CM and its potential benefits during pregnancy and birth (Gaffney & Smith, 2004a). Healthcare professionals are influential in the use of CM, and research indicates that the majority of midwives would recommend CM for pregnancy and labour support (Adams, Lui, et al., 2011; Kalder et al., 2011; Samuels et al., 2010; Wiebelitz et al., 2009).

Literature on CM use during pregnancy indicates that it is widespread (Adams et al., 2009; Adams, Sibbritt, et al., 2011; Fugh-Berman & Kronenberg, 2003; Furlow, Patel, Sen, & Liu, 2008; Steel et al., 2014) and used consistently throughout the three trimesters of pregnancy (Adams et al., 2009). Those who use CM during pregnancy report feeling more actively involved in their care (Adams et al., 2009; Dooley, 2006; Gaffney & Smith, 2004b; Hollyer, Boon, Georgousis, Smith, & Einarson, 2002), and that its practice aligns with their personal philosophies (Dooley, 2006).

The literature further indicates that the four most common CM therapies used during pregnancy include acupuncture/acupressure, aromatherapy, massage, and yoga, and that many women used multiple CM products or therapies (Adams et al., 2009). Australian studies by Skouteris (Skouteris et al., 2008) and Gaffney (Gaffney & Smith, 2004b) show the most common therapies used by pregnant women include massage, vitamins or mineral supplements, meditation and yoga.
The most common CM practitioners consulted were chiropractors, osteopaths, reflexologists and acupuncturists, and the therapies for preparation of labour included massage, aromatherapy, hypnotherapy, raspberry leaf tea, other herbal teas, yoga, acupuncture, breathing techniques, water immersion, meditation and naturopathic and homeopathic remedies (Skouteris et al., 2008).

Women who used CM indicated that they did so as an alternative to conventional medicine due to possible side effects (Adams et al., 2009; Dooley, 2006; Furlow et al., 2008), for example, pharmacological treatment prescribed for conditions such as nausea and vomiting (Adams et al., 2009; Allaire et al., 2000; Anderson & Johnson, 2005; Fugh-Berman & Kronenberg, 2003; Gaffney & Smith, 2004b; Hall et al., 2012; Hastings-Tolsma & Terada, 2009), and as an adjunctive treatment for more severe conditions such as hyperemesis gravidarum (Anderson & Johnson, 2005). Commonly cited uses for CM in pregnancy include: low back pain (Adams et al., 2009; Anderson & Johnson, 2005; Bayles, 2007; Fugh-Berman & Kronenberg, 2003; Gaffney & Smith, 2004b; Steel et al., 2014), reflux (Steel et al., 2014), heartburn (Steel et al., 2014), leg and foot oedema (Anderson & Johnson, 2005; Fugh-Berman & Kronenberg, 2003), mood enhancement (Anderson & Johnson, 2005), stress relief (Adams 2009), malposition (Allaire et al., 2000; Anderson & Johnson, 2005; Fugh-Berman & Kronenberg, 2003; Harding & Foureur, 2009), anaemia (Bayles, 2007; Hall et al., 2012) and relaxation (Hall et al., 2012; Harding & Foureur, 2009; Hastings-Tolsma & Terada, 2009).

CM has also been reported to be widely used for labour and labour preparation (Gaffney & Smith, 2004b; Skouteris et al., 2008; Steel et al., 2014), and commonly used for induction and augmentation of labour (Adams, Sibbritt, et al., 2011; Allaire
et al., 2000; Anderson & Johnson, 2005; Dooley, 2006; Fugh-Berman & Kronenberg, 2003; Furlow et al., 2008; Hall et al., 2012; Harding & Foureur, 2009; Hastings-Tolsma & Terada, 2009), anxiety (Fugh-Berman & Kronenberg, 2003), and management of labour pain (Dooley, 2006; Fugh-Berman & Kronenberg, 2003). In a recent Australian survey, data were examined from a large nationally representative sample of 1,835 women from the Australian Longitudinal Study on Women’s Health. During pregnancy, 60.7% of women used some form of CM and 74.4% used some form of non-pharmacological pain management technique during labour and birth (Steel et al., 2014).

3.1.2 Complementary medicine referral by maternity health professionals

In-depth interviews with Australian midwives reveal that midwives view CM as aligning with their professional practice and philosophy, and providing a vehicle for autonomy of practice for supporting women and normal birth. Midwives valued a holistic approach and believed in supporting women through a combination of CM and midwifery skills and concepts. Midwives believed CM provided a preventative and non-invasive approach to birth and any problems that may arise. They felt that CM empowered women to achieve normal birth, and kept women at the centre of care. However, midwives also thought that the practices were threatening to obstetricians, medical-led care and the hospital hierarchy, which was in part a barrier to integrated practice. However, CM practices were seen as providing additional and complementary skills to the midwifery skills base, and served as a distinction to the practices of their obstetrical colleagues (Adams, 2006).
More recently, in a literature review by Hall and colleagues (Hall et al., 2012) examining midwives’ support of CM, the authors examined 13 articles including quantitative survey data and qualitative interviews data. Information was predominantly collected from midwives; however, some surveys collected information from obstetricians and nurses. Seven of these papers reported CM use and prevalence, and six reported on midwives’ motivation for use of CM. The review states that the surveys estimated between 56% and 100% of midwives were supportive of the use of CM by pregnant women, and between 78% and 96% referred women to see CM practitioners, most commonly massage therapists, acupuncturists, naturopaths, chiropractors, homeopaths and aromatherapists. This is consistent with the findings of Adams et al. (2011), who also discussed regional variations in referral patterns, such as the prevalence of homeopathy in Germany and aromatherapy in UK maternity clinics, and the referral to naturopaths, massage therapists and chiropractors in Australia and Canada, and to homeopaths, osteopaths and herbalists in New Zealand (Adams, Sibbritt, et al., 2011). This review found that referrals to CM therapies and practitioners was mainly midwifery-led rather than obstetrician-led, which is consistent with the findings of Tiran (Tiran, 2006) and Münstedt (Münstedt, Brenken, & Kalder, 2009). However, Furlow (2008) found that in a survey of obstetricians and obstetric/gynaecological patients in the US, physicians, and in particular younger female physicians, were more positive about CM than the patients surveyed (Furlow et al., 2008). The majority of physicians (73.8%) thought that clinical care should be an integration of evidence-based conventional and CM practices, and the therapies most commonly cited as highly or moderately efficacious were biofeedback, chiropractic, acupuncture and meditation. This was in contrast to patients, who most commonly used yoga, herbal remedies, visualisation/imagery,
music therapy and meditation to supplement their conventional treatment for obstetrical/gynaecological concerns.

The review by Hall (2012) also found demonstrated support for relaxation and hypnosis techniques by a broad range of practitioners; however, other CM referral or practice was mainly midwifery-led (Hall et al., 2012). Indications for referring specific CM therapies depended on the presenting problem, such as back pain, for which massage or chiropractic were recommended, or nausea and vomiting, for which herbs or acupuncture were recommended. The most common indications for any CM referral were for labour induction and augmentation, nausea and vomiting, relaxation, back pain, anaemia, mal-presentation, and other postnatal issues.

Motivations for midwives to practice or refer to CM included the belief that CM was philosophically congruent with midwifery practice, that CM was a safe alternative to medical management and intervention, that CM supports women’s autonomy in pregnancy and labour, and that CM enhances the professional autonomy of midwives increasing their repertoire of skills when working with women.

While use of CM is widespread and midwives are supportive of its use, research evaluating its effectiveness has been controversial (Fonnebo et al., 2007; Witt, 2011; Witt & Schutzler, 2013).

### 3.1.3 Complementary medicine, a complex model of care: implications for research

Birth is a complex event, and evidence suggests that CM may be effective for the support and management of pain during labour. The pain experienced in labour is affected by the processing of multiple physiological and psychosocial factors (Lowe, 2002; Simkin & O'Hara, 2002) and where labour is proceeding normally, does not
reflect an abnormal pathological process (Leap, Dodwell, & Newburn, 2010). Perceptions of labour pain intensity vary and interventions used in pain management can have a primary focus of helping women to cope with pain in labour and in relieving pain (NICE & Guideline Development Group, 2008). The intent of pain relief in labour from pharmacological interventions is to relieve pain, while the intent from non-pharmacological methods is to work with and cope with pain (Leap, Dodwell, et al., 2010; NICE & Guideline Development Group, 2008) although their intent and aims can vary with treatment administered (Lowe, 2002; NICE & Guideline Development Group, 2008; Quah-Smith, Sachdev, Wen, Chen, & Williams, 2010; Simkin & O’Hara, 2002; Smith et al., 2006).

The purpose of this chapter is to examine current evidence from systematic reviews of CM for pain management in labour and birth, and to evaluate the methodological frameworks applied to this evidence. To critically evaluate this methodology, it is important to highlight the different clinical questions, designs and outcome measures of individual trials included in these reviews, and to consider how these differences have resulted in conflicting recommendations. The review of the evidence in this chapter also considers the capacity of research to reflect the context in which it occurs, such as hospital-based maternity services, which is relevant for translation of research findings into practice recommendations.

This chapter will provide a critical review of the systematic review evidence for CMs for pain management in birth, including: acupuncture and acupressure; relaxation, including yoga; and manual therapies, including massage. Hypnosis techniques introduced via antenatal education for pain management in labour was addressed in the previous chapter.
**Methods**

Systematic reviews provide a methodology to appraise, collate and summarise data from individual studies (Smith, Devane, Begley, & Clarke, 2011). Where more than one review exists on a topic, and where the results or conclusions may be inconsistent, it is important to compare and contrast the methodology and findings from separate reviews to ascertain the most cohesive evidence possible (V. Smith et al., 2011). A search of the MEDLINE, CINAHL, PUBMED, EMBASE and Cochrane databases was performed regularly over a two-year period from December 2012 to 2014 using the keywords ‘CAM,’ ‘alternative medicine’, ‘complementary medicine’, ‘complementary therapies’, ‘traditional medicine’, ‘Chinese Medicine’, ‘Traditional Chinese Medicine’, ‘acupuncture’ and ‘acupressure’, ‘relax*’, ‘muscle relax*’, ‘breath*’ ‘yoga’, ‘ayurved*’, ‘massage’, and ‘manual therap*’. This was cross-referenced with ‘childbirth’, ‘birth’, ‘labo*r’, and ‘delivery’, and limited to systematic reviews. Reviews were examined for therapeutic use of acupuncture or acupressure (Cho et al., 2010; Huntley et al., 2004; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011), relaxation techniques and yoga (Field, 2011; Gupta & Hofmeyr, 2004; Smith, Levett, et al., 2011), manual therapies and massage (Smith et al., 2012) in maternity care.

The reviews were evaluated based on the following features:

- The research question being asked, with a focus on delineating pain relief and pain management in labour
- The population of women included in the studies, being primiparous, multiparous or of mixed parity
• Treatment modality or therapy used, manual acupuncture, electro-acupuncture, ear acupuncture or acupressure; relaxation, including yoga; manual therapies, including massage

• Treatment approach utilised, mainly individualised, standardised or semi-standardised therapies

• Indicating whether the study was an efficacy or effectiveness study design (described below)

• Control used, being placebo or sham control, no treatment, other CM intervention, other pharmacological analgesia and usual care

• The main outcome measures used, such as VAS pain scores, time intervals utilised, use of pharmacological pain relief, satisfaction scores, anxiety, length of labour and augmentation required

• Approach to data analysis, and studies included in meta-analysis and pooled results, and

• Summarising the authors’ own conclusions as to the review results.

3.2 Current evidence for complementary medicine from systematic reviews

Evidence for CM for pain relief in labour and birth has continued to grow, and has focused on assessing the efficacy and effectiveness of these interventions on pain relief, pain management, and the supportive role of these interventions for women during labour. Over the last decade, many systematic reviews on CM for pain relief or pain management in labour and birth have been published: four systematic reviews for acupuncture and acupressure (Cho et al., 2010; Huntley et al., 2004; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011); two for relaxation, including...
yoga (Field, 2011; Smith, Levett, et al., 2011); and one review of manual therapies including massage and reflexology (Smith et al., 2012).

These reviews provide evidence using the historic hierarchy of evidence framework (NHMRC, 2011). This use of a hierarchy of evidence, where RCTs are the gold standard, strongly aligns with the biomedical model of pharmacological investigation. Using this framework is further useful for summarising potentially disparate evidence and encourages collaboration of research groups, and consideration of protocols that are reportable, reproducible, and therefore reasonably incorporated into clinical practice.

Evidence previously summarised in the Cochrane systematic review ‘Complementary and alternative therapies for pain management in labour’ (Smith et al., 2006), has subsequently been split into CM categories, with more narrowly defined reviews that reflect areas of growing research activity. These reviews share a common or generic protocol, and contribute to an overview of systematic reviews of pain relief for women in labour (Jones et al., 2012).

Four separate Cochrane Reviews have been evaluated for evidence regarding commonly cited CM therapeutics associated with providing physiological support and pain management in labour (Smith, Collins, & Crowther, 2011; Smith, Collins, Crowther, et al., 2011; Smith, Levett, et al., 2011; Smith et al., 2012). They are divided into three categories: mind–body interventions (e.g. yoga, hypnosis, relaxation therapies); alternative medical practice (e.g. homeopathy, TCM); and manual healing methods (e.g. massage, reflexology).
Acupuncture and acupressure research has the largest body of evidence in the systematic reviews available for pain management in labour and birth, and provides a good example of the complexities of applying biomedical research methods to complex systems of medicine, and has been the topic of a publication by this author (Levett et al., 2014) (see Appendix A).

Many of the trials included in the CM reviews, particularly acupuncture and acupressure, were designed to address the research questions using placebo or sham controls with the aim of isolating the ‘active ingredient’ (Linde, Niemann, Schneider, & Meissner, 2010; Witt & Schutzler, 2013) and are based on reductionist biomedical assumptions (Paterson & Dieppe, 2005). These trial designs have dominated studies of CM to date (Fonnebo et al., 2007; Macpherson, 2004; Witt, 2011; Witt & Schutzler, 2013), and focus on specific parameters of the CM intervention. These parameters include use of narrow outcome measures, use of sham procedures as controls, and the lack of patient-centred outcomes, which have resulted in research designs that may not capture the broader effects of CM treatments (Macpherson, 2004; Verhoef et al., 2005; Witt, 2011; Witt & Schutzler, 2013). These broader effects reflect CM as complex interventions (Paterson & Dieppe, 2005) and include the context of care (MacPherson et al., 2008). Within maternity care, the broader effects could include: the supportive role of CM in the process of labour and birth; the benefits of focused time and physical touch from partners and midwives; changes in requirement for medication; changes in relaxation or energy levels; changes in understanding about the benefits of a natural labour; changes in choice of birth position; and feelings of involvement in decision-making, autonomy and control. This may represent the idea of CM as ‘whole systems of medicine’ (Verhoef et al., 2005) (Hall et al., 2012; Witt, 2011). To ignore these aspects of treatment may lead
to an underestimation of the effectiveness and usefulness of the treatment in clinical practice (Dooley, 2006).

### 3.3 Efficacy and effectiveness studies

Reviews were examined specifically as to whether they were designed to answer questions of efficacy or effectiveness for acupuncture or acupressure (Cho et al., 2010; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011), relaxation techniques and yoga (Field, 2011; Gupta & Hofmeyr, 2004; Smith, Levett, et al., 2011), and manual therapies and massage (Smith et al., 2012). These trial designs are dependent on the clinical or research question being asked; however, the terms are sometimes used interchangeably and are often misunderstood. Efficacy trials are designed to show the extent to which a specific treatment or component of an intervention is effective under ideal experimental circumstances with patient populations specifically selected (Last, 2001). The intervention is often compared to a placebo, such as sham or minimal acupuncture. On the other hand, effectiveness trials are designed to elucidate the effect of the entire therapy, when introduced to the general patient population in the routine clinical environment. These studies are often pragmatic designs (Macpherson, 2004), where the therapy is frequently an addition to usual care, and is compared to usual care alone (Last, 2001).

### 3.4 Results

#### 3.4.1 Acupuncture and acupressure reviews

One Cochrane systematic review and three other systematic reviews were identified from the search and evaluated for effects on labour outcomes (Cho et al., 2010; Huntley et al., 2004; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011). They
covered the CM interventions of acupuncture and acupressure for pain management in labour and birth and included both efficacy and effectiveness studies (Table 3.1).

Smith et al.(2011), in the most recent Cochrane systematic review of acupuncture and acupressure, examined evidence from RCTs to answer the question of whether acupuncture and acupressure were effective for the supportive use of pain management in labour (Smith, Collins, Crowther, et al., 2011). The review included 13 trials, nine trials of acupuncture and four of acupressure, reporting on 1,986 women. Studies were mixed with regard to comparator controls, and treatment regimes, including electro-acupuncture (EA), manual acupuncture (MA), and acupressure (Table 3.1).
<table>
<thead>
<tr>
<th>Included paper</th>
<th>Year</th>
<th>n</th>
<th>Study question</th>
<th>Treatment method</th>
<th>Frequency/duration</th>
<th>Participants</th>
<th>Control</th>
<th>Efficacy / Effectiveness</th>
<th>Outcome measure/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith</td>
<td>2011</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chung</td>
<td>2003</td>
<td></td>
<td>Pain intensity</td>
<td>Standardised LI4+BL67 acupressure</td>
<td>5 mins pressure to points. 5 cycles completed in 5 mins – repeated for 20 mins total</td>
<td>Mixed parity</td>
<td>1. Efflurage 20 mins 2. Talking with patient</td>
<td>Efficacy</td>
<td>VAS scale to measure intensity of labour pain, qual data collected on women's experience of labour pain, frequency and intensity of contractions monitored by EFM</td>
</tr>
<tr>
<td>Hantoushzadeh</td>
<td>2007</td>
<td>150</td>
<td>Pain intensity</td>
<td>Semi-standardised Acupuncture</td>
<td>Manually stimulated to achieve de qi, and left until end of labour or removed due to discomfort</td>
<td>Primiparous</td>
<td>Sham needling at non-acu-points</td>
<td>Efficacy</td>
<td>VAS pain scores at 30 mins, 60 mins, 120 mins, then hourly until the end of labour</td>
</tr>
<tr>
<td>Hjelmstedt</td>
<td>2010</td>
<td></td>
<td>Pain intensity</td>
<td>Standardised Sp6 acupressure</td>
<td>During contractions over a 30 min period</td>
<td>Primiparous</td>
<td>1. Light touch 2. Standard care</td>
<td>Efficacy</td>
<td>VAS pain scores, oxytocin augmentation, pharmacological pain relief, CS, mode of delivery, episiotomy, birth weight, birth length, Apgar (5 min). Retrospective ratings of labour pain, coping with labour pain and experience of childbirth</td>
</tr>
<tr>
<td>Huang</td>
<td>2008</td>
<td>324</td>
<td>Pain intensity</td>
<td>Semi-standardised electro-acupuncture</td>
<td>In established labour for 30–60 mins</td>
<td>Primiparous</td>
<td>1. TENS 2. EDB 3. Breathing &amp; local massage</td>
<td>Efficacy</td>
<td>VAS pain scores pre-pain, 30 mins, 60 mins, 120 mins, end of active stage, complete dilation, second stage, third stage and 1 day after labour</td>
</tr>
<tr>
<td>Kashanian</td>
<td>2010</td>
<td>120</td>
<td>Pain intensity</td>
<td>Standardised Sp6 acupressure</td>
<td>In established labour for 30 mins</td>
<td>Primiparous</td>
<td>Light touch Sp6</td>
<td>Efficacy</td>
<td>VAS pain scores, duration of active phase of labour, mode of delivery, use of oxytocin, neonatal weight, Apgar scores</td>
</tr>
<tr>
<td>Lee</td>
<td>2004</td>
<td>89</td>
<td>Pain intensity</td>
<td>Standardised Sp6 acupressure</td>
<td>During contractions over a 30 min period</td>
<td>Mixed parity</td>
<td>Light touch Sp6</td>
<td>Efficacy</td>
<td>VAS pain scores at entry, pre-intervention, post-intervention, 30 mins and 60 mins after intervention. Duration of labour, use of pain relief, maternal anxiety.</td>
</tr>
<tr>
<td>Mårtensson</td>
<td>2008</td>
<td>128</td>
<td>Pain intensity</td>
<td>Semi-standardised acupuncture</td>
<td>40 mins treatment with stimulation every 10 mins</td>
<td>Mixed parity</td>
<td>SWI</td>
<td>Efficacy</td>
<td>VAS pain scores, and VAS relaxation scores immediately before and 30, 60, 90, 120, 150 and 180 mins after treatment</td>
</tr>
</tbody>
</table>

Table 3-1: Systematic reviews – characteristics of included original studies
<table>
<thead>
<tr>
<th>Included paper</th>
<th>Year</th>
<th>n</th>
<th>Study question</th>
<th>Treatment method</th>
<th>Frequency/duration</th>
<th>Participants</th>
<th>Control</th>
<th>Efficacy / Effectiveness</th>
<th>Outcome measure/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang</td>
<td>2008</td>
<td>324</td>
<td>Pain intensity</td>
<td>Semi-standardised acupuncture</td>
<td>In established labour for 30–60 mins</td>
<td>Primiparous</td>
<td>1. TENS 2, EDB 3, Breathing, local massage</td>
<td>Efficacy</td>
<td>VAS pain scores pre-pain, 30 mins, 60 mins, 120 mins, end of active stage, completion dilation, second stage, third stage and 1 day after labour</td>
</tr>
<tr>
<td>Ziae</td>
<td>2006</td>
<td>90</td>
<td>Pain intensity</td>
<td>Standardised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery</td>
<td>Mixed parity</td>
<td>1. Minimal needling 2. No intervention</td>
<td>Efficacy</td>
<td>Pain intensity, relaxation, duration of labour, need for augmentation by oxytocin, caesarean delivery</td>
</tr>
<tr>
<td>Skilnand</td>
<td>2002</td>
<td>210</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery or removed due to discomfort, or conventional analgesia required</td>
<td>Mixed parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
</tr>
<tr>
<td>Ramnerø</td>
<td>2002</td>
<td>100</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ for 1–3 hrs</td>
<td>Stratified by parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
</tr>
<tr>
<td>Qu</td>
<td>2007</td>
<td>36</td>
<td>Pain intensity</td>
<td>Standardised Sp6 + L.I. 4 electro-acupuncture</td>
<td>De qi obtained and needles retained for 2 mins, EA commenced and stimulation gradually increased until 20 mins. Repeated 7-8 cm dilation.</td>
<td>Primiparous</td>
<td>No pain relief</td>
<td>Efficacy</td>
<td>VAS pain scores and degree of relaxation every hour, use of analgesics, augmentation with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar, infant birthweight</td>
</tr>
<tr>
<td>Skilnand</td>
<td>2002</td>
<td>210</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery or removed due to discomfort, or conventional analgesia required</td>
<td>Mixed parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
</tr>
<tr>
<td>Cho, et.al</td>
<td>2010</td>
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<tr>
<td>Authors</td>
<td>Year</td>
<td>Sample Size</td>
<td>Group</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>Mårtenson</td>
<td>2008</td>
<td>128</td>
<td>Pain intensity</td>
<td>Semistandardised acupuncture</td>
<td>40 mins treatment with stimulation every 10 mins</td>
<td>Mixed parity</td>
<td>SWI</td>
<td>Efficacy</td>
<td>VAS pain scores, and VAS relaxation scores immediately before and 30, 60, 90, 120, 150 and 180 mins after treatment</td>
</tr>
<tr>
<td>Nesheim</td>
<td>2003</td>
<td>198</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained and left in place for 10–20 mins, and removed after needling or taped and left</td>
<td>Mixed parity</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>Use of meperidine, use of other analgesics, duration of labour, mode of delivery and Apgar VAS pain scores</td>
</tr>
<tr>
<td>Ramnerö</td>
<td>2002</td>
<td>100</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ 1–3 hrs</td>
<td>Stratified by parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores and degree of relaxation every hour, use of analgesics, augmentation with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar, infant birthweight</td>
</tr>
<tr>
<td>Skilnand</td>
<td>2002</td>
<td>210</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery or removed for discomfort, or conventional analgesia required</td>
<td>Mixed parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
</tr>
<tr>
<td>Zhang</td>
<td>2006</td>
<td>120</td>
<td>Pain intensity</td>
<td>Standardised Sp-6 electroacupuncture</td>
<td>Electro-acupuncture at Sp-6, duration NR</td>
<td>Primiparous</td>
<td>1. Placebo EA with non-penetrating needle at Sp6 2. No treatment</td>
<td>Efficacy</td>
<td>VAS pain scores, 15 mins, 30 mins and 1, 2 and 3 hours after treatment, duration of labour, Apgar</td>
</tr>
<tr>
<td>Zhou</td>
<td>2007</td>
<td>111</td>
<td>Pain intensity</td>
<td>Standardised Sp-6 electroacupuncture</td>
<td>Electro-acupuncture at Sp-6, duration NR</td>
<td>Primiparous</td>
<td>1. Placebo EA with non-penetrating needle at Sp6 2. No treatment</td>
<td>Efficacy</td>
<td>VAS pain scores, 15 mins, 30 mins and 1, 2 and 3 hours after treatment</td>
</tr>
<tr>
<td>Ziaei</td>
<td>2006</td>
<td>90</td>
<td>Pain intensity</td>
<td>Standardised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery</td>
<td>Mixed parity</td>
<td>1. Minimal needling 2. No intervention</td>
<td>Efficacy</td>
<td>Pain intensity, relaxation, duration of labour, need for augmentation by oxytocin, caesarean delivery</td>
</tr>
<tr>
<td>Lee, et. al</td>
<td>2004</td>
<td></td>
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<td>SR</td>
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<tr>
<td>Nesheim</td>
<td>2003</td>
<td>198</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained and left in place for 10–20 mins, and removed after needling or taped and left</td>
<td>Mixed parity</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>VAS pain scores and degree of relaxation every hour, use of analgesics, augmentation with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar, infant birthweight</td>
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<td>Ramnerö</td>
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<td>Stratified by parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores and degree of relaxation every hour, use of analgesics, augmentation with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar, infant birthweight</td>
</tr>
<tr>
<td>Skilnand</td>
<td>2002</td>
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<td>Management of labour pain</td>
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<td>Mixed parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
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<tr>
<td>Huntley</td>
<td>2003</td>
<td></td>
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<td></td>
<td></td>
<td>VAS pain scores and degree of relaxation every hour, use of analgesics, augmentation with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar, infant birthweight</td>
</tr>
<tr>
<td>Ramnerö</td>
<td>2002</td>
<td>100</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ 1–3 hrs</td>
<td>Stratified by parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
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<tr>
<td>Skilnand</td>
<td>2002</td>
<td>210</td>
<td>Management of labour pain</td>
<td>Individualised acupuncture</td>
<td>De qi obtained, needles left in situ until delivery or removed due to discomfort, or conventional analgesia required</td>
<td>Mixed parity</td>
<td>Conventional analgesia</td>
<td>Effectiveness</td>
<td>VAS pain scores, 30 mins, 1 and 2 hours after treatment, need for conventional pain relief and use of oxytocin</td>
</tr>
</tbody>
</table>

Acupress: Acupressure
CS: Caesarean section
EA: Electro-acupuncture
EDB: Epidural block
EFM: Electronic fetal monitoring
Indiv.: Individualised acupuncture protocol
MA: Manual acupuncture
NR: Not reported
Semi-stand.: Semi-standardised acupuncture protocol
Stand.: Standardised acupuncture protocol
SWI: Sterile water injections
TENS: Transcutaneous Electrical Nerve Stimulation
VAS: Visual analogue scale
3.4.2 Summary of results – acupuncture/acupressure

The results and p values of the systematic reviews are summarised below and in Table 3.2. All values are <0.05 unless otherwise indicated.

**Review: Smith et al., (Smith, Collins, Crowther, et al., 2011)**

Where acupuncture was compared with standard care, there was:

- reduced requirement for pharmacological analgesia (significant heterogeneity)
- lower rates of instrumental vaginal deliveries, and
- greater relaxation.

Where acupuncture was compared with placebo, there was:

- reduced requirement for pharmacological analgesia
- reduced length of labour in the active phase; and from initiation of acupuncture, and
- increased satisfaction with pain relief.

Where MA and EA was compared with no treatment, there was:

- reduced pain intensity (1 study MA), and
- reduced pain intensity (1 study EA).

Where acupressure was compared with placebo, there were:

- lower rates of CS
- reduced length of labour
- reduced pain intensity, and
- less anxiety.

Where acupressure was compared with a combined control (placebo and standard care):

- pain intensity was reduced.

**Review: Cho et al (Cho et al., 2010)**

Where EA was compared with placebo EA:

- reduced pain scores were significant at 30 minutes post treatment. The effects at 2 and 3 hours post treatment continue to favour acupuncture, but the results were no longer significant.

Where acupuncture was compared with minimal acupuncture:

- results for reduced pain scores favour acupuncture, but are non-significant between the groups. The heterogeneity scores, however, are extremely high in this analysis ($I^2 = 92-98\%$).

Where acupuncture was compared with no intervention:

- reduced pain scores were significant at 30 minutes ($p<0.001$), and at 1 hour ($p=0.05$). The effects at 2 and 3 hours post treatment continue to favour acupuncture, but the results are no longer significant ($p=0.07$, $p=0.09$ respectively). The pooled results at the 1, 2 and 3 hour marks show significant heterogeneity with the inclusion of the Ziaei (Ziaei & Hajipour, 2006) results at these time points ($I^2 = 94\%, 84\%, 53\%$ respectively).

Where acupuncture was compared with conventional analgesia, the acupuncture group reported:

- less meperidine required
• fewer incidences of EDB use, and
• less requirement for all other analgesic methods. Heterogeneity was low for these pooled results.

The following secondary outcomes were also reported:

• women in the acupuncture group had a significantly shorter duration of labour (Thompson & Miller, 2014; Zhang, 2006; Zhou, 2007), and used less oxytocin (Romano, 2008; Thompson & Miller, 2014; Zhou, 2007), and
• women in the acupuncture group were more satisfied with their pain relief (Zhang, 2006; Zhou, 2007), were more relaxed (Ma et al., 2010), or expressed a willingness to choose acupuncture for future deliveries (Zhou, 2007).

Review: Lee et al (Lee & Ernst, 2004)
Where acupuncture was compared with control, the acupuncture group showed:

• reduced requirement for meperidine, and
• reduced requirement for an EDB.

Where acupuncture was compared with usual hospital-based care, the acupuncture intervention groups showed:

• reduced requirement for meperidine, and
• reduced requirement of an EDB.

Where acupuncture was compared with placebo acupuncture (superficial needling in non-acupuncture points), the acupuncture intervention groups showed:

• reduced requirement for meperidine, and
• reduced requirement for an EDB.
Review: Huntley et al (Huntley et al., 2004)
Where acupuncture was compared with minimal acupuncture (one study n=210) (Skilnand et al., 2002), the acupuncture intervention groups showed:

- significantly lower pain scores at 30, 60 and 120 minutes after treatment and 2 hours after birth
- significantly less need for an EDB, and
- significantly less need for intramuscular pethidine.

Where acupuncture was compared with conventional analgesia (one study n=90) (Ramnerö et al., 2002), the acupuncture intervention group showed:

- significantly reduced need for EDB
- significantly greater relaxation, and
- no difference in pain scores.
Table 3-2: Systematic reviews of acupuncture and acupressure for labour – summary of outcomes

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Review type</th>
<th>Studies</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee</td>
<td>2004</td>
<td>SR</td>
<td>3</td>
<td>496</td>
<td>Acupuncture</td>
<td>Mixed control (3)</td>
<td>Less likely to use meperidine – RR = 0.36 [0.24, 0.54]**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Active control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>298</td>
<td>Acupuncture</td>
<td>Active control</td>
<td>Less likely to use EDB – RR = 0.45 [0.29, 0.69]**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Usual care</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>90</td>
<td>Acupuncture</td>
<td>Usual care</td>
<td>Less likely to use meperidine – RR = 0.32 [0.18, 0.58]**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>208</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>Less likely to use meperidine- RR = 0.40 [0.23, 0.69]**</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Sham acupuncture</td>
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<tr>
<td>Cho</td>
<td>2010</td>
<td>SR</td>
<td>10</td>
<td>2038</td>
<td>Acupuncture</td>
<td>Active control (8) Usual care (3) Mixed control(2)</td>
<td>VAS pain scores – 15 mins – MD = -4.09 [-8.05, -0.12]* Reduced pain intensity – 30 mins – MD = -5.94 [-9.83, -2.06]**</td>
</tr>
<tr>
<td></td>
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<td>2</td>
<td>230</td>
<td>Electro-</td>
<td>Placebo</td>
<td>VAS pain scores – NS MD = -10.15 [-23.18, 2.87] Heterogeneity scores for this analysis /² = 92-98%</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>acupuncture</td>
<td></td>
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<td></td>
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<td>3</td>
<td>444</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>VAS pain scores – 30 mins: MD = -10.56 [-16.08, -5.03]**</td>
</tr>
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<td></td>
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<td></td>
<td>Electro-</td>
<td>No intervention</td>
<td>60 mins: MD = -7.71 [-15.48, 0.06], p=0.06</td>
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<td></td>
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<td>2</td>
<td>230</td>
<td>acupuncture</td>
<td></td>
<td>2 hours: -6.23 [-12.91, 0.46], p=0.007</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>4</td>
<td>644</td>
<td>Electro-</td>
<td></td>
<td>3 hours: -5.58 [-11.97, 0.81], p=0.009</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>acupuncture</td>
<td></td>
<td>Significant heterogeneity with inclusion of the Ziaei study (Ziaei &amp; Hajipour, 2006)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>3</td>
<td>895</td>
<td>Acupuncture</td>
<td>Usual care</td>
<td>Less meperidine: RR = 0.20 [0.12, 0.33]**</td>
</tr>
<tr>
<td></td>
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<td>2</td>
<td>805</td>
<td>Acupuncture</td>
<td>Active control (1)</td>
<td>Other analgesia: RR = 0.75 [0.66, 0.85]**</td>
</tr>
<tr>
<td></td>
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<td>2</td>
<td>697</td>
<td>Acupuncture</td>
<td>1 trial acupuncture</td>
<td>Use of EDB: RR = 0.68 [0.46, 1.00]**</td>
</tr>
<tr>
<td>Smith</td>
<td>2011</td>
<td>SR</td>
<td>13</td>
<td>1986</td>
<td>Acupuncture / Acupressure</td>
<td>Active control (8)</td>
<td>Usual care (3)</td>
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<tr>
<td>1</td>
<td>90</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>VAS scores – significant improvement in VAS scores, 30mins, 60mins, 2 hours after birth **</td>
<td>Reduced need for EDB (RR= 0.52 [95% C.I.: 0.30, 0.92])*</td>
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<tr>
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<td>Significantly greater relaxation (MD= -0.93 [95% C.I.: -1.66, -0.20])</td>
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<td></td>
<td>No difference in pain scores (MD= -0.29 [95% C.I.; -0.90, 0.32])</td>
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<tr>
<td></td>
<td>1</td>
<td>163</td>
<td>Acupuncture</td>
<td>No intervention</td>
<td>Reduced pain intensity – SMD= -0.42 [-0.65, -0.18]**</td>
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<td></td>
<td>2</td>
<td>240</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>NS Pain intensity score – SMD= 0.04 [-0.22, 0.30]</td>
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<td></td>
<td>1</td>
<td>150</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>Increased satisfaction with pain relief – RR=2.38 [1.78, 3.19]*</td>
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<td></td>
<td>1</td>
<td>136</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>Reduced pharmacological analgesia – RR= 0.72 [0.58, 0.88]**</td>
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<tr>
<td></td>
<td>3</td>
<td>704</td>
<td>Acupuncture</td>
<td>Standard care</td>
<td>Reduced pharmacological analgesia – RR= 0.68 [0.56, 0.83]**</td>
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<tr>
<td></td>
<td>3</td>
<td>704</td>
<td>Acupuncture</td>
<td>Standard care</td>
<td>Fewer instrumental deliveries – RR= 0.67 [0.46, 0.98] *</td>
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<tr>
<td></td>
<td>1</td>
<td>150</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>Reduced length of labour (active phase) – p&lt;0.001 **</td>
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<td></td>
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<tr>
<td></td>
<td>1</td>
<td>210</td>
<td>Acupuncture</td>
<td>Sham acupuncture</td>
<td>Reduced length of labour MD= 71 fewer minutes [-123.7, -18.30] *</td>
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<td></td>
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<tr>
<td></td>
<td>1</td>
<td>120</td>
<td>Acupressure</td>
<td>Placebo</td>
<td>Reduced pain intensity – SMD= -0.55 [-0.92, -0.19] *</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>322</td>
<td>Acupressure</td>
<td>Combined control</td>
<td>Reduced pain intensity – SMD= -0.42 [-0.65, -0.18]**</td>
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<td></td>
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</tbody>
</table>

* indicates statistically significant result <0.05  
** indicates statistically significant result <0.01  
EDB: Epidural block  
MD: Mean difference  
NS: Non-significant  
RR: Relative risk  
SMD: Standardised mean difference
Smith et al. (Smith, Collins, Crowther, et al., 2011), noted that there was some risk of bias, such as inadequate reporting of blinding procedures, publication bias due to a focus on English language databases, and reporting bias. They concluded that acupuncture and acupressure may have a role in reducing pain, use of pharmacological pain relief, and CS rates, and increasing satisfaction with pain management. Overall, self-reported pain intensity scores were reduced significantly in acupressure studies, as were rates of CS, levels of anxiety and length of labour. Pain scores were not significantly reduced for acupuncture studies; however, the reduction in use of pharmacological analgesia was significant when compared with both placebo control (including minimal needling) and standard care. Length of labour was reduced and satisfaction with pain relief was increased. For EA, pain intensity was reduced only when compared with no treatment (Table 3.2).

An earlier review by Cho et al. (2010), included 10 RCTs involving 2,038 women (Cho et al., 2010) (Table 3.1). The main research question being addressed was the efficacy of acupuncture for pain relief, with the main outcome measure being patient-rated pain scores at specific time intervals during labour. Eight of the ten studies in this review were also reported on in the Smith (2011) review (Smith, Collins, Crowther, et al., 2011) (Table 3.1). The studies included in the Cho review examined acupuncture and EA studies (Zhang, 2006; Zhou, 2007). The primary outcome of interest relates specifically to pain scores in three pooled analyses, and to use of pharmacological analgesia in one pooled analysis.

The authors state that overall the evidence does not support use of acupuncture for pain relief in labour, due to the non-significant reduction in pain scores past
30 minutes. However, we noted there was evidence of a continued trend towards favoring acupuncture up to 3 hours post-intervention (Table 2).

