Acupressure for post-date pregnancy: a sequential mixed-methods feasibility study

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as part of the collaborative doctoral degree and/or fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

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Do not follow where the path may lead. Go instead where there is no path and leave a trail. – Ralph Emerson

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Statement of contributions to jointly authored works contained in the thesis

This thesis consists of four publications that were produced during my PhD candidature and that are incorporated as chapters 2, 4, 5 and 7. All four publications are data-based papers that involve analysis of primary or secondary data to create new insights, and are published in peer-reviewed scholarly journals.

Publication details for each chapter are outlined below, together with statement of contribution and percentage contribution for each author. The publications are included with permission of Elsevier.

INCORPORATED AS CHAPTER 2

Mollart. L. (LM), Adam, J, (JA) & Foureur, M. (MF). 2015, '**Impact of acupressure on onset of labour and labour duration: a systematic review**', *Women and Birth*, vol. 28, no. 3, pp. 199–206. DOI:10.1016/j.wombi.2015.03.007.

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Other relevant published works by the author not forming part of the thesis

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Mollart, L., Foureur, M. & Skinner, V. 2015, 'Pregnant women and health professional's views on CAM in pregnancy specifically acupressure and being involved in a randomised controlled trial', *Women and Birth*, vol. 28, S1, p. S50. 19th Biennial National Conference Australian College of Midwives, Gold Coast, Queensland.

Mollart, L. 2017, 'Midwives and complementary and alternative medicine (CAM): personal use and impact on clinical practice', paper presented at the *9th Virtual International Midwives Day Annual On-line Conference*, 5 May 2017. (https://vidofmid.wordpress.com/midwives-and-complementary-and-alternative-medicines-cam-personal-use-and-impact-on-clinical-practice).

Mollart, L., Skinner, V. & Foureur, M. 2017, 'Midwives and pregnant women's partnership: conversations about complementary and alternative medicine (CAM)', Conference Abstracts Book of the *3rd Australian Nursing and Midwifery Conference: Collective Conversations,* Newcastle, NSW, 14–15 October.

Mollart, L., Skinner, V., Foureur, M. 2017, 'Australian Midwives and complementary and alternative medicines (CAM): what is the practice out there?', paper presented at the *20th Biennial National Conference Australian College of Midwives*, Adelaide, South Australia, 30 October – 2 November.

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Abbreviations

ACM	Australian College of Midwives
AIHW	Australian Institute of Health and Welfare
ALSWH	Australian Longitudinal Study on Women's Health
CAM	Complementary and alternative medicine
CHBQ	CAM Health Belief Questionnaire
CI	Confidence Interval
CS	Caesarean section
CMP	Community team Midwives Program
CTG	Electronic fetal monitoring
DAU	Day assessment unit
EPO	Evening primrose oil
FRCT	Feasibility randomised controlled trial
GP	General Practitioner
HREC	Human Research Ethics Committee
LHD	Local Health District
MAC	Midwife Antenatal Clinics
MGP	Midwifery Group Practice
MCRMR	Maternity Clinical Risk Management Committee
NCCIH	National Centre for Complementary and Integrated Health
NMBA	Nursing and Midwifery Board of Australia
NPT	Non-pharmacological treatment
NSW	New South Wales
NSWNMA	New South Wales Nurses and Midwives Association

NSWNMB	New South Wales Nurses and Midwives Board
PR.E.P.A.RE	PRimigravida Experiencing Post-date pregnancy Acupressure REsearch
RA	Research assistant
RCT	Randomised controlled trial
SA	South Australia
SPSS	Statistical Package for Social Science
TCM	Traditional Chinese medicine
US	United States
UK	United Kingdom

Acupressure—meridians

BL	Bladder
GB	Gall bladder
KI	Kidney
LI	Large intestine
SP	Spleen

Abstract

Around one-quarter of women experiencing their first full-term pregnancy continue past the due date, leading to an induced labour with potential negative sequelae. Acupressure may increase the likelihood of spontaneous labour onset in post-date pregnancy, but current evidence is very limited and of poor quality. There is also scarce information on complementary and alternative medicine (CAM) strategies that midwives in Australia discuss or recommend to women experiencing a post-date pregnancy.

Aim

This project aimed to assess the feasibility of undertaking a randomised controlled trial (RCT) of acupressure for post-date pregnancy in the Australian maternity setting by addressing the eight components of 'feasibility': acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing.

Methods

A sequential mixed-methods study was undertaken. Study 1: a feasibility RCT of acupressure to assist spontaneous labour onset for primigravid women experiencing a post-date pregnancy (n=44), together with a survey of trial participants (n=29) and five focus groups with health professionals (n=25). Study 2: a national survey of members of the Australian College of Midwives (n=571/3552) regarding their professional discussions, personal use, attitudes and knowledge of CAM, particularly acupressure, for post-date pregnancy. Quantitative analysis included descriptive and logistical regression modelling (SPSS v.23); thematic analysis was undertaken for qualitative data using generic qualitative description.

Results

The RCT was feasible in this setting, where acupressure is an established part of clinical practice. Randomisation was well received, with 65.7% of eligible women willing to participate, and compliance with the acupressure protocol was high (81%).

The representative national survey found that most midwife respondents discuss (91.2%) and recommend (88.6%) self-help/CAM strategies to women experiencing a post-date pregnancy. Midwives were more likely to discuss strategies if they personally used CAM ($p<0.001$), were younger ($p<0.001$) or had worked fewer years as midwives ($p=0.004$). Australian midwives demonstrated interested in learning about CAM and 50% had completed some form of CAM education.

Conclusion

While providing valid and important insights into the components of feasibility, the small number of women and staff participants in Study 1 limits generalisability of the findings. An acupressure RCT is feasible, but may need to be conducted in settings where acupressure is not an established part of clinical practice to ensure that the required sample size of 994 (80% power, $\alpha=0.05$) can be met. Two implications arising from this study are the need for a CAM module in midwifery education curricula, and the publication of a national position statement on midwifery practice and CAM.

Chapter 1: Introduction

1.1 Chapter overview

This chapter provides a brief introduction to the issue of concern for this thesis: complementary and alternative medicine (CAM) use in maternity care, particularly the use of acupressure for post-date pregnancy and whether it is feasible to conduct randomised controlled trials (RCTs) to test its efficacy. This introduction outlines the thesis context, which is presented in detail subsequent chapters through a series of related publications arising from original research. It also explains the overall thesis aim and the objectives of each component of this mixed-methods study, and offers an overview of the study design.

1.2 Background

Pregnant and birthing women have been identified as substantial CAM users internationally and in Australia (Adams, Sibbritt & Lui 2011; Bishop et al. 2011; Gaffney & Smith 2004b; Kalder et al. 2011; Lapi et al. 2010; Skouteris, Wertheim & Rallis 2008; Steel et al. 2012). In 2013, when this study began, limited research had been conducted on the use of specific CAM modalities, such as acupressure, for women whose pregnancies extended beyond their due date (Ingram et al. 2005). There was also little information on the CAM strategies midwives in Australia discuss or recommend to women experiencing post-date pregnancy. This apparent lack of research may be because it is challenging to undertake research using CAM modalities, particularly in Australian maternity care settings, an issue that this thesis explores. For pregnant women, ‘going overdue’ is a relatively common but emotional event that often results in an induced labour with potentially serious consequences, such as increased risk of caesarean section (CS) operations (Patterson et al. 2011; Roberts et al. 2012). While CS can be lifesaving, it is also important to consider that it increases rates of short- and long-term maternal and neonatal morbidity (Villar et al. 2007; Souza et al. 2010). Therefore, there is a need to conduct appropriately powered RCTs to establish whether acupressure is an effective therapy to stimulate the spontaneous labour onset in post-date pregnancy. The research conducted for this thesis thus addresses an issue of significant concern.

My interest in CAM stems from my 30 years of professional, clinical midwifery practice, particularly in antenatal care. I am also an experienced CAM practitioner who teaches acupressure and reflexology to midwives in three countries (Australia, New Zealand and Japan), and have presented at national and international conferences on the topic of CAM in maternity care. Midwives are ideally placed to recommend CAM, as they work with women throughout many months of pregnancy, during childbirth and up to six weeks after a baby's birth. In my experience, many midwives actively recommend CAM to pregnant women. Therefore, establishing an empirical basis for such practices is an imperative undertaking.

The following section presents the research aims and objectives and provides a brief overview of the study design and methods, including a description of the project's structure.