Importantly there were statistically significant reductions in the use of meperidine or any other analgesia in labour. In the secondary outcomes, the authors report, the women experienced significantly shorter duration of labour, used less oxytocin, and were more satisfied with pain relief, more relaxed and more willing to choose acupuncture for future deliveries (Table 3.2).

The authors acknowledge the diversity of the primary studies, contributing to heterogeneity in the review (Table 3.1).

The review by Lee and Ernst (Lee & Ernst, 2004), included 3 RCTs involving 496 women (Nesheim et al., 2003; Ramnerö et al., 2002; Skilnand et al., 2002) (Table 3.1). All three studies were included in the Cho et al. review (Cho et al., 2010) (Table 3.1). The main research question addressed by Lee and Ernst (Lee & Ernst, 2004) was the efficacy of acupuncture as a supportive analgesic method, with the main outcome analysis based on use of meperidine and EDBs (Table 3.2). The results show a reduced use of meperidine and EDBs compared with active control, sham treatment and usual care. The authors suggest that the evidence for acupuncture as an adjunct therapy is promising, as is reflected in their outcome of interest; use of pharmaceutical analgesia, but they state that there is paucity of trial data (Lee & Ernst, 2004).

The Huntley review (Huntley et al., 2004) (Table 3.1), included two studies of acupuncture, reporting on 300 women of mixed parity (Ramnerö et al., 2002; Skilnand et al., 2002). The data were not pooled in a meta-analysis. The authors note that while there are too few studies included in the review to make a definitive
statement, it appears that acupuncture may have an influence on pain management and in reducing the use of pharmacological analgesia in labour despite some equivocal findings on pain ratings (Table 3.2). The equivalent pain scores could indicate that acupuncture analgesia was as effective as pharmacological analgesia, as both the study and control groups in the original study were equally satisfied with their pain relief (Ramnerö et al., 2002).

3.4.3 Relaxation including yoga

The Cochrane Review of relaxation techniques for pain relief in labour included 11 trials, reporting on 1,374 women (38) (Table 3.3). There were six trials of relaxation, four effectiveness trials, and two efficacy trials; and two trials of yoga, one efficacy and one effectiveness. The other studies of audio-analgesia and music will not be reported here.
<table>
<thead>
<tr>
<th>Included paper</th>
<th>Year</th>
<th>No.</th>
<th>Study question</th>
<th>Treatment method</th>
<th>Frequency/duration</th>
<th>Participants</th>
<th>Control</th>
<th>Efficacy / Effectiveness</th>
<th>Outcome measure/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith</td>
<td>2011</td>
<td>1374</td>
<td>Pain management</td>
<td>SR</td>
<td>During contractions</td>
<td>Primiparous</td>
<td>Usual care (nursing)</td>
<td>Effectiveness</td>
<td>Self-assessment state / trait anxiety; VAS pain intensity</td>
</tr>
<tr>
<td>Almeida</td>
<td>2005</td>
<td>65</td>
<td>Pain intensity</td>
<td>Psychrophylaxis Breathing &amp; relaxation</td>
<td>Throughout all stages of labour</td>
<td>Mixed parity</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>Pain intensity on numerical rating scale: low (1–4), mild (5–6), severe (7–8), very severe (9–10)</td>
</tr>
<tr>
<td>Bagharpoosh</td>
<td>2006</td>
<td>62</td>
<td>Pain intensity</td>
<td>Progressive muscle relaxation</td>
<td>Throughout all stages of labour until birth</td>
<td>Mixed parity</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>Pain intensity on numerical rating scale: low (1–4), mild (5–6), severe (7–8), very severe (9–10)</td>
</tr>
<tr>
<td>Bergström</td>
<td>2009</td>
<td>1087 women 1064 partners</td>
<td>Pain intensity</td>
<td>Psychrophylaxis Antenatal education</td>
<td>30 min training at each antenatal education session. Used throughout all stages of labour</td>
<td>Mixed parity</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>EDB during labour; labour pain; mode of delivery; experience of childbirth (baseline &amp; 3 months); Swedish Parenthood Stress Questionnaire (baseline &amp; 3 months)</td>
</tr>
<tr>
<td>Chuntharapat</td>
<td>2008</td>
<td>74</td>
<td>Pain intensity</td>
<td>a) Yoga, incl: asanas, chanting, breathing awareness, yoga nidra and dhyana; b) education; anatomy of birth</td>
<td>6 x 60 min yoga practice sessions</td>
<td>Mixed parity</td>
<td>1. Usual care 2. Seen by researchers at each antenatal visit 3. weekly phone calls to ensure compliance</td>
<td>Effectiveness</td>
<td>VASTC; MCQ; VAS labour pain; behavioural observation; Apgar score; length of labour; augmentation; pethidine usage</td>
</tr>
<tr>
<td>Dolcetta</td>
<td>1979</td>
<td>53</td>
<td>Pain intensity</td>
<td>RAT – Respiratory Autogenic Training</td>
<td>≥5 antenatal training sessions</td>
<td>Mixed parity</td>
<td>Traditional psychrophylaxis</td>
<td>Efficacy</td>
<td>Pain, pain experience, Apgar score, length of labour, emotional state during labour and after childbirth</td>
</tr>
<tr>
<td>Durham</td>
<td>1986</td>
<td>30</td>
<td>Pain intensity</td>
<td>Music plus Lamaze breathing</td>
<td>Antenatal training</td>
<td>Primiparous</td>
<td>Lamaze breathing alone</td>
<td>Efficacy</td>
<td>Use of pain relief</td>
</tr>
<tr>
<td>Liu</td>
<td>2010</td>
<td>103</td>
<td>Pain intensity</td>
<td>Music plus standard care</td>
<td>30 mins during latent phase and active phase</td>
<td>Primiparous</td>
<td>Standard care</td>
<td>Effectiveness</td>
<td>VAS for pain (VASP), present behavioural intensity (PHI), anxiety measures, VAS anxiety (VASA), questionnaire about effectiveness of music intervention</td>
</tr>
</tbody>
</table>

Included paper | Year  | No.          | Study question                  | Treatment method                                      | Frequency/duration          | Participants | Control                  | Efficacy / effectiveness | Outcome measure/s                      |

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<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Parity</th>
<th>Intervention</th>
<th>Duration</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moore</td>
<td>1965</td>
<td>25</td>
<td>Audio-analgesia: white noise at 120 decibels</td>
<td>Once in established labour until tired, or if midwife considered pain relief inadequate</td>
<td>Mixed parity White noise at 90db Efficacy Midwife’s opinion of pain relief from audio-analgesia, women’s satisfaction with ‘sea noise’</td>
</tr>
<tr>
<td>Phumdoong</td>
<td>2007</td>
<td>207</td>
<td>Postural management (yoga) 4 experimental groups: 1) PSU Cat position alt. head high position + music 2) 1 without music, 3) PSU Cat alt. supine, 4) high head</td>
<td>From 3–4 cm dilation until 10 cm dilation or at least 4 hours. 30 mins in each alternating position as prescribed for group</td>
<td>Primiparous Supine position Effectiveness VAS sensory pain, VAS distress pain, length of active phase of labour</td>
</tr>
<tr>
<td>Yildirim</td>
<td>2004</td>
<td>40</td>
<td>Breathing techniques, nurse administered massage, self-administered massage + info about labour</td>
<td>Instruction and info during latent phase of labour, accompanied during labour until birth</td>
<td>Primiparous No additional education or supportive nursing care Efficacy Pain assessed at 2 cm, 4 cm, 6 cm, 8 cm and 10 cm, behaviour observed and classified by investigator, interview 2 hours post-birth</td>
</tr>
<tr>
<td>Field</td>
<td>2011</td>
<td>2038</td>
<td>SR</td>
<td>VASTC; MCQ; VAS labour pain; behavioural observation; Apgars; length of labour; augmentation; pethidine usage</td>
<td></td>
</tr>
<tr>
<td>Chuntharapat</td>
<td>2008</td>
<td>74</td>
<td>a) Yoga, incl: asanas, chanting, breathing awareness, yoga nidra and dhyana; b) education; anatomy of birth</td>
<td>6 x 60 min yoga practice sessions</td>
<td>Primiparous 1. Usual care 2. Seen by researchers at each antenatal visit 3. Weekly phone calls to ensure compliance Effectiveness VASTC; MCQ; VAS labour pain; behavioural observation; Apgars; length of labour; augmentation; pethidine usage</td>
</tr>
</tbody>
</table>

Db: decibels
Indiv.: Individualised protocol
MCQ: Maternal comfort questionnaire
NR: Not reported
Stand.: Standardised protocol
VAS: Visual analogue scale
VASTC: Visual analogue scale total comfort
3.4.4 Summary of results – relaxation and yoga

The results and p values of the systematic reviews are summarised below and in Table 3.4. All values are <0.05 unless otherwise indicated.

Where relaxation was compared with standard care, relaxation techniques showed:

- reduced pain intensity in the latent phase
- reduced pain intensity in the active phase
- increased satisfaction with pain relief, and
- lower assisted vaginal delivery.

Where relaxation was compared with control, relaxation showed:

- lower caesarean delivery (one study)
- no difference caesarean delivery (one study), and
- no difference Apgar <7 at 5 minutes.

When yoga was compared with control, yoga for labour was associated with:

- reduced pain intensity in the latent phase of labour, and
- increased satisfaction with pain relief in the latent phase.

When compared with usual care, yoga was associated with:

- increased satisfaction with the childbirth experience, and
- reduced length of labour.

When compared with supine position, yoga was associated with:

- reduced use of pharmacological pain relief, and
- reduced length of labour.
In the Smith review (Smith, Levett, et al., 2011), two yoga studies were included. One yoga study (Chuntharapat et al., 2008) reported outcome data for self-reported pain scores, and both reported data for length of labour and pharmacological pain relief (Chuntharapat et al., 2008; Phumdoung, Youngvanichsate, Jongpaiboonatana, & Leetanaporn, 2007). The Phumdoung (Phumdoung et al., 2007) study had five study groups, with the control group required to give birth in the supine position.

The conclusions of the review of 11 trials suggest that relaxation techniques and yoga may help to manage labour pain. However, the authors state that there was considerable heterogeneity among the trials in terms of the ‘relaxation’ technique that was utilised as well as variations in trial methodologies, regime, or time to practice. Individual trials or a small number of trials reported less intense pain, increased satisfaction with pain relief, increased satisfaction with childbirth and lower rates of assisted vaginal delivery. However, due to the small numbers and considerable variation, more research is needed to clarify the role of relaxation and yoga for pain relief in childbirth. A high risk of bias was noted in most trials.

In a review conducted by Field (2011) (Table 3.2), researchers found that yoga contributed beneficial effects from pain relief during labour and reduced length of total labour when compared with usual care (Field, 2011). These benefits included:

- Higher levels of maternal comfort, both during labour and 2 hours post labour
- Less labour pain
- Shorter duration of the first stage of labour
- Shorter total time spent in labour, and
- Lower prematurity rate.
This review contained one original study of yoga for labour pain by Chuntharapat (Chuntharapat et al., 2008), which was also included in Smith’s 2011 systematic review (Smith, Levett, et al., 2011).
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Studies</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith et al.</td>
<td>2011</td>
<td>11</td>
<td>1374</td>
<td>Relaxation/Yoga</td>
<td>Standard care/Control</td>
<td>Reduced pain intensity – latent phase – MD = -1.25 [95% C.I.: -1.97 to -0.53]</td>
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<td>Reduced pain intensity – active phase – MD = -2.48 [95% C.I.: -3.13 to 0.83]</td>
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<td></td>
<td>Increased satisfaction with pain relief – RR = 8.0 [95% C.I.: 1.10 to 58.19]</td>
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<td>Lower assisted vaginal delivery – RR = 0.07 [95% C.I.: 0.01 to 0.50]</td>
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<td>No difference caesarean delivery – RR = 0.13 [95% C.I.: 0.02 to 0.93]</td>
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<td></td>
<td>No difference Apgar &lt;7 – RR = 0.47 [95% C.I.: 0.02 to 10.69]</td>
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<td></td>
<td>Reduced pain intensity – MD = -6.12 [95% C.I.: -11.77 to -0.47]</td>
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<td></td>
<td>Increased satisfaction with pain relief – RR = 7.88 [95% C.I.: 1.51 to 14.25]</td>
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<td></td>
<td>Satisfaction with childbirth experience – MD = 6.34 [95% C.I.: 0.26 to 12.42]</td>
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<td>Reduced use pharmacological pain relief – RR = 0.05 [95% C.I.: 0.01 to 0.35]</td>
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<td></td>
<td>Reduced length of labour – MD = -139.91 [95% C.I.: -252.50 to -27.32]</td>
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<td></td>
<td>Reduced length of labour – MD = -191.34 [95% C.I.: -243.72 to -138.96]</td>
</tr>
<tr>
<td>Field</td>
<td>2011</td>
<td>1</td>
<td>74</td>
<td>Yoga positions</td>
<td>Control</td>
<td>Higher levels of maternal comfort during labour (VASTC): time 1: 52.88 (SD 13.57) vs 45.00 (SD 12.84), p&lt;0.05; time 2: 40.03 (SD 11.84) vs 33.33 (SD 10.85), p&lt;0.05; time 3: 29.64 (SD 9.31) vs 23.67 (SD 9.22), p&lt;0.05.</td>
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<td></td>
<td>Higher levels of maternal comfort 2 hours post labour (MD = 6.34 [95% C.I.: 0.14 to 12.53], p&lt;0.05)</td>
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<td></td>
<td>Less labour pain: time 1: 51.79 (SD 10.46) vs 57.91 (SD 12.83), p&lt;0.05; time 2: 67.24 (SD 9.41) vs 71.91 (SD 7.70), p&lt;0.05; time 3: 83.48 (SD 8.89) vs 88.03 (SD 8.05), p&lt;0.05.</td>
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<td></td>
<td></td>
<td></td>
<td>Shorter duration of labour – 1st stage: Mean 519.88 (SD 185.68) vs 659.79 (SD 272.79)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Shorter duration of labour – total length: Mean 559.06 (SD 203.43) vs 683.58 (SD 287.40)</td>
</tr>
</tbody>
</table>

RR: Relative Risk; MD: Mean Difference; VASTC: Visual analogue scale total comfort
3.4.5 Manual therapies

One review for manual therapies or massage was located. This Cochrane Review of manual healing methods for pain management in labour included massage and reflexology (41) (Table 3.5). This review evaluated six trials, with data reported for five trials that involved 264 women. The review found no other trials of different modalities, and therefore did not include any other trials. Three trials were effectiveness trials, and three were efficacy studies.

3.4.6 Summary of results – manual therapies (massage)

The results and p values of the systematic reviews are summarised below and in Table 3.6. All values are <0.05 unless otherwise indicated.

Where massage were compared with usual care, massage showed:

- less pain during labour – first stage, and
- reduced anxiety during the first stage of labour.

Where massage was compared with music, massage showed

- reduced labour pain, and
- reduced pharmacological pain relief.

The authors note that massage may be useful for reducing pain and anxiety in labour, and while trial quality was reasonable, no trial was at low risk of bias.
<table>
<thead>
<tr>
<th>Included paper</th>
<th>Year</th>
<th>No.</th>
<th>Study question</th>
<th>Treatment method</th>
<th>Frequency</th>
<th>Participants</th>
<th>Duration treatment</th>
<th>Control</th>
<th>Efficacy / Effectiveness</th>
<th>Outcome measure/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith</td>
<td>2011</td>
<td>326</td>
<td>Pain management</td>
<td>SR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abasi</td>
<td>2009</td>
<td>62</td>
<td>Pain intensity</td>
<td>Massage applied from sacral spine upward to lumbar spine and back to sacrum</td>
<td>30 mins during each phase of labour</td>
<td>Primiparous</td>
<td>Latent, active and second stages</td>
<td>Standard care</td>
<td>Effectiveness</td>
<td>VAS for pain intensity</td>
</tr>
<tr>
<td>Chang</td>
<td>2002</td>
<td>60</td>
<td>Pain intensity and anxiety</td>
<td>Massage for 30 mins during uterine contractions by researcher and taught to partner. Comprising: abdominal effleurage, sacral pressure and shoulder and back kneading</td>
<td>30 mins during each phase of labour</td>
<td>Primiparous</td>
<td>First, active and second stages</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>Pain intensity, need for pain relief</td>
</tr>
<tr>
<td>Field</td>
<td>1997</td>
<td>28</td>
<td>Pain intensity, pain management</td>
<td>Massage + Lamaze breathing learned in antenatal education. Massage = 20 mins of head, shoulder/back, hand and foot massage in order</td>
<td>10 min training taught to partners in antenatal period</td>
<td>NR</td>
<td>20 mins every hour, repeated for 5 hours</td>
<td>Lamaze breathing exercises learned in antenatal education</td>
<td>Effectiveness</td>
<td>Mood states depression scale, pain, stress level, labour and neonatal measures</td>
</tr>
<tr>
<td>Karami</td>
<td>2007</td>
<td>60</td>
<td>Pain intensity</td>
<td>Massage using effleurage techniques administered on sacrum, buttocks, shoulders, waist, food and hand</td>
<td>During labour</td>
<td>Primiparous</td>
<td>During different stages of labour</td>
<td>Usual care</td>
<td>Effectiveness</td>
<td>VAS pain intensity, some clinical outcomes</td>
</tr>
</tbody>
</table>

Page 108 of 345
Kimber 2008 90 Pain intensity Massage program with relaxation techniques taught to birth partner 1 x 2.5 hour antenatal class + practice 3 times per week at home Mixed parity Throughout labour 1. Active control: music with relaxation techniques (breathing and visualisation) 2. Usual care Efficacy 2 separate VAS for self-reported pain during labour and birth, 90 mins following birth, and before transfer from labour care, use of pharmacological analgesia, obstetric interventions, birth outcomes, maternal satisfaction, sense of control LAS, birth-related maternal worries (Cambridge Birth Worry Scale)

Taghinejad 2010 101 Pain intensity Massage Massage points on lower area of abdomen, shoulders, back and pressed pubic area Primiparous 30 mins to each area Music Efficacy VAS pain intensity before and after intervention, duration of latent phase of labour, need for other pain relief

Las: Labour Agentry Scale
NR: Not reported
VAS: Visual analogue scale

Table 3-6: Manual Therapies – massage and reflexology

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Studies</th>
<th>participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith et.al.</td>
<td>2011</td>
<td>5</td>
<td>264</td>
<td>Massage</td>
<td>Usual care / Music</td>
<td>Less pain during labour – 1st stage – SMD= -0.82 [95% C.I.: -1.17 to -0.47]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>225</td>
<td>Massage</td>
<td>Usual care</td>
<td>Less pain during labour – SMD= -0.40 [95% C.I.: 0.18 to 0.89]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>101</td>
<td>Massage</td>
<td>Music</td>
<td>Reduced anxiety – 1st stage – MD= -16.27 [95% C.I.: -27.03 to -5.51]</td>
</tr>
</tbody>
</table>

MD: Mean difference
SMD: Standardised mean difference
3.5 What is the evidence really saying? Are we comparing apples with oranges?

In this review of the evidence, it is important to highlight the different clinical questions as the basis for the reviews themselves, but also the methods, designs and outcome measures of individual trials included in each review (Tables 3.1, 3.3 and 3.5).

In the Smith et al. review (Smith, Collins, Crowther, et al., 2011), three of the 13 trials reflected effectiveness designs using ‘usual care’ as the control group. The other ten studies in the review were efficacy trials, which used a placebo control such as sham acupuncture, sham EA, or sham acupressure. The Smith review focused on the supportive aspect of acupuncture and acupressure for the management of labour pain, with patient-reported pain intensity and the use of pharmacological analgesia as main outcome measures, along with secondary birth outcomes, such as mode of delivery, augmentation required, length of labour, satisfaction and relaxation scores.

The Cho et al. review (Cho et al., 2010), reported on 10 trials, two of which were effectiveness studies, and eight were efficacy studies using a placebo control or mixed controls. Many of the trials were in both reviews (see Table 3.1). This review specifically focused on the efficacy of acupuncture’s analgesic effects, with the primary outcome measure of self-reported pain scores, and secondary outcome measure of requirement for conventional analgesia. The review concluded that acupuncture was not effective in reducing pain scores beyond 30 minutes and does not support its use in controlling labour pain. However, there was a trend towards acupuncture for reduction in pain scores up to 3 hours post-intervention and a significant reduction in the requirement for EDBs and all other analgesic methods.
In the earlier review by Lee (Lee & Ernst, 2004), the three trials reflected two effectiveness trials and one efficacy trial, and all used individualised treatment protocols. Use of pharmacological analgesia and pain scores were used as objective and subjective reporting measures. The authors suggest that acupuncture alleviates labour pain and helps reduce analgesic consumption (Lee & Ernst, 2004, p. 1577).

The Huntley et al. (Huntley et al., 2004) review included one effectiveness study and one efficacy study. The results were not pooled in an analysis, and the review concluded that while self-reported pain scores were positive in the efficacy study and equivocal in the effectiveness study, both demonstrate a reduction in the use of EDBs and other analgesic methods, including intramuscular pethidine.

In the four acupuncture/acupressure reviews, there was disparity in authors’ interpretation of the data and subsequent conclusions. Many trials were common to all reviews; however, the conclusions drawn from the Cho review are in contrast to the conclusions drawn from the Smith, Lee and Huntley reviews. The different focus of the Cho review in determining the efficacy of acupuncture for labour analgesia is distinct from the other three reviews, which focused on acupuncture and acupressure for supportive care in labour.

The studies included in these four reviews differ in terms of the study question being asked, study design, population of women, treatment administered, control group, and outcome measures used (see Table 3.2). The inclusion of outcome measures ranged from a narrow focus on pain intensity and methods of pain relief to a broader range of outcomes impacting on women as a result of pain, for example relaxation, length of labour, augmentation required and satisfaction with analgesia.
This significant heterogeneity of studies makes analysis of the collective results extremely difficult and potentially inappropriate. This may prove problematic in making recommendations about the collective benefits and harms of acupuncture for labour in general. This includes type of acupuncture, type of stimulation, population of women and conditions of care.

In the relaxation review by Smith (Smith, Levett, et al., 2011), pain intensity is the primary research question, and the authors suggest that relaxation may be beneficial for reducing pain in labour and increasing satisfaction with pain relief. The outcomes suggest that rates of assisted delivery were also reduced. There are conflicting reports for CS, with one study showing a reduction in CS (Gatelli, Panzeri, Casadei, & Pagan, 2000) and one study showing no difference (Bergström et al., 2009a); however, these studies could not be combined due to significant heterogeneity. This is also problematic in terms of recommendations to women and maternity care providers.

In three of the studies (Dolcetta et al., 1979; Durham & Collins, 1986; Gatelli et al., 2000), the control group intervention was standard psychoprophylaxis, which was the treatment group intervention in other studies, such as the Bergström et al. study (Bergström et al., 2009a). This may have a significant impact on labour outcomes, and make a comparison with the treatment group intervention less clear. These three studies were published more than 15 years ago, with the Dolcetta et al. study (Dolcetta et al., 1979) published 36 years ago. Standard care, or traditional psychoprophylaxis, may reflect a considerably different maternity care regime than is currently practised.
In the yoga section of the review, the largest study (n=207) (Chuntharapat et al., 2008) had five study groups, which may dilute the statistical effectiveness of the study outcomes, and used birthing in the supine position as the control measure. The supine position is arguably the least physiological position in which to labour and give birth (Dahlen et al., 2011), and this should be taken into consideration when reviewing the outcomes of pharmacological pain relief and length of labour for the control group. Using these prescribed treatment protocols, compared with individualised positions may have also had an impact on the outcomes. What constitutes usual care, or whether supine birthing positions are common in the hospital where the study was undertaken, is unknown. The outcomes for yoga may be difficult to distinguish from benefits gained from being upright in labour, or may in fact reflect such benefits (Gupta & Hofmeyr, 2004).

In Western settings, one of the most significant outcomes of childbirth occurring more frequently in hospital is that women are often required to lie in a recumbent or supine position to more readily accommodate medical-led care with an increased emphasis on monitoring and medical management (Priddis, Dahlen, & Schmied, 2012; Simkin & O'Hara, 2002). This in itself may lead to increased pain and therefore medical intervention. Therefore the benefits of yoga and upright positions may be important in Western settings.

In the manual therapies review by Smith et al. (Smith et al., 2012), six studies were reported on from five trials of massage including 326 women, with pain intensity being the primary outcomes measure. The authors determined that the studies were of reasonable quality, but participant numbers are still low, making overall evaluation difficult. All studies included active controls, including usual care, music,
and breathing techniques. Four studies recruited only primiparous women, and the other two were of mixed parity. Overall, less pain during labour was reported compared with usual care, and compared with music. Less anxiety was also reported compared with usual care.

### 3.7 Treatment intent and capturing the treatment outcome

The question of matching the intent of treatment protocols with study design, as well as the outcome measure used, is useful to consider. Generally, the reviews report that in studies where acupuncture, relaxation, yoga or massage was compared with usual care, often reflecting pragmatic trial designs, broader outcomes of the effect of treatment as a whole were often more apparent. These included reduced requirement for pharmacological analgesia, lower rates of instrumental deliveries, greater relaxation and satisfaction, and less anxiety. However, for example, when acupuncture/acupressure was compared with placebo or no treatment, which may be more indicative of efficacy studies, the assessment of specific acu-point effects on pain outcomes focused on pain intensity; length of labour; satisfaction with pain relief, and rates of pharmacological analgesia.

When considering acupressure trials, these generally used a point-specific approach and specific pain outcomes such as pain intensity, use of pharmacological analgesia, and length of labour, as well as more general effects, such as reduced anxiety and rates of CS, to capture their effect. An example of treatment intent and the relevancy to clinical outcome is illustrated by studies using the most commonly reported points Sp-6 (Sanyinjiao) and L.I.-4 (Hegu). These points are reported to have the point-specific effect of increasing strength of uterine contractions and shortening length of labour in the first stage (Sanyinjiao, Sp-6), and general analgesic effect for...
pain relief (Hegu, L.I.-4) (Betts & Budd, 2011; Kashanian & Shahali, 2010; Lee, Chang, & Kang, 2004). The physiological mechanism of action (Sanyinjiao, Sp-6) is proposed to be through stimulation of oxytocin release from the pituitary gland (Lee et al., 2004). Therefore, the effect would be seen primarily in the requirement for synthetic oxytocics, length of labour, and, given that natural oxytocin has a relaxing effect, pain scores may also be influenced. Hegu (L.I.-4) is proposed to have an effect on the release of natural opioids (Hamidzadeh et al., 2012), thus affecting the experience and perception of pain. Therefore the effect of Hegu (L.I.-4) may be best reflected in pain scores (subjective), or the reduction of EDBs or other conventional analgesia (objective).

Interestingly, of the four acupressure trials included in the Cochrane Review (Smith, Collins, Crowther, et al., 2011), all four trials were standardised, placebo-controlled studies. Three trials (Hjelmstedt et al., 2010; Kashanian & Shahali, 2010; Lee et al., 2004) used only the single point of Sp-6 (Sanyinjiao). The outcome data from these three trials did in fact reflect the point action of Sp-6 (Sanyinjiao), which was to increase uterine activity and the release of oxytocin. This was seen in the outcomes reported: reduced rates of augmented labour, shorter length of labour, less anxiety, and fewer CSs. The remaining study (Chung, Hung, Kuo, & Huang, 2003) used the point L.I.-4 (Hegu), indicated primarily for pain relief, and may also result in shorter labours as a secondary outcome due to the reduction of pain and a relaxation effect. The outcomes for this study include a reduction in pain intensity scores only.

Where management of normal labour and labour pain is the research question and pharmacological analgesia rate is the outcome of interest, the lowering of this rate in the acupuncture group may in fact be where the benefit lies. Apart from being an
objective measure of pain relief, using acupuncture to assist women to manage their labour pain to avoid the potential side effects of pharmacological interventions may be of significant benefit in clinical practice. Importantly, when reporting pain scores as the outcome of interest, where the control group includes conventional analgesia, a non-significant difference or equal pain score for the two groups may demonstrate the equivalence of acupuncture to conventional analgesia in managing labour pain, rather than no benefit from acupuncture. Huntley et al. (Huntley et al., 2004) reports that acupuncture compared with conventional analgesia gave ‘as good’ pain relief (Ramnerö et al., 2002), hence equivalence of method, and consequently required fewer EDB interventions.

Reviews of relaxation, including yoga and manual therapies, including massage tended to remain focused on pain intensity, which was reported in various ways and using various controls.

For relaxation, considerable differences in relaxation methods were reported. Generally, studies reported reduced pain intensity and increased satisfaction. Evidence from two studies report reduced instrumental vaginal births, which is a considerable outcome indicating good effect from relaxation compared with usual care. The reported benefits of relaxation include an increase in oxytocin and prolactin, and a decrease in adrenalin, especially in the second stage of labour (Buckley, 2002). This could be reflected in the reduction in instrumental births. However, the trials were not delineated according stages of labour, and the active control measures used may have confused the outcomes. ‘Usual care’ was quite heterogeneous among the studies, with the largest study (Bergström et al., 2009a) using psychoprophylaxis as the treatment intervention, and other studies using
psychoprophylaxis as ‘usual care’ (Dolcetta et al., 1979; Durham & Collins, 1986; Gatelli et al., 2000). Results from the studies may be obscured by these active controls, as discussed previously for acupuncture/acupressure.

Consideration of reductionist methodologies, as for acupuncture/acupressure, may also be useful for evaluating the effectiveness of massage therapies. Massage protocols allowed for a timed administration of the massage techniques, which may also undervalue the potential effects from massage. Women who are able to freely request massage when required may benefit more substantially from this intervention as physical touch has been shown to increase feelings of control and release of oxytocin for labour (Buckley, 2002). However, in keeping with a reductionist framework, the effects of massage may be limited by the methodology used.

3.8 Discussion

Women are frequent consumers of CM, and they continue to use it during pregnancy and labour. Evidence from these four systematic reviews of acupuncture and acupressure for labour (Cho et al., 2010; Huntley et al., 2004; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011) suggests that acupuncture and acupressure techniques show promising point-specific effects and more generalised holistic effectiveness in the support and management of pain in labour and birth; however the results are varied. Reviews of relaxation and yoga (Field, 2011; Smith, Levett, et al., 2011) show beneficial effects for pain reduction, satisfaction and reduced instrumental births, as well as some specific effects for yoga such as reduced pain and other benefits of upright birthing. The massage review (Smith et al., 2012) also shows pain reduction effects in labour, but potentially limited by reduced access.
The use of CM techniques in maternity care could have many additional benefits to the birthing woman, such as a broader choice of analgesic methods; the option to move around the birthing room and the option to use upright birthing positions. The use of CM techniques may also offer the benefits of focused attention and physical touch from partner and midwife; enhanced feelings of autonomy, control and satisfaction; and the option of non-pharmacological tools to use as adjuncts to conventional medical practices. These all may contribute to the practical application of CM techniques for pain management. Additionally, the concepts of informed choice and decision-making for birthing women are implied here (Thompson & Miller, 2014). Research by Romano and Lothian (2008) suggests that women’s experience of labour also indicates a preference for natural management of pain and enhanced control of their own process in labour (Romano & Lothian, 2008).

CM research to date has largely centred on questions of efficacy for the purpose of examining individual components of the CM system. This approach has been the subject of criticism and debate (Fonnebo et al., 2007; Macpherson, 2004; Witt, 2011; Witt & Schutzler, 2013), due to its focus on specific treatment components, narrow outcome measures, use of active controls, lack of patient-centred outcomes, and research designs developed for the evaluation of pharmaceutical products (Macpherson, 2004; Verhoef et al., 2005; Witt, 2011; Witt & Schutzler, 2013). This overlay of the reductionist framework that is the marker of the biomedical model, and designed to evaluate pharmacological therapeutics, does not take into account the complex care models, or ‘whole systems of medicine’ that are representative of CM therapies (Hall et al., 2012; Witt, 2011). These research measures may obscure the real potential of the whole therapy under investigation (Macpherson, 2004). However, the challenge remains in conducting robust and clinically relevant...
research, adequately controlling for extraneous effects that may influence the outcomes, such as the researcher’s presence, is important to address.

Both types of studies, efficacy and effectiveness, may provide evidence relating to different primary questions or outcomes of interest. It is important to match the intent of treatment to the outcomes of interest and appropriately design studies that can adequately provide this information, and analyse them separately in pooled data. Outcomes of interest should also include broader woman-centred measures. Acupuncture and acupressure, relaxation, yoga, and massage may be useful adjunct therapies to help women manage labour pain, and their benefit may lie in helping women avoid unnecessary use of pharmacological analgesia and minimise adverse effects. Further, in reducing rates of medical intervention, CM can potentially address the rising rates of associated morbidity and mortality being reported in reviews of maternity services, both in Australia and internationally (Bryant, 2009; NSW Department of Health, 2010; Roxon, 2008; Senate Committee, 1999; Shearman & Bennett, 1989).

The effectiveness of CM therapies as a viable, safe alternative or adjunct to the conventional analgesia offered to women in maternity care settings would be best addressed by pragmatic trial designs incorporating qualitative and quantitative outcome measures that reflect woman-centred care. Additionally, as labour is a complex process with different physiological and emotional aspects, providing women with a choice of evidence-based therapies, and autonomy and control of the process, would also reflect best practice.

The findings from this study will contribute to the growing evidence base for the use and effectiveness of self-administered CM techniques for the relief of pain during
childbirth. It will provide rigorous assessment of established programs; She Births® and Acupressure for Labour (Betts, 2005).

This chapter has outlined the benefits provided by CM for labour and birth. In Chapter 2, the benefits of the antenatal education structure to provide women and partners with skills and support for labour was discussed. These benefits include increased confidence and agency in labour and birth, but they are limited in terms of changing birth outcomes. CM evidence suggests that these techniques may be effective in changing birth outcomes. To date, there has been no evaluation of an antenatal education program incorporating evidence-based CM practices taught to women and partners for the self-management of labour pain. To evaluate objective outcomes of applying CM in labour and birth, preferences and agency of women, an in-depth understanding of how women, partners and midwives use CM to manage labour, a complex intervention using a mixed methodological approach, would be required, and is the focus of this thesis. The next chapter describes the methodology used to assess the effectiveness, utilisation and acceptability, for women, partners and midwives, of the Complete Birth Study, a complex antenatal education package of care incorporating CM philosophies and techniques for the management of labour and birth for primiparous women.
Chapter 4 – METHODOLOGY

4.1 Introduction

The purpose of this chapter is to describe and justify the choice of a mixed methods research (MMR) design for this study based on the epistemological and methodological assumptions made about the research problem.

This chapter is presented in four parts. The first part will introduce the aim, objectives and concepts of the study program that form the basis of this research: the ‘Complete Birth Study’. The second part will discuss the methodological framework for this research. The overarching paradigm used for this study employs the epistemological assumptions of pragmatism, with a feminist stance, and uses an MMR design. The third part will discuss the implications of using MMR to evaluate a complex intervention, and an assessment of its validity and capacity to integrate the inferences drawn from each component of the research study. The fourth part of this chapter will describe the implementation, data collection and analysis used for both the qualitative (QUAL) and quantitative (QUAN) components of the mixed methods study. These comprised an RCT (QUAN) and validated and structured questionnaires (QUAN), in-depth interviews with a subsection of women from the study group (QUAL), and finally a focus group with midwives (QUAL).
4.2 Overall aim

The aim of this research was to examine the use of complementary therapies for the support and management of labour and birth for first-time mothers and their birth partners.

The study is not only contemplating whether complementary therapies are effective for reducing the requirement for pharmacological pain relief, but to understand the experiences of women and their partners in using complementary therapies as a support for their labour and birth. How the participants utilised the CM therapies and how meaning is constructed about their labour and birth from the complementary therapies antenatal education workshop (Complete Birth) is a central component of the thesis. How this meaning is shaped by the institutional influences of the hospital setting is also important. Focus groups with midwives about CM use and the Complete Birth Study were also conducted to ascertain what, if any, convergence or divergence of ideas and practices exists between midwives and the women for whom they cared.

4.3 Research objectives

The objectives of this study are to:

1. To examine the effectiveness of an antenatal education package of CM therapies (Complete Birth Study) in addition to standard care, to reduce EDB rates in primiparous women, compared with standard care alone.
2. To examine how women and their partners, who participate in the Complete Birth Study, characterise the effectiveness of the program and its components.

3. To examine how midwives perceive the use of the Complete Birth Study techniques for women and their partners and what they see as the potential facilitators and inhibitors in the public hospital system.

4.4 Epistemological assumptions

Given that the research examines the experiences of women giving birth, and that these births occur in patriarchal medical institutions where there is an inherent power dynamic, a feminist stance or lens will be used (Crotty, 1998; Johnson & Onwuegbuzie, 2004). A feminist stance is also explored more broadly to conceptualise the way in which the research was conducted as reflecting a feminist way of constructing meaning through the pragmatic framework.

Our epistemological assumptions refer to the way we gain and view knowledge. ‘What we look for, what we expect to find, and how we believe we are to go about finding and justifying “knowledge”’ (Johnson, Onwuegbuzie, & Turner, 2007, p. 114). To understand the complexities inherent in a multidimensional phenomenon, it is important to understand the way in which we are attempting to gain knowledge, and the contextualisation of this knowledge. Our epistemological orientation is not always explicitly stated, but its influence must be understood, as it informs the way in which we will design and conduct our research. The epistemological assumptions
that underlie this research have emerged from a need to implement central components of differing epistemologies such as ‘Constructionism’ and ‘Objectivism’ (Crotty, 1998; Johnson & Onwuegbuzie, 2004), in the critique and understanding of women’s experiences of a holistic intervention for the support of labour and birth. A pragmatic epistemology or worldview using a mixed methodologies approach gathering both qualitative and quantitative data has emerged as the most appropriate framework within which to answering the proposed research questions (Cresswell & Plano Clark, 2011; Evans, Coon, & Ume, 2011; Freshwater & Cahill, 2013; Morgan, 2007), and can be viewed as reflective of a feminist style of research (Crotty, 1998; Seigfried, 1991).

Current scientific thinking is seen to reflect a very masculine way of knowing (Assiter, 1996) and it is this patriarchy that has framed our medical system and the superior status given to medical or scientific thinking. This thinking continues to permeate our cultural attitudes towards health care in general and maternity care in particular. Therefore, this study’s investigation of women’s health issues within a patriarchal medical context relates the idea of holism and incorporation of different ways of knowing to a feminist stance (Seigfried, 1991) and to the investigation of traditional medicine (Fonnebo et al., 2007; Macpherson, 2004). The use of a pragmatic epistemology is debated and its relevance to investigations of CM (Schroer, Kanaan, MacPherson, & Adamson, 2012), women’s health and feminism is considered.
4.5 Pragmatism

Pragmatism has an interesting history with early exponents of American pragmatism coming out of both a constructionist and critical interpretivist standpoint (Crotty, 1998). Today it is considered in terms of ascertainment of knowledge; as having a ‘what works’ approach to the research question (Cresswell & Plano Clark, 2011; Evans et al., 2011; Johnson & Onwuegbuzie, 2004). The traditional tension that exists between the three main epistemologies – objectivism, constructionism and subjectivism – has played a significant role in the study of health sciences (Forthofer, 2003) and nursing and midwifery research (Twinn, 2003), which has seen the pragmatic epistemology, using a mixed methods approach, emerge (Tashakkori & Teddlie, 2003).

Constructionism as an epistemology purports that ‘all knowledge, and therefore all meaningful reality as such, is contingent upon human practices being constructed in and out of interaction between human beings and their world, and developed and transmitted within an essentially social context’ (Crotty, 1998, p. 42). This is in contrast with objectivism, which believes that there is an objective truth independent of any consciousness. That truth and meaning are inherently in the object, as a tree may have ‘treeness’ regardless of the consciousness of any observer (Crotty, 1998). Western science has been grounded in this objectivist epistemology from the ancient Greek philosophers through the Middle Ages into the Enlightenment era, and it is strongly present today in the search for objective truth with the contingent research methods to deliver certainty in knowledge (Crotty, 1998). Constructionism, however, maintains that there is no reality or meaning without consciousness to construct it,
and this is done within a context of the social world; that people seek understanding of their world and experiences through social constructions (Cresswell & Plano Clark, 2011).

Creswell and Plano describe four major overarching ‘worldviews’ (Cresswell & Plano Clark, 2011), being Postpostivist (Objectivism), Constructivist, Participatory and Pragmatist worldviews. Each worldview differs in terms of ontology, epistemology, axiology and methodology, and rhetoric (Cresswell & Plano Clark, 2011). Traditionally, quantitative research has been aligned with an objectivist epistemology, espousing that truth is independent of the observer. Crotty (1998) describes objectivist epistemology to hold that ‘meaning, and therefore meaningful reality, exists as such apart from the operation of any consciousness’ (Crotty, 1998, p. 8). Pragmatism is perceived to reject some traditional assumptions about how we know what we know, that is, about the nature of knowledge, and the ‘truth’ value of the nature of inquiry. The notion that only a single method of scientific enquiry will allow us to arrive at the truth is refuted and that pragmatism, being rooted in common sense, will have the capacity to drive transformation of culture and the resolution of conflict (Sleeper & Burke, 1986).

Pragmatism first emerged in the 1930s American context as a critical philosophy by Charles Peirce. Pragmatism was seen as a reflexive activity where concepts and ideas were methods to investigate ordinary events. The early pragmatists were critical of the narrow methods by which philosophy was seeking to understand social phenomena. They viewed the positivist model of value neutrality as ‘a self-deceptive mask for unacknowledged interests and advocated a radical social agenda…. [they]
were to be advocates for transformation rather upholders of the status quo’
(Seigfried, 1991, p. 6). Pragmatists viewed these social events as contextual in time
and place, and with meaning that had reference to the conditions in which they
occurred (Crotty, 1998). Dewey, a later proponent of pragmatism and probably its
best known, sees pragmatism’s concept of ‘meaning’ as an understanding of culture,
rooted in time and place. Pragmatism’s idea about the nature of human experience is
necessarily intersubjective or ‘relational’, rather than either objective or subjective
(Dewey, 1938). A phenomena’s meaning is derived from historical, cultural and
personal context, and to understand it, pragmatists look to those who experienced it
and see the intellectual drama of ‘philosophising’ as a means rather than an end
(Seigfried, 1991). Social phenomena are by their very nature complex and
context-dependent, and to view them from a purely objective or subjective position,
and by necessity use purely their associated qualitative or quantitative techniques to
explore meaning, would cause a loss of understanding about the phenomena as a
whole (Greene & Caracelli, 2003).

The position of pragmatic philosophy is in terms of cultural and historical values
with an emphasis on active engagement in solving the everyday problems of society
by the investigation of concrete experiences (Seigfried, 1991). There is a realigning
of theory with praxis and a rejection of the jargon and highly technical aspects of
philosophical enquiry which excludes oppressed groups and distances the researcher
from the actual experience of the researched (Dewey, 1938; Seigfried, 1991).
4.6 Pragmatism and complementary medicine

In their quest to conduct ‘valid’ and ‘scientific’ research, be faithful to the holistic underpinnings of the medicine itself, maintain mindfulness of patient-centred outcomes and reflect current clinical practice, CM researchers are looking for an epistemology which can incorporate these needs. Pragmatic research designs have been advocated as the most appropriate methodology for the study of CM, especially acupuncture research, as it reflects model validity and credibility in investigating holistic practices as performed in clinical reality (Fonnebo et al., 2007; Macpherson, 2004; Schroer et al., 2012; Witt, 2011).

In viewing this research, it would be fruitless to conceive of the phenomenon of labour and birth as being separate from the woman or her social and historical context. Equally, to conceive of a single active measurable ingredient in CM therapies that exists independently of either the medicine or the context in which it is used would be valueless. However, this is the central point of criticism that has been voiced by CM researchers trying to fit a ‘scientific’ schema, traditionally for evaluating pharmaceutical products, to the research of complex CM interventions (Fonnebo et al., 2007; MacPherson et al., 2008; Walach et al., 2006; Witt, 2011; Witt & Schutzler, 2013). Quantitative methods, traditionally associated with objectivism, such as clinical trials and survey research, are useful tools to assist in understanding whether packages of care or research programs can change outcomes for complex conditions. These pragmatic trials are quantitative measures viewed within a social context to make meaning of the outcome. However, they use a reductionist framework, by which results are measures and presented as a single variable
compared by proportion or number to a comparable variable and analysed statistically for significance of effect size. Quantitative methods are useful tools to examine effectiveness, but they may not shed light on the processes by which it happened, or whether it was representative of real-world practice and how people experienced it, or whether it was feasible in the context in which it occurred. To understand the complexities of the research, qualitative measures will be required to help complete the picture.

In the era of evidence-based medicine and evidence-based practice, the gold standard of original research is the RCT. CM researchers have endeavoured to be as scientific as possible to adhere to the evidence-based practice requirements. The emphasis has been on whether CM ‘works’. This is a very subjective term, as what it means to ‘work’ will be different for many people and stakeholders. From the patient’s perspective, a non-treatment aspect of the therapeutic encounter could be what triggers relief from the condition being treated. These are considered to constitute part of the placebo effect of CM. As outlined in Chapter 3, efficacy trials are designed to show the extent to which a specific treatment or component of an intervention is effective under ideal clinical circumstances with patient populations specifically selected (Last, 2001). In the scientific reductionist model, researchers are required to use all possible means to strip the treatments down to the single ‘active’ ingredient to ‘prove’ that it works. This has led to the use of placebo or sham treatments as part of the model of inquiry (Witt, 2011; Witt & Schutzler, 2013). This is not only unrepresentative of what happens in real life, it does a serious injustice to the holistic nature of the medicine itself (Schroer et al., 2012; Walach et al., 2006;
Witt, 2011). As researchers, we are interested in the effectiveness and efficacy of the treatment as well as the patient experiences. Potentially, this has an impact on policy makers whose decision-making is influenced by evidence-based research. Researchers of CM are looking to take a broader position in addressing the ‘complexity of the human condition’ (MacPherson et al., 2008, p. 7), which is especially relevant to chronic diseases or where there is a complex interplay of social, emotional, physical, geographic, medical and institutional issues playing out, such as in pregnancy care.

In China, the development of acupuncture as a system of medicine was shaped by the philosophical influences of Confucianism and Daoism (MacPherson et al., 2008), where all causes of disease are seen as interconnected through ‘Heaven, Earth and Man’ (Kaptchuk, 2002). Similarly, yoga emerged from the philosophies of Hinduism, Buddhism and Jainism as a holistic means to maintain the health of the spiritual, mental and physical bodies (Bryant, 2009). These philosophies have shaped cultural processes and contexts and have emerged very differently than in ‘the West’. It is these origins, social and historical, that require consideration in how to view CM in the Western medical construct.

4.7 Feminist stance

A feminist stance was considered an appropriate lens through which to view this research and provides a valuable perspective in MMR (Cresswell & Plano Clark, 2011). This study is by a woman about women, exploring the lived experience of childbirth, which is uniquely the domain of women. Although there are many forms
of feminist research, researchers apply the principles of feminism to existing methodologies and theoretical perspectives and are primarily concerned with the feminist struggle (Bailey & Cuomo, 2008). According to Brooks and Hesse-Biber (Brooks & Hesse-Biber, 2007; Hesse-Biber, 2010), by highlighting women’s experiences, concerns and private lives, the gendered stereotypes and biases that women face form the basis of concepts that challenge existing ideas and institutions that oppress women. By illuminating women’s subjugated knowledge, traditionally-accepted male concepts that have been considered the reference point are contrasted with women’s lived experiences. The findings of research, and the methods used to obtain it, have largely reflected objectivist and reductionist research methodologies traditionally aligned with a male thinking. Feminist research seeks to engage in consciousness-raising about how women experience life and give voice to their experiences, through appropriate research methods.

Feminist research generally takes the view that women’s knowledge is largely determined by their social position and that women are viewed as an oppressed class within society (Gray, 2013; Stanley & Wise, 1993), and oppressed within patriarchal systems (Stanley & Wise, 1993). The feminist framework recognises the influence that social constructs, such as healthcare systems, have on the experiences of women (White, Russo, & Travis, 2001). This is particularly relevant where it concerns maternity care and the patriarchal medical system.

The qualitative components of this study provide the personal narratives of women’s experience of childbirth and the experiences of midwives who care for them. This exposes the oppression faced by women in the system and the professional struggle
between midwives and doctors (Hastings-Tolsma & Terada, 2009). Feminist research emphasises the importance of social transformation and social justice for women by women (Hesse-Biber, 2010). Through a feminist lens, the profound influence that hospital-based maternity care has on women’s experience of childbirth can be made apparent. Additionally, the holistic approach that underpins feminist research is complementary to the holistic systems of medicine that are the subject of this study.

Maternity care has seen a shift over the past 100 years from a social to a medical/surgical context (Dahlen et al., 2011), and has accompanied a commensurate change in women’s acceptance of higher rates of medical intervention as part of a normal birth (Green & Baston, 2007; Kitzinger et al., 2006). This ‘medicalised’ way of viewing labour and birth has also shifted the expertise of maternity care to physician-based care, and a medical model of maternity care which reflects a paternalistic objectivist’s standpoint (Crotty, 1998; Hesse-Biber, 2010). The importance of this model has been seen in a reduction of deaths both maternal and neonatal, and the reduction in unnecessary complications of childbirth, such as prolonged labour, malposition and haemorrhage (NSW Department of Health, 2010). The criticism of maternity care comes from many directions, as outlined in Chapter 2, but is generally reflective of the adverse effects from over-treatment and the over-medicalisation of maternity care, the cascade effects of medical intervention, and the loss of expertise and control experienced by women in their own labour and birth (Green & Baston, 2007; Kitzinger et al., 2006; NSW Department of Health, 2010; Tracy & Tracy, 2003). It is this final phenomenon that this research seeks to
understand, and the potential benefits of education for women around the principles of normal birth and where CM may be useful in helping to manage a normal labour.

The position of women is seen as constituting a power imbalance with the medical system, where scientific knowledge guides treatment in an often impersonal way, and where some alternative treatment choices are limited even when they are deemed to have had improved outcomes, such as continuity of care midwifery programs and birth centre utilisation (Sandall et al., 2013). In this way, the feminist standpoint is seen as appropriate, as women’s experience of birthing within the hospital context must at least consider the impact of the paternalistic position that ‘medical knowledge’ is the trump card when constructing maternity care. There is a need to hear women’s voices and reflect on the potential for transforming women’s views of maternity care and their role within it. We must consider how mechanisms within medicine which seek to exclude women can be deconstructed and seen in a critical light (Seigfried, 1991), and in doing this we can engage with women’s experiences of birthing and the use of CM to support the principles of normal labour.

The historical, social, medical, and interpersonal aspects of this research are very complex, and the use of both qualitative and quantitative methodologies to explore the influences inherent in this research is seen to significantly enhance the outcomes of the research and to be in the service of the research questions (Crotty, 1998; Johnson & Onwuegbuzie, 2004). Hesse-Biber describes the use of the feminist stance in an MMR study investigating the experiences of women with post-partum depression as ‘[placing] the emphasis on contextualising the quantitative findings through understanding the lived experience of mothers …. The qualitative findings
open up space to empower women’s voices and reframe clinical findings and interpretations’ (Hesse-Biber, 2010, p. 144). Pragmatism, which is typically associated with MMR, utilising pluralistic and concrete methods, seeks to actively engage with contemporary cultural issues by way of interaction with the individual and their environment. The examination of one’s own experience and everyday problems places the priority of human relations and actual experiences over abstract conceptual distinctions. Through shared understanding and problem solving, pragmatism advocates for revision of our contemporary issues, and is therefore the framework in which this research is grounded.

4.8 Reflexivity

Typically, researchers come to their research with a range of expertise, experiences, biases and values, which naturally influences and informs much of the research process (Cresswell & Plano Clark, 2011). The process of reflexivity allows researchers to identify and acknowledge these background influences and position themselves within the research to understand their role in the process. This also allows them to address any power imbalance with the participant, ultimately for the empowerment of women who are the experts of their own lived experiences (Hesse-Biber, 2010). The personal philosophies of the researcher also come to bear on the methodology used to examine the topic under consideration (Lambert, Jomeen, & McSherry, 2010).

As a researcher, I have been involved in perinatal clinical research using quantitative methods for many years, and as an acupuncture practitioner and health educator, I
have a particular interest in holistic maternity care and facilitation of natural birth techniques. However, my own experience of the birth of my three daughters has most heavily influenced my position in this research project. Having experienced a highly medicalised birth as a normal primipara through lack of knowledge, to experiencing an entirely natural water birth through the transformation of natural childbirth education and CM techniques, I feel a sense of identification with the women who participated in the study. I informed the participants in the treatment arm about my background during the course, and gave a brief overview of my transformation through education and empowerment.

Being an ‘insider’ in this experience (Burns, Fenwick, Schmied, & Sheehan, 2012; Dwyer & Buckle, 2009) gave a sense of a shared experience with the women and enhanced the sense of trust that was developed in the courses. I was able to reflect on the use of techniques during actual birth, and enhance the theoretical knowledge that was being provided with personal experiences. Women often asked about my experience of using CM during actual labour and managing certain situations as they arose. Having experienced two medicalised births, and the complications that arose from these, and a non-medicalised birth, I was able to offer a unique perspective on the influences of these events and the potential for personal empowerment within the medical system. Close relationships were developed during the courses and many women and partners were able to share intimate information due to the intimate structure of the course. In this situation, being an insider was beneficial for the development of trust and the transmission of knowledge through shared experiences.
As a researcher, health educator and practitioner of acupuncture, I was also an ‘outsider’ and this potentially created a power imbalance with the participants (Burns et al., 2012; Dwyer & Buckle, 2009; Hesse-Biber, 2010). This position, however, also provided a sense of trust that I had authoritative and professional knowledge of the methods that I was teaching and advocating. Therefore, being an outsider was advantageous. I was mindful of these two roles and tended to situate myself more strongly in the outsider’s role, while allowing some fluidity between the two.

In conducting the in-depth interviews, it was decided that an independent researcher with expertise in qualitative methods and who was unknown to the participants would conduct them. As an ‘insider’, and having run the course being evaluated, conducting the interviews may have potentially created a bias. Additionally, as an ‘outsider’ the power imbalance may have led women to reflect more positively about aspects of the course for fear of damaging the relationships that had been built during the time of the study and wanting to please the ‘teacher’.

During the study period, some field notes were kept in an attempt to allow subjective reflections to be integrated into the data without threatening the validity of the research (Elliott & Lazenbatt, 2005; Lambert et al., 2010), where crosschecking and identification of biases could occur. By situating myself within the research, I understood many of the concerns and experiences of the participants, and by acknowledging the shared experiences of childbirth, I could reflect on the impact this was having on the research. By conducting MMR and by using an integrated approach to data analysis, the different research methods could be used to verify the findings of the research. There was also regular communication with the supervisors.
(CS and HD) to reflect on the data in relation to their professional experiences of women using CM and women in midwifery care. Through this verification from different data sources and acknowledgment of personal experiences, reflexivity was employed to ensure the validity of the research findings.

4.9 Mixed methods research

The MMR approach refers to the combination of quantitative and qualitative research methods to enable the researcher to utilise different methodological approaches to investigate, analyse and answer the research question fully (Andrew & Halcomb, 2009). It is ‘an approach to knowledge (theory and practice) that attempts to consider multiple viewpoints, perspectives, positions, and standpoints (always including the standpoints of qualitative and quantitative research)’ (Johnson et al., 2007). Cresswell (2011) describes the mixed methods approach as ‘a research design (or methodology) in which the researcher collects, analyses, and mixes (integrates or connects) both quantitative and qualitative data in a single study or a multiphase program of inquiry’ (Johnson et al., 2007). According to Johnson and colleagues, one rationale for implementing MMR is that of ‘significance enhancement’ to the research. It aims to facilitate the ‘thickness and richness of data, augmenting the interpretation and usefulness of findings’ (Johnson et al., 2007). The use of only one methodology may provide an incomplete understanding of the initial question, and further explanation is required to gain full comprehension of the problem at hand (Cresswell & Plano Clark, 2011).
The MMR approach reflects a pragmatic framework to research that provides a practical, reasonable and fuller understanding of the question at hand in a cultural and historical context. It is particularly well suited to examining the changing complexities of health care. Social research aims to evaluate complex phenomena, and for that purpose complex three-dimensional investigation and analysis is required if we are to properly understand the what, how and why of the question.

4.9.1 Validity of mixed methods research

MMR is like any methodological approach: it has its strengths and weaknesses. MMR is a complex method of research and great care is required to conduct all the components with equal importance and robustness. Researchers with less experience in one study type or another should be mindful of this when conducting MMR studies (Cresswell & Plano Clark, 2011). MMR is time-consuming and complex, and researchers need to account for large and sometimes unwieldy data sets, to ensure that the method’s validity is paramount. The strengths of MMR include a holistic and fuller understanding of the issues being researched, and a greater capacity to hear different voices with regard to what is important about the research issues and what outcomes are evaluated (Schroer & Adamson, 2011).

Model validity for CM evaluations need to include measurements of credible outcomes. This reflection of internal validity requires that measurements of cause and effect are determined. However complex packages of care should reflect what both participants and practitioners value, as well as being able to reflect what would be seen in real clinical practice (Schroer & Adamson, 2011). To determine what some of these outcomes are is the job of MMR. To highlight how these complex
packages of care are feasibly conducted within certain contexts is part of the outcomes that are identified and evaluated. Where interventions are expected to impact of a wide range of factors, appropriate instruments and methods are required to capture the data. Where external validity or generalisability is concerned, the complexity captured by MMR gives us increased understanding of who our participants are, what they value and what outcomes occurred. This provides a very good position to determine what populations will align with this CM research, and as stated earlier, add to the literature about who uses CM and why.

The decision to give more or less weighting to one aspect or another should be decided a priori. In the case of this research, the main weighting sits with the RCT and in-depth interviews. The focus group with midwives is an important component to determine if there is dissonance or convergence with women’s experiences of CM for labour and birth; however, its weighting is less than the other two study methods.

Transparency of methods is an essential component, and is sometimes a criticism levelled at qualitative research analysis and data integration (Farmer, Robinson, Elliott, & Eyles, 2006; O’Cathain et al., 2010). Ensuring the most transparent account of the study is of primary importance. When these items are accounted for, MMR is a highly effective and elucidating methodology bringing enhanced understanding and a gestalt-like quality to the research questions under study (Hesse-Biber, 2010).

4.9.2 Mixed methods research for Complete Birth

The Complete Birth Study package is a multifaceted and complex intervention. It has not been subject to evaluation in terms of either quantitative outcome measures or
qualitative experiential measures. To understand the complexity of the intervention as a whole and the effect that each component of the intervention may have on the experience of the couple, an integration of quantitative and qualitative methodologies needs to be considered. According to Johnson and colleagues (2007), one rationale for implementing a mixed methodology is that of ‘significance enhancement’ which aims to facilitate the ‘thickness and richness of data, augmenting the interpretation and usefulness of findings’ (Johnson et al., 2007). Cresswell and Plano Clark (2011) describes the case where the results of a particular study provide an incomplete understanding of the initial question, and that further explanation is required to gain full comprehension of the problem at hand (Cresswell & Plano Clark, 2011).

Towards this end, to evaluate the effectiveness of this CM antenatal package of care, an RCT was considered the most appropriate method to answer the research question regarding effectiveness of the intervention as demonstrated by a reduction of medical interventions, specifically EDBs. The RCT will be a valuable tool to help establish if a relationship exists between the program of interest, Complete Birth, and the primary outcome, EDB rates. However, the research seeks to understand the effect of the program on other outcomes, as well as unravelling the experiences of the participants and the midwives caring for them.

The main aim of RCTs is to reduce bias and allow direct comparison of two groups with regard to effectiveness as evidenced by specific outcomes. However, this design alone cannot address questions regarding how and why the program has an effect, or not, on the incidence of pharmacological pain relief used, or if the program produces a change in attitude, or if the ‘holistic’ nature of the program was able to support
women’s labour and help to prevent the cascade of interventions. Nor does it address
the pragmatic aspects of implementation, which are essential for the evaluation of
research into practice expectations. Aspects of the study concerning effectiveness,
acceptability, satisfaction and implementation will be required to address fully the
primary and secondary outcomes. To understand the program and gain insight into
how women, partners and midwives view and use this complex intervention, it will
also be necessary to undertake qualitative research into both the participants’
experiences and the midwifery staff’s pragmatic evaluation of the program.

Once the couple have experienced the package as a whole and have had the
opportunity to use it in their labour and birth, then it becomes important to examine
aspects such as whether the experience of the package as a whole created their
experience, whether the components were useful individually, or if the role of
rehearsal facilitated change in attitudes. This examination is essential to
understanding how the program may operate effectively in the future.

To allow for a more detailed understanding of the general acceptability of the
program and the reasoning of the study participants in utilising the CM techniques, a
more in-depth and personal analysis is required. Therefore, a series of in-depth
interviews with a subset of women participating in the treatment arm of the RCT
would be the most appropriate method for this qualitative evaluation.

To provide insight into the process as well as the acceptability of the Complete Birth
program, midwives from the main study hospital (HKH) will be invited to participate
in a focus group. Their views on the effectiveness of CM techniques, their role in
working with couples who have experienced the intervention and what pragmatic approaches are required for implementation would be invaluable in the evaluation of the program and would contribute greatly to this body of knowledge.

Commonly, there are many different research designs reported for MMR, including designs that are sequential, nested or concurrent, and a purpose that may be exploratory, explanatory or transformative (Andrew & Halcomb, 2009). Here, sequential refers to staging of data collection, with one stage informing the development of the next, while concurrent describes the simultaneous collection of data (Andrew & Halcomb, 2009).

4.10 Concurrent and sequential explanatory design

Both concurrent and sequential explanatory methods will be employed for this research. This involves a minimum of two stages of data collection. These designs are useful as the research initially utilises a quantitative phase in which women are randomised to the study group or the control group and given an opportunity to use the program in their labour and birth. While the study is ongoing, and before any assessment of trends and relationships is considered, in-depth qualitative interviews were conducted with an independent researcher to gather qualitative data which can later be compared to the findings from the quantitative data to examine or explain the mechanism behind the numbers (Cresswell & Plano Clark, 2011). Following the initial analysis of the in-depth interviews, once the themes have been examined, the focus groups were conducted and the findings from the in-depth interviews were
used to guide the questions posed in the focus group. Concurrence or divergence of themes was examined.

4.11 Integration of findings in this thesis

The strategies for integrating these findings and the role of each will be explored in the discussion and integration chapter (Chapter 7). The explicit role of each of the methods is as explanatory to the other methods. The use of triangulation to integrate the findings will be important so there is not dominance of one approach over another (O'Cathain et al., 2010). This is discussed further later in this chapter, in section 4.16.
<table>
<thead>
<tr>
<th>Stage</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
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<td><strong>In-depth Interviews</strong></td>
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<tr>
<td></td>
<td><strong>Q’aires</strong>&lt;br&gt;1. LAS 2. ATBQ - pre &amp; post</td>
<td><strong>Midwife Focus Group</strong></td>
</tr>
<tr>
<td>Data type</td>
<td><strong>QUAN Data</strong>&lt;br&gt;Descriptive &amp; Inferential Statistics</td>
<td><strong>QUAL Data</strong>&lt;br&gt;Interviews &amp; focus group Transcribed &amp; coded</td>
</tr>
<tr>
<td>Data analysis</td>
<td><strong>Analysis using SPSS version 22</strong></td>
<td><strong>Thematic Analysis</strong></td>
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<tr>
<td>Data integration</td>
<td>Triangulation method of data integration</td>
<td></td>
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Figure 4-1 Study flow diagram
4.12 Study design

a. Parallel RCT of the ‘Complete Birth Study’ as an antenatal package of care, in addition to standard care, compared with standard care alone, for primiparous women.

b. Qualitative in-depth interviews with quasi-randomly selected participants from the research arm of the RCT, until thematic saturation occurs.

c. Focus groups to elicit views from midwives on the perceived effectiveness of the program of care for women participating in the study.

4.13 The randomised controlled trial (Stage one)

4.13.1 The intervention: the Complete Birth Course

The Complete Birth Course is an adaptation of the She Births® course, which is a private birth preparation course founded by Nadine Richardson and run in Sydney. A substantial acupressure component was added to the course using the ‘acupressure for pain relief in labour’ protocol developed by Debra Betts (Betts, 2005). The creators of these, Nadine Richardson and Debra Betts, have given permission to use their work as the basis of the study. The She Births® course was adapted to reflect the scientific evidence more carefully. In Chapters two and three the evidence for the effectiveness of antenatal education and individual complementary therapies was examined. These findings influenced what was included in the course, whereby components that did not have a sufficient evidence base were removed from the final study course, and those that demonstrated evidence of effectiveness were included.
Nadine Richardson has expertise in yoga, birth education and as a doula, while the author’s expertise is in acupuncture, birth education, perinatal research, evidence-based practice and epidemiology. Through this process of preparing the materials for the study, each person added their strengths in an iterative process to create the Complete Birth Course for research purposes.

The explicit message in the course was about giving couples natural options for managing labour, and reserving medical intervention as a backup for when required, not as first line option. The purpose of the course was to educate couples about alternative methods of managing pain during labour and possible ways of dealing with complications such as posterior presentations or slow progress using acupressure and yoga positions and movements. More importantly, however, were overt messages about practices that could perhaps make complications less likely, such as upright birthing positions, yoga postures and relaxation techniques. Information about the benefits of enhancing the body’s own hormonal pain-relieving systems and delaying or avoiding pharmaceutical pain relief if possible was discussed.

The importance of decision-making was discussed in the course, as were ways to negotiate with staff to implement aspects of birth that were important to the couple, such as comfort items from home, materials to put on the floor, music, positions to birth in, use of water, etc. It was discussed with participants how they might approach decision-making with regard to medical interventions that might be suggested during labour if required. They were given an acronym ‘BRAND’ as a way to assess any intervention – they were asked to evaluate; (what are the) Benefits,
Risks, Alternatives, what would happen if they did Nothing, and then being given time to Decide. Even if the couple did use the medical management suggested, their involvement in the decision-making process was highlighted as being the focus, rather than the intervention (Appendix B).

4.13.2 Primary hypothesis

Rates of EDB use will be reduced in primiparous women who participate in a complex antenatal education program incorporating CM techniques (Complete Birth Course), in addition to standard care, compared with primiparous women who receive standard care alone.

4.13.3 Secondary hypothesis

The use of CM techniques via an antenatal education program will be associated with:

- Reduced morbidity associated with medical induction, augmentation, other analgesia, length of labour, instrumental deliveries, CS, and duration of hospital stay.

- Increased positive attitude towards birth in the antenatal period, and greater feelings of empowerment/agentry of labour in the postnatal period.

- Reduced neonatal morbidity associated with resuscitation required at birth, Apgar scores and SCN/NICU (Special Care Nursery/Neonatal Intensive Care Unit) admissions.
4.13.4 Ethics approval and trial registry

Approval for this study to be conducted at HKH was granted through the Northern Sydney Local Health District (LHD) Human Research Ethics Committee (HREC) on 3rd April 2012 (NEAF Protocol 1111-476M) (HREC/11/HAWKE/268). The site-specific approval for the study to be conducted at Nepean Hospital was granted 2nd November 2012 (SSA/12/NEPEAN/58). Additional approval was granted from the University of Western Sydney (UWS) ethics committee on 1st July 2012 (UWS H9579), which allowed for recruitment through media advertisement not based at a particular hospital (Appendices C-E).

The study was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 27th October 2011 (Trial ID: ACTRN12611001126909) (Appendix F and G)

4.13.5 Study site characteristics

Two NSW hospitals were chosen as the primary study sites for the RCT. These were HKH and Nepean Hospital (Nepean). The following demographic details for hospitals were obtained from the 2010 Mothers and Babies Report from the Centre for Epidemiology and Evidence (Centre for Epidemiology and Evidence, 2012). HKH is a smaller unit, with 1,275 births in 2010, and services the Hornsby–Ku-ring-gai area in the Northern region of Sydney, which is regarded as a middle to high socio-economic area. It is designated as a Level 4 Maternity Unit, indicating that this hospital cares for mothers and babies at low and moderate risk from 34 weeks’ gestation onwards, and has a Level 3 Neonatal Service. Nepean is a large unit, with 3,545 births in 2010. It services the Nepean, Blue Mountains area in Sydney’s
Western region, which is regarded as a lower socio-economic area (Australian Bureau of Statistics, 2012). It is a Level 6 maternity unit, indicating that it cares for women of low, moderate and high risk at all gestations and is staffed with Feto-Maternal specialists and an Anaesthetic Registrar on site 24 hours per day and available exclusively for obstetrics. It has a Level 5 Neonatal Service. These hospitals were chosen primarily as they represented two distinctly different socio-economic demographics in Sydney, which has been reported in the literature as influential in use of CM (Adams, Easthope, et al., 2003). Secondly, these two hospitals both have an EDB rate of around 45% (Centre for Epidemiology and Evidence, 2012), which provided sufficient power to demonstrate a clinically meaningful reduction in EDB rates. This will be discussed later.

During the recruitment phase of the study, an additional site, the UWS, was added to enhance recruitment. UWS was added following an unexpected delay in obtaining site-specific ethics approval at the Nepean LHD Ethics Committee. Recruitment to the UWS site was through newspaper and magazine advertising and word of mouth. Women recruited through UWS could be birthing at any NSW hospital, both public and private, and were subject to the same inclusion and exclusion criteria as the two main recruiting hospitals. There were 12 hospitals represented in this UWS cohort of women: Bathurst Base; Blacktown; Canterbury; Manly; Mona Vale; Prince of Wales; Royal Hospital for Women; Royal North Shore; Royal Prince Alfred; St George; Sydney Adventist; and Sutherland. These hospitals ranged from a birth rate of 600 births in 2010 at Bathurst Base Hospital (BBH) to more than 5,000 births at Royal Prince Alfred Hospital (RPAH). Maternity Services Levels ranged between
Level 2 to Level 6 (BBH and RPAH), with Neonatal Units from Level 3 to Level 5 (BBH and RPAH). All other hospitals fell within these ranges (see Table 4.1).

Table 4-1: Site characteristics

<table>
<thead>
<tr>
<th>Hospital Site (2010)</th>
<th>HKH</th>
<th>Nepean</th>
<th>UWS</th>
</tr>
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<tbody>
<tr>
<td>Recruited</td>
<td>$n = 102$</td>
<td>$n = 30$</td>
<td>$n = 40$</td>
</tr>
<tr>
<td>Births per year</td>
<td>1275</td>
<td>3545</td>
<td>&gt;600-5216</td>
</tr>
<tr>
<td>Level Maternity Services</td>
<td>4</td>
<td>6</td>
<td>3-6</td>
</tr>
<tr>
<td>Level Neonatal Unit</td>
<td>3</td>
<td>5</td>
<td>3-5</td>
</tr>
</tbody>
</table>

HKH: Hornsby Ku-ring-gai Hospital; Nepean: Nepean Hospital; UWS: University of Western Sydney

4.13.6 Inclusion criteria

- Gestational age between 24 and 34 weeks of completed pregnancy
- Primiparous
- Singleton pregnancy
- Low-risk pregnancy as defined by their care givers
- Sufficient English for participation in a two-day workshop

4.13.7 Exclusion criteria

- High-risk pregnancy as defined by their care givers
- Multiparous
- Multiple pregnancy
- Congenital abnormalities
- Participation in similar program of complementary antenatal education
Participation in a continuity of care midwifery model

Participation in a continuity of care midwifery programs was an exclusion criteria due to the demonstrated improvement in outcomes for women in these programs (Hatem, Sandall, Devane, Soltani, & Gates, 2008).

4.13.8 Recruitment

Following ethics approval, recruitment was undertaken by the student at the antenatal clinics of the two study hospitals, HKH and Nepean, and where low-risk primiparous women are seen for the management and care of their pregnancy. Clinics included midwives’ clinics, doctors’ clinics, and clinics operating under a GP shared care model.

The study was publicised to midwives and doctors who attended each of the clinics by the study investigator personally, and via written pamphlets and advertising materials (Appendix H). The investigator attended team and staff meetings, research forums and staff handovers in the beginning stages of the trial, and where the discussion of the study was appropriate. The study was advertised to women via written materials put up in visible areas of the clinics and some closely located bathrooms or other commonly used amenities within the clinic area.

Following booking in to the hospital, indicating intention to birth at that hospital, low-risk primiparous women who were greater than 24 weeks’ gestation were approached in the antenatal clinics and the study was briefly described. If women were interested in further information, the investigator provided an explanation of the
study in more detail, presenting a patient information sheet, indicating the inclusion
and exclusion criteria, and describing the nature of the intervention in general terms,
and ensuring that the woman understood the nature of random allocation for the
purposes of this study. If they were then interested in participating, a Participant
Information Sheet and Consent Form (PICF) was given or sent to the woman
(Appendix I, J and K). She was then followed up after a period of 24–36 hours to
allow some time for consideration of the trial. If the woman stated that she wished to
participate, a final assessment of inclusion criteria was made, and patient information
sheet and informed consent were presented for review and signature. Baseline and
demographic information were collected via a Trial Entry Form (Appendix L).
Following this, the participants were randomised to receive the intervention (in
addition to standard care) or standard care alone.

Recruitment to the third study site, UWS, occurred through newspaper and magazine
advertising. Ethics approval for the advertisement script used was obtained through
the UWS Ethics Committee. Over a period of four months, three advertisements
were placed in the magazine Sydney’s Child. These advertisements occurred in the
issues for November 2012, combined December/January 2012/13, and February
2013. Additionally, the UWS Communications Unit issued one short story to each of
the Campbelltown area local newspapers: the Campbelltown-Macarthur Advertiser
and the Macarthur Chronicle (both in November 2012). A general description of the
study was included as well as the inclusion and exclusion criteria. If women fit the
criteria and were interested in the study, they were directed to contact the researcher
directly.
Additionally, an open Facebook group was established for people already in the study (https://www.facebook.com/#!/groups/completebirthstudy/), where group members could recommend the study to other people they knew. Participants were also encouraged to tell any primiparous friends (word of mouth recruitment) about the study.

4.13.9 Randomisation
The generation of the randomisation sequence was undertaken centrally via the Sealed Envelope website: (https://www.sealedenvelope.com), and concealed by computer generation. Stratification occurred for hospital site, yielding three randomisation lists: ‘HKH’, ‘Nepean’, ‘UWS’. Women were randomised according to site and were randomly allocated to either the Complete Birth antenatal CM education program in addition to usual care (study group) or usual care alone (control group). Randomisation occurred on a 1:1 allocation ratio to ensure equal numbers in each group at each hospital.

4.13.10 Study intervention
All women received standard antenatal care. Standard care constituted all regular care received at the birthing hospital and any courses that the woman chose to do at the hospital. Antenatal education classes at each of the hospitals are optional, but the women were encouraged to attend.

4.13.11 Control group
Participants in the control group were encouraged to attend the standard antenatal education classes offered by the hospital. Antenatal education classes at each of the
hospitals are optional, and most hospitals carry a fee for attendance. Sometimes this is a sliding scale depending on needs. They range in duration depending on the hospital and intended participants. Generally, they are held in the evenings and on weekends to accommodate working parents.

Antenatal education classes in Sydney have been influenced strongly by the work of Svennson et al. (Svennson et al., 2008) from the Royal Hospital for Women, Randwick (RHW). There has been a general shift towards providing information for women and their partners covering the entirety of pregnancy and the early postnatal period. Issues surrounding pregnancy, birth options, interventions during labour, breastfeeding and the early parenting period are addressed. This shift in focus includes providing unbiased general information, where the classes are not specifically directed to natural birthing.