1.3 Aim

This research project has one primary aim:

To determine the feasibility of conducting an Australian trial of acupressure, a CAM modality, focusing on acupressure for post-date pregnancy.

1.4 Objectives

To address the above aim, the project has four objectives:

1. to undertake a feasibility randomised controlled trial (FRCT) on the efficacy of acupressure to initiate spontaneous labour onset for primigravid women experiencing post-date pregnancy
2. to explore participant women's views of acupressure, CAM and RCTs to increase understanding of the feasibility of RCTs in this area
3. to explore participant health professionals' views of acupressure, CAM and RCTs to increase understanding of the feasibility of RCTs in this area
4. to conduct a national survey of Australian midwives exploring their practices, beliefs, knowledge, skills and training in CAM and acupressure to increase understanding of the feasibility of conducting trials in using acupressure and CAM modalities during pregnancy and birth.

1.5 Study design and thesis structure

This thesis adopted a sequential mixed-methods design with two linked studies: Study 1 and Study 2. Study 1 addresses the first three objectives, and Study 2 addresses the fourth objective. Both studies contribute to meeting the primary aim. The thesis also includes four first-author publications, presented in chapters 2, 4, 5 and 7.

Chapter 2 brings together the literature describing two distinct fields of knowledge and information: 1) 'keeping birth normal', which focuses on increasing spontaneous labour onset by reducing medical interventions such as inducing labour for post-date pregnancies, and 2) CAM and self-help strategies to initiate uterine contractions when approaching or going past the due date. An integral component of this chapter is a systematic review on the effect of acupressure for initiating uterine contractions and labour duration; this is included as **Publication 1**.

Study 1 is detailed in chapters 3–5. ***Chapter 3*** justifies using the sequential mixed-methods study design, and provides details of the three components that comprise Study 1 and a description of the methods used to collect and analyse the data in each component. The mixed methods include an feasibility RCT that measured maternal and neonatal clinical outcomes, an RCT participant women's postnatal survey and focus groups with maternity health professionals at the study sites. The chapter also describes in detail the ethical considerations, sample selection procedures, data collection and processes of quantitative and qualitative data analysis and interpretation. ***Chapter 4*** explains the outcomes of the FRCT (**Publication 2**) and addresses some of the eight feasibility focus areas of acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing. ***Chapter 5*** reveals the findings of the FRCT participant women's survey and provides the thematic analysis of the maternity health professionals' focus groups (**Publication 3**). The four themes that emerged from the women's survey were 'Using CAM to start labour', 'Feeling empowered through action', 'Desiring randomisation to acupressure group' and 'Welcoming the opportunity to assist in research'. The five themes that emerged from the health professional focus groups were 'Personal awareness and

attitudes towards CAM', 'Supporting and empowering women', 'Complements the wellness model of pregnancy and childbirth', "Need for evidenced based practice' and 'Randomisation "doing it on the sly"'. This chapter also details the rationale for further research that focuses on CAM use among Australian midwives, which was undertaken in Study 2.

Chapter 6 describes Study 2, and includes a review of the literature exploring midwives' views and attitudes towards CAM, midwives' CAM education and organisational and professional support for using CAM in clinical practice. This chapter details the design of the National Survey of Australian Midwives on CAM and self-help strategies. The national survey results are presented in three separate chapters, as they provide details of separate aspects of the survey. ***Chapter 7*** gives the findings in relation to midwives' personal use of CAM and the effect of this personal use on their discussing and recommending self-help and CAM modalities to women experiencing post-date pregnancy (**Publication 4**). ***Chapter 8*** describes the findings in relation to midwives' beliefs and views on CAM, including findings from the CAM Health Belief Questionnaire (CHBQ) and support for integrating CAM/self-help options into clinical practice (Lie and Boker 2004). ***Chapter 9*** details the findings concerning midwives' training and education regarding CAM modalities.

The concluding chapter, ***Chapter 10***, discusses key findings from chapters 2–8 explores the limitations of the sequential mixed-methods study. Reflecting upon the findings from this program of research, I then propose a way forward to increase education on CAM in undergraduate and postgraduate midwifery programs, and posit the need to develop a national position statement on midwifery and CAM. The chapter concludes with proposing a future, fully powered RCT on the use of acupressure to stimulate spontaneous labour onset for primiparous women experiencing a post-date pregnancy—an RCT that includes an acupressure placebo and addresses the critical issue of feasibility.

1.6 Chapter summary

This chapter has provided a brief overview of the issue of concern for this thesis; CAM use in maternity care, particularly the use of acupressure for post-date pregnancy and whether it is feasible to conduct an RCT in Australia to test its

efficacy. The chapter has established the aim and objectives of this mixed-methods study and given an overview of the study design. It has also explained the thesis structure, which includes four related publications arising from original research.

The next chapter presents a review of the literature on CAM use in pregnancy and using CAM and self-help strategies to prevent post-date pregnancy. Chapter 2 also features Publication 1, a systematic review of the use of acupressure for initiating labour and its effect on labour duration and pain.

Chapter 2: Keeping birth normal and CAM

2.1 Chapter overview

This chapter brings together two fields of knowledge and literature describing 1) efforts to increase the spontaneous labour onset by reducing medical interventions such as induced labour for women with post-date pregnancies, and 2) CAM and self-help strategies, with a focus on acupressure, pregnant women use to initiate uterine contractions. It includes Publication 1, a systematic review of one aspect of the literature: Mollart, Adam, Foureur. **Impact of acupressure on onset of labour and labour duration: A systematic review**. *Women Birth*, 2015, 28, (3):199–206. DOI:10.1016/j.wombi.2015.03.007 (section 2.8). Since its publication in 2015, a further 10 studies have been published, and these are included in section 2.9.

2.2 Attempting to keep birth normal

In Australia and worldwide, concerns have been raised by health care professionals and government bodies about rising CS operation rates and the associated increase in maternal and neonatal morbidity, neonatal mortality and healthcare costs (New South Wales [NSW] Ministry of Health 2010). Many studies over the last two decades provide evidence in support of this concern. An international study of 24 countries and 286,565 births found that CS was associated with an intrinsic risk of increased severe maternal outcomes such as death, admission to intensive care, blood transfusion and hysterectomy (Souza et al. 2010). Despite this publication now being nearly a decade old, its findings are still very relevant in modern maternity care (Karlström, Lindgren & Hildingsson 2013; Mylonas and Friese 2015; Mahomed, Pungsornruk & Gibbons 2016). A key contributor to the rising rate of CS is the medical and/or surgical induction of labour using drugs such as prostaglandins and oxytocics, or procedures such as artificial rupture of the membranes or use of a balloon catheter (Dahlen et al. 2014; National Institute of Clinical Excellence 2008; Roberts et al. 2012).

Of concern is the increased rate of failed induction resulting in a CS in first-time (nullipara) mothers. Mealing and colleagues' (2009) NSW population-based

study on the trends in induction of labour reported the failed induction rate in nullipara is six times higher than that in multipara resulting in CS and impacting on management and outcomes for subsequent pregnancies (Mealing, Roberts, Ford, Simpson and Morris 2009). One Australian cohort study found that for women experiencing their first full-term pregnancy who were induced, the proportion of CS rose from 20.4% in 2001 to 33.9% in 2009 (Roberts et al. 2012). This increased CS rate was not accompanied by any significant decrease in perinatal mortality, but a small (3–3.2%) yet statistically significant increase in severe neonatal morbidity such as hypoxic-ischemic encephalopathy (Roberts et al. 2012). In a 2001–2007 subset of Roberts et al.'s 2012 data describing the outcomes for term nulliparae, Patterson et al. (2011) found that the majority of women (37.6%, n = 25,387) were induced at 41 weeks' gestation, or were post date (Patterson et al. 2011). Therefore, induced labour for post-date pregnancy and specifically for first-time mothers, is an issue of significant concern and a justifiable focus for this research.

2.3 Post-date pregnancy and labour induction

The most common reason for inducing labour is when a pregnancy continues past the due date, and is then regarded as post-date or post-term. Term pregnancy is identified as a pregnancy lasting between 37 and 42 completed weeks' gestation from the first day of the last menstrual cycle (Gülmezoglu et al. 2012). Therefore, post-term pregnancy is when a pregnancy exceeds 42 completed weeks of gestation or 294 days (Mandruzzato et al. 2010). Internationally, evidence of variable quality has been available for more than 60 years suggesting that perinatal mortality is higher in post-term pregnancy (Gülmezoglu et al. 2012).