Svennson’s program follows a general format of six sessions, each lasting for 2 hours. The following subjects (from Svennson’s program) overlap with the study program:

- Labour and birth physiology information – 20 mins
- Education about 1st stage of labour – 10 mins
- Preparing for labour – 25 mins
- Labour stations (active demonstration and practice) – 15 mins

For a sample antenatal education program from HKH, please see Appendix M.
4.13.12 Treatment arm

In addition to standard antenatal care and education, the treatment intervention consisted of a two-day workshop (no cost to participants) to be held at either HKH or Nepean on a nominated weekend. The workshop consisted of the following program (see Table 4.2):

Table 4-2 Program contents

<table>
<thead>
<tr>
<th>Complete Birth components</th>
<th>Description</th>
<th>Practice recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concepts of normal physiology of birth and inner resources</td>
<td>Describes the process and hormones involved in normal birth to establish what can be expected in a normal labour and ways to facilitate it.</td>
<td>Reading of articles and information provided in the booklet</td>
</tr>
<tr>
<td>Acupressure protocol</td>
<td>Acupressure points for physiological and emotional support during labour. Point location and point combinations for different situations.</td>
<td>A booklet accompanied this session to facilitate home practice. Practice was recommended prior to labour, but as desired.</td>
</tr>
<tr>
<td>Breathing</td>
<td>4 techniques: Blissful Belly (BB) breaths, Soft Sleep (SS) breath, Cleansing Calming (CC) breath, and the J breath</td>
<td>Home practice recommended</td>
</tr>
<tr>
<td>Relaxation</td>
<td>Description of the relaxation response and progressive</td>
<td>Home practice</td>
</tr>
<tr>
<td><strong>Relaxation Included in Visualisations</strong></td>
<td><strong>Recommended</strong></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>----------------</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Visualisation</strong></th>
<th><strong>4 x 30-40min visualisations practiced</strong></th>
<th><strong>CD provided for home practice</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Movement and Yoga</strong></th>
<th><strong>Positions to encourage open hips, and use of gravity and the mother’s alignment to assist with labour’s progress</strong></th>
<th><strong>Booklet provided with pictures for home practice</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Concepts of Outer Resources</strong></th>
<th><strong>Description of what creates a warm, relaxed and conducive environment for optimal birth, and what elements may disrupt birth.</strong></th>
<th><strong>Revised during course</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Heat</strong></th>
<th><strong>Heat packs for belly and back to relax the muscles and reduce pain</strong></th>
<th><strong>Recommended for during labour</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Water</strong></th>
<th><strong>Warm bath, when cervix &gt; 4 cm dilated, relaxes body and allows uterus to be more effective. Softens the perineum to reduce tearing</strong></th>
<th><strong>Recommended for during labour</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Music</strong></th>
<th><strong>Music for relaxation</strong></th>
<th><strong>Recommended for during labour</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Massage – strong and endorphin techniques</strong></th>
<th><strong>Strong massage: use during contractions</strong>&lt;br&gt;<strong>Endorphin technique: soft (effleurage) and used between contractions to increase the release of natural opiates</strong></th>
<th><strong>Home practice recommended</strong></th>
</tr>
</thead>
</table>


| Birth plans | Preparations and techniques that may be useful and desired in labour | To be completed if desired at home and in consultation with midwife or doctor |

**Complete Birth protocol** – the program, philosophy and techniques 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 (Buckley, 2002). The program introduces concepts of birth as a natural physiological process, and evidence-based CM tools by which the birth process can be managed (Jones et al., 2012). These tools are discussed as being either ‘inner resources’ or ‘outer resources’. This refers to whether the tool is internally generated, such as relaxation, visualisation, yoga postures or breathing, or externally generated, such as massage, acupressure, or the use of water, heat or cold packs. The participant booklet is attached in Appendix N, and the tools are described below.

**‘Acupressure for pain relief in labour’ protocol** – Acupressure consists of applying moderate pressure to acu-points using locations described in TCM texts. The points selected for use, were based on the work of Betts (2005), who describes the point functions and uses during labour (Betts, 2005). A description of these point functions and uses is outlined below. The location and uses of a variety of acupressure points for assisting the physiological processes of labour, as well as for the emotional support of 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 (Betts, 2005) (see Appendix O).

Participants were advised to practice at home from 37 weeks’ gestation; practicing once a week for 5 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 an EDB is 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 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, as well as the reactions of the body when each is 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, further concepts can be introduced.
The hormonal cycle during birth – Hormones 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 (Syntocinon) for induction and augmentation is introduced was also described.

Inner resources:

The resources that are described below are techniques used in the She Births® course, and are based on the literature and experience of the founder of the course. Nadine Richardson is a qualified and experienced yoga teacher and birth educator, and incorporates these practices into the course. Yogic traditions and mind-body practices, as described in the Cochrane Reviews (Smith, Levett, et al., 2011) are at the foundation of the selected techniques.

Breathing: Mindfulness of breath or conscious breathing combined with relaxation are powerful tools for labour (Smith, Levett, et al., 2011). The Cochrane Review describes breathing techniques as ‘designed to improve oxygenation and interfere with the transmission of pain signals from the uterus to the brain’ as described by Velvovsky (1960) (cited in Smith, Levett, et al., 2011). No specific techniques are proposed in the review. There are four types of breathing techniques taught in Complete Birth. The first was 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. The Golden Breath was an alternative to the BB breath, where a golden light was imagined that expanded on the in breath, and shrunk on the out breath. These were rehearsed numerous times during the course. The second technique was the Soft Sleep (SS) breath, which was to be used in between contractions and which resembles the soft relaxed breathing that occurs when going to sleep. This was to refocus the woman between each contraction and conserve energy. The third breathing technique is the Cleansing Calming (CC) breath, and is used during transition. The CC breath is a yogic breathing technique where the throat is slightly constricted and there is an audible sound on the out breath. The purpose of this is to slow down the breathing, inducing relaxation and refocusing the woman. The fourth 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 practised by the women to demonstrate the difference in focus. In the J breath, the focus is 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:** 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 practised 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.

Relaxation is described in the Cochrane Review as guided or progressive muscle relaxation where ‘women are encouraged to focus on sensations associated with the release of muscle tension and feelings of comfort. Imagery may involve encouraging participants to scan their bodies to identify areas of pain and to imagine replacing pain with comforting sensations such as heat or cold (Smith, Levett, et al., 2011).

Visualisation: 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. Visualisation is described in the Cochrane Review (2011) as ‘a learned technique whereby the patient recalls an enjoyable and relaxing experience, which is used to decrease the intensity of pain or to substitute an unpleasant sensation. The main purpose of this technique is to evoke an altered state where a person can stimulate and utilise significant bodily functions and products that are not usually available to us (Schorn, cited in (Smith, Levett, et al., 2011).

Movement and yoga positions: Participants were taught positions with hips wide open, which use gravity and the mother’s alignment to assist with labour’s progress. Participants were taught how to use standing and leaning, using furniture, fit balls, or partner support, to aid the baby’s descent. Participants were taught movement should
be effortless and meditative. Yoga positions were taught that aid labour and can be performed by women in labour, and are described in the Cochrane Review (Smith, Levett, et al., 2011) as a ‘mind-body practice, and various styles of yoga can be used for health purposes by combining physical postures, breathing techniques and meditation or relaxation. A commonly practised form of yoga includes Hatha yoga. This includes breath awareness and internal centring to remove external concerns, achieve focus and become sensitive towards internal feelings (Smith, Levett, et al., 2011).

There were five yoga postures taught (see Appendixes P and Q):

**Baddha Konasana** (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 Konasana** (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 practised 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.

**Outer Resources:** Awareness of what creates a warm, relaxed and conducive environment for optimal birth, and what elements may disrupt birth.

**Heat:** Heat packs for belly and back to relax the muscles and reduce pain.

**Water:** Warm baths, when the woman’s cervix is more than 4 cm dilated, relax the whole body and allow the uterus to be more effective. This allows freedom of movement and softens the perineum to reduce tearing.

**Music:** For relaxation.

**Massage:** Massage techniques are useful during birth for pain relief. The Cochrane Review (Smith et al., 2012) describes massage therapy as including specific physical techniques or manual therapy, such as deep tissue work, Swedish massage, neuromuscular massage or shiatsu, and light effleurage, and that different massage techniques may suit different women (Smith et al., 2012). Based on Melzack’s (1965) work, the benefits of massage may come from pressure the pre-empting the processing of painful stimuli because pressure fibres are longer and more myelinated, and relay signals to the brain more quickly than pain fibres (Melzack 1965).
Two techniques were taught, and home practice was encouraged as often as the couples liked. The techniques were:

**Strong massage** is a technique 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 (see Appendix Q).

**Endorphin technique** is a soft technique (effleurage) 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.

**Birth plans**: Birth plans are a consideration of what preparations and techniques will be useful for the labour. They facilitate communication with the woman’s birth partner as to expectations, what practice is required and establishing a routine and commitment for practice. The couples were encouraged to look up birth plans on the internet that may be useful for facilitating communication with their midwives or doctors caring for them. Many discussed the birth plan with the midwife at their antenatal check-up prior to labour.

**4.13.13 Primary study endpoint**

The primary outcome measure was the incidence of EDB use.

**4.13.14 Secondary outcomes**

**Maternal**
Need for pharmacological pain relief during labour; induction of labour; failed
induction of labour; augmentation of labour; instrumental vaginal birth; CS; length of
labour; and attitude toward birth and sense of personal control measures.

**Infant**

Apgar scores <7 at 5 minutes; admission to SCN/NICU; respiratory distress;
antibiotic administration; perinatal mortality; duration of stay in special care unit;
duration of stay in hospital; birth weight; any assisted ventilation; medical
investigations, such as blood tests for infection.

**4.13.15 Follow-up of women and babies**

In following up women and babies, validated tools for assessing women’s sense of
agency and levels of antenatal and postnatal depression were selected due to their
widespread use, and comparisons to outcomes in other literature. The the Labour
Agentry Scale has been used in particular to assess factors relating to satisfaction
with birth (Goodman et al., 2004) (Appendix R), and the Edinburgh Postnatal
Depression Scale (Appendix S) has been widely used in research, and has been
validated in the Australian context (Boyce, Stubbs, & Todd, 1993).

- Sense of personal control measures:
  - The Labour Agentry Scale (LAS) (Hodnett & Simmons-Tropea,
    1987) by 72 hours following birth, and
Edinburgh Post Natal Depression Scale (EPDS) at baseline and six weeks’ post partum (Boyce, Stubbs, & Todd, 1993; Cox, Holden, & Sagovsky, 1987).

4.13.16 Data collection and question description of instruments

At baseline, all women were asked to complete the Attitude Towards Birth Questionnaire (Humenick & Bugen, 1981) (please see Appendix T). This questionnaire is designed to assess a woman’s attitude towards birth in the antenatal period. The intervention aimed to increase women’s confidence and positive feelings towards childbirth.

The study group also completed the questionnaire again following attendance at the course. The purpose of this was to assess change in attitude towards birth as a result of the intervention. The questionnaire contains 10 items using a 7-point Likert scale for response. This questionnaire took about 10 minutes to complete, and was completed by all women before leaving on the final day of the course.

In hindsight, it would have been valuable to have the control group complete this questionnaire again to determine if there was a natural change over the course of pregnancy. However, difficulty with compliance in returning questionnaires precluded the addition of another questionnaire for the women to complete.

Women were followed up within 72 hours of birth. Each month, the ward clerks at the participating hospitals had a list of women who were participating in the study and were due to give birth that month. When the women presented to the hospital, the investigator was notified and made arrangements for the LAS (Hodnett &
Simmons-Tropea, 1987) to be given to the woman and completed (see Appendix R). Each week, women who were due to give birth from the University of Western Sydney site, and who had not contacted the investigator independently, were contacted. If they had not yet given birth, they were sent a follow up questionnaire and asked to take it to the hospital with them and return following birth, or asked to complete and return it if they had given birth. The majority of women independently contacted the investigator when they had given birth.

This questionnaire is an instrument measuring expectancies and experiences of personal control during childbirth. The questionnaire contains 29 questions using a 7-point Likert scale for response. It measures feelings of control and confidence during labour and birth. The questionnaire has been rigorously tested and is a ‘validated and reliable instrument measuring childbirth control’ (Hodnett & Simmons-Tropea, 1987). Testing for reliability and validity was done ‘via item analyses, factor analysis, and dual-scaling techniques, while the field studies yielding evidence of discriminant and predictive validity’ (Hodnett & Simmons-Tropea, 1987). This questionnaire took about 10–15 minutes to complete.

4.13.17 Sample size

The trial was designed to demonstrate an absolute reduction of 20% in EDB use from 46% in those women managed with usual care to 26% in those women managed with CM antenatal care package. This reduction was based on an estimate of what would be feasible in the context of the study, and what would constitute a clinically important change in epidural rates.
This requires a total sample size of 170 women for an 80% power at a significance level of p=0.05. Recruitment continued until 173 women had been enrolled, and those randomised to the treatment group had either completed the course or were known to have missed their course (flow diagram of RCT – see Figure 5.1).

4.13.18 Blinding and data entry

Neither the investigator nor the women were blind to their group allocation. Therefore, some women in the control arm may have participated in other private birth preparation courses. They were asked prior to randomisation if they were attending Calm Birth or Hypnobirthing, and were excluded if they were considering it. Other women reported attending yoga courses.

The data were entered by an independent person, who was blind to group allocation. The data entry was crosschecked by the investigator with a random sample of 20 participants.

4.13.19 Data analysis

In analysing the primary and secondary outcome data, intention to treat analysis was used, and a range of statistical techniques were employed by the researcher, including contingency table and t-test for univariate analysis of categorical and continuous data, respectively, and chi-square test for trend analyses. Chi-square tests were used association between CM usage and birth outcomes. Regression analysis was used to test for associations of factors with use of EDB, and CM. Attitude Towards Childbirth and LAS measures were analysed using t-tests for comparison of means. Significance was set at an alpha of 0.05. When conducting the analysis, the
investigator was blind to group allocation and was unblinded when analysis of main outcomes was complete.

4.14 In-depth interviews (concurrent – Stage two)

Qualitative face-to-face in-depth interviews using quasi-randomisation with selected participants from the research arm of the RCT were conducted with 20 women and their partners, until data saturation occurred.

**Objective:** To investigate what characterises the selective use, rehearsal, decision-making methods and perceived effectiveness of the components of the Complete Birth education package for labour and birth.

4.14.1 Methods

**Sampling methods**
Randomisation to groups occurred first to reduce the potential for selection bias and to ensure that couples/women participating in treatment group are essentially the same as those receiving standard care alone. From those women who were allocated to the treatment group, every second woman who was randomised was approached for participation in the in-depth interviews. Women and their partners were given an information sheet following participation in the course, and followed up after giving birth to a live baby to confirm interest. An independent researcher then contacted the woman, and her partner if interested, by telephone at around 6 weeks’ post-partum for the interview.
4.14.2 Data collection

A pilot interview was conducted with the first participant who agreed to be part of the interview group. The independent researcher sent an audio file of the interview to the researcher (KL), and supervisors (CS and HD). Following review of the interview a meeting was held where the final semi-structured questions for the subsequent interviews were agreed upon. The independent researcher was also instructed to allow the participants a degree of freedom to discuss things that happened in their birth, the way they felt about a certain aspect of the birth that may have been unique, or things that were not part of the questions. This was thought to allow information that had not been previously considered to be included in the data, and allow a range of voices to be heard. The interviewer was asked broadly to focus on influences on changes in trust, fear, confidence and relaxation.

Semi-structured in-depth interviews were conducted with the participants and some of their birth partners, where agreed upon and convenient, about the program and aspects they used and found useful, not useful, or interesting.

The interviews were conducted by the same independent researcher by telephone with the woman and some birth partners at a time and place convenient to them. The interviews were recorded by the researcher using a digital recorder, and transcribed verbatim by the transcribing service ‘Pacific Solutions’. Interviews were each about an hour in length.

The interview script is provided in Appendixes U and V. The questions were semi-finalised before the intervention commenced, but small changes to the final questions
were informed by the outcomes of the previous in-depth interviews and were
iterative in development.

It was expected that between 10 and 20 women would be interviewed, with the final
sample being determined by data saturation, which can be difficult to determine
(Guest, Bunce, & Johnson, 2006). However, saturation was conceptualised as the
point at which no new themes or novel information is derived from the interview
data (Francis et al., 2010; Guest et al., 2006).

Although the interviews were semi-structured, a guide for questions was used to
ensure all points were covered. These included questions about experience of the
course, practice during antenatal period, experience of labour, how labour began,
how labour progressed, most and least useful tools or techniques, and why,
experience of support from partner, and relationship with the midwives and doctors
who cared for the women. Maintaining the focus on how the course as a whole and
CM techniques influence natural birth was important.

The questions at interview included, but were not limited to:

a. Thinking back to the ‘Complementary Therapies for Labour and Birth’ study
   weekend, what do you remember most?

b. Partner: What is it that stands out most from the weekend for you?

c. What skills did you learn during the weekend?

d. What parts did you feel were most useful and what parts were least useful?

e. Explain whether you had any changes in feelings about the birth after the
course.
Looking at changes in trust, fear, confidence, and relaxation, the questions altered during the interviews, with more questions that verified previous concepts elaborated on. For example, the pilot interview participant discussed how her understanding of labour and birth led to her particular way of approaching labour. When she understood what happens to the body during labour, this really influenced her ability to incorporate the tools in labour to facilitate the birth. This led to further questions about how understanding the body facilitated the use of the tools in labour, and having control of that process, which eventually led to the core theme of ‘making sense of labour’.

Demographic data were obtained from the women prior to interview. These data included age, ethnicity and educational level (see Table 5.5 in Chapter 5).

**4.15 Focus group interviews with midwives (Stage three)**

**4.15.1 Objectives**

The objectives of the focus groups were to elicit views from midwives on the perceived effectiveness of the program of care for women participating in the study, and to explore the potential facilitators and barriers for implementing the program in the hospital setting. A discussion of the findings from the in-depth interviews informed the questions to be used in the focus groups.

**4.15.2 Sample**

Midwives from the main study hospital (HKH) were invited to participate. The group consisted of 8–12 participants, and all midwives were invited to attend, so all participants had an opportunity to speak.
4.15.3 Methods

From the information received and themes discussed in the in-depth interviews, questions were formulated for the focus groups to be conducted with midwives. Main themes that emerged from the thematic analysis of interviews provided a basis for the focus groups. We explored with midwives their attitudes and experiences of supporting couples who have used CM techniques, as well as those from midwives who had not been involved in the care of treatment group women. As midwives provide the majority of the labour and birth care in Australia and can both facilitate and inhibit women from using CM techniques, involvement of all midwives in the focus group was thought useful in providing valuable insights into the pragmatics of implementation.

4.15.4 Data collection

Focus groups were conducted at the HKH study site within the hospital antenatal clinic. The group was conducted for 1–2 hours with structured questions regarding midwives’ experiences and opinions of the Complete Birth program and its implementation, as well as their opinion about CM in general for labour and birth support. Their opinions about the program’s capacity for facilitating natural birth constituted the primary theme. Questions regarding barriers and facilitators to implementing a CM program were examined.

Focus groups were recorded and facilitation of groups was conducted by the study supervisor (HD), who has expertise in qualitative methods and focus group facilitation, and the researcher (KL). Questions were informed by the in-depth interviews (see Appendixes U and V). Concepts that were raised by women and
partners were followed up in the focus groups as a means of assessing midwives’ perspectives. Using a triangulation/integration approach (discussed in the next section), concepts could considered on the basis of ‘convergence’, where information agrees, ‘complementarity’, where data provide complementary information, or ‘dissonance’, where there is disagreement (Farmer et al., 2006; O’Cathain et al., 2010). For example, midwives were presented with a statement from the in-depth interviews, saying that ‘couples in the study have described the midwives as part of their team, and as being advocates for them. How do you respond to that statement?’ In this way, the data could be assessed from different perspectives, which then led to the theme of ‘getting the team on board’ which discussed the idea of recruiting partner and midwife to the team through the use of knowledge of labour and use of CM tools to facilitate labour.

The focus group was digitally recorded and transcribed verbatim by the transcribing service ‘Pacific Solutions’.

4.15.5 Analysis and interpretation – interviews and focus groups
The data transcription was examined by hand in an iterative process and thematic analysis of the data was undertaken (Andrew & Halcomb, 2009; Braun & Clarke, 2006). These interviews provided an opportunity for the researchers to develop an in-depth understanding of the experiences of women and their birth partners following participation in the Complete Birth Study program and its use during the labour and birth of their child. It allowed for exploration of the individual experiences and interactions with healthcare services.
The focus group provided an opportunity for the researchers to develop an in-depth understanding of the way in which the Complete Birth Study program in particular, and CM in general, can be used during labour and birth from the point of view of midwives who are independent observers of CM in action in hospitals. It will also allow exploration of the way the program operates within healthcare services.

Thematic analysis, as described by Braun and Clarke (Braun & Clarke, 2006) and Curry et.al. (Curry, Nembhard, & Bradley, 2009), is an iterative process where concepts, categories or themes, and relationships with other categories or themes, are constantly refined through the following steps:

- Multiple readings of the data – reading and rereading the data, and listening to the recorded data to become immersed in the data.

- Identification and labelling of concepts in the data and development of preliminary themes or categories from these concepts. These are captured in phrases and, where appropriate, using the language of the participants.

- Further coding of the data in each theme, identification of linkages and relationships between themes.

### 4.16 Integration of data

Integration is the term used to describe the points during the research process at which mixing of qualitative and quantitative data occurs, and can occur at multiple points throughout the data collection and analysis process (Andrew & Halcomb,
Integration of data involves identification of themes that are common to the analysis of data from each stage. These themes are considered after the analysis of each stage separately, and brought together, compared and contrasted, and then discussed in an integrated way. The effective interaction of the quantitative and qualitative components of a mixed methods study produces a result, or interpretation or understanding, which is greater than either study could achieve on its own. One of the three techniques described by O’Cathain et al. (2010) that are used for integrating data in MMR is ‘triangulation’ (O'Cathain et al., 2010). This refers to using different methods to understand a research question and takes place at the interpretation stage, after the data sets have been analysed separately (O'Cathain et al., 2010).

‘Methodological’ triangulation, as described by Farmer and colleagues (2006), involves the use of more than one research method or data collection technique (Farmer et al., 2006). The key feature of triangulation is that the main findings from each data set are listed and analysed for three components: ‘convergence’, where the findings from the data sets are in agreement; ‘complementarity’, where the findings from the data sets provide complementary information, allowing for a fuller understanding of the same issue; and ‘dissonance’, where the findings contradict or diverge from each other (Farmer et al., 2006; O'Cathain et al., 2010). There is also the possibility of ‘silence’ where one data set produces some findings that are not found in the other data set or sets (Farmer et al., 2006).

The method of triangulation can be viewed an approach to enhancing validity (Cresswell & Plano Clark, 2011) where the data from qualitative sources are validated from quantitative sources. This approach seems to assume a positivist
framework underpins the research (Hesse-Biber, 2010), as it implies that the quantitative results are the ‘accurate’ data set. This researcher takes the approach that the findings from each set are enhanced and explained by the other sets, allowing the researchers to gain a greater understanding of the issues as a whole, thus increasing validity and understanding its capacity for generalisability to a broader population. Generalisability is an important component of this research, as we gain an understanding of the population for whom this research was meaningful, we can continue to contribute to the literature regarding CM usage and mapping the population of users.

4.17 Summary

This chapter has explained the methodology chosen for my study. The epistemological underpinnings and history of pragmatism have been outlined and a feminist lens applied to the question and context. An MMR approach was chosen for this study because of its flexible style, and its capacity to bring enhanced understanding of the research question and be reflective of CM as a holistic system. The study is concerned with effectiveness of CM, using quantitative analysis, and also in understanding the experiences of women, their partners and midwives in using CM to support natural labour and birth, using qualitative analysis. The next chapter will describe the quantitative results from the RCT.
Chapter 5 – QUANTITATIVE RESULTS

5.1 Introduction

This chapter presents the findings from the RCT of the Complete Birth Study. The primary objective was to examine the effects of a complementary therapies antenatal education course on the labour and birth of low-risk, first-time mothers (primiparas). This chapter will also present the findings of quantitative questionnaires reflecting women’s personal sense of control during labour, as well as the self-reported items of practice and use of CM therapies. The qualitative results from the in-depth interviews with participants and focus group with midwives are presented in Chapter 6, and the integration of these results will be discussed in Chapter 7.

The first section of this chapter outlines the hypotheses and research questions proposed and undertaken in the quantitative arm of the study. The second section describes baseline characteristics of the women who participated in the study, and participant progress, followed by the analysis of primary and secondary study outcomes. The third section provides an analysis of the validated questionnaires comparing the outcomes for the intervention group with the control group. A post-hoc analysis includes examination of amount of rehearsal of CM techniques in the antenatal period, and the influence of practice on likelihood of EDB use.

5.2 Primary hypothesis

The Complete Birth Study package, in addition to standard care, will reduce rates of EDB use for primiparous women, compared with standard care alone.
5.3 Secondary hypotheses:

The Complete Birth Study package, in addition to standard care, for primiparous women and their birth partners, compared with standard care alone will demonstrate:

Maternal outcomes:

1. Reduced CS and instrumental birth rates;
2. Reduced use of other pharmacological methods of pain relief;
3. Reduced requirement for other medical interventions, including: induction of labour; artificial rupture of membranes (ARM); medical augmentation of labour;
4. Reduced maternal morbidity including: PPH; perineal trauma; reduced length of labour (first stage, second stage, total);
5. Increased experience of confidence and personal control during childbirth.

Neonatal outcome:

6. Reduced neonatal morbidity and complications including: resuscitation required at birth, Apgar <7 at 5 minutes, and SCN/NICU admissions.

5.4 Post-hoc secondary question

1. Are rates of antenatal practice and rehearsal of CM therapies associated with decreased use of EDBs in labour and birth?

5.5 Participants

5.5.1 Participant progression

Two hundred and eighty-six women were screened for participation in the study at the two study hospitals, or contacted the study investigator directly via the newspaper
or magazine advertisements, which is described in the methods section of Chapter 4. Women were recruited to the trial primarily from HKH and Nepean, and other UWS recruits were from 12 other NSW hospitals. One hundred and thirty-nine women were excluded from the study, including 34 women who did not meet the inclusion criteria (see Table 5.1).

Table 5.1: Women not meeting inclusion criteria

<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Confirmed mod–high risk pregnancy (by medical practitioner)</td>
<td>5</td>
</tr>
<tr>
<td>2. Diagnosed congenital abnormality (by ultrasound or DNA testing)</td>
<td>0</td>
</tr>
<tr>
<td>3. In continuous care midwifery program</td>
<td>10</td>
</tr>
<tr>
<td>4. Insufficient English for participation</td>
<td>7</td>
</tr>
<tr>
<td>5. Attending similar private birth preparation classes (specifically Calmbirth and Hypnobirthing)</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34</strong></td>
</tr>
</tbody>
</table>

Those who declined to participate numbered 105 women. Reasons given for non-participation are shown in Table 5.2, and included: not interested in CM (47); already decided to have an EDB or CS (4); couldn’t make the classes on weekends (15); insufficient transport (7); husband/partner not interested (8); English identified as an issue by potential participant (3); church/religious commitments (9); attending other classes (such as yoga) and felt this was sufficient preparation (12).
<table>
<thead>
<tr>
<th>Reason for non-participation in study</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not interested in CM</td>
<td>47</td>
</tr>
<tr>
<td>Already decided to have an EDB or CS</td>
<td>4</td>
</tr>
<tr>
<td>Couldn’t make the classes on weekends</td>
<td>15</td>
</tr>
<tr>
<td>Insufficient transport</td>
<td>7</td>
</tr>
<tr>
<td>Husband/partner not interested</td>
<td>8</td>
</tr>
<tr>
<td>English identified as an issue by potential participant</td>
<td>3</td>
</tr>
<tr>
<td>Church/religious commitments over weekend</td>
<td>9</td>
</tr>
<tr>
<td>Attending other classes</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>105</strong></td>
</tr>
</tbody>
</table>

In total, 176 women were randomised to the study: 89 were allocated to the study group and 87 allocated to the control group. The final analysis of the primary outcome included 171 women, 88 in the study group and 83 in the control group. The progression of participants in the trial is presented in the CONSORT diagram in Figure 5.1.
Assessed for eligibility (n=315)

Excluded (n=139)
- Not meeting inclusion criteria (n=34)
- Declined to participate (n=105)

Randomised (n=176)

Allocated to intervention (n=89)
- Received allocated intervention (n=75)
- Did not receive allocated intervention (n=12)

Allocated to control (n=87)
- Received allocated intervention (n=87)
- Did not receive allocated intervention (n=0)

Follow-up

Lost to follow-up (primary outcome) (n=1)
Discontinued follow up (unable to access files) (n=1)

Lost to follow-up (withdrew) (n=2)
Discontinued follow up (1^0 outcome) (n=2)

Analysis

Analysed (n=88)
- Excluded from analysis (files not located) (n=1)

Analysed (n=83)
- Excluded from analysis (withdrew) (n=4)

Total n=171

Figure 5-1: CompleTe Birth Study – CONSORT Diagram
5.5.2 Withdrawals, non-compliance, and losses to follow-up

Withdrawals
Four women from the control group subsequently withdrew their consent, as two subsequently revealed that they only wished to participate if they were allocated to the study group, and two women withdrew consent during the follow-up period. No reasons were provided. One woman from the study group, who transferred hospitals late in her pregnancy, was lost to follow-up as her files were not able to be located, giving 171 women included in the analysis of the primary outcome measure of EDB use. Of the 89 women randomised to the study group, 12 did not receive the intervention. Reasons for non-attendance and withdrawal from the study are given in Table 5.3.

Table 5-3: Reasons for non-attendance and withdrawal

<table>
<thead>
<tr>
<th>Number</th>
<th>Allocated group</th>
<th>Study site</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Withdrawal of consent | 4 | Control group | UWS (3)  
Nep (1) | Only wanted to participate if in study group (2).  
No reason provided (2) |
| Non-attendance at workshop | 12 | Study group | HKH (3)  
Nep (7)  
UWS (2) | Early labour (3);  
Forgot (2)  
No reason provided (8) |
| Loss to follow-up: No primary outcome measure | 1 | Study group | HKH (1) | Late transfer to another hospital and records were not able to be located. |

HKH: Hornsby Ku-ring-gai Hospital; Nep: Nepean Hospital; UWS: University of Western Sydney
Non-compliance of study forms

Other secondary outcomes measures were obtained from self-reported follow-up forms. These were: the baseline form and the antenatal EPDS completed at randomisation; the postnatal questionnaire within 72 hours, which contained the LAS Questionnaire; and the postnatal EPDS 6 weeks following birth. Forms that were not completed or returned are outlined in Table 5.4. No reasons were generally given for non-return of forms.

When the women in the study group were compared to the control group, it was apparent that a higher proportion of the control group (24 women) did not provide responses for demographic questions compared with the study group (8 women). Non-responses can be identified most prominently in the categories of cultural background, income and education.

The missing responses constitute over 5% of the total sample, and as such there is a potential for bias to be introduced into the analysis of these factors. Tests for homogeneity and equality of variance were performed to ensure interpretation of data, where missing data were present, could account for bias that may have been introduced.
Table 5-4: Non-compliance of study forms

<table>
<thead>
<tr>
<th></th>
<th>Study Group (n)</th>
<th>Control Group (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline data</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Antenatal EPDS</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>Post-partum questionnaire</td>
<td>16</td>
<td>31</td>
</tr>
<tr>
<td>6-week follow-up – EPDS</td>
<td>27</td>
<td>41</td>
</tr>
</tbody>
</table>

EPDS: Edinburgh Postnatal Depression Scale

5.6 Baseline characteristics of women

5.6.1 Demographics

One hundred and seventy-six women were enrolled in the study, with 89 allocated to the study group and 87 allocated to the control group (Table 5.5 analysis by randomisation). One hundred and three women were recruited from HKH, 33 women were from Nepean, and 40 women were recruited through UWS (Table 5.6 analysis by site). Data from five women were not included in the analysis, one from the study group, who was lost to follow-up (HKH=1), and four from the control group, three who withdrew consent and one who was lost to follow-up (UWS=3, Nep=1). Data analysis is reported for 171 women, with 88 in the study group and 83 in the control group.

Women’s ages ranged from 18 to 42 years of age. Seventy-six percent of respondents were born in Australia, 18% from Asian countries and the remaining 6% were from the Middle East, New Zealand or Europe (see Table 5.5 and Table 5.6). One hundred
and sixty-five women described themselves as being in a relationship, and five women described themselves as being single. The majority of participants were in the top two income brackets and had post-secondary qualifications.

All participants were primiparous, having their first baby over 20 weeks’ gestation, and giving birth in a NSW hospital. The majority (160 women) gave birth in a public hospital, and 10 women gave birth in a private hospital. Of the 160 public hospital women, three gave birth in a public hospital with a private obstetrician. Women gave birth in the delivery suite at their chosen hospital, as planning their birth in a birth centre was an exclusion. Two women gave birth unexpectedly at home, one having not reached the hospital in time, and one having been sent home from hospital and giving birth soon after. Demographic data and p values for comparisons are presented in Table 5.5.

5.6.2 Between-group baseline measures of demographics

Group differences in the demographic background of the participants were examined according to randomisation. Participants in the study and control groups were not significantly different from each other in terms of their age, BMI, cultural background, level of education, income, hospital status, or model of care. The difference in age was nearing significance, and this may have been attributable to two women randomly allocated to the study group who were over 40 years of age. These two subjects could have skewed the data slightly. However, the difference represents only about 15 months, which is not clinically significant (p values presented in Table 5.5).
<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Study Group n = 87</th>
<th>Control Group n = 85</th>
<th>Difference statistic, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years, ± SD)</td>
<td>30.41 (± 4.99)</td>
<td>28.87 (± 5.24)</td>
<td>p=0.06</td>
</tr>
<tr>
<td>BMI (mean ± SD)</td>
<td>22.66 (±4.47)</td>
<td>23.35 (±3.93)</td>
<td>p=0.35</td>
</tr>
<tr>
<td>Cultural Background</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>58 (73.4)</td>
<td>44 (72.1)</td>
<td>$\chi^2 (2)=0.124$ p=0.77</td>
</tr>
<tr>
<td>Asian</td>
<td>10 (12.7)</td>
<td>11 (18.0)</td>
<td></td>
</tr>
<tr>
<td>ATSI and other</td>
<td>11 (13.9)</td>
<td>6 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;60</td>
<td>12 (15.4)</td>
<td>12 (19.7)</td>
<td>$\chi^2 (2)=5.393$ p=0.25</td>
</tr>
<tr>
<td>60-80K</td>
<td>7 (9.0)</td>
<td>10 (16.4)</td>
<td></td>
</tr>
<tr>
<td>80-100K</td>
<td>17 (21.8)</td>
<td>10 (16.4)</td>
<td></td>
</tr>
<tr>
<td>&gt;100K</td>
<td>42 (53.5)</td>
<td>29 (47.5)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSC/TAFE</td>
<td>24 (29.6)</td>
<td>20 (33.3)</td>
<td>$\chi^2 (2)=0.220$ p=0.64</td>
</tr>
<tr>
<td>University/Post-Grad</td>
<td>57 (70.4)</td>
<td>40 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Hospital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public status</td>
<td>82 (94.3%)</td>
<td>79 (92.9%)</td>
<td>$\chi^2 (2)=0.124$ p=0.77</td>
</tr>
<tr>
<td>Private Status</td>
<td>5 (5.7%)</td>
<td>(7.1%)</td>
<td></td>
</tr>
<tr>
<td>Model of Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwifery</td>
<td>67 (82.7)</td>
<td>64 (85.3%)</td>
<td>$\chi^2 (2)=3.232$ p=0.20</td>
</tr>
<tr>
<td>Doctors Care</td>
<td>4 (4.9%)</td>
<td>7 (9.3%)</td>
<td></td>
</tr>
<tr>
<td>Shared Care</td>
<td>10 (12.3%)</td>
<td>4 (5.3%)</td>
<td></td>
</tr>
</tbody>
</table>

ATSI: Aboriginal or Torres Strait Islander
5.6.3 Demographic characteristics by site

The purpose of examining differences by site of recruitment was to confirm that the sites were representing demographically different areas of Sydney, which was underlying the choice of hospitals. These demographics differences show that the study was successful in identifying different demographic groups. The mean age and standard deviation for women at HKH was 29.80 years [SD=4.71], the mean age for women giving birth at Nepean Hospital was 25.44 years [SD=5.22], and the mean age for other UWS women was 32.86 years [SD=3.90]. The majority of respondents from all sites were in the top two income brackets, 67%, 64% and 80% from HKH, Nepean and UWS respectively. Seventy-two percent of HKH women, 39% of Nepean women, and 75% of UWS women had at least university or post-graduate qualifications.

The ages and educational attainment of the women from the study sites were significantly different (p<0.001, p<0.0001 respectively). Educational attainment was different for Nepean women compared with HKH and UWS women (p<0.01). HKH and UWS were not significantly different from each other for educational attainment. Analysis of the participant’s model of care also showed a significant difference, with women from the UWS cohort more likely to be in private or in a GP shared care model (p<0.01).