Risks associated with prolonged or post-date pregnancy (longer than 42 weeks' gestation) can result in complications for either the mother or the baby. Complications for the newborn are reported to be stillbirth, macrosomia with traumatic injury (such as would occur with shoulder dystocia), meconium aspiration, intrapartum asphyxia with sequelae and neonatal death (Hermus et al. 2009; Walker & Gan 2015). Maternal complications for prolonged pregnancy are closely linked with the labour and fetal risk of macrosomia, and include labour

dystocia, genital tract trauma or CS and postpartum haemorrhage (Walker & Gan 2015). Therefore, inducing labour at 40 - 41 completed weeks (post-date) has evolved as a cornerstone of contemporary obstetric practice in an attempt to reduce the risk of perinatal death. As a consequence, it is very rare for any woman in Australia to experience a post-term pregnancy of 42 completed weeks (Li et al. 2011). A major challenge to this is the consistent finding, over several decades, that perinatal mortality rates have not decreased with induced labour at this earlier gestation (Gülmezoglu et al. 2012; Patterson et al. 2011).

Therefore, it is justifiable to explore other options to the surgical or medical/pharmaceutical labour induction that might increase the likelihood of spontaneous labour onset in women approaching their 42nd week of pregnancy. One potentially important contribution to this area may be the practice of acupressure, a therapy that sits within the field of CAM.

The next section of this chapter presents an overview of the literature on the use of CAM during pregnancy, as well as literature exploring the use of CAM and self-help strategies to 'induce' or initiate spontaneous uterine contractions to address the issue of post-date pregnancy, and the use of acupressure in particular.

2.4 CAM use during pregnancy

The National Centre for Complementary and Integrated Health (NCCIH) defines CAM as a 'group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine' (NCCIH 2011). Conventional medicine (also called Western or allopathic medicine) is medicine as practised by medical doctors and allied health professionals such as physical therapists, psychologists, registered midwives and nurses. CAM practices are often informally grouped into broad categories, such as natural products, mind and body medicine and manipulative and body-based practices (NCCIH 2011).

CAM is most often used by the general public as complementary to, or as an adjunct to, conventional medicine. The boundaries between CAM and conventional medicine are not absolute as, over time, specific CAM practices have become widely accepted as mainstream healthcare practices (NCCIH 2011). Internationally and in Australia, CAM use is increasingly prevalent, with

women identified as the largest consumers (Adams, Sibbritt & Lui 2011; Hunt et al. 2010; Lunny & Fraser 2010; Sarris et al. 2010).

The growing use of CAM has been linked to the pursuit of more choice, control and autonomy in healthcare decision-making (Frawley et al. 2015b; Gaffney & Smith 2004a; Harding & Foureur 2009; Warriner, Bryan & Brown 2014; Westfall & Benoit 2004). One United Kingdom (UK) study found that women perceived using CAM during their pregnancy as supporting their health and wellbeing through active participation, in contrast to their assuming the passive, compliant and obedient role traditionally ascribed to patients (Warriner, Bryan & Brown 2014). An Australian study echoed this finding, revealing that pregnant women believed CAM promoted a holistic approach to health and gave them more control over their health and body (Frawley et al. 2015b).

An early Australian study of 23 primigravid women found that those experiencing a post-date pregnancy felt pressured to give birth before requiring a medical/surgical induction. Gatward et al. (2010) found two key themes describing the women's experiences. The first was a sense of 'time's up', and starting on the treadmill of timed procedures and labour induction if their body did not progress as per the hospital protocol. The second theme was a 'shift in expectations' from the original plan for their labour and birth experience, wherein 'the women searched for information to assist them in shifting expectations and used self-induction methods to avoid induction' (Gatward et al. 2010, p.6). The women in this study gained their information from their caregivers, family/friends, books and the internet. Therefore, it is important to identify the key sources of CAM information in pregnancy.

2.5 Key sources of CAM information for use during pregnancy

A multi-national study of 9,459 women (including 161 Australian women) found the key source of recommendations to use the CAM modality, herbal medicine, in pregnancy came first from the woman's own initiative (28.6%), followed by her physician (21.6%), family/friends (16.8%), the internet (11.3%), a midwife/nurse (7.8%) and lastly from pharmacy personnel (6.1%) (Kennedy et al. 2013). The key source of recommendations from the Australian cohort was slightly different, with 29.8% from the woman's own initiative, followed by family/friends (21.1%),

doctor (9.9%), midwife/nurse (9.3%), the internet (9.3%) and pharmacy personnel (8.1%) (Kennedy et al. 2013).

Similar rates were found in an Australian survey completed by 1,835 women who were pregnant or had recently given birth that explored the various sources of information that would influence these women's decision to use CAM during pregnancy (the women were able to indicate more than one source) (Frawley et al. 2014). Nearly half (48%) were influenced by their own personal experience, and 43% by families and friends. Other popular sources of CAM information were general practitioners (GPs) (27%), obstetricians (21%), midwives (19%), the internet (11%) and pharmacists (7%) (Frawley et al. 2014). Therefore, it is important that any RCTs testing efficacy or effectiveness of CAM also explores the experiences of health professionals. This requires a mix of methods of enquiry.

In a later study, Frawley et al. (2015b) found most women agreed that maternity healthcare professionals such as midwives (73%) should be able to advise them about commonly used CAM. Midwives are increasingly the main providers of antenatal care to Australian women—it is thus essential that they possess knowledge about commonly used CAM options to correctly and safely advise women. This issue is further explored in Study 2.

2.6 CAM use by pregnant women

As women are the largest consumers of CAM, it is not surprising to find that an emerging body of literature exists on the use of CAM during pregnancy in Australia and elsewhere. Some studies have investigated overall CAM use in pregnancy (Adams et al. 2009; Adams, Sibbritt & Lui 2011; Bishop et al. 2011; Kalder et al. 2011; Lapi et al. 2010; Skouteris, Wertheim & Rallis 2008; Steel et al. 2012), while others have focused on a single CAM strategy, such as herbal medicine use in pregnancy (Bercaw et al. 2010; Broussard et al. 2010; Frawley et al. 2015a; Holst et al. 2009; Kennedy et al. 2013; Nordeng et al. 2011).

Over the past 10 years, pregnant and birthing women have been identified as substantial CAM[1] users internationally, with prevalence rates of 26.7–57.1% in

[1] Overall CAM use. Studies on herbal medicine use only are not included.

the UK (Bishop et al. 2011, Hall & Jolly 2014), 50.7% in Germany (Kalder et al. 2011), 68% in Italy (Lapi et al. 2010) and 35–78% in the United States (US) (Holden, Davis & Yeh 2014; Johnson et al. 2014). Of the Australian studies, the CAM prevalence rate ranged from 32.8% to 81% (Adams, Sibbritt & Lui 2011; Frawley et al. 2013; Skouteris, Wertheim & Rallis 2008; Steel et al. 2012; Steel et al. 2014a). From the three Australian studies describing CAM modalities used by pregnant women, the top five modalities were vitamins/minerals, herbal remedies, massage, aromatherapy and yoga (Adams, Sibbritt & Lui 2011; Gaffney and Smith 2004b; Skouteris, Wertheim & Rallis 2008).

There is very little research specifically investigating women's use of CAM for post-date pregnancy to stimulate labour. An early qualitative study by Gatward et al (2010) found of 23 primigravid women some used CAM options such as acupuncture and raspberry leaf. Grabowska and Weston (2013) also reported an increasing demand at a UK hospital antenatal, complementary therapies clinic. Specifically, women experiencing a post-date pregnancy sought aromatherapy and reflexology to stimulate contractions thus avoiding a medical/surgical induction of labour.

Three Australian studies have investigated CAM professionals visited by pregnant women (Adams, Sibbritt & Lui 2011; Skouteris, Wertheim & Rallis 2008; Steel et al. 2012). A survey of 321 Australian women found that a third (36.8%) had visited a CAM practitioner during their pregnancy, with the top five practitioners being chiropractor (10.6%), osteopath (5.6%), reflexologist (3.4%) and acupuncturist (3.1%) (Skouteris, Wertheim & Rallis 2008). Using data from 897 women drawn from the Australian Longitudinal Study on Women's Health (ALSWH), Adams, Sibbritt and Lui (2011) found that pregnant women visited slightly different practitioners: chiropractors (14%), naturopath/herbalists (10%), acupuncturists (6%) and osteopaths (4%). In a similar study using data from 1,835 pregnant women also drawn from the ALSWH, even more CAM practitioners/practices were identified, including massage therapists (34.1%), meditation/yoga (13.6%) and aromatherapists (0.6%) (Steel et al. 2012).