Women from the UWS cohort tended to be older than the HKH and Nepean cohorts (p<0.001), and more likely to be under private obstetric care than the HKH or Nepean women (p<0.001). The HKH women were mostly between the other two groups in all variables: they were better educated (p=0.02), and older (p<0.001) than
the Nepean women. There were no significant differences between the three groups with regard to income, BMI, cultural background, and previous use of CM therapies.
Table 5-6: Participant demographics by site

<table>
<thead>
<tr>
<th>Hospital (public status) (%)</th>
<th>HKH $n = 102$</th>
<th>Nepean $n = 30$</th>
<th>UWS $n = 40$</th>
<th>Between-Group Difference statistic, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years, ± SD)</td>
<td>29.82 (+4.71)</td>
<td>25.44 (+5.22)</td>
<td>32.86 (+3.89)</td>
<td>&lt;0.001**</td>
</tr>
<tr>
<td>BMI (mean SD)</td>
<td>23.06 (+4.10)</td>
<td>24.29 (+6.04)</td>
<td>21.95 (+3.21)</td>
<td>0.140</td>
</tr>
<tr>
<td>Cultural Background:</td>
<td>n = 86 (%)</td>
<td>n = 18 (%)</td>
<td>n = 36 (%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>63 (73.26)</td>
<td>15 (83.33)</td>
<td>29 (80.56)</td>
<td>0.009**</td>
</tr>
<tr>
<td>Asian</td>
<td>20 (23.26)</td>
<td>1 (5.56)</td>
<td>4 (11.11)</td>
<td></td>
</tr>
<tr>
<td>ATSI and other</td>
<td>3 (3.48)</td>
<td>2 (11.12)</td>
<td>3 (8.33)</td>
<td></td>
</tr>
<tr>
<td>Income (%)</td>
<td>n = 86 (%)</td>
<td>n = 18 (%)</td>
<td>n = 36 (%)</td>
<td></td>
</tr>
<tr>
<td>&lt;40K</td>
<td>8 (9.30)</td>
<td>(18)</td>
<td>(30)</td>
<td>0.171</td>
</tr>
<tr>
<td>40-60K</td>
<td>10 (11.63)</td>
<td>(6)</td>
<td>(3)</td>
<td></td>
</tr>
<tr>
<td>60-80K</td>
<td>10 (11.63)</td>
<td>(12)</td>
<td>(14)</td>
<td></td>
</tr>
<tr>
<td>80-100K</td>
<td>16 (18.60)</td>
<td>(18)</td>
<td>(22)</td>
<td></td>
</tr>
<tr>
<td>&gt;100K</td>
<td>42 (48.84)</td>
<td>(46)</td>
<td>(58)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSC/TAFE</td>
<td>24 (27.91)</td>
<td>11 (61.11)</td>
<td>9 (25.0)</td>
<td>&lt;0.01**</td>
</tr>
<tr>
<td>University</td>
<td>40 (46.51)</td>
<td>4 (22.22)</td>
<td>15 (41.67)</td>
<td></td>
</tr>
<tr>
<td>Post-Grad</td>
<td>22 (25.58)</td>
<td>3 (16.67)</td>
<td>12 (33.33)</td>
<td></td>
</tr>
<tr>
<td>Hospital (public status)</td>
<td>86 (100)</td>
<td>18 (100)</td>
<td>26 (72.22)</td>
<td>&lt;0.01**</td>
</tr>
<tr>
<td>Model of Care (MW/Dr/Shared)</td>
<td>94 / 3 / 5 (100)</td>
<td>84 / 5 / 11 (100)</td>
<td>66 / 22 / 22 (100)</td>
<td>&lt;0.01**</td>
</tr>
</tbody>
</table>

HKH: Hornsby Ku-ring-gai; Nepean: Nepean Hospital; UWS: University of Western Sydney
5.6.4 Clinical characteristics

We examined differences in the background clinical characteristics of the participants according to randomisation. These results are presented in Table 5.7. Women in the study and control groups were similar in their clinical characteristics. All women were determined to be of low risk, and were reviewed if risk status changed. There was no statistical difference between groups for mode of conception, pre-existing medical conditions, or use of medicines during pregnancy. There was however a significant difference in gestational age at recruitment, with women in the study group being of a slightly earlier gestation than the control group women. However, the difference between these gestations is one week and one day, which is clinically insignificant for the purposes of antenatal education, and both lie within the inclusion criteria of 24 weeks’ gestation to 34 weeks’ gestation.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Study Group</th>
<th>Control Group</th>
<th>Difference statistic, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 83 (%)</td>
<td>n = 60 (%)</td>
<td></td>
</tr>
<tr>
<td>Mode of conception</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVF: n (%)</td>
<td>7 (8.75)</td>
<td>5 (8.33)</td>
<td>$\chi^2 (2) = 0.931$</td>
</tr>
<tr>
<td>Natural: n (%)</td>
<td>73 (91.25)</td>
<td>55 (91.66)</td>
<td></td>
</tr>
<tr>
<td>Gestational age at recruitment</td>
<td></td>
<td></td>
<td>$t = -2.395$</td>
</tr>
<tr>
<td>Weeks + days (mean)</td>
<td>28 + 6</td>
<td>30 + 0</td>
<td></td>
</tr>
<tr>
<td>Pre-existing medical conditions: n (%)</td>
<td>12 (14.46)</td>
<td>8 (13.33)</td>
<td>$\chi^2 (2) = 0.37$</td>
</tr>
<tr>
<td>Medication use: n (%)</td>
<td>14 (16.87)</td>
<td>10 (16.67)</td>
<td>$\chi^2 (2) = 0.975$</td>
</tr>
</tbody>
</table>

* Mean and standard deviation (SD)
Medication use did not differ between groups (14 in the study group and 10 in the control group, p=1.0). Some women used more than one medication.

The most common reasons for using medication were: antibiotics for infection/urinary tract infection (7 study group, 8 control group); paracetamol for headaches (7, 8); anti-emetics for nausea and vomiting (4,3); steroids or puffers for asthma (4, 2); cold and flu medications (3, 2); iron supplements (3, 2); aspirin for blood thinning (2, 1); heartburn medications (2, 1); musculoskeletal pain medication (1, 2); hypothyroid medication (2, 0); vitamin D supplements (1, 1); and medications for: sinusitis (0, 2); toothache/gingivitis (0, 2); thrush (1, 1); dermatitis (0, 1); PCOS (1, 0); insulin resistance (0, 1); herpes (1, 0); mood swings (0, 1); rash (0, 1); and ‘unwell/not recorded’ (4, 4).

5.6.5 Lifestyle characteristics

Lifestyle factors were assessed at trial entry (Table 5.8). More than 41% of the study group and 27% of the control group identified having used CM previously. While a large proportion of the control group did not provide responses to this item, there was no significant difference between the study group and control group (p=0.08). The majority of women exercised between 1–3 hours per week, with 52% of the study group and 41% of the control group in this category. There was no significant difference between groups for exercise per week (p=0.29). With regard to alcohol consumption, the majority of women consumed no alcohol during pregnancy. For comparison with smoking status, there was again no significant difference between groups, with 83% and 88% of study and control group women stating that they were non-smokers, and 15% and 12% stating that they had given up smoking when they
found out they were pregnant. Two women from the study group stated that they were still smoking during pregnancy.

Table 5-8: Lifestyle characteristics

<table>
<thead>
<tr>
<th></th>
<th>Hospital N=141</th>
<th>Study Group n = 82 (%)</th>
<th>Control Group n = 59 (%)</th>
<th>Difference statistic, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous CM use</td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>34 (41.46)</td>
<td>16 (27.12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 hour/week</td>
<td>11 (13.58)</td>
<td>12 (19.67)</td>
<td></td>
<td>$\chi^2 (2)=4.987$</td>
</tr>
<tr>
<td>1-3 hrs/week</td>
<td>42 (51.85)</td>
<td>25 (40.98)</td>
<td></td>
<td>p=0.30</td>
</tr>
<tr>
<td>3-5 hrs/week</td>
<td>25 (30.86)</td>
<td>21 (34.43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 5 hrs/week</td>
<td>3 (3.7)</td>
<td>1 (1.69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol consumption:</td>
<td></td>
<td></td>
<td></td>
<td>$\chi^2 (2)=4.287$</td>
</tr>
<tr>
<td>Nil:</td>
<td>74 (90.24)</td>
<td>51 (86.44)</td>
<td></td>
<td>p=0.12</td>
</tr>
<tr>
<td>1-3 glasses/week</td>
<td>8 (9.88)</td>
<td>5 (8.47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-5 glasses/week</td>
<td>0</td>
<td>3 (5.08)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking status:</td>
<td></td>
<td></td>
<td></td>
<td>$\chi^2 (2)=1.744$</td>
</tr>
<tr>
<td>Non-smoker:</td>
<td>68 (82.93)</td>
<td>52 (88.13)</td>
<td></td>
<td>p=0.42</td>
</tr>
<tr>
<td>Stopped when preg:</td>
<td>12 (14.63)</td>
<td>7 (11.86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker:</td>
<td>2 (2.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CM: Complementary medicine
5.6.7 Complementary medicine use during pregnancy

Examining CM use more closely, we found that 50 women (35.5%) from the whole study cohort identified as having used CM during their pregnancy (Table 5.9). These 50 women had used 96 separate CM therapies or modalities. Twenty-three women used only one CM modality or therapy during their pregnancy, 27 women recorded using two or more CM therapies or modalities, 13 women used three or more different CM, and six women used four different therapies during their pregnancy.

Of the therapies identified, the four most commonly used were pregnancy vitamins, yoga, massage and acupuncture. Chiropractic, herbal medicine and meditation were equal fifth most commonly used. Of those women who stated that they used CM, 44% used pregnancy vitamins or supplements. Forty percent identified having practised yoga during pregnancy, 12% used massage, and 9% used acupuncture. Chiropractic, herbal medicine and meditation were all used by 7% of respondents.
Table 5-9: Complementary medicine use whole cohort

<table>
<thead>
<tr>
<th>Complementary medicine therapy used</th>
<th>n = 50 (29.4%) *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy vitamins</td>
<td>22 (44.0)</td>
</tr>
<tr>
<td>Yoga</td>
<td>20 (40.0)</td>
</tr>
<tr>
<td>Massage</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>9 (18.0)</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>7 (14.0)</td>
</tr>
<tr>
<td>Herbs</td>
<td>7 (14.0)</td>
</tr>
<tr>
<td>Meditation</td>
<td>7 (14.0)</td>
</tr>
<tr>
<td>Naturopathy</td>
<td>3 (6.0)</td>
</tr>
<tr>
<td>Osteopathy</td>
<td>3 (6.0)</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>2 (4.0)</td>
</tr>
<tr>
<td>Hypnosis</td>
<td>2 (4.0)</td>
</tr>
<tr>
<td>Kinesiology</td>
<td>2 (4.0)</td>
</tr>
<tr>
<td>Pilates</td>
<td>2 (4.0)</td>
</tr>
</tbody>
</table>

* Respondents’ total use equals more than 100%, due to multiple uses per individual
5.7 Questionnaire data

5.7.1 Baseline measurement of self-report questionnaire

At trial entry all women completed the Attitude Towards Birth Questionnaire (ATBQ) (Humenick & Bugen, 1981). This measure was repeated following the intervention for the study group. Following birth all women completed the LAS (Hodnett & Simmons-Tropea, 1987) examining expectancies and experiences of personal control during childbirth. The results from the baseline measure are presented here, and results following the intervention are presented later in this chapter (section 5.10.2.2).

**Attitude Towards Birth Questionnaire**

At randomisation, women were asked about their attitude towards birth via the ATBQ questionnaire. A baseline comparison of this measure was obtained prior to the intervention to determine any existing between-group differences. There were 32 missing data points: five in the study group and 27 in the control group. Equality of variance was not significantly different between groups (p=0.37), and therefore equal variance was assumed. At trial entry, the study groups recorded similar scores of 51.98 and 51.61 respectively (Table 5.10). There were no significant baseline difference between the groups prior to the intervention (p>0.05).
Table 5-10: Pre-randomisation Attitude Towards Birth Questionnaire

<table>
<thead>
<tr>
<th>ATBQ pre-intervention</th>
<th>Study Group $n = 82$</th>
<th>Control Group $n = 59$</th>
<th>Difference Statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean (SD)</td>
<td>51.62 (7.12)</td>
<td>51.90 (7.11)</td>
<td>MD = -0.276</td>
<td>[95% CI: -2.678, 2.125] p=0.82</td>
</tr>
</tbody>
</table>

* ATBQ: Attitude Towards Birth Questionnaire; CI: confidence interval; MD: mean difference

**Antenatal Edinburgh Postnatal Depression Scale**

As part of the baseline information, the validated questionnaire EPDS was administered in the antenatal period to determine if any differences existed between the study group and control group with regard to levels of depression. We found that there were no significant differences in the mean EPDS score between the study and control group prior to the intervention (see Table 5.11). However, to account for the missing responses from the control group we performed a Levene’s test for equality of variances, and found no significant differences between the variances of the two groups, so assumptions of normal distributions hold.

Table 5-11: Antenatal Edinburgh Postnatal Depression Scale Questionnaire

<table>
<thead>
<tr>
<th>Baseline Antenatal EPDS</th>
<th>Study Group $n = 83$ (SD)</th>
<th>Control Group $n = 56$ (SD)</th>
<th>Difference Statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(average score)</td>
<td>4.93 (3.67)</td>
<td>5.25 (4.07)</td>
<td>MD = -0.32</td>
<td>[95% CI: -1.63, 0.99] p=0.63</td>
</tr>
</tbody>
</table>

* EPDS: Edinburgh Postnatal Depression Scale; CI: confidence interval; MD: mean difference
5.8 Summary of demographics

The women who participated in this study tended to be Caucasian, around 29–30 years of age, non-smokers and consume no or low amounts of alcohol. Around 34% had used CM previously, and most commonly used pregnancy vitamins, yoga, massage and acupuncture. The majority were well educated, in the higher income brackets and accessing public maternity care. The women in the study group and the control group were similar in their demographics, and in their baseline measures of antenatal depression and attitude towards childbirth. The majority of women were from the HKH site, and tended to be better educated, with a higher income and slightly older than the Nepean women. HKH women were slightly younger, but otherwise similar to the UWS women. The sites represented different demographics of participants.

5.9 Primary outcome measure: epidural blocks

The effectiveness of the Complete Birth Study program was measured by the primary outcome measure of EDB use, and was examined for difference between the study group and the control groups.

A statistically and clinically large reduction in EDB rates was found for the intervention group compared with the control group. The rate of EDB use in the control group was 68.7%, and was reduced to 23.9% in the study group (risk ratio: 0.37 [95% C.I.: 0.25, 0.55] p=<0.0001), (Table 5.12). This is a highly significant result and shows a large effect of the intervention on reducing EDB rates in the study group.
<table>
<thead>
<tr>
<th>OUTCOMES</th>
<th>Study Group (n=88)</th>
<th>Control Group (n=83)</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural block</td>
<td>21 (23.9%)</td>
<td>57 (68.7%)</td>
<td>0.37 [0.25-0.55]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P&lt;0.0001**</td>
</tr>
<tr>
<td>Spontaneous Onset Labour</td>
<td>62 (70.5%)</td>
<td>54 (65.1%)</td>
<td>1.13 [0.82-1.57]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.51</td>
</tr>
<tr>
<td>Augmentation</td>
<td>25 (28.4%)</td>
<td>48 (57.8%)</td>
<td>0.54 [0.38-0.77]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P&lt;0.0001**</td>
</tr>
<tr>
<td>Mode of Birth: NVB</td>
<td>60 (68.2%)</td>
<td>39 (47.0%)</td>
<td>1.56 [1.12-2.17]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=&lt;0.01**</td>
</tr>
<tr>
<td>Mode of Birth: CS</td>
<td>16 (18.2%)</td>
<td>27 (32.5%)</td>
<td>0.52 [0.31-0.87]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.017*</td>
</tr>
<tr>
<td>Mode of Birth: Instrumental</td>
<td>12 (13.6%)</td>
<td>17 (20.5%)</td>
<td>0.57 [0.30-1.09]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.09</td>
</tr>
<tr>
<td>Nitrous Oxide (Gas)</td>
<td>40 (45.5%)</td>
<td>49 (59.0%)</td>
<td>0.77 [0.57-1.03]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.092</td>
</tr>
<tr>
<td>Pethidine</td>
<td>19 (20.5%)</td>
<td>15 (19.3%)</td>
<td>1.11 [0.78-1.56]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.70</td>
</tr>
<tr>
<td>Perineal Trauma (NVD=72, 56)^</td>
<td>61 (87.1%)^</td>
<td>54 (96.4%)^</td>
<td>0.88 [0.78-0.98]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.02</td>
</tr>
<tr>
<td>Major Perineal Trauma (NVD=72, 56)^</td>
<td>49 (68.1%)^</td>
<td>37 (66.1%)^</td>
<td>1.03 [0.81-1.32]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.81</td>
</tr>
<tr>
<td>PPH</td>
<td>13 (14.8%)</td>
<td>15 (18.1%)</td>
<td>0.82 [0.41-1.61]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.68</td>
</tr>
<tr>
<td>Resuscitation (Suction +/- O₂)</td>
<td>12 (13.6%)</td>
<td>24 (28.9%)</td>
<td>0.47 [0.25-0.87]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.015*</td>
</tr>
<tr>
<td>Apgar &lt; 7 (5 min)</td>
<td>3 (3.4%)</td>
<td>4 (4.8%)</td>
<td>0.99 [0.95-1.03]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=1.0</td>
</tr>
<tr>
<td>SCN/NICU admit</td>
<td>7 (8.0%)</td>
<td>11 (13.2%)</td>
<td>0.59 [0.24-1.46]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P=0.25</td>
</tr>
</tbody>
</table>

* <0.05; ** <0.01

^ percentage is from total vaginal births

CS: Caesarean section; NVB: Normal vaginal birth; PPH: Post-partum haemorrhage; SCN/NICU: Special Care Nursery/Neonatal Intensive Care Unit
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 all had an EDB and the one study group woman did not have an EDB (best case), the risk ratio was slightly reduced: 0.35 [95% C.I.: 0.24, 0.52] p<=0.0001 (see Table 5.13). 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 (see Table 5.14).

Table 5-13: Epidural block by randomisation - best-case–scenario

<table>
<thead>
<tr>
<th>Randomisation</th>
<th>Study Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21 (23.6%)</td>
<td>61 (70.1%)</td>
<td>82 (46.6%)</td>
</tr>
<tr>
<td>No</td>
<td>68 (76.4%)</td>
<td>26 (29.9%)</td>
<td>94 (53.4%)</td>
</tr>
<tr>
<td>Total</td>
<td>89</td>
<td>87</td>
<td>176</td>
</tr>
</tbody>
</table>

EDB: Epidural block

Table 5-14: Epidural block by randomisation– worst-case scenario

<table>
<thead>
<tr>
<th>Randomisation</th>
<th>Study Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22 (24.7%)</td>
<td>57 (65.5%)</td>
<td>82 (46.6%)</td>
</tr>
<tr>
<td>No</td>
<td>67 (75.3%)</td>
<td>30 (34.5%)</td>
<td>97 (55.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>89</td>
<td>87</td>
<td>176</td>
</tr>
</tbody>
</table>

EDB: Epidural block
5.10 Secondary outcome measures

5.10.1 Maternal

With regard to secondary maternal outcomes, women in the study group were statistically less likely to require medical augmentation during labour (RR= 0.50 [95% CI: 0.35-0.73], p<0.001) or birth by CS (RR=0.52 [0.31-0.87], p=0.01); and saw a reduction in the length of second stage of labour (MD= -0.32 [95% CI: -0.64, 0.002], p=0.05) and total length of labour when augmentation in the study group is accounted for (see Table 5.16) p<0.001.

There were also some non-significant trends towards the study group having less likelihood of an instrumental vaginal birth (RR=0.57 [95% C.I.: 0.30-1.09], p=0.09), nitrous oxide (gas) for pain management (RR = 0.77 [95% C.I.: 0.58-1.03], p=0.08), and likelihood of perineal trauma (RR=0.90 [95% C.I.: 0.82-1.0], p=0.07), but no difference in major perineal trauma.

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 PPH (RR=0.95 [95% CI: 0.57-1.55], p=0.81) and rates of major perineal trauma (second/third/fourth degree tear or episiotomy) (RR=0.82 [95% CI: 0.41-1.61], p=0.56). These results are displayed in summary Table 5.12.

To examine any differences in length of labour we compared the study group and control group using independent sample t-tests for: first stage of labour; second stage of labour; and total length of labour. We found that the average length of first stage
of labour for the study group was 6 hours, 12 minutes and for the control group the average length was 6 hours, 53 minutes. This represents a difference of 41 minutes, but this was not statistically significant (p=0.56). For the second stage of labour, we found the difference was bordering on statistical significance in the length of second stage for the study group (1.00 hours) and the control group (1 hour, 32 minutes), with a mean difference of 32 minutes (p=0.05). When total length of labour was examined, there was a difference of 37 minutes, however this was not statistically different (p=0.31) between the two groups (Table 5.15).

**Table 5-15: Length of labour**

<table>
<thead>
<tr>
<th>OUTCOMES</th>
<th>Study Group (n=86)</th>
<th>Control Group (n=85)</th>
<th>Difference Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (hrs) (SD)</td>
<td>Mean (hrs) (SD)</td>
<td>MD [95% CI]</td>
</tr>
<tr>
<td>1st stage</td>
<td>6.12 (3.95)</td>
<td>6.53 (3.90)</td>
<td>MD= -0.41 [-1.79, 0.98] p=0.56</td>
</tr>
<tr>
<td>2nd stage</td>
<td>1.00 (0.87)</td>
<td>1.32 (0.98)</td>
<td>MD= -0.32 [-0.64, 0.002] p=0.05</td>
</tr>
<tr>
<td>Total length of labour</td>
<td>7.43 (4.13)</td>
<td>8.20 (4.37)</td>
<td>MD= -0.77 [-2.26, 0.72] p=0.31</td>
</tr>
</tbody>
</table>

* p=0.05

MD: Mean difference

However, given that women in the control were more likely to require augmentation in labour, it was considered that the difference between groups in length of labour may be greater than is statistically apparent. If women in the control group more frequently required augmentation, and this had the effect of shortening their length of labour, a true difference in length of labour may have been masked. To investigate this we examined group allocation and augmentation for significant interaction.
Using a linear regression to examine the interaction term of ‘augmentation*group allocation’ on the item length of labour between the study group and control group, we found that when augmentation was factored into the analysis, there was a significant difference in time of first stage of labour for ‘augmentation*group allocation’ (F=4.18, p<0.01), and for total length of labour for ‘augmentation*group allocation’ (F=4.71, p<0.01). Given that there was significant interaction of group with requirement for augmentation (see Table 5.16), and this interaction term was significantly associated with length of labour, this represents a significant difference in length of labour between groups when augmentation is adjusted for in the model.

Table 5-16: Length of labour (adjusting for augmentation)

<table>
<thead>
<tr>
<th>OUTCOMES</th>
<th>1(^{st}) stage MD [95% CI] p-value</th>
<th>2(^{nd}) stage MD [95% CI] p-value</th>
<th>Total length of labour MD [95% CI] p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation* Group allocation</td>
<td>F=4.182, p&lt;0.01**</td>
<td>F=1.59, p=0.195</td>
<td>F=4.709, p&lt;0.01**</td>
</tr>
</tbody>
</table>

CI: Confidence interval; MD: Mean difference

5.10.2 Post-intervention questionnaires

**Attitude Towards Birth Questionnaire**

With regard to pregnant women’s feelings of confidence and control, the study group were asked to complete the ATBQ questionnaire again following participation in the Complete Birth Study, to examine if the course had any impact on attitudes and feelings about birth compared to baseline. We found a significant increase in scores following the course, women in the study group had significantly increased positive attitude towards childbirth following the antenatal education intervention compared
with baseline scores (as measured by the ATBQ) (MD= -9.27 [-10.90, -7.64] p <0.0001) (see Table 5.17).

### Table 5-17: Post-intervention Attitude Towards Birth Questionnaire

<table>
<thead>
<tr>
<th>ATBQ</th>
<th>Study Group</th>
<th>Study Group</th>
<th>Difference Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ATBQ – pre</td>
<td>ATBQ – post</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 67</td>
<td>n = 67</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>51.37 (6.98)</td>
<td>60.97 (5.76)</td>
<td>MD = -9.27 [-10.90, -7.64] p &lt;0.0001**</td>
</tr>
</tbody>
</table>

**p < 0.01

ATBQ: Attitude Towards Birth Questionnaire; CI: Confidence interval; MD: Mean difference

### Labour Agency Scale

The LAS was completed by women within 72 hours of giving birth. Using a t-test to compare the mean values for study and control groups, we found a statistically significant difference between the two groups for this score (Table 5.18). A large number of women did not complete this form, and therefore there is the possibility of reporting bias in the results. Using a Levene’s test for equality of variance, we found the variance between the two groups was not significantly different (p=0.59), therefore we can make some interpretation of this finding that women in the study group were likely to have increased feelings of personal control in their birth following participation in the Complete Birth Study in addition to usual care, compared with women receiving usual care alone.
Table 5-18: 72 hour Postnatal Labour Agentry Scale

<table>
<thead>
<tr>
<th>LAS within 72 hours</th>
<th>Study Group $n = 72$</th>
<th>Control Group $n = 52$</th>
<th>Mean Difference $[95% \text{ CI}]$ p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-birth Mean (SD)</td>
<td>164.97 (27.06)</td>
<td>150.92 (30.03)</td>
<td>14.05 [3.84-24.26] p &lt; 0.01*</td>
</tr>
</tbody>
</table>

CI: Confidence interval; LAS: Labour Agentry Scale

5.10.3 Postnatal Edinburgh Postnatal Depression Scale

Six weeks following the birth, participants completed an EPDS questionnaire. As seen previously in Table 5.4, 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 5.19).

Table 5-19: Six week post-partum: Edinburgh Postnatal Depression Scale

<table>
<thead>
<tr>
<th>EDPS Postnatal</th>
<th>Study Group $n = 61$ Mean (SD)</th>
<th>Control Group $n = 42$ Mean (SD)</th>
<th>Mean Difference 95% CI p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postnatal EPDS</td>
<td>4.49 (3.44)</td>
<td>4.07 (3.93)</td>
<td>MD= 0.42, [-1.03, 1.87] p=0.57</td>
</tr>
</tbody>
</table>

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

Babies’ gestational age at birth was similar in both group, with the average age for the study group being 39 weeks and 4 days (SD=1.38), and for the control group being 39 weeks and 6 days (SD=1.33). Using a t-test to determine difference, there was no significant difference between the groups (p=0.8).

The secondary outcome measures examined the effect of the Complete Birth Study on the following neonatal measures:

1. Reduced neonatal morbidity and complications including: resuscitation required at birth; Apgar <7 at 5 minutes; and SCN/NICU admissions.

Babies of women in the study group were 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.

No significant differences were found in the secondary outcome measures for babies of: Apgar <7 (5 minutes) (RR = 0.99 [0.95-1.03], p=1.0), or admission to the SCN/NICU (RR= 0.59 [0.24-1.46], p=0.2). These results are displayed in summary Table 5.12.

The primary and secondary outcomes have been presented and show that the intervention is highly effective in reducing rates of EDB use as well as secondary outcomes: synthetic augmentation required in labour; length of labour (second stage), and length of labour (first stage and total length) when augmentation is adjusted for; rates of CS; requirement for resuscitation of the newborn. There was a trend towards...
greater likelihood of spontaneous onset of labour in the study group, use of nitrous oxide for pain management, and reduction in instrumental vaginal birth. Using vaginal birth as the denominator, the study group showed a slightly decreased rate of perineal trauma; however, there were no differences between the groups for major trauma.

The outcome measures of PPH and Apgar scores are also reflective of safety measures. No differences were seen between the groups with regard to these measures, indicating no harm generated by the intervention on birth outcomes. However, harms resulting from mode of birth (CS), such as resuscitation and admission to the SCN or NICU may indicate an increased risk resulting from the increased EDB, augmentation and CS rates in the control group.

5.10.5 Post-hoc analyses

The post-hoc analyses examined the data of the Complete Birth Study for the following questions:

1. Are rates of antenatal practice and rehearsal of CM therapies associated with increased use of CM therapies in labour and birth?

5.10.6 Antenatal practice of complementary medicine relates to epidural block use during labour

We examined whether the amount of practice of CM techniques in the antenatal period had an effect on the outcome of EDB rates. Looking at times practised per week for each therapy, we determined a total amount per week by multiplying each therapy by times per week and averaging by amount of therapies practised. The
analysis of patterns of CM use revealed that amount of practice in the antenatal period was not associated with EDB use. Using an independent sample t-test we examined the EDB versus no EDB groups for differences in total practice per week. The group that had EDBs had a mean total practice of 13.37 (SD=10.56) times per week (for all therapies), and the group that did not have EDBs had a mean total practice of 12.81 (SD=9.5) times per week (for all therapies) (t=0.218 [95% CI: -4.51, 5.6], p=0.828). On average, women in the study group practised overall 12.94 (SD=9.7) times per week for all therapies combined.

We also examined if any individual technique used during labour, rather than in the antenatal period, as reported by the woman following birth, was associated with EDB use (Table 5.20). We found that there was no association between use of any individual CM study techniques during labour and the use of EDBs for pain relief in women in the study group (n=88).

<table>
<thead>
<tr>
<th>Complementary Therapy Used</th>
<th>No EDB n=67 (%)</th>
<th>Yes EDB n=21 (%)</th>
<th>Risk ratio</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupressure</td>
<td>29 (43.3%)</td>
<td>12 (57.1%)</td>
<td>0.78 [0.61-0.98]</td>
<td>p=0.11</td>
</tr>
<tr>
<td>Belly Breaths (first stage)</td>
<td>42 (62.7%)</td>
<td>11 (52.4%)</td>
<td>1.1 [0.23-2.04]</td>
<td>p=0.68</td>
</tr>
<tr>
<td>‘J’ Breaths (second stage)</td>
<td>23 (34.3%)</td>
<td>8 (38.1%)</td>
<td>0.91 [0.7-1.2]</td>
<td>p=0.56</td>
</tr>
<tr>
<td>Yoga</td>
<td>29 (43.3%)</td>
<td>11 (52.4%)</td>
<td>0.83 [0.65-0.79]</td>
<td>p=0.22</td>
</tr>
<tr>
<td>Massage</td>
<td>30 (44.8%)</td>
<td>10 (47.6%)</td>
<td>0.91 [0.70-1.2]</td>
<td>p=0.55</td>
</tr>
<tr>
<td>Visualisation</td>
<td>38 (56.7%)</td>
<td>11 (52.4%)</td>
<td>0.99 [0.72-1.35]</td>
<td>p=1.0</td>
</tr>
</tbody>
</table>

EDB: Epidural block
5.10.7 Patterns of use

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, 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 J Breaths were used by 35.2% of women during labour (see Figure 5.2 below).

We asked women of the techniques used during labour, what techniques were ‘most’ used. Of those who responded (n=65), the ‘most’ used techniques during labour were, Belly Breaths (at 38.6%); visualisation (30.7%); acupressure (23.9%); J Breaths and massage (each 19.3%); and yoga (14.8%). See Figure 5.3 below.
5.11 Summary of findings

For the primary outcome measure, the results demonstrate that there was a significant reduction in the use of EDBs for women in the study group receiving the antenatal CM birth education course. The sample size was based on an absolute reduction of 20% from an estimated 46%, which is the previously reported average at the two main study hospitals (Centre for Epidemiology and Evidence, 2012). The data from our sample show that the EDB rate was 23.9% in the study group and 68.7% in the control group. This represents a decrease in risk of 0.35 [0.23-0.52] (p<0.001) which is highly significant. We performed an ITT analysis to determine the outcomes when the five withdrawn women were included for the main outcome analysis. The result shifted slightly, and remained highly statistically significant for the ‘best case’ scenario and ‘worst case’ scenario. The high rate of EDB use in the control group will be considered in the discussion chapter.

There was some very significant secondary study endpoints. Women in the study group were less likely to require augmentation with Syntocinon during labour and to
give birth by CS. There was a non-significant trend towards decreased instrumental vaginal births and perineal trauma in the study group. Length of labour was significantly shorter for the second stage of labour for women in the study group. When we adjusted for augmentation, length of labour was also significantly different between groups for first stage of labour and total length of labour. The babies of mothers in the study group were less likely to require resuscitation at birth. There were no differences reported for PPH or perineal trauma.

Data from questionnaires administered at baseline, following the intervention, birth, and the birth summary, have provided a significant overview of the practices of women during the antenatal period, and during labour and birth. There was some differences evident between the study sites; however, stratification of sites and subsequent randomisation should theoretically account for the variation and evenly distribute between the study group and control group. There was no significant difference between the study group and the control group for age, educational attainment, income status, medical risk, or gestational age at birth. While there was a significant difference in gestational age at entry to the study, the difference of one week and one day was not thought to be clinically significant.

Of the 171 women, only 141 (82%) provided responses to the lifestyle questions. This may be a source of reporting bias when included in some analyses, and was considered as described below when performing each statistical analysis. We found that the women from the control group at the Nepean site were less likely to complete their baseline demographics form, but the main outcome data were obtained for all women who remained in the study (n=171). Where these missing
data were likely to cause the statistics model to become less reliable, we performed a Levene’s analysis of variance to determine any difference between the groups with regard to variability of the data.

Women were not different in their ATBQ scores at baseline, but the study group women showed a significant increase in their positive attitude towards birth following the Complete Birth Course. This is indicative of increased feelings of control and confidence towards birth. The control group were not re-evaluated on this item for practical and logistical reasons, however, and this is a limitation of the study, which will be considered in the discussion chapter.

Determining that the CM antenatal education course has shown a significant reduction in use of EDB as the primary outcome, and reduction in other secondary outcomes such as: augmentation; length of labour (augmentation adjusted for); resuscitation of newborn; and admission to SCN/NICU, is a significant contribution to the research around reducing interventions in birth.

Analysis of patterns of CM use in labour reveal women used 3.94 (SD=1.4) techniques during labour, and reported an average of 2.06 (SD=0.98) ‘most’ used techniques during labour, and practised various techniques for an average total of 12.94 (SD=9.7) times per week. 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.
The study findings from the RCT provide high-quality evidence that the Complete Birth Course was an effective and important adjunct to antenatal education, and contributes to the evidence for best practice. The following chapter provides the findings from the in-depth interviews, which will elucidate women’s experiences of using CM for the management of labour. We will investigate how women experienced the course, used the CM tools and how and why they implemented different tools during labour. We will also examine the experiences of partners and midwives in their perceptions and use of CM in labour and birth.
Chapter 6 – Qualitative Results

6.1 Introduction

The previous chapter presented the results of the RCT. This chapter presents qualitative data from in-depth interviews with women and partners, and from the focus group with midwives. Once a couple has experienced the Complete Birth program as a whole and had the opportunity to use it in their birth, it is important to examine how the program was perceived by them and how it may have influenced their approach and experience of labour and birth. Triangulating data from midwifery focus groups was used to compare, contrast and add perspective to the data from the women and their partners, and examine its role in the public maternity system. These two data sets were examined in relation to the quantitative data. Together, these findings will help to show how the program can operate effectively in the future.

The objectives for the qualitative research were to:

1. Explore women and their partner’s perspectives on what characterises the selective use, rehearsal, decision-making methods and perceived effectiveness of the components of the Complete Birth Study antenatal education program for labour and birth
2. Understand the way the Complete Birth Study antenatal education program impacts on women and their partner’s perspectives of labour and birth
3. Determine midwives’ perceptions of the Complete Birth Study program, and

4. Determine the potential facilitators and inhibitors that midwives identify in the public hospital system.

The overarching theme that emerged from the data was ‘making sense of labour and birth’. Within this overarching theme, several other themes and subthemes are explored. These are presented below in Table 6.3. The analysis is described in detail in the methods chapter (Chapter 3).

6.2 Demographic data

Thirteen women and six men participated in the in-depth interviews with all the women coming from similar backgrounds. Twelve women identified as Caucasian, and all were born in Australia with English as their first language. One woman identified as Asian, with Malaysia as her country of birth. She spoke excellent English (Table 6.1). Nine women lived within the Hornsby local district, two in the Western suburbs and two in the Eastern suburbs of Sydney. All women were using the public antenatal clinics as their model of hospital care. The midwives’ backgrounds and ethnicity was not established; however, of the five midwives who actively participated in the focus group, all but one spoke English as their native language, and the one who did not was from a Middle Eastern background, but spoke English well.
Women’s ages ranged from 24 to 39 years, and most were aged between 29 and 34 years. Most were married, with four being in a de facto relationship. Demographic data for partners were not collected. The women were well educated, with three women having master’s degrees, six having bachelor’s degrees, two having post-secondary diplomas, and one woman had a Year 12-equivalent qualification. For all women this was their first baby. Ten women had a total family income in the top two income brackets, and about half (seven out of 13) had used some kind of CM before (Table 6.1).
Table 6-1: Demographic data of women participants

<table>
<thead>
<tr>
<th>Woman</th>
<th>Partner interview</th>
<th>Age (years)</th>
<th>Public or private Sector</th>
<th>Previous CM use</th>
<th>Education level</th>
<th>Model of care</th>
<th>Income level</th>
<th>Cultural background</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
<td>29</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>29</td>
<td>Public</td>
<td>No</td>
<td>TAFE/Dip</td>
<td>Midwifery</td>
<td>$80-100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>3</td>
<td>No</td>
<td>33</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>$40-60K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>39</td>
<td>Public</td>
<td>No</td>
<td>TAFE/Dip</td>
<td>Midwifery</td>
<td>$60-80K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>5</td>
<td>No</td>
<td>24</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>$80-100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>6</td>
<td>Yes</td>
<td>30</td>
<td>Public</td>
<td>No</td>
<td>Univ</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>7</td>
<td>Yes</td>
<td>30</td>
<td>Public</td>
<td>Yes</td>
<td>Post-grad</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>8</td>
<td>Yes</td>
<td>34</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Asian</td>
</tr>
<tr>
<td>9</td>
<td>Yes</td>
<td>30</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>$80-100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>10</td>
<td>No</td>
<td>31</td>
<td>Public</td>
<td>No</td>
<td>Post-grad</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>11</td>
<td>No</td>
<td>27</td>
<td>Public</td>
<td>No</td>
<td>Post-grad</td>
<td>Midwifery</td>
<td>&gt;$100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>12</td>
<td>No</td>
<td>28</td>
<td>Public</td>
<td>No</td>
<td>Yr 12-equiv</td>
<td>Midwifery</td>
<td>$80-100K</td>
<td>Caucasian</td>
</tr>
<tr>
<td>13</td>
<td>No</td>
<td>33</td>
<td>Public</td>
<td>Yes</td>
<td>Univ</td>
<td>Midwifery</td>
<td>&lt;$40K</td>
<td>Caucasian</td>
</tr>
</tbody>
</table>

CM: complementary medicine; Post-grad: Post-graduate; TAFE/Dip: TAFE/Diploma; Univ: University; Yr 12-equiv: Year 12-equivalent

The details of the women’s births are shown in Table 6.2. In this group of 13 women, none had caesarean deliveries and 11 had normal vaginal births, with three being induced. The two remaining women required forceps for birth, and both had EDBs: one for maternal exhaustion (baby weighed >4.5kg) and one for a brow presentation.
<table>
<thead>
<tr>
<th>Woman (+/- partner)</th>
<th>Study site</th>
<th>G/age at birth</th>
<th>Onset of labour</th>
<th>Augment labour</th>
<th>EDB</th>
<th>Other pain relief</th>
<th>Mode of birth</th>
<th>Length labour hr.min</th>
<th>PPH ≥500ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (-p)</td>
<td>1</td>
<td>40+1</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>none</td>
<td>NVB</td>
<td>10.20</td>
<td>no</td>
</tr>
<tr>
<td>2 (+p)</td>
<td>1</td>
<td>41+5</td>
<td>spont</td>
<td>yes</td>
<td>yes</td>
<td>none</td>
<td>forceps</td>
<td>23.36</td>
<td>yes</td>
</tr>
<tr>
<td>3 (-p)</td>
<td>1</td>
<td>41+5</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>8.05</td>
<td>no</td>
</tr>
<tr>
<td>4 (+p)</td>
<td>1</td>
<td>39+0</td>
<td>IOL</td>
<td>no</td>
<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>3.45</td>
<td>no</td>
</tr>
<tr>
<td>5 (-p)</td>
<td>1</td>
<td>40+4</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>7.17</td>
<td>no</td>
</tr>
<tr>
<td>6 (+p)</td>
<td>1</td>
<td>39+5</td>
<td>spont</td>
<td>no</td>
<td>yes</td>
<td>none</td>
<td>forceps</td>
<td>12.12</td>
<td>no</td>
</tr>
<tr>
<td>7 (+p)</td>
<td>1</td>
<td>40+1</td>
<td>spont</td>
<td>yes</td>
<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>4.37</td>
<td>yes</td>
</tr>
<tr>
<td>8 (+p)</td>
<td>1</td>
<td>38+5</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>5.48</td>
<td>yes</td>
</tr>
<tr>
<td>9 (+p)</td>
<td>3</td>
<td>40+0</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>none</td>
<td>NVB</td>
<td>11.12</td>
<td>no</td>
</tr>
<tr>
<td>10 (-p)</td>
<td>3</td>
<td>39+3</td>
<td>spont</td>
<td>no</td>
<td>no</td>
<td>none</td>
<td>NVB</td>
<td>9.25</td>
<td>no</td>
</tr>
<tr>
<td>11 (-p)</td>
<td>2</td>
<td>37+1</td>
<td>IOL</td>
<td>no</td>
<td>no</td>
<td>none</td>
<td>NVB</td>
<td>4.15</td>
<td>no</td>
</tr>
<tr>
<td>12 (-p)</td>
<td>2</td>
<td>41+1</td>
<td>IOL</td>
<td>yes</td>
<td>no</td>
<td>none</td>
<td>NVB</td>
<td>3.50</td>
<td>no</td>
</tr>
<tr>
<td>13 (-p)</td>
<td>1</td>
<td>41.5</td>
<td>spont</td>
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<td>no</td>
<td>NO₂</td>
<td>NVB</td>
<td>10.05</td>
<td>yes</td>
</tr>
</tbody>
</table>

EDB: epidural block; G/age: gestational age; IOL: induction of labour; NO₂: nitrous oxide gas; NVB: normal vaginal birth; PPH: post-partum haemorrhage; spont: spontaneous vaginal birth
6.3 The themes

The overarching theme that emerged from the data was ‘making sense of labour and birth’. This section will describe this overarching theme and the themes and subthemes that emerged (Table 6.3).

The names for the themes and subthemes emerged from the data, and as such are often the women’s own words. Participants were given pseudonyms for anonymity, and quotes are linked with these names in the text. Where a quote came from field notes, this is indicated, and initials are used to link the quote to the woman or partner.

Table 6-3: A map of themes and subthemes of making sense of labour and birth

<table>
<thead>
<tr>
<th>Themes</th>
<th>Subthemes</th>
</tr>
</thead>
</table>
| 1. Working for normal | a. Change of mindset<br>  
                         b. Transforming fear<br>  
                         c. My body is meant to do it<br>  
                         d. Medicine as back-up – not birth as risky |
| 2. Having a toolkit   | a. Having a strategy – confidence and decision-making<br>  
                         b. Getting partners on board<br>  
                         c. getting the team on board – Midwives pursuing normal<br>  
                         d. Navigating a (broken) system |
| 3. Finding what works | a. Finding the rhythm – what works for me<br>  
                         b. Understanding the process – getting past the wall<br>  
                         c. Patterns of use of complementary medicine tools |
6.4 Overarching theme: making sense of labour and birth

In the workshops, it was clear that couples were often unaware of what was involved in labour and that they could have an active role in the process:

*I mean, we had no idea. You read the books about ‘this is the stages of labour’, but we didn’t really know what we could do during these times* (Hilary).

Their approach to birth evolved during the course, from a passive acceptance of ‘whatever happens on the day’, to understanding that they had the capacity to influence some outcomes, and finally to an active involvement in the preparation for the birth they wanted. This change came about primarily because women and their partners developed an understanding of labour and birth and the importance of taking a central and active role in the process.

With the majority of births occurring in hospitals or birth centres (Bryant, 2009; Li et al., 2013), most women have never seen a real birth until they have their own baby. Many of the women in this study felt unprepared for their labour and birth, and became aware during the course that their ideas about birth largely came from television, or from stories told by others. These stories were often negative:

*I didn’t know what to expect. But then coming out of it [the end of the workshop], we actually had a semi-birth plan, and we were both on the same page with things …. Essentially it was just stuff that we never really thought about …. like people labouring on their back. My husband went*
'oh my God, how are you supposed to labour, if you're not labouring on your back?' His presumption was that I would just be lying down and – like on my back, and that would – that’s how labour goes. Then I guess it gave us a little bit more knowledge, and gave us more ideas about what we could actually do and what was allowed as such (Hilary).

Women were attracted to the idea of using CM techniques to support their labour. However, before they could incorporate the CM techniques taught, they required an understanding of what constituted the normal physiological process of labour and birth:

*I mean, even the whole, what you have naturally inside you, the chemicals [hormones], all that stuff I had no idea about really (Rachel).*

This contextualised why and how to use the techniques to help them manage labour:

*I think the techniques were good, but it was – that theory as well, was really, really helpful – the way of thinking about labour and then approaching the pain and that sort of thing (Tessa).*

Women felt that by understanding their bodies, and the stages of labour, they could make sense of the birth process and take charge of their labour:

*I was trusting myself that I knew what to do. I think it came from the course, really, because you know your body and you know the stages .... Yeah, but*
with knowing the stages helps you understand and helps me understand what
was the next level, that’s the difference (Yvette).

Midwives believed that exposure to education about normal birth should be ‘part of
the antenatal care’; however time limitations on midwives and antenatal visits made
this difficult:

\begin{quote}
But we can’t do that in a 25 minute antenatal appointment, but this is why
we want them to do these courses because we can’t do it at our
appointments, we can only do so much (Midwife 1).
\end{quote}

The midwives stated that it would be useful to have antenatal education using CM
techniques, and perceived this as educating the woman so that she could participate
actively in her own birth, which might also facilitate the midwife’s role:

\begin{quote}
We need to offer these things to the women. I mean we can’t obviously do
it all at antenatal [visits], but yes they’ve got to take some – we can’t make
someone do this. So they need to take ownership and we need to offer a
course like this as well (Midwife 1).
\end{quote}

\begin{quote}
Yes I definitely think we should be doing more psychological preparation
for labour and acknowledging the importance of hormones and positive
thoughts in facilitating normal birth. I think it’s really important. But I
don’t think we do enough of it or get enough time to do it. You have to
practice, you do (Midwife 3).
\end{quote}
The midwives stated that women who are educated about birth are often more motivated, want to know more about what to expect, and are willing to do the research on their own. These women are actively trying to make sense of the purpose of each part of their labour. Others, who were not educated seem to have more of an ‘oh it will just happen’ mindset (Midwife 3). Midwife 1 stated that when a woman is informed it changes the way she would relate to the woman. Midwife 2 expanded on this, stating:

_The body’s not going to labour as effectively if you’ve got – if the woman’s sitting there and not knowing what she’s doing and ‘what are they giving me’, and you know, ‘what position is this?’ Not knowing what her body’s going through._

These ideas gave rise to the overarching theme of ‘Making sense of labour and birth’. Under this theme, three other main themes emerged; these were; ‘working for normal’, ‘having a toolkit’, and ‘finding what works’. These themes and their subthemes will now be discussed.

### 6.5 Working for normal

Women’s ideas about ‘normal birth’ changed over the Complete Birth Course. Additionally, the concept of ‘working for normal’ came about through different processes. Most participants became open to, and excited about, the idea of a normal natural birth and began to understand that the most beneficial way to give birth was a normal physiological labour, and they started looking for ways to support themselves to do this:
I was originally prepared for drugs if I found out that that was the best way to go or that there was no impact. I started going and looking at the facts, I realised that it might be useful to have a natural physiological birth without drugs. I just needed to know how I could do that (Rachel).

In the education component of the course, couples learned about what the natural hormones of labour do to create the physiological processes for giving birth. When there is medical intervention, the natural hormones are not released in the same way to facilitate the birth process. Learning about the body and its hormones, women understood their unique ability to labour and give birth. This gave women and their partners the relevant context to understanding the purpose of a natural birth, and inspired them to work towards a normal birth:

It sort of solidified more in my mind once I learnt all the hormones involved and everything and how things can disrupt all that sort of thing ... I think learning about the hormone cascade and how that can really be disrupted by artificial drugs (Annabel).

Partners were also inspired and felt that they could make some choices around birth, and were educated about the process:

It did make it even more so that I didn’t want to have any drugs and it made my husband as well, very much – ‘yeah let’s try and get through this without having an epidural or anything like that’. He became a bit more, ‘yeah we can do it without it’ (Olivia).
Midwives found that when women are more engaged with the process of pursuing a normal birth, and they’re educated about it, they are more confident and less fearful:

... they’re confident and they’ve got decreased fear of the unknown, then I think they do – not necessarily labour easier, but are more relaxed and just kind of let the body do what it wants (Midwife 2).

Information regarding the complex interplay of hormones between the mother, the baby, and the father, gave an added dimension to the desire for a normal birth. Benefits such as positioning during labour, descent down the birth canal, natural turning for birth, dilation of pupils and alertness at birth, bonding and attachment, breastfeeding and settling (Buckley, 2002) were discussed. This was a large motivating factor for women and partners, and a desire for connection with their baby:

I believe that babies get something out of having a natural birth. They get something out of going through that birth canal and having that process. It’s important for them and for me. So a lot of the decision was also what was best for the baby (Tessa).

The educational information about the benefits of the natural hormones of labour for the women and babies, and how these hormones work together to create natural pain relief and the natural progression of labour, was new and exciting information for the participants. They began to incorporate these ideas into their mindsets and their perception of labour began to change.
Several subthemes emerged from the data as part of this theme. These were; ‘change of mindset’, ‘transforming fear’, ‘my body is meant to do it’, and ‘medicine as backup, not birth as risky’. These will now be explored in more detail.

6.5.1 Change of mindset

Frequently women found that they had a ‘change of mindset’ after participating in the course, and this was key to their embracing the techniques. After exposing participants to education about the hormones and principles of labour, and showing them relaxed and natural ways of giving birth, their whole way of viewing labour changed. They were often unaware that they had a ‘medical mindset’, and had just incorporated this as normal birth. With this new understanding of ‘normal’ labour they developed a confidence in their capacity to manage labour:

As I said, it’s just my whole mindset changed after the workshop. As I say, I went from reasonably fearful and just not really feeling confident in my body, to feeling super confident, super relaxed, ready to give birth. I was looking forward to give birth, which is strange. It changed my mindset

(Mia).

Participants discussed the idea of the ‘medical mindset’ in the context of society-at-large. There was a general view that people have relinquished control of their health to medicine and science, and have lost awareness about personal responsibility for health. This personal responsibility included having an active role in decision-making about treatment, as well as in prevention of illness. They were aware of the
dominant medical paradigm and expressed the idea that our society does not tend to look for the root causes of things, and would rather use medications to patch it up:

*Our society is overmedicated. Everyone is just quick to take the pill (Jim).*

Couples became aware of some other influences on normal birth, such as hospital policies centred around risk management, or hospital imposed time frames for birth to occur, and subsequent medical management of labour if they were not meeting these time frames. Couples felt that hospital procedures were geared towards the concept of looking for problems, not facilitating normal. This was one participant’s interpretation of hospital procedure:

*This is what’s going to happen – if we put a trace on and it gives us a bad reading, we’re going to give you drugs to speed up the contractions. If that doesn’t – and if there’s certain so many hours, there’s not progression, then we’re going to think about like forceps, and then we’re going to think about C sections. That’s it and at the end you’ll have a healthy baby, so relax. This is how it’s going to go (Damien).*

When the process of intervention was described, and the potential outcomes they faced, they understood the value in staying at home for as long as possible to be in the comfort of their own surrounds, and not disturbing labour by observation and environmental disruption. They made plans for what they would do at home to help them manage their labour. They moved from a position of fear that needed a hospital
to manage them, to understanding the process and feeling safe and secure at home with their partner and a variety of tools to assist them:

*Because of the classes, I waited, otherwise I wouldn’t have known, I would have just picked up the phone and quickly gone to the hospital. Her class taught me to wait until it’s a lot more intense and just to relax or go for a walk or make yourself comfortable (Caitlin).*

The midwives found that women who understood what their bodies were going through and what they could do to support themselves often did better in their labour. This appears to be dependent on the woman’s self-acquired knowledge about the system and alternative ways to manage, which changed her mindset from medical management to a confident self-management with support.

*They certainly stay at home for longer ... make sure you’re a bit more established and then come in. They seem to do better than the ones that come in and not in labour (Midwife 3).*

To which Midwife 1 responded:

*Because we don’t intervene.*

When a couple’s mindset changed from a medical framework to a more natural framework, this allowed them to understand the purpose of labour and developed trust that their bodies were capable of coping with labour:
I felt stronger; I felt like I could cope, like I wasn’t worried about it and as long as I stayed calm then I’d get through it all (Gemma).

6.5.2 Transforming fear

The information about the physiology of normal birth sometimes had a profound effect on women, in how they could influence their own labour. This led to a feeling of confidence about their capacity to give birth, reducing fear and anxiety:

- *If you go in fearful your body will tighten up. It will actually make it more painful. So I just needed something to relax. After having done this course I felt completely relaxed, completely confident that I could do it, that I could do it without drugs or without epidural or a caesarean. Yeah I was ready for it. I was actually looking forward to giving birth, to practise everything that I was taught, to go for it.* (Mia)

A key part of changing mindsets was managing and reconstructing fear of labour and birth. Some women were very afraid of labour and wanted some techniques to reduce their fear. They were fearful of; pain, the unknown, complications, loss of control, tearing, forceps, episiotomy, etc.:

- *Very scared of the birth before the classes and came away feeling that it’ll be OK and I’ll get through it. That was a really big key.* (Yvette)

- *In all honesty I was quite terrified of the whole process, being pregnant and going into labour, and I did it [the course] because it was information and I just pushed myself to take a new experience. So at that point I was*
very fearful of what to expect and I was suffering a lot of depression throughout my pregnancy and a lot of worries about it, so it was good to just be taught what to expect and techniques on how to handle it. So I kind of went from one extreme to the other... I ended up having a really good birth (Caitlin).

Couples sometimes felt that the usual hospital antenatal classes served to perpetuate their fears. They had been informed about medical pain relief and medical management, which confirmed ideas about pain and the ‘risky’ nature of birth (Davis-Floyd, 2001), and that medical management was necessary for a safe birth. Some women were dissatisfied with the medical interventions offered, or dissatisfied with the lack of information about natural ways to manage labour:

They told you about the medical interventions, but they didn’t really tell you what you could do instead. I think that was the main difference (Olivia).

They wanted an alternative to medical management and felt that neither antenatal classes nor the system offered this:

In the antenatal class, they didn’t really talk about endorphins and how breathing and massage can help that, and relaxation, they didn’t talk about relaxation and reducing your anxiety can help that (Olivia)
I was hoping to find alternatives to drugs in my labour and birth. I wanted to have as natural as possible birth that I could do, and I felt like this course could certainly give me some tools to get me through (Nadine).

Some participants were fearful of the hospital imposing medical management on their labour. Increasing options for managing labour helped to transform some of the fears expressed in the classes:

Knowing that we had some choices, it alleviated my concerns (Damien).

Midwives described that women who are more informed have greater choices, which leads to more confidence, and less fear:

I find that labour is 90% mental and 10% physical. So if they’ve got that mental stability and they’re confident and they’ve got decreased fear of the unknown, then I think they do [labour differently] (Midwife 2).

6.5.3 My body is meant to do it

By understanding the purpose of labour and birth, women came to understand that their bodies had evolved specifically for the job, and that their bodies were meant to do it. Challenging and overcoming the idea that the birth process was somehow flawed and that improvements could be made by medical assistance, allowed women to really connect with their bodies and see their capacity for natural birth:
I felt a lot more confident after the course. Thinking it was going to be the most painful thing – and came away thinking, my body can do this. Helped being confident about everything – Life changing (Tessa).

They began to trust their bodies and could go deeper into the techniques and the experiences to support their desire and ability to achieve a natural labour:

Mostly, what stuck in my mind ... was that my body is made to do this ... It just really strikes feeling confident and assured by that, throughout everything. No matter what was to happen, I knew that my body was made to do this, and I’ll get the end result (Isobel).

Taking responsibility for the birth gave couples a sense of control; ‘it gave me also the sense that I was doing something’ (Tessa). The couples began to take a proactive approach to their role in the labour, using the techniques to manage and control what was happening. This was in contrast to a passive role, where decision-making was left to the hospital and the medical staff. They now perceived labour as something their bodies were capable of, and that they could work towards. The midwives also described how that changed their practice and the way they related to the woman when she was actively participating in her own birth:

But if they’ve got the education then I’m just going to be there for her, to help her, not educate her. But some of them you have to tell them what to do. So it does affect my practice in a way, yes (Midwife 1).
In using the CM tools, couples were encouraged to go with what their bodies needed. There was no requirement for the course participants to birth in any particular way, and they were not restricted to any particular CM protocols or time limits for administration, or from any form of pain relief that was available:

_between the contractions, I did have time to think about things. I did relate everything back to the workshop as such, because as I said, I imagined my body as a funnel. I imagined the uterus coming up and pushing down and what not, and really working with my body. Because I knew the physiology – physically what my body could do, I just let it do what it needed to do (Hilary).

They were encouraged to be involved in any decision-making processes, and to take responsibility for their role in the process. Perceiving their bodies as something that was responsive to mental and emotional conditioning for labour was important:

_I found that course has got to be for people that are a bit more open minded; so a little bit more willing to let their body do the work, rather than the drugs do the work (Nadine).

The techniques were not about taking pain away, or removing oneself from the pain, it was about developing trust in the body’s natural ability to birth, and allowing oneself to go inside the body and connect with the intuitive part of themselves. Women were able to listen to their bodies and go with the labour:
At that point when you’re in labour it felt pretty instinctual to me so I was pretty much going with what my body was telling me to do (Caitlin).

They were able to use the techniques to manage the birth of their baby in a controlled way:

Because of the classes, I waited, otherwise I wouldn’t have known. I breathed him down, and I didn’t tear (Gemma).

Partners also saw how women could allow the body to do the work by relaxing into the labour:

At the end ‘Rachel’ was able to just control that, and just let herself open up – and baby came out, and she didn’t tear or anything (Damien).

Women expressed that they gained a great sense of confidence and satisfaction from this experience:

I felt pretty good. I knew what was happening in my body, and I knew what I should be doing and everything, I felt pretty confident like, yeah I can do this (Nadine).

6.5.4 Medicine as backup, not birth as risky

By understanding the normal birth paradigm, couples were able to contrast that with the dominant paradigm of birth as risky, and that hospital policy is heavily influenced by a risk agenda. Couples derived a sense of security from having the hospital there, and expressed the idea that they could work towards a natural birth,
but if something went wrong the medical system was there as the backup, rather than the first, or only, line of management:

*We’ll do it as natural as possible without any drugs, but if there’s a need to – for intervention then there’s no question about it (Yvette).*

There was also awareness that women could delay or minimise medical pain relief and its consequences by using the tools from the course:

*The more we had read about childbirth and things like that, we really were trying to do everything more naturally. It was something that we wanted to try and if we were able to, to go through a natural childbirth, with minimal drugs and just for our own sake, that's what we really wanted (Diana).*

Midwives also noticed when women are educated they come in a lot more motivated and prepared, and actively look for information that will support them in pursuing a normal birth:

*But the ones who do those courses are more motivated not to get intervention, medical intervention. They definitely want to try everything they can before medical intervention (Midwife 1).*

Women reported that they became more aware of the ‘risk lens’ that is commonly applied to birth within the hospital system and in society in general. Most couples found that this risk orientation was strongly present in their antenatal classes and visits:
It’s OK to go in with the idea that you will have drugs, but it’s not OK to go in thinking that you won’t. I went in there (hospital) with expectations and I was kind of frowned upon for that because they were telling me that I would come out the other side not great mentally if it didn't go to plan (Nadine).

The couples expressed repeatedly that the risks from medical interventions or pharmaceutical pain relief were either minimised or not clearly explained by the medical staff or in the hospital antenatal classes. The short- and long-term effects of drugs or interventions were not properly understood, or communicated to couples, and they felt that the side effects were brushed over:

Just the way that it can affect the baby because I read that the epidural … can make the child dozy initially and I just – I don’t want her affected in any way like that, it’s not natural, it’s not normal, and we don’t know how that can affect them in the long run. You hear a lot of things like ah, no, this doesn’t do anything or there’s no side effects, but down the line they might find something that they don’t know (Caitlin).

The couples also found the concept of the ‘cascade of intervention’, where there is a requirement for further medical interventions to manage the side effects of the previous interventions, was novel and astonishing:
Why do something to relieve one sort of pain and then cause yourself another problem? I didn’t believe that there was any drug or medical way of solving the natural labour altogether (Tessa).

Their experiences of the hospital antenatal classes (from several different hospitals), reinforced the idea that medical pain relief is a part of a normal labour.

In the other course we did [hospital-based antenatal education] there was a whole section on the drugs you can take, like that’s the normal way (Tessa).

It seems that in society, natural birth is considered rare and unnecessary. Women discussed the need for justifying their choice for natural births, as if it were something different from the norm. This serves to reinforce the idea that medical management is normal:

A few people said ‘oh, you’re brave.’ A couple said ‘oh, caesarean’s the easy way to go’ or a few people say ‘are you going to have an epidural or caesarean’ and I go ‘no, I’m going to go natural’ and they go ‘good luck’. But no one actually pooh-poohed the idea, like, they didn’t turn around and go ‘that’s stupid’ or ‘you’ll never be able to do it.’ I think everyone’s just – yeah, a lot of people thought it might have been wishful thinking (Gemma).

Other people in the woman’s life expressed feeling fearful for her, and with a risk lens applied to birth. They subscribed to the medical model of birth, perpetuating the
concepts of fear. One of the interviewees attended the course alone, as her partner chose not to come due to the time it took. His ‘medical model’ thinking pervaded despite her wishes to have a natural birth. He was interviewed and had some interesting insights from an ‘outsider’s’ point of view:

*I think an extended labour at home, practicing relaxation techniques and working around pressure points is something that I’d be confident in doing. But once things are fully in motion I think you just listen to the medical advice at the time from the midwives. They’re the ones that deliver the babies and they know best. So I would enter the hospital, doing as much as we could as a team but then obviously going with the hospital* (Neville).

Some couples were also aware of the impact that medical interventions were having on their general perceptions of what is normal and achievable in birth:

*I have several close friends who have given birth in the past nine months to one year and none of them have managed a natural vaginal delivery. So that stands as an example of the kind of climate we’re raised in, in that we are – we enter our pregnancies in which is one [climate] where it’s rare. So you tend to think it’s not normal and that if they couldn’t do it, why should I be able to?* (Rachel)

This particular woman (Rachel) was adamant that she wanted to try to have a natural birth even prior to the course. She found the hospital where she was birthing to be
especially unsupportive and risk adverse. She and her partner found that they battled with the staff considerably, just to maintain some normal perceptions around birth. This hospital was not one of the two main study hospitals, although five women enrolled in the study birthed at this hospital, and all reported similar experiences. They felt a great pressure to yield to the medical staff:

\[
I \text{ kind of feel like they overstepped their mark and have a warped apprehension of} - \text{ warped conception of the risks. When did we start to become fearful or apprehensive about something that is done by thousands of women every day of the year, since life began? (Rachel).}
\]

This couple reported that the antenatal class at their hospital was in favour of exposing couples to the medical interventions they may face. The educator constructed a mock EDB and CS for the couples to undergo, with the rationale that they would not be too confronted at the time of birth:

\[
\text{So they don't have women freaking out when it came to like a surgical intervention, they had us wear surgical masks and smocks, and} \quad
\text{... basically had an epidural mock basically done to him, and} \quad
\text{demonstrated this is how it's going to happen. Yeah, this is what you're to expect (Damien).}
\]

They felt disappointed that the classes were geared towards reducing expectations of birth to just being grateful for a healthy child, despite the cost to the mother. This couple reported that their experience at the hospital was consistently focused on the
risk to the baby if the couple did not accept medical monitoring and intervention. In one of the antenatal classes, they played a ‘game’ where the couples were given 15 cards that related to experiences during birth. They were asked to remove a card one by one in order of what they were prepared to give up if things didn’t go according to plan:

So it was 15 cards, it was things like aspects of a birth. It was like take away a card that you could accept not having in your birth, like say – there was an intervention, so you take away that card. There was certain things that happen, and you take away that card, and eventually you get down to the last card and it goes, at the end of the day the last card says – which you didn’t have to be a genius to work out – oh, you have a healthy child. So they took away all those things. So it was almost like this checklist, and I didn’t like it, because it was pretty much – if you read between the lines, these are the loophole to get a C-section .... So when this thing came up, this complete study came up, I jumped at the opportunity and we went to that and it was like a totally different experience (Damien).

Participants moved from a passive position in relation to the medical system, to a feeling of strength and control, with a capacity to manage their own labour. Understanding the risk-management framework of their hospital was part of their strategies for managing a normal labour, with medicine as the backup if they needed some assistance.
Within the theme of working for normal, the data suggest that women developed confidence in their bodies and understood how the framework of ‘normal’ shaped their approach to labour. They came to understand that hospital policies and systems view birth through a risk lens requiring medical management, and this is reinforced by a pervasive societal perception of birth as risky. By confronting these ideas and reorienting their concept of birth as normal, their fears and thinking were transformed. They began to trust that their bodies were meant for natural birth and felt empowered to work towards it. Once their mindsets had changed, they were able to incorporate the next step, using the CM tools to support their birth:

So with the complementary medicines, it was something that I assumed would be mostly natural and could be used in conjunction with just a natural birth (Hilary).

6.6 Having a toolkit

Showing couples the CM techniques for labour provided them with a ‘toolkit’, from which they could draw what they needed on the day. This was an essential part of managing the labour process; ‘having them [tools] there, I felt ready and more prepared’ (Isobel). ‘Having a toolkit’ is the second major theme that has emerged from the interview data:

That’s why it’s nice to have a range of techniques, isn’t it – that’s like sort of tools in your kit bag (Isobel).
The tools were useful in giving women and their partners a sense of control. Having different tools to draw from gave women choices and combinations to use to support their labour:

I didn’t do the visualisation but we did do acupressure points. I definitely was doing my yoga positions and I didn’t practice any of my breathing techniques, but once I was in labour I used them …. I must admit actually I did use a little bit of visualisation when I was on the fit ball and I closed my eyes. I just was, well obviously this is happening and I’m picturing it happening (Nadine).

Essentially, different women found different techniques helpful for different reasons and at different times:

For me it was the yoga positions. I really found that, especially when I was in labour at home, I was sitting on my fit ball, I was getting into those positions, I was doing the hip movements and I really found them very helpful (Nadine).

I actually noticed that I was listening to the meditation tapes every single day in the morning and night on the train back and forth to work. It just completely relaxed me, completely (Mia).

I really went internally and focused on my breathing a lot (Hilary).
I did a fair bit of meditation and because I’d done it before I found it very easy .... I could sort of slip into that mindset quite easily (Annabel).

Having a toolkit also allowed partners to feel involved in the labour preparation:

He was totally involved in them and he was excited to be involved in them, particularly when we got to day 2 [of the course] and we were doing the acupressure. So that was something that I think he started to be able to feel a bit more hands on (Diana).

He always reminds me ‘you need to do your breathing practice’ (Yvette).

And that demonstration and practice was seen as a support for partners. In this way they could encourage and assist their partners with practice prior to labour and support them during labour:

The movement and yoga, for me again, for supporting knowing the positions that ‘partner’ would need to practice or use then that certainly would help from my side of things (Bruce).

In the course, role-playing was used to put together a variety of techniques for different situations, and there was discussion about what things might be good to do at certain times. It gave couples options to consider when in labour:

Like getting that information and actually learning from [researcher] with regards to, if we’re in this kind of situation, what is the actual method to
actually do this or do that. So I guess I got a little bit of both, which I really was satisfied with the outcome (Xavier).

Midwives also saw the value in women and their partners having a range of tools and options:

_It makes them feel more empowered that they’ve got knowledge and that they’ve got options. If this doesn’t work then I can try this. So I think they come in more confident because they know they’ve got options and strategies. Even if they don’t work, they, I think they still feel proud that they utilised different things. Look, I tried this, and I tried that. They used what they had practiced at home or in the classes during the labour and birth (Midwife 2)._ 

Midwives discussed the value in being able to go with what happened on the day, and not sticking too rigidly to a prescribed technique or plan that may not be working. They described a process of being able to ‘follow the woman’ (Midwife 3) in her labour, going where she leads depending on what’s happening, and listening to her what her body needs. They felt that it was important for antenatal courses to incorporate the idea that labour is changeable and unpredictable:

_I think with these courses they have to know in pregnancy and in labour there is the possibility of everything. You can’t just focus on one thing (Midwife 4)._
6.6.1 Having a strategy – confidence and decision-making

Having tools to work with provided couples with a strategy to deal with different aspects of labour:

> It actually provided us with the tools and the strategies for the birth that we wanted for our son (Diana).

And having a strategy allowed the couples to feel more prepared:

> [At antenatal classes] you are really just being talked to. They were good for just covering all the basics of what is going to happen but you are really just getting information. You’re not really getting anything to really manage – you’re not given any tools to manage the labour. You’re just told about what it’s going to be like. So information is great, but when you’ve actually got a strategy or tools to use, to help you, that was the big thing with the Complete Birth Study (Diana).

Feeling empowered by the information and tools learned, couples gained confidence through this process. This idea was expressed by many of the interviewees and by the course participants in general. Confidence and preparation was the precursor to implementing the tools:

> I went in with a little bit more preparation in terms of how I was going to deal with the pain. I also went in with a little bit more confidence that I could do it and I could achieve the natural birth that I had set out to achieve (Nadine).
Couples had options and information about how to self-manage what came up for them on the day of labour, such as tension, nausea, discomfort, hormonal changes, positional issues or fear. Having options and being prepared gave them a sense of calm:

*I think just being aware of everything, being more aware of my body, later on. Yeah, just having that under my belt now, all those tools from earlier on as well, so being able to implement the acupressure and the visualisation and things like that and the breathing, just calm from the very beginning* (Isobel).

Partners also said that this gave them a sense of feeling prepared and confident; that they had something they could do to help their partner in labour:

*So at the end of the workshop, I guess after that session I can say that I felt that everything I have learnt in that workshop I could actually apply. I was equipped – I had something that I can actually do or actually use if something comes my way* (Xavier).

Midwives also commented on the feelings of confidence seen in women who were prepared and empowered by knowledge of natural birth and their own body’s capabilities:

*But knowledge is power I think, when it comes to labour and birth. The more information they’ve got the more ability they have to choose what*
they want. I think that it makes them feel empowered that they’ve got
knowledge and that they’ve got options (Midwife 2).

Midwives stated that preparing before the birth is the important part, and allows the
midwives to work with the woman when she gets to the hospital:

If you’re going to have a baby, which is equally life changing, if not far
more, you need to do all your preparation, but a lot of them just don’t. I
like the ones that do (Midwife 3).

Communication between the couples was emphasised and the course gave them a
structure within which to do that. When talking about the stages of labour, they
discussed with each other what they thought they might like to do during the labour.
For example, ‘what things might you like to do during pre-labour (up to 4cm
dilation) which would be relaxing and focusing on things at or near your home?’
Their strategy for pre-labour centred on conserving energy, staying at home for as
long as they felt comfortable, and finding ways of relaxing and getting into the
‘zone’. They were asked to imagine alternately whether it was day or night-time, and
be alert to bodily signs that would let them know when they moved into the next
stage of labour. They suggested things like having a bath, going for a walk, sitting on
the fit ball and relaxing, doing some cooking, listening to music, or watching a DVD.
They were shown positions and acupressure points to augment their contractions or
to allow relaxation or pain relief. The couples discussed some ideas with each other
and shared preferences or concerns. The partner was encouraged to just keep trying
different things, with the overall focus being on things that would promote natural
oxytocin release, such as soft touch (massage), kind words, gentle movement, encouragement, dim lights, warmth, eye contact, supportive and protective actions coupled with the CM techniques. When pain relief or deeper support was required, the partner considered things like acupressure for endorphin release, strong massage, counting for breathing techniques, optimal positioning, encouraging and supportive words and eye contact:

*I told him my back is painful. So he started the – doing the acupressure.*

*Then he was just saying relax, and then inhale, exhale. He just – he’s very supportive both in touching and words. So I know that – it’s like action speaks louder than words. I think that’s the perfect time for that, because yeah, you can feel that he’s also into it. Like, the journey is together, it’s not just me having the baby. It’s also him and that he’ll be involved, and every time I had a pain he’s there as well. Yeah, he made sure that he knows where to press the areas as well. The workshop helped him with that, because he knows which point to press ... and having the demo made a difference, like, your confidence of doing it* (Yvette).

During the course several combination techniques were used for specific purposes; for example, if the baby is posterior, putting a strategy together such as using acupressure on the little toe turning point, forward yoga positions, massage and spiralling hips to turn the baby around. Guidance for partners was welcomed, as they wanted to be involved in the birth and be useful to their partner:
Things that were a little bit more hands on, that gave him a bit of guidance on what he should be doing. I think that’s where he was a bit worried – he wasn’t really sure what he should be doing to support me, and I think that things like showing him how to do the massage and that sort of thing – that was what helped him, and telling him what he should be saying and that sort of thing (Olivia).

Midwives found that couples who were working together, communicating with each other and the midwife, and were making collective decisions, had a fluid strategy about the different ways they could deal with what happened, and were easier to work with. This facilitated the midwife’s role and the birth of the baby. When women were using their tools, midwives noticed that the women:

... can have control of themselves, their own – it helps them not lose it. It helps them just get on with it (Midwife 3).

You almost see them go into themselves .... It gives them something’ (Midwife 2).

Even when women experienced forms of medical management or used pharmaceutical pain relief, they found that their knowledge and confidence from the course enabled them to retain their decision-making power and control during labour:

I felt a bit more empowered .... So even though they strapped me – I obviously had the monitors all over me, and I had the drip. They said I
could only really go on the bed or around the bed. I made that my little space. Took charge of the space a little bit more (Hilary).

This may have assisted women in minimising interventions that are seen as part of the cascade of interventions. Women who had an induced labour for example, were mindful of using the tools to help them manage that, and could delay or avoid using pharmacological management and regain control of their labours:

_The course just gave us a really good stepping stone as to what we actually wanted, and some really good techniques and tools that we hadn't really thought about before. Yeah, it actually made for an experience that, at first, was beyond my control [induction]. But then we regained control, and we had a really good birth experience. I think part of it was definitely because of what we’d learnt in the course. So I’m glad that we went, and I know that we’re both glad that we went. So yeah, it was really good (Hilary)._

The sense of increasing options and preparation was also relevant to how they approached ‘decision-making’ during their birth. Feeling ‘in control’ of the birth process facilitated their management of it. Active involvement in decision-making has been identified as key to birth satisfaction (Buckley, 2002; Hodnett, 2002):

_You have the knowledge that you can choose. It’s the idea and they stress out so much about if the plan does not go as it should be, but it’s being_
able to decide for yourself and to make a decision, not just to be pushed along one area and just go along with it (Yvette).

Preparing and understanding the decisions they were making was seen as maintaining control over the birth process. Couples reported in the interviews that even where there was medical management, they felt happy with their decision-making about it:

I actually did feel in control. Although I had the epidural, and although, you know, things throughout the labour sort of went away from what we wanted, nothing was ever forced upon me. I was the one giving the orders. The only thing that they suggested was about the – from memory – was about the oxytocins. Everything else was my call. They suggested about the forceps and all that stuff too, but I knew that was coming. I knew. But I did really feel in control. I did, yes, and I think because the midwives were really encouraging with my breathing and really encouraging with their words as well – even through the pushing, they were you know, you’re doing a really great job you’re nearly there. It felt like each midwife we had at each stage was the best one for me at that time (Isobel).

6.6.2 Getting partners on board

The course explicitly taught partners how to be involved and supportive in the labour process, and they were shown what might be useful for the different stages of the labour. Partners verbalised a sense of relief in understanding what was happening and what they could do:
I actually understood why this was happening. Some of the changes during her pregnancy and all that. So learning those things was actually – it doesn’t make us worry a lot, like why it’s happening, because learning these lessons and learning that information actually made us understand (Xavier).

Partners who were interviewed all expressed their enjoyment of the acupressure techniques in particular – they became their ‘number one weapon’ (Xavier). They had control of something and knew the purpose of the specific points. They were given a DVD and pictures of the points to take home and practice (Debra Betts’ acupuncture protocol for labour and birth (Betts, 2005)). Also included in the take-home information were: visualisation CDs, pictures of the yoga postures and massage techniques, and information regarding the physiological and hormonal responses of the body. Cues for the breathing practices were provided and practice at home was encouraged:

Having done the course he realised that he was actually an instrumental part in terms of keeping me calm, keeping me relaxed, trying to make this as pain-free as possible and instead of just sitting there doing nothing he was actually – he wanted to be more involved (Nadine).

Women said their partners gained confidence and empowerment through knowledge of the tools:

He was very keen. He was as passionate about the whole idea as me, of learning techniques and helping me with a natural birth. He very much
wanted to be an active birth partner. ... He found that theory stuff was
good, as I did .... The info in the course made a lot of sense to him. He felt
like it was – he felt more empowered, I think, after it. The acupressure stuff
– he really enjoyed having something he could do (Tessa).

Partners expressed wanting to have an active involvement in the labour. This was
also observed during the workshops:

\[ \text{I guess it was really great to have experienced the class. I knew I would be involved but not as much to the level I was – all I can say is that it actually exceeded my expectations (Xavier).} \]

Couples expressed that the tools gave feelings of usefulness for the partner and bonding together as a couple:

\[ \text{He was able to be really hands on. After we had finished the course and we started using acupressure and the massage and things like that, [husband] actually felt like he was a part of the pregnancy. There were things he could do to help me and things that he could actually be involved in now, instead of just being on the sidelines I suppose. During the labour and birth he said as well that it really brought us together. It was something that was really great for our relationship as well, being able to go through that together (Diana).} \]

It was mentioned a few times that where it concerned birth, men felt that the media portrayed them in a farcical and patronising way. Men saw this stereotypical
character as inept and insensitive to his partner’s needs. This stereotype, in most cases, was readily relinquished when positive actions and behaviours were explicitly demonstrated and role-played in the course. They understood that when a woman could trust her support people and go into herself without having to control the situation, her labour could be more manageable:

_Having the support person as well versed as possible in everything that’s going to happen and everything they may come across makes it much easier for the mother because they’re confident that their support person is going to be able to support them when they need them and know what needs to be done_ (Bruce).