A potential limitation of these Australian studies is the restricted range of options for CAM practitioners and/or CAM modalities on study checklists from which participants could choose (Pallivalappila et al. 2013). None of the aforementioned

Australian studies included acupressure as a CAM option, whereas at least three international studies have reported acupressure use as a CAM option by pregnant women (Bishop et al. 2011; Gibson 2001; Hollyer et al. 2002). Therefore, there is a gap in knowledge about the use of acupressure by pregnant women in Australia.

2.7 CAM and its effect on uterine contractibility

Women have used several CAM modalities or 'self-help strategies' to prime the uterus for labour, or to 'naturally' induce labour. There is no formal definition of self-help strategies, although they can be described as natural lifestyle options administered or ingested by the pregnant woman. Self-help strategies aimed at inducing labour may include sexual intercourse, ingesting spicy foods or castor oil and breast/nipple stimulation (Chaudhry, Fischer & Schaffir 2011; Hall, McKenna & Griffiths 2012b; Kozhimannil et al. 2013). Studies suggest that using self-help strategies enables the woman to feel in control and an active participant in her care. Such strategies may require a high level of commitment, as they may take several days to produce results (Evans 2009). The timeframe is not too dissimilar to prostaglandin labour-induction methods but, with this medical method, the woman plays a passive role and may be less satisfied with her birth experience (Hall, McKenna & Griffiths 2012b).

A small number of studies have examined the CAM strategies used to naturally induce labour, including ingestion of herbs and fruits such as evening primrose oil (Dove and Johnson 1999; Ty-Torredes 2006), raspberry leaf (Simpson et al. 2001; Parsons, Simpson & Ponton 1999), blue cohosh (Dugoua et al. 2008) and date fruit (Al-Kuran et al. 2011; Kordi et al. 2014), and body-based modalities such as reflexology (Clausen & Moller 1996) and acupuncture (Smith et al. 2011). Since these modalities are used for the same purpose—to induce labour or prevent 'going overdue'—Table 2.1 presents studies examining both self-help and CAM strategies, which are discussed in more detail in the following section of this chapter.

Table 2.1: Studies of self-help and CAM to initiate spontaneous labour onset

Author, year, country	Study/design	Participants and gestation	Dosage	Findings: direction of effect
Self-help modality: castor oil				
Kelly, Kavanagh & Thomas 2013 US (1) Iran (1) Israel (1)	Cochrane systematic review	3 trials n = 233 gestation 40–42 weeks primiparous/multiparous in each study	2 trials: single dose of 60 ml castor oil compared with routine care 1 trial: single dose of 60 ml castor oil compared with sunflower oil	No effect on rate of instrumental delivery, meconium-stained liquor or Apgar score less than 7 at 5 minutes No difference in CS rate (RR 2.04, 95% CI 0.92 to 4.55). All women who ingested castor oil felt nauseous (RR 59.92, 95% CI 8.46 to 424.52)
Self-help modality: breast/nipple stimulation				
Kavanagh, Kelly & Thomas 2010 Nigeria (2) US (2) Singapore (1) India (1)	Cochrane systematic review	6 trials n = 719 primiparous (3 trials) multiparous (1 trial) information not provided (2 trials) all studies conducted with women at term	Varied between studies: 1 hr per day for 3 days, 1 hr 3 times per day	Significant reduction in the number of women not in labour at 72 hours (62.7% versus 93.6%; RR 0.67, 95% CI 0.60 to 0.74) not significant for women with an unfavourable cervix and did not reduce CS rates
Singh et al. 2014 India	Single-blind RCT Aim: to prevent post-date pregnancy	n = 200 primigravid women at term	Massage each breast for 15 to 20 minutes 3 times a day or control (usual care) from	Higher Bishop score in intervention group at 39 weeks' gestation compared with control group ($p < 0.0001$). Increased rate of vaginal birth in the intervention group

			38 weeks' gestation	(p = .044). CS for failed induction lower in intervention group (3%) compared with control group (10%) (NS p = 0.056).
Self-help modality: sexual intercourse				
Kavanagh, Kelly & Thomas 2007 Norway	Cochrane systematic review	1 trial, n = 28 women at 39 weeks (parity not described)	Intercourse for 3 consecutive nights; the control group to abstain from sexual intercourse for the same period. Both groups were asked to avoid nipple stimulation.	Study underpowered and reports very limited data, from which no meaningful conclusions can be drawn
Tan et al. 2007 Malaysia	Single-blind RCT	210 low-risk women at term 108 intervention (53.7% nulliparous), 102 control (49% nulliparous)	Vaginal sex as frequently as possible, compared with a control group (sex neither encouraged nor discouraged)	No significant difference in spontaneous labour onset (55.6% compared with 52.0%, RR 1.1, 95% CI 0.8–1.4; p = .68) No difference in CS rate and neonatal outcomes
Omar et al. 2013 Malaysia	Single-blind RCT	1,200 low-risk women with a partner/husband from 36 weeks' gestation nulliparous (59.8%	Frequent vaginal sex from 36 weeks until labour onset, and informed	Coitus prior to labour occurred more often (p = 0.019) and more frequently (p = 0.006) in intervention than control group. No

		intervention, 61.7% control)	that sex safely expedites labour and reduces need for labour induction compared with control group, informed that sex is safe but has no effect on labour	significant difference in intervention to delivery interval (p = 0.417) or labour-induction rates (p = 0.112). No difference in other obstetric and neonatal outcomes.
CAM: evening primrose oil (oenothera biennis)				
Dove et al. 1999 US	Retrospective quasi-experimental	108 low-risk nulliparous women at term 54 intervention, 54 control	500 mg orally 3 times per day for 1 week at 37 weeks' gestation, then 500 mg orally once per day until labour onset	No significant difference in gestation at birth between EPO (281.69 days) and control group (279.00 days). Women in the EPO group had a shorter length of labour than control group (p = 0.002).
Ty-Torredes 2006 Philippines	Double-blind, placebo-controlled RCT	71 women at term (parity information not available)	1 capsule 3 times daily for 7 days at term	Significant difference in mean Bishop score (p = .0001) and cervical length (p = .001) in the intervention group compared with the placebo group. No difference between groups from start and end of treatment to labour onset. More women delivered vaginally in intervention group (70%) compared with placebo (51%)

				(p value not available).
CAM: raspberry leaf (*rubus idaeus lin)*				
Parsons, Simpson & Ponton 1999 Australia	Retrospective observational study	109 women (days 1–4 postnatal) 57 intervention, 51 control 48 multiparous, 60 primiparous	Tea and tablet dosage varied between participants each day. Commence-ment varied between 8 to 39 weeks' gestation.	Average length of first stage of labour was shorter in the intervention group compared with control group (p = .007). Normal vaginal birth rate was higher in the intervention group (77.2%) compared with control (66.7%).
Simpson et al. 2001 Australia	Double-blind, placebo-controlled RCT	192 nulliparous women from 32 weeks' gestation 96 intervention, 96 control	1.2 g, 2 times a day	Raspberry leaf reduced the incidence of forceps delivery (19.3% vs 30.4%, p = .19 NS) and shortened second stage of labour (p = .28) (NS)
CAM: date fruit				
Al-Kuran et al. 2011 Jordan	Prospective controlled trial	114 women from 36 weeks for approx. 4 weeks 78% nulliparous and 22% primiparous in study 69 intervention, 45 control	6 date fruit (60–67 g) per day.	Higher mean cervical dilatation upon admission (p < .005) and higher rate of spontaneous onset labour (p = .024) in the intervention group compared with control
Kordi et al. 2014 Iran	RCT	210 primiparous women at term 105 intervention, 105 control	70–75 g per day (divided into 3 doses per day) from 37 weeks'	Mean Bishop score higher on admission in intervention group (p < .001). Mean cervical dilatation was greater in

			gestation until labour onset	intervention group compared with control ($p < .05$). Higher rate of vaginal birth after labour induction in the intervention group compared with control ($p = 0.036$).
CAM: reflexology				
Clausen & Moller 1996 Denmark	Single-blind RCT	99 women at term: 49 intervention, 50 control (parity and gestation not included in article)	Reflexology for 30 minutes, rest for 30 minutes, reflexology for additional 30 minutes when primary uterine inertia occurred	Some receiving foot reflexology required less syntocinon infusions than the control group ($p = 0.0439$) and greater change in cervical dilatation ($p = .002$)
CAM: acupuncture				
Smith et al. 2011	Cochrane systematic review	14 trials n = 2,220	Acupuncture points and dosage differed in studies	Women receiving acupuncture had a noticeable change in cervical ripening compared with the sham control, (MD 0.40. 95% CI 0.11 to 0.69) and when compared with usual care (MD 1.30, 95% CI 0.11 to 2.49)
CAM: Acupressure				
Mollart, Adam & Foureur 2015 India, Egypt, Iran, UK, Korea & Taiwan	Systematic review	7 trials: 1 study on initiation of labour (n = 142); 6 trials on labour duration and pain intensity (n = 734)	Acupressure points and dosage differed in studies	Details provided in Publication 1 (see section 2.8)

2.7.1 Self-help strategies to initiate spontaneous labour onset

2.7.1.1 Castor oil

Anecdotal experience dating from Ancient Egypt suggests that castor oil stimulates labour onset. As indicated in Table 2.1, a Cochrane review, updated in 2013, identified three trials of castor oil for post-date pregnancy involving 233 women (Kelly, Kavanagh & Thomas 2013). Based on these trials, there was no evidence of castor oil having a significant effect compared with a placebo/no treatment on the range of outcomes measured. Despite the unpleasant side effect of nausea experienced by all women in these trials and no evidence that castor oil reduced pregnancy length or interventions, women continue to use this technique despite the availability of more pleasant options (Gatward et al. 2010; Kozhimannil et al. 2013).

2.7.1.2 Breast/nipple stimulation

A Cochrane review of breast/nipple stimulation for cervical ripening and labour induction involved six studies of 719 women (Kavanagh, Kelly & Thomas 2010) (Table 2.1). The collated findings found that breast stimulation appears beneficial in relation to the number of women not in labour after 72 hours, and reduces postpartum haemorrhage rates (Kavanagh, Kelly & Thomas 2010). However, the limitations of these studies are many: they are old (1984–1993) and thus may not represent current obstetric maternity practices. Different study protocols, such as two studies requiring participants to practice breast stimulation for one hour per day for three days, or two studies requiring stimulation for three hours per day, limit the understanding of the dosage that might be most effective. Two studies (n = 119) were conducted on women requiring medical labour induction—that is, comparing breast stimulation or oxytocin infusion, which mixes CAM and pharmacological paradigms. One study on high-risk women (India) was stopped when three perinatal deaths occurred (Kavanagh, Kelly & Thomas 2010).

A more recent and robust RCT in Northern India with 200 low-risk primigravid women at term found the Bishop score at 39 weeks' gestation improved more in the breast stimulation intervention group compared with the control ($p < 0.001$) (Singh et al. 2014). This study shows that breast stimulation is a simple, safe, effective and economical intervention to reduce labour induction for post-date

pregnancy (Table 2.1). The authors acknowledge the small sample size as a limitation, but do not explain how the sample size was determined.

2.7.1.3 Sexual intercourse

Anecdotally, it has been suggested that sexual intercourse may be an effective means of initiating uterine contractions, as human sperm contains a high amount of prostaglandin, a hormone-like substance that has the potential to ripen the cervix and help labour commence (Tan, Yow & Omar 2007). The Cochrane review (updated in 2007) found only one study of 28 women conducted in 1990 that reports very limited data, from which no meaningful conclusions could be drawn (Table 2.1) (Kavanagh, Kelly & Thomas 2007).

Since the 2007 updated Cochrane review, two single-blind RCTs have been conducted (Omar et al. 2013; Tan, Yow & Omar 2007) (Table 2.1). The first study of 210 women at term found that increased sexual activity as per the study protocol did not increase the rate of spontaneous labour at term (Tan, Yow & Omar 2007). The study limitations were that pre-labour ruptured membranes were considered spontaneous labour onset (which is not a usual diagnosis of labour onset), and that the frequency of sexual activity was not reported in either group. The second study, with 1,200 women at 36 weeks' gestation (Omar et al. 2013), found a significant difference ($p = 0.006$) in the 'frequency of reported coital acts between randomisation and delivery' for the intervention group (average 3, range 2–5) and the control group (average 2, range 1–4), (Omar et al. 2013). Again, in this study, ruptured membranes were considered labour onset; however, women had a choice of either waiting 24 hours for contractions to begin spontaneously, or immediate augmentation, which may have influenced the intervention to delivery interval findings. Despite the significant difference in the frequency of coitus, there was no significant difference in the rate of spontaneous labour onset. Therefore, although commonly recommended to pregnant women, there is currently not enough evidence to determine whether sexual intercourse is effective or to show how it compares with other methods.

2.7.1.4 Spicy food

Although eating spicy food has been cited in several studies as a self-help strategy to initiate labour (Chaudhry, Fischer & Schaffir 2011; Mackenzie 2006;

Bovbjerg et al. 2014), no published research was found to investigate this practice.

2.7.2 CAM modalities to initiate spontaneous labour onset

2.7.2.1 EPO

Evening primrose oil (EPO), extracted from the biennial weed *Oenothera biennis*, is one of midwives' most commonly recommended non-pharmacological agents, as it is considered to act like prostaglandin for cervical ripening (Bishop et al. 2011; Hall, McKenna & Griffiths 2012a; McFarlin et al. 1999). The two published studies conducted on the use of EPO and labour initiation or effect on cervical ripening are included in Table 2.1 (Dove & Johnson 1999; Ty-Torredes 2006). The first study, conducted in the US, found that 500 mg oral EPO from the 37th gestational week until birth does not shorten gestation or decrease the overall length of labour (Dove & Johnson 1999). The second double-blind placebo RCT compared one EPO capsule thrice daily for one week versus placebo (Ty-Torredes 2006), but a major limitation of this study was that the authors do not include the EPO dosage in the article. In summary, EPO is one of the most common CAM suggested by midwives around the world, but the least studied CAM, with no clinical evidence for its efficacy, safety, dosage or route of administration (oral or vaginal); further research is thus warranted (Evans 2009).

2.7.2.2 Raspberry leaf

Since the 16th century, the use of raspberry leaf in pregnancy has been a well-established traditional herbal therapy taken in tea or tablet form as a 'labour aid' during the last two months before birth (Holst, Haavik & Nordeng 2009; Holst et al. 2009; Forster et al. 2006; Kennedy et al. 2013). The mechanism of the action of red raspberry, *Rubus idaeus lin,* is unclear, but it seems from the in vitro and animal study findings to influence a decrease in tonic tissue contraction and increase relaxed tissue contraction, thus having a stabilising or balancing property (Holst, Haavik & Nordeng 2009).

Two studies have been conducted in Australia, as shown in Table 2.1. As the first was a retrospective observational study, the consumption dose and duration (tablets, tea, tincture and combinations) varied among the users. There were no adverse effects noted in either group (Parsons, Simpson & Ponton 1999), which

provided support for a double-blind, randomised placebo-controlled trial with 192 nulliparous women randomised at 32 weeks' gestation to consume either 1.2 g of raspberry leaf twice daily or a placebo (Simpson et al. 2001). Although raspberry leaf consumption during pregnancy appears to be a well-established traditional therapy (Bayles 2007; Bishop et al. 2011; Broussard et al. 2010; Forster et al. 2006; Gatward et al. 2010; Holst et al. 2009; Kennedy et al. 2013; Skouteris, Wertheim & Rallis 2008), all previous studies had been performed on rats; this was the first RCT with pregnant women. Thus, the dosage (2.4 g daily) used in the study was lower than commercial products available to pregnant women (3–4 g per day), possibly to gain ethics approval and cause no adverse side effects. However, this raises the question that a safe but higher dosage could have contributed to a more clinically significant outcome. Further research is thus required. It is interesting to note that other than raspberry leaf, no studies were located that have investigated the mechanism of action of ingestible CAM.

2.7.2.3 Blue cohosh/black cohosh

The self-help and CAM strategies previously discussed have no identified associated harmful effects, except for blue cohosh. Blue cohosh (*Caulophyllum thalictroides*), also known as 'blue ginseng or squaw root', is a traditional herbal therapy that has been used by Native American women for many years (McFarlin et al. 1999). As early as 1885, the *US Pharmacopoeia* listed blue cohosh as a labour inducer, and midwives in the US continue to recommend it (Hastings-Tolsma & Terada 2009; McFarlin et al. 1999). A search of the literature failed to identify any clinical trials on blue cohosh (Hall, McKenna & Griffiths 2012b). There is some evidence to suggest that blue cohosh should be avoided during pregnancy, as it contains an alkaloid known to produce toxic effects on the myocardium of laboratory rats, and has been reported to have had adverse side effects on a small number of human mothers and babies (Dugoua et al. 2008).