Partners understood that their role was not trying to fix the pain, and they became responsive to the cues their partners gave them. In the course, as we practised the techniques, we role-played some non-verbal cues indicating to the partner that this particular thing was not wanted at that moment. Partners understood that they could take these as non-offensive gestures, and they could then just try something else. They learned how to just be there and give the support that the woman wanted:

_I felt like I was pretty much – I felt relatively in control because all I needed to do was say to my husband ‘it’s coming’ and he would be there and doing whatever he could do to help and he would say, ‘do you want this?’ I would nod or shake my head, but I felt like I was still in control of things_ (Olivia).
‘Rachel’ describes her partner’s realisation that if a natural birth is going to be the most beneficial thing for the mother and the baby, and help with bonding and attachment post-birth, then he now has an investment in helping to make that happen. His role is extremely important for her to succeed in a natural birth, especially given the highly medicalised model of the hospital where she is giving birth:

*There was a huge benefit to doing it naturally if you succeeded, which justified going to the effort of doing it naturally. So suddenly there was an investment in him helping me doing it naturally. Not just like an expectation that I would (Rachel).*

Several of the interviewed men stated that the course enabled them to feel part of the birth, and their knowledge created agency for their role:

*I felt part of it, just trying to be there and get her relaxed and breathing. I was as involved as much as I could be. I’d do it again in a heart-beat (Jim).*

*It was a good role. There was plenty of things for me to do. I didn’t know I could help so much (Damien).*

Women expressed feeling supported by their partner, and as a team were able to effectively communicate their desires to their caregivers in labour:
I knew I was going to have weak moments in labour and I needed him to be there to stick up for me, sort of thing. I wanted him to be strong and to say look, you can hold on, you can do it (Olivia).

Midwives also found that when there was effective partner support, it reduced the woman’s anxieties, her confidence was greater, and her feelings of safety and trust were apparent. When the couple ‘are on the same page’, and engaged with the process, they found that it was easier to pursue normal birth. The midwives talked at length about the beautiful experiences of partners who were supportive and connected, and the amazing feeling this gives them:

But when you’ve got a couple who are so connected and are just doing their thing, you almost have the ability to just stand back and watch .... To me that is just wonderful. To be able to just observe and then when the baby’s born it’s even more amazing watching that connection (Midwife 2).

An exchange between two midwives describes the impact that that has on the woman:

You can see that she doesn’t have that tension, she’s relaxed (Midwife 2).

She’s not worried about him and what he’s doing (Midwife 1).

Yeah, she knows he’s here for her and ... (Midwife 2).

With her, they’re having the baby – not just her having the baby ...

(Midwife 1).
The midwives discussed how disruptive it can be for the birth when partners were disengaged, or did not understand what to do; ‘Partners always make the scenario worse than it is for the patient and for the midwife’ (Midwife 4). When women are worried about what their partner is doing, or that the partner is not supportive of her, then they find it difficult to go into themselves:

Yeah, when he leaves the room they suddenly go into good labour

(Midwife 2).

However, they said that there were all kinds of ways that women felt supported, and that it was not always what you expected. Midwives felt that communication between the couple and with the midwife about the couple’s preferences was very important for teamwork.

6.6.3 Getting the team on board – midwives pursuing normal

In the focus groups, midwives were supportive of the use of complementary therapies for labour, and believed them to be in line with their own midwifery philosophy and practice. They had used them, seen them in action, advocated for their use and supported women and their partners through labour with a variety of techniques. Midwives talked about working with what the couples bring into the labour and attempt to ‘follow the woman’. They gave a sense of guiding women and their partners to the best of their ability, but it was the mindset and preparation of the woman and partner that were the key to the labour:
I think though if you do have a woman come in who’s so positive you’re going to feed off that (Midwife 2).

Yeah she motivates you to motivate her (Midwife 3).

Midwives discussed great satisfaction in pursuing normal birth with motivated and educated women, but many women are just not prepared or educated, and some seem unwilling in the antenatal period. Time limitations also had an impact on what they could impart to women at the antenatal visits. However, overall, the effect of the relationship between the woman and the midwife was seen as valuable and beneficial. The midwives felt that this relationship had a positive effect:

If they've got a good relationship with their midwife they tend to come in a lot more positive (Midwife 4).

The tools and techniques allowed an interaction between the woman, partner and midwife. The women and partners described how they developed a rapport with the midwives and were able to involve them in the birth plan. They discussed attending the course, and found that most of the midwives were supportive of the techniques used and the philosophical approach to natural labour:

At [hospital] they’re all for it. They’re just – ‘yes, we just go totally with you unless we need to intervene and then we talk you through it’. Yeah. Well they actually said to us they prefer to do it as naturally as they can too, so that was good (Gemma).
Midwives often had knowledge of the tools and were able to actively engage with the couple in using the tools to support labour:

*The midwife knew all the acupressure points as well and different visualisation techniques and [partner] used the golden light. He used that visualisation for me a few times.... So I was still going through the contractions and so [partner] was holding me, and I was spiralling, and ‘A’, the midwife, was doing the acupressure points on my inner ankles. So it was a triple team (Diana).*

The midwives found that when women were not in the mindset of trying to labour naturally, it could sometimes be difficult. When they had a lot of fear, or were negative about birth, then getting her into the right headspace and working together could be difficult:

*Most of the time you haven’t met her before. So then it’s that whole building trust, getting the relationship, plus trying to make her feel comfortable and safe and you know. It’s difficult sometimes (Midwife 3).*

This relationship based on mutual interest in normal birth was desirable for midwives, and gave a feeling of fulfilment in their role as midwife. The relationship with the midwife also gave couples an added ability to be able to navigate the hospital system, and understand what was happening to them. They expressed an increased decision-making capacity, and couples were given time to decide what they wanted and what was best for the woman and the baby:
She was very supportive .... She said 'I’m happy to work through the pain with you’. So she was very accommodating to whatever I decided and gave me and ‘partner’ a moment to think about it (Nadine).

They found that the midwives became advocates for them, and that if a medical intervention was needed, their midwife was able to express what the couple wanted for their birth to the doctors and other medical staff. They felt an increased sense of being cared for, being heard, and being respected:

> My midwife was absolutely wonderful in helping me stick to my birth plan and sticking up for me with the registrar who was the one who started talking about induction to speed things up. She was like ‘no, let’s try the acupressure points and stuff’ so ‘partner’ did a couple of those ... and by that stage I was nine centimetres, so I had progressed quite a bit in those two hours (Annabel).

Women and partners both suggested that it would be very beneficial if midwives knew these techniques. When they did know them, especially in acupressure, the couple felt a great deal of support, comfort and encouragement by the midwife. This gave them added feelings of confidence that they could do it:

> I’m not sure about the other midwives, I just don’t know how involved they usually would be because they were letting ‘A’ (student midwife) do everything. I definitely think it would be really great, particularly for the hands on midwives, the ones who really like to be involved (Diana).
The women in this study were all in the standard fragmented antenatal care models, however the techniques provided a common ground to work with the couples for a common outcome.

In the field notes, a story was recorded from a woman who had attended the course. She related the story after her birth. She had been labouring for a long time and had become exhausted, and eventually had an EDB. It became apparent that the baby was in a posterior position, and the woman said she was confronted by a registrar who came into the room, without telling her his name, and said they were going to take her to have a CS if she ‘didn’t get this baby turned around’. She said that she felt affronted, overwhelmed, and powerless in this situation. After he left, the midwife, who was in the room at the time, quickly said ‘don’t listen to that, we can get this baby turned around’. The midwife and the woman’s partner helped the woman get up on all fours, even with the EDB, and started massaging the inner ankle acupressure point (Sp 6), and lower back points (Bl32-33). By the time the doctor returned, the baby, who weighed over 4 kg, had turned and been born facing the right way (HL – field notes).

In the focus group, the midwives recognised that some women have high anxiety when it comes to birth, or want methods to pursue natural labours, and that having options like complementary therapies courses for managing labour is a good addition to the hospital system:

_I think everyone here is receptive as well. You won’t find anyone not receptive here on complementary skills (Midwife 1)._
They felt that the effects were real and not the result of a placebo effect:

*It’s not hocus pocus, it works. We know it works and I think people need to get past that and realise that* (Midwife 2).

*We just need to keep medics out of the room – keep the doctors away* (Midwife 1).

In recognising the highly medicalised system that they were actually working in, but trying their best to keep birth normal, they understood that sometimes the system was difficult to navigate. However it was apparent that midwives and couples needed to ‘meet’ with regard to their desires and expectations. When women and their partners came in motivated and informed, midwives were motivated to work with them. Where this motivation and information was lacking midwives were less likely to make the effort to encourage CM techniques. Where couples were educated about techniques, they wanted midwives to engage with them in using the tools.

Midwives discussed that when the practices are divergent from their own thinking, or challenging to their authority, or independent of the system, they sometimes found that difficult to manage. This was an interesting aspect to their general discussion:

*... I think also when the husband becomes the conduit for communication, you’re kind of left in a situation of, well I’m a midwife and supposed to be with the woman, how do I do this* (Midwife 1).

*It also makes you feel that they think that you’re trying to be this horrible person. It’s horrible being made to feel that* (Midwife 2).
The other thing is the doula. When they come with doula it’s more difficult than just doing ... (Midwife 4).

Generally, midwives wanted to provide more to women, but felt that hospital context, models of care and time were all limitations to this. And they acknowledged that women’s mindsets were often already established:

It’s in their mindset. You can’t stop that (Midwife 1).

They believed that courses such as Complete Birth were essential not only to educate and support women in achieving normal births, but in reducing fears and anxieties, and providing an understanding of the purpose of labour and birth. Midwives enjoyed working with these tools to support and follow women in their birth experience. They wanted to be more educated about the practices and develop their own professional toolkit.

6.6.4 Navigating a broken system

The impact of medicalisation in the form of common practices such as induction of labour, augmentation and electronic fetal monitoring (EFM) were apparent in the interviews and with stories reported back from other participants. The effect that these practices have on women is broader than is often considered. Many women described feeling overwhelmed by how fast and intense their induced labour was. They discussed not having time to implement their strategies because their labour was just too fast. Having to cope with the electronic equipment, designed to monitor and give a sense of risk mitigation, became an irritating distraction. It kept them out
of the mindset they were trying to achieve. Having to navigate the impact of these interventions is an important component in labour and birth:

The EFM and contraction monitor was not attached well. I had one hand holding the monitor and one trying to do the points. Midwives were coming in and out and fumbling around and we had the drip in and a trolley. They need to improve the strapping device – it was really limiting. In hindsight, it was possibly overkill, having it on the whole time when everything was going normally – it seemed too much but that’s the hospital’s responsibility when inducing with Syntocinon (Neville).

However, despite some women receiving interventions, the ‘concepts’ of the course played a specific role in assisting their approach to labour. We discussed in the course how to approach situations where intervention did occur and ways couples could manage or navigate the system to give them a greater sense of control and confidence:

I feel very sorry that I wasn’t able to use a lot of the techniques. But having said that, just the change of my mindset after this course, helped me through it. It gave me a lot of confidence, it made me a lot stronger and that’s how I got through it. So even though I wasn’t able to use of lot of it, yeah it helped me a lot (Mia).
Women began to be aware of what was behind some of the decisions that hospitals made, and then felt more able to make informed decisions. However, they didn’t always feel successful in their navigation of the system:

*I found that out later. I was under the impression from what the obstetricians were saying, that my blood work, my liver function and that, was a lot worse than it was, and I was actually a little bit annoyed later on when a doctor ... came in and said, ‘they were just borderline, why did they induce you?’ I was a bit frustrated that they jumped the gun a bit* (Olivia).

At times, they felt that the decision-making was taken from them, as if it were assumed they did not understand the options available to them. Some women felt intimidated by the hospital:

*I felt like I probably could have waited a lot – a couple of days more at least or something, but they were pretty adamant that you’ve gone overdue. If we can get you started this date, then you’d be – it was like a scare-mongering sort of thing so I didn’t really feel in control at all* (Hilary).

At times, the impact of the midwife was apparent. Women feel very vulnerable in labour and especially in unfamiliar places. The midwife can have a large impact on how secure the woman can feel:
I had a very unsupportive and negative midwife, and I panicked on the gas. I was unaware of the episiotomy being performed. This all negatively impacted my birth experience (HS fieldnotes).

The midwives in the focus group did not seem to have an awareness of the potentially negative impact on women they may have by not communicating and explaining procedures that they may take for granted that women will know. The midwives were at times suggesting that women did not know what they were doing and by the time they were in labour, it was almost too late:

We shouldn’t be having to explain anything in labour because women are in such a heightened state of everything – you can’t expect them to be able to take in anything (Midwife 2).

Adherence to the ‘medical model’ as a form of defensive medical practice was evident in some women’s experiences in the hospitals. There was the sense that the mother’s wellbeing should be sacrificed for the ‘perceived’ safety of the baby:

The midwife goes, well what about your baby. That really annoyed me, because they were playing like the emotional side of it, the emotional card, and it was like the beginning of the end. Like you could see, it was like this is the turning point. Do we get stay, because we’re frightened – or do we leave, because we were informed – and the only problem is with the midwife, is that she couldn’t tell the difference (Damien).
The theme of ‘having a toolkit’ showed how women and partners made sense of how and when to use the tools and techniques available to them, in order to facilitate the optimal birth experience. In the following section, the third main theme that emerged from the data, ‘finding what works’, discusses how women and partners used their ideas and beliefs about labour, their bodies and the tools available to them to find what worked for them on the day.

6.7 Finding what works

The interviewees discussed finding their rhythm in labour and using the tools that worked. What worked on the day was not necessarily what they thought would be the thing that they used. This was previously discussed as one of the benefits of learning a number of techniques, that different techniques will work at different times in the labour:

*I think for me it was the acupressure, knowing that there was something that could help without drugs or an epidural. That could help you with pain relief and to get through it. So for me, I had really, really high hopes to use the acupressure during my labour (Mia).*

Some women discussed how they made the techniques work for them. ‘Olivia’ modified the breathing technique to help her get through the contractions in her own rhythm and in a way that worked for her. She was able to combine techniques and have her partner supporting her with massage and pressure points, working together through each contraction:
I counted my breaths – I would count eight breaths and then I’d be at the peak of a contraction and then I would know; okay the contraction’s going to go now and I could relax more. My husband was – he was massaging like doing the pressure massage on my hips and then in between I was bouncing around on the ball and just trying to – with my head on the bed just trying to relax and that was it (Olivia).

6.7.1 Finding the rhythm – what works for me

The tools used by the couples were an individual choice and often multiple tools were used over the course of the labour. They were looking for what worked and what allowed them to get a sense of rhythm in their labour; ‘until you got the rhythm happening, and it felt more like, “okay, I can do this”’ (Olivia). This gave them an ability to ‘go within’ and let their body do the work:

I guess from the time that it started like – the early labour started, the time that it started really hurting and I went into active labour was only probably about an hour or two. So because of that, it gave us enough time to figure out what was working so we found that if I leaned forward – like if I was moving around in between contractions, and then during contractions I was leaning forward and – I can’t remember what she called it but was where the – my husband was putting his hands on either side of my hips at the back and putting pressure inwards .... We found that that was really good (Olivia).
Women felt that the techniques helped to keep them calm and described a sense of control in the labour. Having choices from the course, and watching the DVDs helped to give some women ideas about things they could do in their labour. Exposure to these tools beforehand helped to provide women with options:

So I decided to get up and out of the bed and start in the shower. So I was in the shower and then I went to the bath. At these points I was still breathing through the contractions. In the shower I’d actually started to swivel my hips. I was doing those round motions that I’d seen in some of the DVDs at the course. I found that really helped. The motion, the swirling. So I’m holding on to the bars in the shower and doing the swirling motion (Nadine).

Midwives also felt that women should stay flexible, and not stick too closely to the ‘script’: ‘It’s not scripted’ (Midwife 3). They felt that those who were educated had options and choices for labour; ‘if this doesn’t work then I can try this. We wrote down this and this worked at home’ (Midwife 2). This gave flexibility and ability to follow the women where her body wanted to go.

6.7.2 Understanding the process – getting past the wall

Through the course, couples felt they gained an understanding of the process of labour. In hard times, such as transition, they understood what was happening and this helped them to manage the process and employ tools to assist. By discussing it in the course, couples became aware of some signs of when active labour was established; when they had a posterior presentation; or when they were going
through transition. When their partners or midwives told them that they were going through transition, or gave them a framework for their labour, they found this useful and it helped them get past the ‘wall’:

That’s when I started to go through transition, which I didn’t realise at the time was transition. So I wasn’t very happy, I was like “get me out of this bath.” I just looked at my mum and said “I can’t do this anymore.” Then when they pulled me out of the bath the midwife said “you’re going through transition” and I went “okay, well if I know where I’m at, then I know this is supposed to happen, so I’m feeling better again” (Gemma).

Midwives also agreed that understanding that labour was not just a physical event, that the hormonal and psychological component are equally important in the labour proceeding, or stalling in some cases; ‘If you know what’s happening and why it’s happening you can accept it’ (Midwife 1). The implication of the context of this comment was understanding the nature of birth gave women a capacity to work with it and take control of it.

Many women talk about having a wave of doubt or hitting the wall. Times like this were discussed at the course, and what partners could do to help. Suggestions to try to manage the situation included things like reassurance, kind words, encouragement, gentle physical touch, counting to regulate breathing, and managing the environment.

Just, I needed something to help me push through that section of time.

Then we came out the other side and I was back on track (Diana).
I actually told him, even if I say I want something, don’t let me unless it’s needed, because I’ll show some weakness somewhere. Just keep me going (Tessa).

So when I was going through those difficult parts it wasn’t that I knew my body could do it, but it was what I knew I wanted, that’s what I wanted for our child (Diana).

Partners were aware that this was a normal part of labour so that they could go with it, and not try to fix the pain, as has been previously discussed:

I felt like I was helping as much as I could, with trying to get her to breathe and just be in there and try and be a good birth partner ...

Because you can’t take the pain away yourself. You want to get in there and help out (Jim).

6.7.3 Patterns of use of complementary medicine tools

Couples reported using acupressure for labour induction and augmentation, breathing and visualisation for relaxation purposes, yoga and active birth movement for managing pain and finding rhythm, massage for pain relief and emotional support, and the knowledge of the hormones and principles of labour to create an understanding of labour and birth:

We practised the acupressure. We thought that was really good and we spent a lot of time preparing with that one. It gave a sense of empowerment. It gave me also the sense I was doing something. Whether it
worked or not, we did some of the induction points and she did come on
her due date (Tessa).

This helped create a mindset and framework for normal birth, and the inner and outer
resources to facilitate it.

Midwives also identified many techniques that they had experienced as effective in
the labours they had attended:

*A lot of the things they do are related to physiological events during
labour. So you talk about acupressure so they know what the points are
and they know what it’s going to do* (Midwife 2).

Yoga positions and breathing techniques were found to have:

*Such an incredible effect. Just increasing that exhalation and just I think –
I mean I’m a believer of activating the different parasympathetic and
sympathetic systems and using your breath to be able to kind of regulate
that. I think it is quite a simple task to be able to do, and if you kind of
know the importance of the breath that the partner does, it’s something
that you can just turn on quite quickly* (Midwife 3).

They consider the effect of CM as a serious adjunct to their practice, and with each
birth try to facilitate a natural process by using some of these techniques taught in the
workshops:
But still we do some massages we talk through the labour pains and everything. So it’s not like we are not familiar with what you’re talking about. So maybe it helps the patient to know about these things and it help to cooperate better (Midwife 4).

With regard to incorporating CM into their practice, many midwives had done acupressure courses, and routinely gave out acupressure sheets at antenatal clinic visits. Midwives expressed interest in doing courses in a variety of techniques to help build their practice. However, they found that one of the biggest barriers was the cost of the courses: ‘it’s so expensive but the techniques should be readily available to midwives’ (Midwife 2); ‘We shouldn’t have to pay to do our jobs’ (Midwife 1); ‘No it should be part of the training’ (Midwife 2). The midwives felt that if they wanted to meet the Towards Normal Birth in NSW targets, then ‘the area health has to put some more courses on and subsidise them’ (Midwife 1).

In ‘finding what works’ women and partners discussed the way they implemented different tools and techniques to manage their labour and go with what happened on the day. Midwives, who supported the use of the tools in facilitating normal labour, encouraged this flexibility. In exploring this theme differences in women’s use during their birth is highlighted.

6.8 Summary

The overarching theme for the qualitative interviews was ‘making sense of labour and birth’. The other themes were: ‘working for normal’, ’having a toolkit’, and ‘finding what works’. This chapter has reported on the findings of the interviews
with women and partners, triangulating the findings with the data from the focus group with midwives. Women and their partners reported that attending the course allowed them to ‘make sense of labour’ and understand the benefits and purpose of a natural physiological birth. This inspired them to work towards a natural birth, and by understanding their bodies, their feelings of confidence in pursuing this grew.

Women were able to perceive the risk lens applied to birth by the dominant medical paradigm and by societal perceptions, and were able to contrast that with the benefits of normal physiological labour. In understanding this perspective, couples shifted their thinking about the role of medicine in birth, and began to perceive that medicine was a backup if there was a problem, rather than part of the routine management of normal birth. With this awareness, couples were able make choices based on their understanding and knowledge of tools available to them. Midwives were supportive of women who wanted to pursue normal birth and followed them in this process.

Midwives were able to work well with a couple who were knowledgeable and proactive, and they found a sense of professional and personal satisfaction in working with inspired, prepared women.

By providing a variety of techniques, like a toolkit, and by educating partners about providing supportive care, women were able to find the rhythm of their labour and discover what worked for them, increasing their ability to navigate difficult times. By having increased choices and understanding, couples were able to manage their labour and actively participate in decision-making around options in their labour. These themes and concepts elucidate the processes by which couples were able to make sense of labour and birth.
Chapter 7 – DISCUSSION AND CONCLUSION

7.1 Introduction

This research aimed to examine the role that complementary therapies, using a complex antenatal education package, may play in the facilitation of natural birth. This was achieved by carrying out three studies using an MMR design. Included in this mixed methods design was an RCT, used to examine the effectiveness of the Complete Birth Study, in addition to standard care, in reducing rates of EDB use in primiparous women compared with standard care alone. To characterise the use and effectiveness of the program and its components, in-depth interviews were conducted with women and partners, and a focus group was conducted with midwives to explore how they perceived the use of the study techniques and what they see as the potential facilitators and inhibitors of implementing evidence-based CM techniques in the public hospital system.

This study provides strong evidence for the use of CM techniques in an antenatal education format, informing women and partners about how labour and birth work, and for the support and self-management of pain in labour and birth for first-time mothers. The findings show that the Complete Birth Study course is effective in reducing rates of EDB use as the primary outcome measure and significantly reducing other secondary outcomes.

This study is the first RCT in Australia that has investigated and demonstrated the effectiveness of a complex birth preparation course, incorporating multiple evidenced-based CM techniques, for the support of natural birth for first-time
mothers. The study has uniquely demonstrated the effectiveness of an antenatal education program allowing women and partners to have control and agency in their birth process and use information and CM tools and techniques to manage their own labours effectively.

The *Towards Normal Birth in NSW* policy (NSW Department of Health, 2010) advocates reducing intervention rates, often resulting in unnecessary CS, by supporting women with education and supportive care. This study demonstrates the capacity for a novel antenatal education program using CM techniques to reduce rates of EDB use, augmentation, length of labour, CS and the need for resuscitation of the newborn. It provided women with choice and variety, with couples being free to choose what worked for them on the day.

The findings from this study can be described in terms of three main themes: ‘understanding labour and birth’, ‘using CM to work together’ and ‘stemming the cascade of interventions’ (Rossignol et al., 2014; Tracy et al., 2007; Tracy & Tracy, 2003).

This chapter discusses the findings from the RCT, in-depth interviews and the focus group in an integrated way by using the triangulation method of incorporating information from the different data sources to address the study questions (Farmer et al., 2006). Recommendations for education, clinical practice and research are discussed at the end of the chapter, and the strengths, limitations and conclusions to the study are stated.
7.2 Main findings

In addressing the aims of this research, the Complete Birth Study examined the role that complementary therapies may play in the facilitation of normal birth using an MMR design. The RCT demonstrated the effectiveness of this complex antenatal education program for first-time mothers by showing a significant reduction of rates of EDB use as the primary outcome measure. An absolute reduction of 45%, and a relative reduction of 65% (RR=0.35 [95% C.I.: 0.23-0.52], p<0.001) in the EDB rate was demonstrated in the study group compared with the control group. This is a highly significant result.

The Complete Birth Study also showed effectiveness in significantly reducing secondary outcomes, such as rates of augmentation, length of labour, CS and resuscitation of the newborn, and showing a trend towards reducing instrumental vaginal births and major perineal trauma. This study also provides evidence for an increase in positive attitude towards birth in the antenatal period and increased feelings of agency during labour and birth.

In characterising the effectiveness of the program and its components through in-depth interviews with women and partners, the main theme of ‘making sense of labour and birth’ emerged. Women and partners reported that through education about the natural physiology and hormones involved in labour, and the benefits and purpose of birth for the mother and the baby, women gained an overall understanding of labour and birth. This helped to describe and explain the context in which epidurals and other interventions were able to be reduced. Once women and partners
understood what was meant to happen in their bodies when the normal physiological processes of labour were unfolding, they were able to work towards pursuing a normal birth by engaging with what their bodies needed, seeking support from partners and midwives, incorporating the CM tools and techniques in a meaningful way, and putting it all together to find what worked for them during labour.

Women and partners learned various techniques for managing labour and developed a toolkit of techniques that they could use, depending on what happened and how they felt during their labour. This provided them with choice and a sense of confidence and empowerment for labour. We found that women used multiple tools during labour and this depended on what worked on the day. Couples perceived that they had options and were able to develop a strategy for managing labour. Women rated breathing techniques, visualisation and acupressure as the most useful tools learned in the course, and as the most used tools during labour. However, there was no particular technique that was independently associated with reduced rates of EDB use, suggesting that the overall package enabled women, and their partners, to manage labour and birth. Partners identified acupressure as being the most useful tool.

Findings from the focus group explored midwives’ perceptions of the CM techniques, and potential facilitators and barriers to introducing the techniques into the public hospital system. We found that midwives were supportive of the use of CM for labour and birth, and in favour of providing women and partners with enhanced knowledge and tools for normal birth in the antenatal period. ‘Making sense of labour and birth’ was the overarching theme that also applied to the findings
from the focus group. Midwives felt that women and partners who were educated and had a strategy were empowered to take responsibility for their birth and this facilitated labour and the midwives’ role in supporting them. While midwives were supportive of the knowledge and use of CM in general, some expressed the potential for loss of professional control. Overall, they felt that the course was useful in supporting women to pursue normal birth options within the hospital system.

This study provides evidence that antenatal education using CM techniques is an effective and viable method of managing pain during labour, increasing personal control for women, enabling partners and midwives to provide appropriate support, and thereby reducing the medical interventions. These clinically and statistically significant results are important in establishing an evidence base for the use and effectiveness of an independent antenatal education program incorporating CM techniques for the management of pain during childbirth.

7.3 Making sense of labour and birth

The overarching theme that most strongly emerged from the qualitative interview and focus group data and explained the RCT findings was ‘making sense of labour and birth’. This concept linked the themes, explained the findings across all the data sets and reflected the dominant attitude of women, partners and midwives. Three subthemes emerged from the qualitative data that described the influence of the course on couples, and their caregivers, in trying to achieve normal birth. These were ‘working for normal’, ‘having a toolkit’, and ‘finding what works’. Women’s
strength, understanding and ability to incorporate the tools of the program to achieve normal birth, were seen in the significant findings of the RCT.

Making sense of labour and birth is the thread connecting the data sets in this study, and can be understood as a process and a strategy that enabled women to take control of their labour and utilise the CM tools to manage pain in labour. The outcome of this was reflected in the reduction of EDB rates and other interventions seen in the results of the study. The process by which this occurred is one of gaining knowledge, described in the in-depth interviews that told of women and partners coming to understand the meaning of normal labour, and being able to employ a strategy to help manage their labour. Strategies included such things as staying at home for extended periods; staying upright and off the bed; using water, vocalisation and movement; and applying CM techniques appropriately for particular stages of labour. Women were given instruction on relaxation and partner support to increase oxytocin release, acupressure for augmentation, upright yoga postures to facilitate progress, breathing to lower adrenalin and fear, hip swivelling and massage for labour progression and pain relief, and explicit messages for partners to support and facilitate labour.

By understanding the purpose of labour, couples became invested in pursuing normal birth, and by understanding what was happening in their bodies, they were empowered to use the CM tools to self-manage and facilitate the labour process. In the focus group, midwives discussed the power of knowledge, and its capacity to transform the experience of labour, and allow midwives to work effectively with women based on a shared understanding of the value of normal birth. Midwives saw that education of women is the key to normal birth; women need to understand what
is happening to them in labour to empower themselves to manage their labour and work in partnership with the midwives towards normal birth.

The process of empowerment that occurs through this understanding ‘strengthens women individually and collectively and gives them the confidence to learn and to take charge of their lives’ (Mazumdar & Sunjaya, 2009, p. 83). Within the context of maternal health, by enabling this process of understanding and empowerment, women can more fully contribute to defining their birth, and become their own agents of social change.

Questionnaire data following the course showed an increase in positive attitude towards childbirth for the study group compared with baseline. The LAS showed significantly higher mean scores for the study group compared with the control group following birth. This is indicative of greater feelings of control or ‘agency’ in labour in the study group, which is a significant predictor for satisfaction with birth (Attanasio et al., 2014; Christiaens & Bracke, 2007; d'Orsi et al., 2014; Fair & Morrison, 2012; Goodman et al., 2004; Hodnett, 2002; Howarth et al., 2010, 2011; Humenick & Bugen, 1981). This may also indicate reduced feelings of anxiety and fear (Sjogren & Thomassen, 1997).

Women and partners confirmed this idea in the in-depth interviews, by describing the feelings of excitement they had going into labour; the feelings of confidence they had by having tools and techniques to support them and from their understanding of what was happening during the labour; and the options they felt were available to them to manage their labours. Midwives also described the confidence that women displayed
who were educated and able to utilise tools during labour. The literature supports this idea of antenatal educational interventions increasing confidence and control, and CM interventions providing options for management of pain and labour progress (Gagnon & Sandall, 2007; Jaddoe, 2009; Jones et al., 2012). The increased scores for the study group women in this study for both the LAS and ATBQ are consistent with the birth education literature and CM literature (Byrne et al., 2014; Gagnon & Sandall, 2007; Jones et al., 2012). The increased scores are complementary to the main outcome data for this study showing decreased rates of intervention.

Within Australia, Fahy (2002) discusses the sharing of childbirth knowledge as a sharing of power, and describes the knowledge/power concept proposed by Foucault (Fahy, 2002). This idea of knowledge-imbued power is discussed as a process by which women make sense of, and are empowered in, their childbirth choices (Fahy, 2002). The idea of sharing knowledge is also reflected in the work of Leap (Leap, 2009), where the individual woman is seen to be philosophically at the centre of care, and her strength and decision-making capacity for her birth choices are acknowledged (Pairman, Pincombe, Thorogood, & Tracy, 2006). The concept of midwives and women sharing power also promotes a shift of focus away from the institution and towards the woman, and allows midwives and women to work together in a knowledge/power-sharing relationship. This extends to the management of labour with the idea that women and midwives work with the pain, rather than removing it, as part of understanding the importance of normal labour (Leap, 2009; Leap, Dodwell, et al., 2010). There is an acknowledgment that women have expertise about their pregnancy and labour based on their own knowledge of self, family, and
community, and that midwives value this expertise (Leap, Dodwell, et al., 2010; Pairman et al., 2006). Therefore, the understanding that has been generated through ‘making sense of labour and birth’ gives women knowledge and the opportunity to have the power to make their own choices for birth.

Women’s understanding of normal birth changed during the Complete Birth Study course, and called into question the support for normal birth received from routine hospital-based antenatal education. Women’s expertise and capacity to make informed choices was reflected in their ability to critically evaluate the information from different educational sources. Antenatal education literature 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 (Gagnon & Sandall, 2007). However, with respect to routine antenatal care, some commentators view these classes as an induction to hospital policy, and that this implies submission and coercion of women to medicalisation, where their options are limited to medical and pharmacological management (Ferguson et al., 2013; Lothian, 2008a, 2008b; Walker et al., 2009). In some cases, such as the Swedish study by Fabian (2005), the increase in use of EDB by attenders of antenatal education compared with non-attenders (Fabian et al., 2005), may indicate that such an induction is present. By ‘making sense of labour and birth’, women were able to critically view the information provided from hospital-based antenatal education classes and the Complete Birth Study course, and understood that they had more choices and methods to manage labour than what was described in the routine classes. Their understanding empowered them to access information and use tools
that would support normal birth, rather than just ‘going with the flow’ of a hospital managed birth. This made them less vulnerable to the medicalisation that is a reality in hospitals. By using the structure of antenatal education and providing information about the importance of normal birth and non-pharmacological options for managing pain, women were given tools to become the experts in their own labour and birth and minimise common interventions.

Providing knowledge, choices and empowerment for women, using a feminist lens, was discussed as the philosophical underpinning for this research. The in-depth interview and focus group data reflect that women felt they understood the meaning of normal birth, had more choices, more confidence and increased feelings of agency and empowerment during labour. This increased their capacity for normal birth within the context of hospital-centred maternity units by using the knowledge and tools to reduce interventions and thereby reduce morbidity in labour and birth. Data from the questionnaires provided valuable information for the study, giving insight into women’s feelings of empowerment and attitudes towards birth prior to the event and following it. Increased feelings of confidence and agency were seen as part of women’s transformational change in their mindset about birth; however this is not considered sufficient for reducing EDB rates alone, which is consistent with antenatal education literature (Bergström, Kieler, & Waldenström, 2009b; Escott, Slade, Spiby, & Fraser, 2005; Ferguson et al., 2013; Gagnon & Sandall, 2007; Jaddoe, 2009; Koehn, 2002; Svensson, Barclay, & Cooke, 2009).

Through integration of the data sets, it is the thread of ‘making sense of labour and birth’ that describes the process of women’s understanding of normal labour: they
gained confidence in their bodies, became empowered to navigate the hospital system, and invested in working towards normal birth by working with partners and midwives to manage the process of labour. Couples used the CM tools to manage labour and reduce the requirement for interventions, thereby reducing the cascade of intervention. The unique contribution of this thesis is the use of education to empower women to access and utilise supportive care and to self-administer CM tools to facilitate normal labour. Because women and partners understood the purpose of labour and the way medical interventions disrupt labour and contribute to the cascade of interventions (Tracy & Tracy, 2003), women were able to make choices and take charge of their labour and birth with the support of partners and midwives.

7.4 Using complementary therapies to work together

The Complete Birth Study taught couples self-administered CM techniques to facilitate pain management in birth. The course included only evidence-based techniques that had previously been examined individually. We combined the techniques so that women had choice in their labour of what technique or techniques would be most useful at the time.

Women in the study practised different CM techniques during the course, and at home, to facilitate labour progress. They saw this as having a toolkit of techniques to help them get through labour. They were given instruction on relaxation and partner support to increase oxytocin release, acupressure and upright yoga postures for labour augmentation, breathing to lower adrenalin and fear, hip swivelling for labour
progression and pain relief, and explicit messages about using the bed or other furniture to lean on and support upright positions, and not lie down on. Data from the in-depth interviews and questionnaires provide some insight into the nature of the study group’s reduced use of EDBs and other interventions. The combination of knowledge and tools allowed women to work together with partners and midwives to manage their labours, reducing use of medical pain relief, specifically EDBs.

Data from acupuncture and acupressure literature support the findings of reduced pharmacological interventions. As discussed in Chapter 3, acupuncture and acupressure interventions show evidence of reduced use of EDBs and less requirement for all other analgesic methods (Cho et al., 2010; Lee & Ernst, 2004; Smith, Collins, Crowther, et al., 2011). These studies report on CM interventions that are administered to labouring women, and follow a prescribed protocol. Our study was unique as it examined self-administered CM techniques and provided no prescription for protocols or time limitations for use.

While other CM literature, such as relaxation techniques including yoga for labour, did not report on rates of EDB use, relaxation techniques were shown to increase satisfaction with pain relief, and lower assisted vaginal birth rates (Smith, Levett, et al., 2011). Yoga was associated with reduced pain, increased satisfaction with pain relief, and satisfaction with the childbirth experience (Smith, Levett, et al., 2011). In the literature for upright birthing positions, which are similar physiologically to yoga postures, there is evidence from the systematic review by Lawrence reporting that women who were randomised to upright positions were less likely to request EDB (Lawrence, Lewis, Hofmeyr, & Styles, 2013). The review by Priddis et al. also
suggests a benefit in upright positions to reduce rates of EDB use (Priddis et al., 2012).

When massage was examined, less pain during labour was reported compared with usual care during the first stage of labour, and labour pain and use of pharmacological pain relief was reduced in one trial of massage compared with music. One trial also found reduced anxiety during the first stage of labour (Smith et al., 2012).

In the analysis of patterns of CM use in labour in the present study, most women used three to four different techniques, and concentrated on around two ‘most used’ techniques during labour. No individual CM technique, nor amount of rehearsal in the antenatal period, was statistically associated with reduced likelihood of EDB use in the study group, and it was thought that the overall package worked synergistically to facilitate women’s management of their own labour. Couples felt they had a toolkit for birth, and even if they did not use particular tools, they felt confident about labour by just having them if needed. Partners and midwives were engaged with the woman and became a team for the birth.

Women, partners and midwives discussed working together, reflected in the theme ‘getting the team on board’, by using knowledge and CM techniques, and providing supportive care, which also created a bond between couples. Women reported practicing various techniques, especially breathing and visualisations, about twice daily in the antenatal period, and partners encouraged and supported them with this practice. Women were provided with a CD with four different visualisations that they
could listen to at home, and they reported feeling more calm and less fearful listening to the CDs, especially those who listened regularly. The breathing and massage techniques were also reported to be something the couples did together at night before going to sleep. There was a DVD and booklet to practice the acupressure, which couples found to be very useful, as they stated that they needed practice beyond the course to become more competent at finding and using the points.

Women said they practised the yoga postures less often antenatally, but used them in the labour. Hip swivelling and low vocalisations were introduced as a way to move and work with the body’s natural rhythms. This is what Walsh (2007) describes as the ‘dance of labour’, when a woman is able to move intuitively with her body (Walsh, 2007). Midwives also talked about ‘following’ the women in this process.

On average, Belly Breaths, visualisation and acupressure were identified as being the more utilised CM techniques, with yoga, massage and J breaths being less utilised by women. The in-depth interviews also confirmed that women used different techniques during labour, sometimes not the ones they predicted, and sometimes related to what was practised. Partners and midwives were instrumental in providing support in using the techniques, reminding women to practice, or suggesting them during labour.

Women and partners reported in the in-depth interviews using acupressure for induction, augmentation of labour, and pain relief. Midwives reported using acupressure and massage, supporting upright positions or yoga postures, or swivelling of the hips. Midwives discussed the benefit of being able to apply these techniques to women or instruct partners when they were already educated about its
use. When women were aware of their choices and what would be beneficial for their labour process, midwives and partners were able to work with women in the labour. This was reflected in the theme of ‘getting the team on board’.