Black cohosh (Cimicifuga racemosa), not to be confused with blue cohosh, has also been recommended to women by midwives for labour stimulation (Bayes 2007; McFarlin et al. 1999). It has its origins with Native Americans healers mixing it with chamomile, ginger and raspberry tea to induce menses and labour (McFarlin et al. 1999; McKenna et al. 2001; Ulbricht & Windsor 2014). The *Eclectic Dispensary*, published in 1852, recommended a tincture from fresh roots

as useful in small doses during the last four weeks of pregnancy as a labour preparation (McKenna et al. 2001). In more recent times, black cohosh has been recommended for treating premenstrual syndrome and menopausal symptoms because of its implied phytoestrogenic properties (Ulbricht & Windsor 2014). The mechanism of black cohosh remains uncertain, and its effects on estrogen receptors or hormonal levels have not been fully investigated (Hall, McKenna & Griffiths 2012b; McKenna et al. 2001). The unexplored nature of this modality adds weight to the call to establish evidence of efficacy and effectiveness and safety for using CAM modalities in pregnancy (Hall, McKenna & Griffiths 2012b).

2.7.2.4 Date fruit

Two studies examining the ingestion of date fruit and its effect on initiating uterine contractions show that it does have an effect (Al-Kuran et al. 2011; Kordi et al. 2014). Al-Kuran et al. (2011) found that women in the intervention group had significantly higher mean cervical dilation upon admission ($p < 0.0005$) and a significantly higher rate of spontaneous labour ($p = 0.024$) (Table 2.1). The authors conclude that a fully powered RCT is warranted (Al-Kuran et al. 2011). A potential limitation is the transferability of this study to cultures and countries where pregnant women do not regularly consume large amounts of date fruit in their diet.

An appropriately powered RCT with 210 Iranian nulliparous women at 37 weeks' gestation compared the ingestion of 70–75 g date fruit (divided across three servings) per day versus routine antenatal care with no date fruit ingestion (Kordi et al. 2014) (Table 2.1). While the study found a significantly higher mean Bishop score ($p < 0.001$) and mean cervical dilatation $p < 0.05$) on admission for women in the intervention group (Kordi et al. 2014), the authors were unable to determine the amount and duration of date fruit consumption for each participant (Kordi et al. 2014). This highlights the importance of well-controlled trials with pre-study published and consistently applied study protocols.

2.7.3 Manipulative CAM

Other manipulative CAM modalities studied to stimulate uterine contractions and labour include reflexology (Dolatian et al. 2011; Mirzaei, Kaviani & Jafari 2010; Valiani et al. 2010), shiatsu (Ingram et al. 2005) and acupuncture (Ajori et al.

2012; Asher et al. 2009; Gaudet et al. 2008; Modlock et al. 2010; Smith et al. 2008). The modalities relating to labour onset and stimulating uterine contractions are discussed in more detail in the following section.

2.7.3.1 Reflexology

Reflexology is a non-invasive CAM based on a system of reflex zones/areas on the feet, hands or ears that reflect an image of the entire body in exactly the same order and position as they are on the body (Dolatian et al. 2011). The reflexologist uses specific thumb and finger pressure on the reflex zones to elicit a sense of wellbeing and enable healing (Issel 1996). Reflexology's origins can be traced back to 2,500 BC in Egypt and 500 BC in China and India (Issel 1996). The action of reflexology is still unclear, and many theories have been proposed, such as gate control theory and increased secretions of endorphins and encephalins that assist in relieving pain (Dolatian et al. 2011; Issel 1996). Reflexology has been recommended by midwives for use in labour to reduce anxiety (decrease adrenaline) and increase oxytocin release (Enzer 2011, Hall & Jolly 2014, Stewart et al. 2014, Mitchell et al. 2006); it has also been found to reduce labour duration and pain (Dolatian et al. 2011; Mirzaei, Kaviani & Jafari 2010; Valiani et al. 2010).

A literature search undertaken in May 2016 found one RCT (included in Table 2.1) and one quality audit (not included in Table 2.1: Grabowska & Weston 2013) relating to reflexology and cervical dilatation. The Danish RCT compared reflexology (n = 49) with routine supportive care (n = 50) for labour augmentation when failure to progress occurred (less than 7 cm) (Clausen & Moller 1996). Women receiving foot reflexology required less syntocinon infusion than the control group ($p = 0.043$), and a significant change in cervical dilatation was identified ($p = 0.002$) (Clausen & Moller 1996). Further RCT research is necessary to determine if reflexology alone influences initiation of uterine contractions and spontaneous labour onset.

2.7.3.2 Acupuncture

Betts, Smith & Hannah (2012) define acupuncture as a treatment modality that

> Involves the insertion of needles into specific body points to stimulate an energetic response involving qi, also termed the body's life force. The aim

> is to initiate therapeutic responses by promoting the smooth flow of qi within well-defined pathways, known as meridians (p.4).

A Cochrane review on acupuncture for labour induction included 14 trials with data on 2,220 women randomised to receive acupuncture compared with sham acupuncture or usual care (Smith, Crowther & Grant 2013) (Table 2.1). Women receiving acupuncture had a noticeable change in cervical ripening compared with the sham control (mean difference [MD] 0.40, 95% CI, 0.11 to 0.69, one trial, 125 women) and usual care (MD 1.30, 95% CI, 0.11 to 2.49, one trial, 67 women). However, the length of labour was shorter in the usual care group compared with acupuncture (average standardised mean difference [SMD] 0.67, 95% CI 0.18 to 1.17, one trial, 68 women) (Smith, Crowther & Grant 2013). There were no other statistically significant differences between groups. Limitations were noted, with the acupuncture trials using different meridian points, number of treatments and methods of acupuncture (manual or electro-acupuncture) (Smith, Crowther & Grant 2013). The review authors recommend that future well-designed RCTs are warranted to evaluate the role of acupuncture in inducing labour, and for trials to assess clinically meaningful outcomes (Smith, Crowther & Grant 2013). There are important similarities and differences between acupuncture and acupressure/shiatsu use in pregnancy that must be considered in the justification for and design of my FRCT.

2.7.3.3 Acupressure/shiatsu

Acupressure and shiatsu are based on acupuncture and Traditional Chinese medicine (TCM) philosophy, as explained in the previous section. The use of acupressure/shiatsu aims to promote the smooth flow of qi, thus enhancing blood flow, nourishing tissue and facilitating normal bodily functions (Chung et al. 2003). Acupuncture and acupressure/shiatsu techniques use the same meridian points, although acupuncture uses needle stimulation on the points, whereas acupressure/shiatsu uses firm thumb or finger pressure, which is less invasive (Betts 2006). Shiatsu also involves gentle exercises and massage in treatment sessions (Tiran & Mack 2000).

Acupressure has been reported to shorten labour and decrease labour pain by releasing oxytocin from the pituitary gland, which directly stimulates uterine

contractions (Chung et al. 2003; El Hamid, Obaya & Gaafar 2013; Hamidzadeh et al. 2012; Kashanian & Shahali 2010; Lee, Chang & Kang 2004). It is thought that acupuncture (and possibly acupressure) may have an effect on the oxytocinergic system. This system, regulated by both oxytocin hormone levels and receptors, is responsive to stressors of both physical and psychological origin (Ormsby et al. 2016). Further indirect evidence has been provided by acupuncture and acupressure RCTs examining the preparation, induction and enhancement of labour with significantly reduced requirements for syntocinon augmentation and reduced length of the first labour stage (Chung et al. 2003; Lee, Chang & Kang 2004; Smith et al. 2011). As there has been an increase in the number of studies focusing on acupressure and labour, a systematic review is warranted to determine if acupressure is as effective as acupuncture in priming the uterus for labour or stimulating uterine contractions, thus leading to the spontaneous labour onset. For this reason, I conducted a systematic review on the effect of acupressure on labour onset and duration.

2.8 Publication 1: Systematic review on the impact of acupressure on onset of labour and labour duration

The following systematic review is a paper published as follows:

Mollart. L. (LM), Adam, J, (JA) & Foureur, M. (MF). 2015, '**Impact of acupressure on onset of labour and labour duration: a systematic review**', *Women and Birth*, vol. 28, no. 3, pp. 199–206. DOI:10.1016/j.wombi.2015.03.007.

Since its publication, 13 further studies on acupressure have been published. Section 2.9 and tables 2.3–2.6 detail the additional studies on both labour initiation and labour duration and pain relief. Tables 2.3–2.6 are located at the end of this chapter (after section 2.10).

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REVIEW ARTICLE

Impact of acupressure on onset of labour and labour duration: A systematic review

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ABSTRACT

Background: There is worldwide concern with increasing rates of pharmacologically induced labour and operative birth. Many women would like to avoid medical or surgical interventions in childbirth; a desire that may contribute towards the popularity of complementary and alternative medicine/therapies.
Method: This systematic review examines the effects of acupressure on labour onset and duration of labour. We searched MEDLINE, CINAHL, AMED, Cochrane Collaboration, and Science Direct from 1999 to 2013 for published randomised controlled trials and controlled trials comparing acupressure with placebo and no treatment. Studies recruited primiparous and/or multiparous women with either spontaneous or induced onset of labour. The outcome measures were labour onset and duration of all stages of labour.
Findings: Seven trials with data reporting on 748 women using different acupressure points and methods of administration were included in the review. One study examined the initiation of labour and six studies examined labour duration and/or pain levels. The two most studied acupoints were Sanyinjiao/Spleen 6 and Hegu/Large Intestine 4. Results suggest acupressure may reduce the length of labour particularly in the first stage.
Conclusion: Further research is required on whether acupressure can shorten labour duration, augment prolonged labour or initiate onset of labour by stimulating uterine contractions. Clinical trials should report the basis for acupressure treatment described in the STRICTA (minus needling) and CONSORT non-pharmaceutical guidelines.

1. Introduction

Increasing rates of pharmaceutically induced labour and operative birth have been reported in the UK, US, Canada and Australia since the early 1990s.[1–5] Government policy recommends that the number of women who embark on a labour and/or go into labour spontaneously needs to increase and the number of labour interventions needs to decrease such as augmentation of labour.[6] Many women require medical and/or surgical augmentation and the systematic reviews report that early amniotomy and oxytocin has a modest reduction in length of first stage of labour only and no effect on mode of birth, epidural analgesia rates or other maternal or foetal/neonatal outcomes.[7–9] The discovery of a non-pharmacological, non-invasive technique to stimulate uterine contractions that is simple, safe, effective and without serious side effects may prove beneficial for both mother and baby especially in areas where pharmacological pain relief may not be available. Acupuncture is a complementary and alternative medicine (CAM) that has been investigated with seven randomised controlled trials (RCTs).[10–16] A systematic review found fewer women receiving acupuncture required use of induction methods (RR 1.45, 95% CI 1.08–1.95) compared with standard care (RR 1.45, 95% confidence interval 1.08–1.95).[17] The three acupoints used by all seven studies were Sanyinjiao/Spleen 6 (SP6), Hegu/Large Intestine 4 (LI4), and Ciliao/Bladder 32 (BL32). The four most cited empirical acupoints (SP6, LI4, BL32, and GB21) are commonly recommended for difficult or delayed labour to assist in descending action of the presenting part and increasing the intensity of uterine contractions.[18] The theory being if labour is slow, contractions are weak or

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the cervix is slow to dilate, stimulating the acupoints may help regulate contractions and restore a balance to the labour.[19] However, acupuncture requires a qualified practitioner and acupuncturists are not easily accessible in maternity settings and there is a cost implication for the woman.

An alternative to acupuncture is acupressure. Acupuncture and acupressure have roots in Chinese medicine and embrace the philosophy of promoting the circulation of blood and Qi (pronounced *chee*), the harmony of yin and yang, and the secretion of neurotransmitters, thus maintaining the normal functions of the human body and providing comfort.[19] Pressure on specific acupoints may also stimulate the release of oxytocin from the pituitary gland, which directly stimulates uterine contractions.[19,20] Acupuncture and acupressure techniques use the same acupoints however acupuncture uses needle stimulation on the points whereas acupressure uses a non-invasive, firm steady pressure using thumb or finger.[18,21–23] It is plausible to propose that acupressure using these same acupoints may be as effective as acupuncture and has the advantage that women, partners and midwives can be taught to use the acupoints safely and easily.[24,25]

There are several systematic reviews of the use of acupressure for the treatment of nausea and vomiting,[26] dysmenorrhea,[27] neurological disorders[28] and insomnia[29] in the general population. There has been one Cochrane review on the use of acupressure (and acupuncture) for pain management in labour.[30] A recent critical narrative review of acupuncture and acupressure for pain management in labour and birth located three systematic reviews. Most of the included trials focussed on acupuncture with only 4 trials of acupressure identified.[31]

This paper reports the first systematic review of RCTs and controlled trials specifically focused on comparing acupressure, rather than acupuncture, with placebo or no treatment for stimulating uterine contractions to initiate labour onset and shorten the duration of labour. We have chosen to focus on acupressure rather than acupuncture as acupressure is a less invasive procedure and has the advantage that the woman or her partner can administer it themselves.

2. Method

The inclusion criteria were peer reviewed research articles reporting new empirical data on pregnant or labouring women who had acupressure administered manually utilising meridian points. Outcomes included effect on stimulating uterine contractions leading to the onset of labour and duration of labour and mode of birth. The time frame is from the first published research article found (1999) to December 2013. Individual studies were assessed for risk of bias at study and outcome levels by the six, risk of bias domains: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias.[32]

Publications such as guidelines, case reports, and conference papers not reporting primary data collection through established research designs were excluded. Papers reporting the use of plasters, devices or wristbands on the acupoints; acupressure on auricular (ear) points; and acupressure for pain in labour only, were also excluded due to the focus of this review. Full text papers published in non-English languages were not included as there was no funding for translation.

2.1. Search methods

A search was conducted via MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Collaboration, AMED (Allied and Complementary Medicine) and Science Direct. All identified titles and abstracts were assessed via inclusion criteria. If the abstract did not provide sufficient information, the full paper was retrieved and examined prior to making a final decision regarding inclusion. The references of retrieved articles were checked to identify any additional studies.

The following search terms were used: acupressure, Sanyinjiao point/Spleen 6 (SP6), Gall Bladder 21 (GB21), Hegu point/Large Intestine 4 (LI4), Bladder 60 (BL60), pregnancy, antenatal, uterine contractions, labour/labor induction, labour/labor and labour/labor duration.

3. Studies located

As shown in Fig. 1, 34 publications were identified. After initial screening, 14 publications were removed with 20 publications remaining. From screening the abstracts, a further five articles were excluded (three systematic reviews; 2 duplications). Of the remaining 15 studies, eight were used for background information only, as the full paper was not available in English, leaving seven studies for formal review.

The seven studies reviewed constitute a diverse international perspective on this topic including research from the UK,[33] Iran,[22,34] India,[35] Egypt,[36] Taiwan[19] and Korea.[20] There was only one study found on the use of acupressure to initiate uterine contractions. This was a pilot non-randomised controlled trial.[33] Six studies were RCTs on labour duration and/or pain relief conducted between 2003 and 2013.[19,20,22,34–36] The six RCTs were evaluated to determine their contribution to the evidence base by applying the CONSORT RCT guidelines checklist for non-pharmacologic treatment [NPT][37]; and the TREND statement checklist[38] was used for the one non-randomised study.[33]

4. Findings

4.1. Ethical considerations

Ethical approval including written and verbal consent for treatment was described by three studies.[20,22,35] Two studies did not explain whether study information was provided to eligible participants, nor outline the consent process or confirm ethics committee approval.[33,34] However a subsequent commentary by Kashanian clarified that written consent had been obtained from their study participants and acknowledged the research was supported by the University and supplied the project number.[39]

Chung et al.[19] did not clarify whether written consent was obtained. Ingram et al.[33] obtained permission from consultant obstetricians to conduct their pilot study and the relevant healthcare trust approved trained midwives to employ acupressure in clinical practice.