Women were knowledgeable about upright yoga postures for labour, which can enhance the body’s physiological position for optimal birthing (Smith, Levett, et al., 2011). Yoga postures, which are upright, forward and focused on opening the pelvis, were used along with techniques such as hip swivelling and low vocalisation in ‘finding what works’. These all have the purpose of facilitating physiological labour, reducing the length of labour and allowing women to feel more in control of the process, as well as reducing pain. The outcomes data for upright positions and yoga in the literature are inconsistent on this issue of augmentation (Gupta & Hofmeyr, 2004; Priddis et al., 2012).

Reports from women and midwives also suggest that increased confidence in the mother and enhanced partner and midwifery support were helpful in labour progress and in being upright and mobile. Midwives were able to suggest different positions to the women or instruct the partner, with good effect. This was also seen in the theme ‘getting the team on board’. Priddis et al. (Priddis et al., 2012) reports that the philosophies and preferences of health professionals for birthing positions impacts upon the position that women adopt during labour. The research states that what women see as culturally appropriate, as well as the influence of midwives, will affect the positions they adopt. In the course workshops and in-depth interviews, women and partners often commented that what they knew about birth often came from television, where they most often see women on their back and in lithotomy position.
One partner remarked ‘if you aren’t lying on your back, then how do you give birth?” It was a revelation to couples to practice different positions and talk about different options, and see them make sense of the anatomical benefits of being upright and forward.

In women participating in the Complete Birth Study, length of labour was also reduced, with a clear outcome of reduced length of the second stage of labour and also a reduction in the length of the first stage of labour when accounting for augmentation. The literature for acupuncture and upright birthing positions also supports this finding. In the Cochrane Review (Smith, Collins, Crowther, et al., 2011), women in the acupuncture group had a significantly shorter duration of labour. Data from upright birthing positions research show that women who were randomised to upright positions had a statistically significant reduction in the duration of first stage of labour compared with supine and recumbent positions (Lawrence et al., 2013). The Cochrane Review on relaxation and yoga (Smith, Levett, et al., 2011) finds that length of labour was reduced for the yoga group when compared to usual care, and when compared with supine position.

Our study showed a trend towards decreased instrumental vaginal birth, and the literature that investigates the effects of CM on rates of instrumental vaginal birth is mixed. Acupuncture research shows that when compared with standard care there were lower rates of instrumental vaginal births (Smith, Collins, Crowther, et al., 2011). In the overview of systematic reviews for pain management in labour, the authors state that relaxation and acupuncture were associated with fewer assisted vaginal births (Jones et al., 2012). In examining upright birthing positions and their
impact on instrumental births, the systematic review conducted by Gupta and Hofmeyr (2004) reported a reduction in instrumental births (Gupta & Hofmeyr, 2004).

One of the concerns of using natural physiological techniques, such as yoga postures and upright positions, is the potential for increased risk of perineal trauma (Gupta & Hofmeyr, 2004). The data from our research show that in women that had vaginal births, 87.1% of the study group had some kind of perineal trauma, compared with 96.4% of the control group. This trend in reduced perineal trauma was not statistically significant (RR=0.90, p=0.07). This reduction could have been due to the non-significant decrease in instrumental vaginal births, and may also reflect the breathing technique that was shown to women to use during the second stage of labour. Women were shown how to breathe using the ‘J breath’, specifically focusing on pushing from the top of the stomach muscle, relaxing the perineum and relaxing the throat. Women were instructed to wait for the baby to start to descend naturally, and not actively push.

Obstetric research investigating active pushing versus passive descent shows that there is no difference in outcomes to perineal status, however there is evidence indicating increased bladder morbidity (Bloom, Casey, Schaffer, McIntire, & Leveno, 2006; Hansen, Clark, & Foster, 2002). A Swedish study reported that increased fear will increase risk of perineal injury, and that women who give birth at home have lower rates of perineal tearing. They identified that increased communication with the midwife before the second stage of labour reduces likelihood of tearing (Lindgren et al., 2011). Dahlen et al. (2007) undertook research
with midwives that also identified lack of effective communication with the woman during the birth, as well as some birth positions, delivery technique, ethnicity and other obstetric influences, as increasing the risk of severe perineal trauma (Dahlen et al., 2007).

Many of the women in the study group reported that they were told to actively push by the midwife and that they found it very difficult to accomplish the J breath in the face of contrary coaching and lack of confidence using the technique. This was one area where the teachings in the course were in contrast to what the midwives advised during labour, and women reported that they felt unable to go against the advice of the midwife while in labour. They subsequently said that they would have liked to have discussed it earlier with the midwife, which is reflected in the research findings by Dahlen et al. (Dahlen et al., 2007) and Lindgren et al. (Lindgren et al., 2011) regarding communication.

The results for PPH and Apgar scores are important outcomes in terms of safety. There is some concern that upright positions for birth increase rates of PPH. This is discussed in Gupta’s review (Gupta & Hofmeyr, 2004), where upright positions tended to increase rates of PPH. However, they also noted the presence of asymmetric funnel plots indicating risk of publication bias. In de Jonge’s study (De Jonge, Van Diem, Scheepers, Van Der Pal-de Bruin, & Lagro-Janssen, 2007), increased risk of PPH was associated with perineal trauma and upright position. However, where perineal trauma was not present there was no increased risk of PPH. They also postulated that upright positions may include birthing on birth stool, which increases risk of oedema and therefore PPH. There was no increased risk of PPH
found in our data, and this is an important measure of safety. The two main hospitals involved in the study did not recommend birth stools, so we assumed that their use was not a risk factor. There was a non-significant reduction in major perineal trauma, which may also indicate no increased risk of PPH, as was found by de Jonge et al. (De Jonge et al., 2007). Additionally, part of the acupressure protocol was using the point Jian Jing (GB21), which is reported to stop blood loss by contracting the uterus (Betts, 2005), and is included as a forbidden point in pregnancy due to this mechanism (Betts & Budd, 2011). Some couples reported using this point if there was an indication of blood loss. It was anecdotally reported to have a good effect in stopping blood flow, until Syntocinon could be administered. Two midwives and a doctor at HKH also reported using the point with good effect for this purpose.

Women working together with partners and midwives using knowledge of normal birth and self-administered CM tools to manage labour reflects the notion of partnership discussed in the midwifery literature. The fundamental principle of partnership is the notion that women as well as midwives have expertise (Pairman et al., 2006). Providing women with information and ensuring the process of ‘informed choice’ (Leap, Sandall, et al., 2010), reflects the idea that not all options are equal (Pairman et al., 2006), and that choice and decision-making are influenced by a woman’s values, background and family, and midwives are supportive of normal birth rather than the medicalised model. Midwives facilitate this process of decision-making by listening to women and what is important to them. Decision-making has shown to be fundamental to satisfaction with childbirth and confidence in early parenting (Green & Baston, 2003; Pairman et al., 2006). However, it is the decision-
making that occurs in partnership that is crucial to women’s experience and embedded in midwifery principles (Pairman et al., 2006). In contrast, what has become fundamental to the antenatal education framework is the idea that all birth choices are presented as equal (Svennson et al., 2008; Svensson, 2005). Essentially this has evolved with the medicalisation of hospital birth, and to avoid the shaming of women who have interventions (Lothian, 2008a, 2008b; Walker et al., 2009). However, this idea sits beside the expectation that women will make choices based on the medical model, and that there is potential coercion of women to comply with hospital policies (Ferguson et al., 2013), as discussed earlier.

The importance of educating women about normal birth and ways to manage labour with non-pharmacological tools independent of routine maternity care was apparent in the study. It became clear during the study workshops that women and partners were largely unaware of all options available to them to help manage their labour and birth. Interviewees and course participants realised that the dominant perceptions and views held about labour and birth had been informed by current medical and media views that perpetuates a heavy overlay of ‘risk’ culture. They discovered many aspects of birth that were within their control, but they had never known. They were surprised at the amount of autonomy and individual preference allowed and even encouraged within the hospital system. They found midwives to be supportive of their choices, but they would have been unaware of natural options for birth and their capacity for personal control if they had not been educated about them. Midwives in the focus group talked about being able to match couples’ plans and desires with support, but it was much more difficult to facilitate physiological births for couples if
they were not already educated about their options. This was confirmed in the theme of ‘getting the team on board’, where midwives described the process of following the woman in her labour. They felt that the woman needed to be educated before labour for the tools of midwifery and CM to be effectively imparted and used. When women come into labour prepared and educated, it was easier for midwives to support them and their partner with the use of natural techniques. Midwives stated that they could then implement acupressure, relaxation, massage and other pain management techniques and work with the woman to help her cope with labour naturally. However, during the antenatal period, midwives reported not having time to educate women in the course of routine visits, and it was up to the woman to educate herself in most cases. Midwives reported that they perceived the value of having a course such as Complete Birth was in educating women and facilitating a common ground on which the midwives could meet them.

There was some evidence from the midwives’ focus group that midwives also felt that CM techniques were very useful, but that they should be under the control of the midwives. This was the only point of dissonance between the interview data and the focus group data. Midwives expressed some dislike of having partners dictate what they could do in labour, as they were the professionals. This aspect of loss of professional autonomy would be an interesting study to follow up in the future. The topic emerged from the focus group data, but there was no opportunity to corroborate this information with couples. Further research in this area would provide information about how CM is facilitated, and by whom, within the system.
7.5 Stemming the cascade of interventions

In this study, the significant primary and secondary outcomes relate to the cascade of interventions as outlined by Rossignol et al. (Rossignol et al., 2014), Tracy et al. (Tracy et al., 2007; Tracy & Tracy, 2003), Dahlen et al. (Dahlen et al., 2014) and Green and Baston (Green & Baston, 2007), where an initial medical intervention leads to further interventions to manage the effects of the first.

The literature reports a clear association of EDBs with other interventions in labour in contributing to the cascade of interventions (Rossignol et al., 2014; Tracy et al., 2007), and increasing the likelihood of other interventions in labour, including augmentation, instrumental vaginal birth and CS (Dahlen, Schmied, et al., 2013; Roberts et al., 2000b; Rossignol et al., 2014; Tracy et al., 2007). By addressing upstream factors, such as methods to reduce unnecessary use of EDBs, and using upright labour and birth positioning, as shown in this study, rates of CS and instrumental vaginal births were also reduced.

The Complete Birth Study RCT data showed that women in the control group were almost three times (RR=2.86) more likely to use EDBs than women in the study group (RR=0.37). Corresponding to the cascade of interventions, women in the control group were also more likely to require augmentation in labour, to have a longer second stage of labour, to have an instrumental or caesarean birth, and to require resuscitation for their babies, compared with the study group. Women in the study group showed a near halving of risk in use of augmentation (RR=0.54); however, the rate in the control group is higher than the reported national averages.
The *Australia’s Mothers and Babies 2011 Report* (Li et al., 2013) indicates that augmentation in labour occurred for 32.8% of mothers with spontaneous onset of labour. However, this figure reflects both multiparous and primiparous women. In our study, which included only primiparous women, we observed a higher than average rate of EDB use, which may have influenced the observed rate of augmentation. This higher rate, however, is consistent with data from primiparous women (Dahlen et al., 2012). Our data showed a strong relationship between these factors, and this finding is consistent with literature on the cascade of interventions (Roberts et al., 2002; Roberts et al., 2000b; Tracy et al., 2007; Tracy & Tracy, 2003).

Findings from antenatal education research show only a small influence on augmentation in labour. In the Cochrane Review, one trial (n=200) reported on requirement for augmentation in labour, and showed a non-significant trend towards antenatal education reducing requirement for augmentation (Gagnon & Sandall, 2007).

Reports in the in-depth interviews from women and partners who used the CM techniques to facilitate physiological labour progress report that, in particular, they used acupressure, hip swivelling and yoga to facilitate upright positions. This reflects the literature on acupuncture and upright positions for reduced requirement for augmentation. The Cochrane Review of acupressure and acupuncture (Smith, Collins, Crowther, et al., 2011) showed that women in the acupressure group used less synthetic oxytocin compared with the control group (Skilnand et al., 2002). The literature suggests that the physiological mechanism of action for the acu-point Sanyinjiao (Sp-6) is proposed to be through stimulation of oxytocin release from the
pituitary gland (Betts, 2005). Therefore, its effect would be seen primarily in the requirement for synthetic oxytocics and length of labour. This is reflected in the research findings of three primary trials of acupressure when this point alone is stimulated (Hjelmstedt et al., 2010; Kashanian & Shahali, 2010; Lee et al., 2004). In the Complete Birth Study, we instructed women and partners specifically about the usefulness of this point for induction and augmentation of labour, even when they already had an EDB (Betts, 2005). Evidence from the in-depth interviews supports the idea that women used this point to facilitate labour and that it was effective even when the woman already had an EDB. Partners describe acupressure as being ‘their number one weapon’. In ‘having a strategy’, they discussed ‘knowing what to do’ when certain issues arose in their partner’s labour, such as slow progress.

Perhaps the most important associated outcome of reduced EDB use to consider is the reduced rate of CS in this study. In the study group, 18.2% of women had a birth by CS, compared with 32.5% in the control group. This represents an absolute reduction of 14.3%, and a near halving of risk (RR=0.52, p=0.017). This outcome is of particular importance, as CS rates are the subject of much controversy and are one of the primary outcome measures used to evaluate maternity services in Australia and internationally (Bryant, 2009; Gibbons et al., 2010; NSW Department of Health, 2010; NSW Health Department, 1989a; OECD, 2013; Senate Committee, 1999). The rate of CS in this study for the control group is near to the national average in Australia of 31.3% in 2011 (Li et al., 2013), and the rate in the study group is nearing that of the recommended WHO target of 15% (Gibbons et al., 2010; OECD, 2013; WHO & HRP, 2015). The recently released WHO report (WHO & HRP, 2015)
continues to state that there is no increased benefit of a CS rate below or above 10-15%.

Evidence from the literature is clear that an association exists with intrapartum interventions, including augmentation of labour and EDBs (Dahlen, Schmied, et al., 2013; Green & Baston, 2007; Tracy et al., 2007). Green’s study (Green & Baston, 2007) examining ‘willingness to accept intervention’ scores found that high willingness scores were a significant predictor of EDB use, and EDB use was strongly related to mode of birth. In Green’s cohort, women who had an EDB, compared with those who did not, had 5.93 times greater odds of a CS or instrumental vaginal birth.

A clear relationship was demonstrated in our study between EDB, augmentation and CS. Where an EDB was used for pain relief, there was a highly significant association with the use of Syntocinon for augmentation of labour, and both augmentation and EDB showed a strong association with CS. This finding is consistent with current research, which is clear about the relationship of EDB, augmentation and CS (Dahlen, Schmied, et al., 2013; Rossignol et al., 2014; Tracy et al., 2007; Tracy & Tracy, 2003). In the Cochrane Review (Anim-Somuah et al., 2011) of EDB versus non-EDB or no pain relief, EDB use was not shown to increase risk of CS. However, the majority of the trials compared EDBs with opioids, and the non-significant effect is thought to be due to the high crossover in the study groups.

Some CM data for acupuncture and acupressure are also supportive of these findings for reducing the impact of the cascade of interventions. The review reports a reduced
rate of pharmacological pain relief and CS. The Cochrane Review (Smith, Collins, Crowther, et al., 2011) on acupuncture and acupressure of pain relief in labour reports that when acupuncture was compared with placebo and standard care, there was reduced use of pharmacological analgesia; and when acupressure was compared with placebo, there were lower rates of CS. However, this has not been consistently reported. Data for other CM therapies do not show reduced CS rates. Additionally, data from antenatal education interventions and psychoprophylaxis and hypnosis data do not show any reduction of analgesic use or CS rates (Bergström et al., 2009b; Byrne et al., 2014; Cyna et al., 2013; Gagnon & Sandall, 2007; Koehn, 2002; Madden et al., 2012).

There are significant data in the literature demonstrating a clear relationship between the use of EDBs and the requirement for instrumental assistance in vaginal births (Dahlen, Schmied, et al., 2013; Roberts et al., 2000b; Rossignol et al., 2014; Tracy et al., 2007). In the present study, there was a non-significant trend towards reduced instrumental vaginal births, in accordance with the literature. In the study group, 13.6% of women gave birth assisted by forceps or vacuum, compared with 20.5% of the control group (RR= 0.57, p=0.09). While this study was not adequately powered to demonstrate a reduction in this outcome, it is important to highlight this within the context of the cascade of interventions, as EDB use has been shown consistently to be associated with higher rates of instrumental vaginal births (Dahlen, Schmied, et al., 2013; Dahlen et al., 2014; Roberts et al., 2002; Roberts et al., 2000a; Rossignol et al., 2014; Tracy et al., 2007). Australian data show that about 1 in 9 mothers (12.1%) had an instrumental vaginal delivery with either forceps or vacuum (Li et al., 2013).
Data from the *NSW Mothers and Babies Report 2010* state that in the Northern Sydney region, which is where the majority of this study’s participants were recruited from, the rates for forceps and vacuum were 13.2% (Centre for Epidemiology and Evidence, 2012). These data are reported for primiparas and multiparas, which may differ from rates in primiparas alone. The results from our study are also in contrast to that of psychoprophylaxis research (Bergström et al., 2009a), that showed no reduction in instrumental birth rates, with instrumental births in 12% of the standard group compared with 14% of the natural group. However, results from acupuncture and acupressure data are supportive of reduced rates of instrumental births when compared with standard care and placebo (Smith, Collins, Crowther, et al., 2011).

The data in our study also show a reduced length of the second stage of labour. The study group had an average length of second stage of 1 hour, and the control group had an average length of second stage of 1 hour 19 minutes: this represents a mean difference of 0.32 hours (19 minutes). Clinically, this is an important outcome, as this represents a 24% decrease in time for the study group. The length of first stage of labour for both groups was relatively short, with the average time being 6 hours 7 minutes for the study group, and 6 hours 32 mins for the control group, calling into question how length of labour is defined. While there was a decrease of 25 minutes, this was not statistically significant. However, given the significant interaction of augmentation and length of first stage of labour and total length of labour, when augmentation was accounted for in the analysis, women in the study group had a significantly shorter labour than women in the control group. This is an
interesting outcome when considered in terms of the cascade of interventions. Reducing the requirement for augmentation did not adversely affect length of labour and this is an important clinical contribution for this study. As discussed previously, this finding is consistent with some CM and midwifery literature, such as the literature on acupuncture and acupressure (Smith, Collins, Crowther, et al., 2011), relaxation and yoga compared with usual care and supine position (Smith, Levett, et al., 2011), and upright birth positions compared with supine and recumbent positions (Lawrence et al., 2013).

Significantly, our data showed a decreased requirement for resuscitation of the newborn. In the study group, this represented a decreased risk of more than half (RR= 0.47, p=0.015). This is a highly significant result, and refutes the concern that natural birth methods increase risks to the baby. The *Australia’s Mothers and Babies 2011 Report* (2011) states that suction and oxygen therapy were the most common types of resuscitation used for babies. Nearly one quarter (24.3%) of all Australian babies required some form of resuscitation at birth, and two thirds of these babies (64.9%) required only suction or oxygen therapy. The data in our study show slightly higher rates of resuscitation for the control group babies, but this is in keeping with the higher than average rates of EDB use, augmentation, instrumental and caesarean birth seen in the control group. There were no differences between the groups for requirements for intubation or cardiac massage.

In terms of major perineal trauma, determined as 3<sup>rd</sup> or 4<sup>th</sup> degree tears, there were no significant differences between the groups (RR=0.82 [0.41-1.61], p=0.56), however, the study was not adequately powered to detect a difference for this rare perineal
outcome. There were also no differences between the groups for rates of PPH, Apgar scores less than 7, at 5 minutes, or admission to the SCN/NICU. With reduced CS, instrumental births and augmentation rates, we may have expected to find some difference in these outcomes; however the study was not adequately powered to detect a difference in these rarer events.

Data from our study show that the control group cohort had a higher rate of EDB use, augmentation and instrumental vaginal births compared with rates reported in the literature in Australia (Dahlen, Schmied, et al., 2013; Tracy et al., 2007) and the UK (Green & Baston, 2003). This could be reflective of recruiting a more highly anxious group of women, which is consistent with some of the literature (Rouhe et al., 2013), or could reflect different rates for primiparous women (Li et al., 2013).

In the present study, the partner aimed to provide continuous support, and it was stressed how important their role was in helping to facilitate normal birth. Explicit information and role-playing exercises were provided to teach partners how to support the mother with physical touch, kind words, protective support to allow her to become internally focused, suggestions for positions, counting for breathing, and so on. While this did not constitute ‘continuity of care’, partners aimed to facilitate labour by providing continuous support. The women in this study were not part of any continuity of care midwifery programs, as this was an exclusion criteria due to the demonstrated improvement in outcomes for women in these programs (Hatem et al., 2008).
Data from the in-depth interviews show how understanding normal labour can influence couples’ approaches to birth. During the Complete Birth Course, couples became aware of how their mindsets had been quite ‘medicalised’ and heavily influenced by our dominant cultural perceptions of medicine as a tool for risk management and labour and birth as dangerous events (Davis-Floyd, 2001). The ‘fear-tension-pain’ cycle concept (Dick-Read, 1957) was used to develop couples’ understanding of how their body and mind are connected (Davis-Floyd, 2001) and how their emotional state can influence the physiology involved in labour and birth (Buckley, 2002). Originally proposed by famous British obstetrician, Grantly Dick-Read (Dick-Read, 1957), the fear-tension-pain cycle has been reiterated by many authors since and is a central tenet of psychoprophylactic or hypnosis training for childbirth, such as the Leboyer method (Nelson et al., 1980), Lamaze techniques (Lamaze, 1970), and hypnosis for childbirth which has now been the subject of a Cochrane Review (Jones et al., 2012). The fear-tension-pain cycle is a useful theory to help women contextualise the hormonal cycle involved in normal childbirth and then how and why the techniques are useful in helping them relax and allow the natural hormones to help facilitate birth. Dr Sarah Buckley (Buckley, 2002) writes about the idea of allowing women to go deep inside themselves and letting the ancient reptilian part of the brain, and limbic system, take over from the cortex, where intake and analysis of extraneous stimuli are received. While these concepts are part of hypnosis training, the tools and techniques in this study are not hypnosis techniques. The idea of the fear-tension-pain cycle was described to women in the study to give them a context for using the tools. Its antithesis; the ‘faith-relaxation-pleasure’ cycle, was also discussed to give them some ideas of what couples could do
to facilitate labour, rather than just what not to do. This positive, strengths-based approach was seen as important. Women in the in-depth interviews discussed how they used these ideas of fear-tension-pain, and faith-relaxation-pleasure to mentally approach their labour.

7.6 Study strengths

Using an MMR approach to this research has provided rich and robust methods to test and confirm the study aims and hypotheses. This is the main strength of this study. The ability to conduct an RCT to examine the direct effects of the program has shown strong evidence for antenatal education providing self-managed CM techniques. However, the reasons for women, partners and midwives connecting with the program, how they used the tools, and what they considered to be the most beneficial part of the program could only be examined by talking with them in in-depth interviews and focus groups. Had this study only focused on using an RCT methodology, an abundance of rich and explanatory data would have been lost. We need to hear women’s voices in research, and observe the direct impact that research has on their wellbeing and their empowerment in a paternalistic maternity setting. This was highlighted by using a feminist lens through which to view this research.

The two original hospital sites, HKH and Nepean, were chosen on the basis of their similar rate of EDB use (around 46%), and because they represented two diverse demographic areas of Sydney. Previous research had highlighted that CM use is higher in women who have higher educational attainment, higher income status, and poorer self-rated health (Adams, Easthope, et al., 2003; Adams et al., 2009;
MacLennan et al., 2002). The Northern and Western areas of Sydney are disparate in terms of average education, income status, and health (Australian Bureau of Statistics, 2012), allowing the researchers to examine the influence of these identified factors on the outcomes of the study.

Women in our study were mostly from the top two income brackets, which is in line with the CM research on likely users of CM in Australia (Adams, Sibbritt, et al., 2011; Adams, Sibbritt, et al., 2003), but were diverse in their educational attainment, which is contrasting. This is a strength as it allows for a meaningful comparison; however, it is also a weakness as discussed below.

There were some differences evident between the participants from each study site, such as age, educational attainment, and cultural background. Participants from the UWS group were also more likely to be in private care or in a GP share-care model. This was an important contribution of the study as women from different demographic backgrounds are represented from the study sites. There were no significant differences between the three groups with regard to income, BMI, and previous use of CAM therapies. Overall, all the women were classified as low-risk primiparas, were around 30 years of age, were likely to be in the top two income brackets and to have post-secondary qualifications. Stratification of sites and subsequent randomisation accounted for the variation that was present, and there were no significant differences when the study group and the control group were compared for age, educational attainment, and income status. This is a strength of this study. While there was a significant difference in gestational age at entry to the
The difference of 1 week and 1 day, this was not thought to be clinically significant.

The use of EDBs was used as the primary outcome measure for this study, rather than pain scores, as EDBs are a mediating factor influencing labour interventions and mode of birth as outlined in the literature describing the cascade of interventions (Dahlen et al., 2012; Green & Baston, 2007; Roberts et al., 2000b). The literature shows clear associations of EDBs with instrumental births and CSs (Dahlen et al., 2012; Roberts et al., 2000b), and maternity services reviews worldwide are calling for a decrease in rates of CS in developed nations (Gibbons et al., 2010; Lauer et al., 2010; NSW Department of Health, 2010; Royal College of Midwives, 2012). This is a highly valuable outcome and a major contribution of this study.

This study extends current CM literature regarding pain management with a primary focus on reduced pharmacological management and the methodology takes into account the concurrent measurement of other moderating factors such as ‘agentry’. This study adopted the use of pharmacological pain relief, specifically EDB, as the main outcome measure. This is an objective measure that can be compared with the literature for antenatal education (Gagnon & Sandall, 2007), and some of the CM literature (Smith et al., 2006). However, the majority of the CM literature has reported on pain scores as the primary outcome measure (Cho et al., 2010; Lee & Ernst, 2004; Smith et al., 2006). Pain scores were considered a very subjective measure and pain perception has been shown to be influenced by many factors such as confidence, environmental factors, caregiver support, and learned values and attitudes to the perception and expression of acute pain (Green & Baston, 2007;
It has been suggested that using pain scores may underestimate and undervalue the contribution of CM in the management of labour pain, as discussed in Chapter 3 (Citkovitz et al., 2011; Levett et al., 2014).

The literature also tells us that the removal of pain does not necessarily lead to greater satisfaction with the birth experience (Morgan et al., 1982; Rainville et al., 2005; Villemure & Bushnell, 2002; Wesselmann, 2008). Therefore, we were aiming to help women change their relationship to pain and work with it, as proposed by Leap (Leap, Dodwell, et al., 2010). By working with their bodies, women developed trust that their bodies could give birth naturally. It was explained to partners that their role was not to take the pain away, but support their partner with some external tools or resources to confidently manage the experience, and support women to use their own inner tools or resources. The MMR design of this study supported examining these outcomes in a rich and interesting way to provide insight into the way in which women used CM to manage labour pain, and work with partners and midwives in their labours.

### 7.7 Study limitations

Limitations of this study included relatively fewer participants enrolled from Nepean. In the whole cohort, most of the participants were English-speaking and Caucasian in origin (80%). The HKH cohort was 75% Caucasian, and 20% were women from an Asian background, which was the next largest group. The majority of recruitment occurred at HKH (58.5%), and perhaps the study outcomes are reflective of the
population at that hospital primarily. Despite having a third of the birth rate of Nepean, increased recruitment at HKH was likely for several reasons. The study approval from Northern Sydney LHD ethics occurred within two months of submission, whereas site-specific approval from the Western Sydney LHD took 11 months, which significantly delayed the project at that hospital. To achieve recruitment goals, a third group was created at UWS during this time. This site was approved within two months, thereby boosting recruitment. When recruitment did begin at Nepean, the process of contacting women was relatively straightforward; however, comparatively fewer women expressed interest, and when they did consent to participate and were randomised to the study group, only turned up to the workshop in half of the cases. Research by Adams indicates that women of lower socio-economic background and educational attainment are less likely to use CM. The women who did participate from Nepean were comparatively less well educated, but were equal in socio-economic status to the HKH and UWS sites, so the sample from Nepean may not be representative of the population who give birth at that hospital. The recruitment of these relatively wealthy, well-educated women is supported by the literature; however further investigation into the reasons for non-participation would provide insight and direction for targeting future studies with a broader population. However, the highest rates of EDB use and CS are also among this advantaged population.

Additionally, there was a much greater interest and ‘buy-in’ from women and staff at HKH. Women referred their friends, who were also giving birth at HKH, as well as at the associated Royal North Shore Hospital (RNSH), Manly and Mona Vale
Hospitals for the UWS group, further enhancing recruitment from the Northern Sydney area. The majority of recruitment time was spent at HKH, with greater incentives to commit time and energy to increasing recruitment. Additionally, women from both groups completed the LAS (Hodnett & Simmons-Tropea, 1987) within 72 hours of giving birth. This was a significant logistical undertaking to ensure all women were able to complete the questionnaire within this time frame. Hospital staff at HKH in particular provided a great deal of advocacy and support for research and ensured the collection of data for this study. The implications for resources required for research is evident in the actual undertaking of research. Overall, this may have affected the recruitment strategy and rate, and potentially created some bias in the sample. Women who participated in the study were generally in the highest two income brackets, and in the HKH and UWS cohorts, 70% had at least university qualifications, and 40% in the Nepean cohort.

Of the 171 women, only 141 (82%) provided responses to the lifestyle questions, and the missing data are mainly from the Nepean sample, particularly from the control group. As this may be a source of reporting bias when included in analyses, we conducted tests of variance to ensure equality when performing each statistical test. While the women from the control group at Nepean were less likely to complete their baseline demographics form, the main outcome data from hospital-based data sources were obtained for all women who remained in the study (n=171). Where there was significant between-group variance in the data, the variable was omitted from the analysis, such as for the item ‘previous CAM use’. There was a non-significant difference between the study group and the control group with respect to
this item, which seemed largely to be due to the non-response of the control group. This may indicate study group’s women wanting to please the researchers by answering positively to this item when randomised to the study group, and the control group’s women disengagement from responding. This may skew the data collected for lifestyle and demographic questions.

Less than half of the control group (49%), and 71% of the study group completed the 6-week questionnaire. Given the large attrition for this form, the data are too unreliable to make any comment about the effect of the course on postnatal depression for this group. This is a limitation of this study.

As women have become more willing to accept medical interventions over time, as reported by Green (Green & Baston, 2007), the rates of EDB use are increasing, particularly in primiparas. In Green and Baston’s study, primiparous women who scored higher on willingness to accept interventions demonstrated an increased risk of EDB use by a magnitude of 5.93-fold [95% C.I.: 5.93 3.88–9.05] compared to women who scored low on willingness to accept interventions. The Australia’s Mothers and Babies 2011 Report (2011) states that of first-time mothers who laboured, 86.2% had some form of pharmacological analgesia administered, which was markedly higher than the proportion of multiparous women (67.1%) who had analgesia (Li et al., 2013). This current cohort of women in the control group may have been more willing to accept interventions than the study group; however, this variable was not assessed in this study. Being primiparas may have led to a higher use of EDBs. Additionally, the nature of the study may have attracted women who were more highly anxious about their birth, and at increased risk of requiring pain
management for labour, which may be reflected in the control group. However, we did not assess this at baseline, therefore it is difficult to say what levels of anxiety were present. Baseline ‘attitude towards birth’ scores were similar in the study group and the control group, which is a strength of using mixed methods. Anxiety measures would however be a useful to include in future studies.

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 primiparous women compared with multiparous women (Dahlen et al., 2012). The data for EDB use in this study are consistent with rates for women who are identified as being highly anxious (Rouhe et al., 2013; Sjogren & Thomassen, 1997). In a 1997 study examining birth outcomes for women with extreme anxiety, researchers found that 79% of their study group had either an EDB or pudendal block, which was significantly greater than the non-anxious reference group (p<0.002) (Sjogren & Thomassen, 1997). In a more recent study in Finland, women with a severe fear of childbirth used EDBs in about 85% of cases in both the study group and the control group (Rouhe et al., 2013).

While this baseline characteristic was not measured, and the participants in this study were not recruited or categorised on the basis of anxiety or fear of childbirth, the literature demonstrates the potential effect on rates of EDB use when women are more anxious than usual. This suggests the possibility of a beneficial effect on fear reduction through the Complete Birth program. This possibility is interesting and warrants further investigation. Randomisation however, should ensure that this
characteristic was evenly distributed between the two groups making the comparison valid.

This study did not include women who had had a previous birth, and the results may have been different for multiparous women. However, the literature focusing on primiparous women allowed a comparison without any confounding effects of previous experience.

With regard to the ATBQ (Humenick & Bugen, 1981), we did not conduct this questionnaire at a second time point with the control group. The significant change seen in the study group scores may have reflected a natural change in attitude over time as birth was approaching, rather than as a result of the course. The control group were not re-evaluated for logistics reasons, as it was considered an increased burden on women to complete additional questionnaires, and a potential risk to loss-to-follow-up statistics, if they perceived participation as contributing to additional unnecessary paperwork. On reflection, it would have been useful to re-evaluate the women in the control group to ascertain whether this increased positive feeling towards birth was a natural occurrence with the passage of time.

Additionally, the low return rate for the 6-week post-partum EPDS may have underestimated the rate of postnatal depression that was present in the women, in particular the control group where less than half the women returned the form.

The lower response rates seen in the control group may be associated with women not being blinded in the study. It was thought that blinding of women and the
researcher was impractical in this pragmatic trial. The outcome assessor was, however, blinded to treatment allocation.

It is also acknowledged that research bias is possible in the interpretation of in-depth interviews and focus group data. I have maintained awareness of the possible influence of my own personal experience and background as a practitioner of CM, and value the corroborative nature of MMR in validating findings from different data sources. The women who participated in the in-depth interviews all had a vaginal birth, and only two had adverse outcomes, resulting in being assisted with forceps. Women who agreed to participate may therefore reflect more strongly those who had positive outcomes and we may not have heard voices of dissatisfied women and partners. Additionally, as I was the only person who conducted the study groups, there may have been some effect due to my personal approach. This is relevant in terms of the difficulty faced in adequately controlling for extraneous influences where blinding is not present in RCTs. Due to the nature of the trial, blinding was not possible, however, it is a limitation in terms of interpreting the influence of the study course alone. This issue of blinding is problematic in areas of maternity care, CM and other allied health alike due to the nature of interventions.

7.8 Study implications

7.8.1 Implications for practice

These are very significant results in light of the current climate of medicalised birth and unprecedented rates of medical intervention. The current state of medical interventions during labour and birth requires urgent attention, and the NSW Health
Policy *Towards Normal Birth in NSW* sets guidance for hospitals to work to lower the rates of medical intervention in hospitals. This study provides evidence for an educational CM intervention that can assist in accomplishing this aim.

Current antenatal education has undergone a distinct shift towards acceptance of all births as normal and preparing women for hospital-centred births. Preparation for normal labour has been de-emphasised in classes, and requires a reorientation towards normal birth. The results from this study suggest that additional content focusing on mental and physical preparation and using CM tools to support the process are beneficial for women, partners, babies and the midwives who care for them.

The study was carried out through the antenatal unit of two public hospitals, representing two different demographic groups in Sydney. The course was in addition to usual care, and was popular among the women and midwives, and seen as supportive to midwifery practice in the antenatal period. This study demonstrates the effectiveness of providing an independent educational program using evidence-based practices and an interdisciplinary approach, through the public hospital system. This research provides us with an opportunity to contribute a valuable dialogue to inform evidence-based policy decision-making addressing the specific challenges of current antenatal education and maternity care in NSW. To this end, the Complete Birth Study has provided concepts of independent antenatal education, complementary therapies, and input from midwifery philosophies to make a change to the way women view labour and birth. This research not only directly addresses issues of increasing rates of medical intervention, but it also challenges the underlying
philosophical position and value system of the dominant medical-led system of maternity care and the constructs and philosophy on which we base our systems of antenatal education (Ferguson et al., 2013; Lothian, 2008a, 2008b; Svensson, 2005; Walker et al., 2009).

7.9 Future research

The use of CM is becoming very popular in Australia and overseas, and a growing evidence base suggests its usefulness in a variety of maternity settings. Further health services research is now needed. Research focusing on implementation within the maternity system and delivering to diverse populations would help reveal the potential for effectiveness in the broader population. Future research should concentrate on effective delivery as an independent program with trained educators facilitating its implementation. This program should also be tested in a broader, more populous setting in Australia, and in international settings such as in the UK where support for midwifery-based care and normal birth are extremely strong.

Policy initiatives supporting normal birth require novel solutions, and this study provides good evidence for such a solution. Future health services research following on from this study should include translation of study outcomes into clinical practices, which might involve a cost-effectiveness study; exploring key stakeholders’ views about changing practice; and incorporating larger data sets to assess the impact of the study in a broader context. Within the concept of evidence translation research, a follow-up study of participants who have had a second birth may provide insight into the flow-on effect of the program.
7.10 Conclusion

The potential benefits of the management of labour with evidence-based CM techniques delivered through a complex antenatal education program are novel and promising. The rising rates of interventions in normal births require action to reduce the morbidities associated with these, as outlined in *Towards Normal Birth in NSW* (NSW Department of Health, 2010). The promotion of birth as a normal physiological event and education centred on this theme will help establish non-pharmacological methods to manage the birth process. The results from this study demonstrate the effectiveness of the Complete Birth Course to provide a holistic, evidence-based, woman-centred approach to care, and to reduce medical interventions and morbidity in labour.

This weekend workshop incorporated six different evidence-based CM practices, providing women, their partners, and the midwives caring for them with tools and techniques to effectively manage labour pain and avoid using EDBs. However, the workshop provided more than just tools and techniques: it gave information, education, awareness and empowerment. It provided a way to engage with and embrace birth, with all its uniqueness and commonplaceness. The couples engaged with each other, with their birth and with their midwives, and they gained an understanding of labour and birth to enable the ‘how, why and when’ to use the CM techniques available to them. This study highlights the effectiveness of a complex antenatal education approach, incorporating CM techniques to address the problem of increasing intervention rates in Australian maternity hospitals.


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APPENDICES LIST

A. Published article – Levett et.al. 2014

B. Protocol

C. Human ethics approval NSLHD

D. Human ethics approval Nep

E. Human ethics approval UWS

F. ANZCTR approval

G. Insurance certificate

H. Advertising script

I. Participant info sheet

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N. Participant booklet

O. D.Betts acupressure protocol

P. Yoga postures
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T. Attitude towards birth questionnaire

U. Questions for interviews

V. Focus group questions