4.2. Methodological differences

Tables 1–4 describe the methodological differences of the seven studies including: inclusion criteria, randomisation, allocation and blinding. Three RCTs did not report whether they performed an intention-to-treat (ITT) analysis but it was apparent that this was done.[22,34,36] Hjelmstedt et al.[35] included the CONSORT flowchart with participant numbers for allocation and analysis showing an ITT. An ITT analysis was not undertaken by two studies.[19,20]

Sample sizes ranged from 66[33] to 212.[35] The method used to determine sample size was not included in six of the seven studies. Hjelmstedt et al.[35] estimated power on the principle outcome of labour pain based on outcomes of the study by Lee et al.[40] and calculated a sample size of 70 women per group. Tables 1–4 outline the findings as described in the following sections.

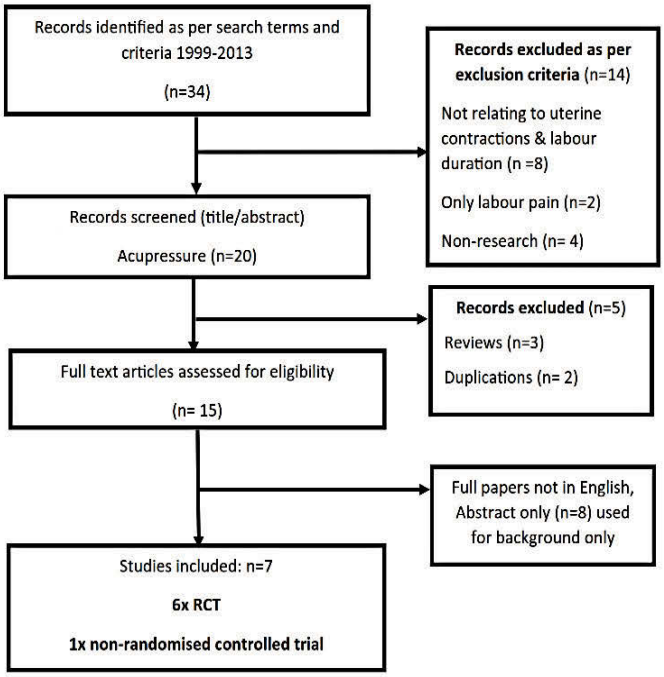

Fig. 1. Flowchart of the literature search process.

Table 1
Description of the studies of acupressure.

	Chung et al. (2003)[12]	Lee et al. (2004)[13]	Kashanian and Shahali (2010)	Hjelmstedt et al. (2010)	Hamidzadeh et al. (2012)	El Hamid et al. (2012)	Ingram et al. (2005)
Inclusion criteria							
Nulliparous/multipara	✓	✓	Nulliparas only	Nulliparas only	✓	Nulliparas only	✓
Singleton pregnancy	✓	✓	✓	✓	✓	✓	✓
Term gestation	✓	✓	✓	✓	✓	✓	✓
Low risk pregnancy	✓	✓	✓	✓	✓	✓	✓
Active labour (cervix dilatation)	2 cm	?3 cm	3–4 cm	3–7 cm	3–5 cm	3–4 cm	*Not in labour*
No augmentation	✓	✓		✓	✓	✓	–
No IV oxytocin	✓	✓		✓	✓	✓	–
No analgesia	✓	✓	✓	✓	✓	✓	–
Membrane status			Intact			Intact	Intact
Group allocation							
Standard care	(n=42)	–	–	(n=70)	–	(n=50)	(n=76)
Placebo	Effleurage (n=42)	Touch SP6 (n=39)	Touch SP6 (n=60)	Touch SP6 (n=71)	Touch LI4 (n=50)		
Intervention acupressure	LI4 & BL67 (n=43)	SP6 (n=36)	SP6 (n=60)	SP6 (n=71)	LI4 (n=50)	SP6 (n=50)	GB21, SP6, LI4 (n=66)
Placebo/intervention duration	Total 20 min	30 min during contractions	30 min during contractions	30 min during contractions	20 min during contractions	30 min during contractions	40+ weeks as often as the woman wanted
Research question/outcomes measured							
Onset of labour							✓
1st stage duration	✓	✓	✓		✓	✓	
2nd stage duration		✓			✓	✓	
3rd stage duration						✓	
Total labour duration		✓					✓
Pain (VAS score)	✓	✓	✓	✓	✓	✓	
Mode of birth			✓	✓			✓
Augmentation – IV oxytocin			✓			✓	
Anxiety level (VAS)		✓					
Postnatal recall memory				✓	✓		

Legend: ✓, included in the study; –, not applicable.

Table 2
Individual Acupressure study findings on initiation and duration of labour.

	Chung et al. (2003)	Lee et al. (2004)	Kashanian and Shahali (2010)	Hjelmstedt et al. (2010)	Hamidzadeh et al. (2012)	El Hamid et al. (2012)	Ingram et al. (2005)
Labour onset	–	–	–	–	–	–	Intervention group (SP6, LIV4, GL21) more likely to labour spontaneously than standard care ($p = 0.038$)
First stage duration	Shorter in intervention group LI4/BL67 $p = .019$ NS	Shorter in intervention group SP6 $p = .009$	Shorter in intervention group SP6 $p = 0.0001$	–	Shorter in intervention group LI4 $p < 0.001$	Shorter in intervention group SP6 $p = 0.002$	–
Mean duration Hrs.mins.sec (SD)	LI4/BL67 = 6.33 (2.55) Placebo = 7.13 (3.14) Standard care = 8.45 (4.39)	#SP6 = 1.48.3 (52.1) Placebo = 2.26.3 (1.07)	SP6 = 4.12.37 (1.48.50) Placebo = 7.21.38 (2.35.88)		LI4 = 2.44 (0.79) Placebo = 3.09 (1.01)	SP6 = 6.02 (1.07) Standard care = 9.45 (2.71)	
2nd stage duration	–	Shorter in intervention group SP6 $p = .082$ NS	–	–	Shorter in intervention group LI4 $p = 0.038$	Shorter in intervention group SP6 $p = 0.04$	–
Mean duration Mins.sec (SD)		# SP6 = 30.3 (22.6) Placebo = 44.8 (40.0)			LI4 = 20.51 (16.4) Placebo = 28.5 (20.8)	SP6 = 23.42 (12.0) Standard care = 34.89 (9.53)	
3rd stage duration	–	–	–	–	–	Shorter in intervention group SP6 $p = 0.48$ NS	–
Mean duration Mins.sec (SD)						SP6 = 6.69 (1.74) Standard care = 6.91 (1.66)	
Total duration of labour	–	Shorter in intervention group SP6 $p = .006$	–	–	–	Shorter in intervention group SP6 $p = 0.03$	Shorter in standard care group $p = 0.19$ NS
Mean duration Hrs.mins (SD)		# SP6 = 2.18 (1.02) Placebo = 3.11 (1.23)				SP6 = 6.52 (1.29) Standard care = 10.14 (2.89)	Acupressure = 6.63 Standard care = 5.27

Mean difference in duration of stage of labour. SP6, Spleen 6; LI4, Large Intestine 4; BL67, Bladder 67; GB21, Gall Bladder 21; NS, not statistically significant; SD, standard deviation; Hrs, hours; mins, minutes; sec, seconds.

4.3. Acupoints used

The seven studies examined the effects of bilateral pressure on the specific acupoints on uterine contractions. Five studies examined the impact of one acupoint: SP6[20,34–36]; and LI4.[22] One study used two points: LI4 and BL67[19] and one study used three[33] SP6, LI4 and Gall Bladder 21, as described in Table 5.

4.4. Describing the acupoint technique: location and pressure

Three studies included explanation and diagrams of the acupoint/s location,[20,33,36] two studies described the acupoint location,[22,35] and two studies used diagrams without explanation.[19,34]

4.5. Amount of pressure used

Literature recommends using pressure on the acupoints to the woman's comfort.[25,41] Two studies explained the bilateral sustained pressure used on the acupoint was adapted to reach each participant's pain threshold.[33,35] However, the study by Ingram et al. was the only one in which participants self-administered the acupressure points while awaiting the onset of labour. Hjelmstedt et al.[45] explained that for consistency, the same person administered acupressure or the placebo touch but no further detail on amount of pressure was provided.

Originally the Chung et al.[19] study protocol included three acupoints (SP6, LI4 and BL67) with a standardising of applied pressure at 3–5 kg by the five nurse/midwives trained in the techniques. The authors reported that SP6 was eliminated after pilot testing "due to a high rejection rate by subjects because of the intolerable pain brought by stimulation of the acupoint" (p. 253). The pressure on SP6 may have been too strong for participants as TCM philosophy suggests SP6 will be painful if the energy flow or qi is blocked or not flowing easily.[25,42]

Lee et al.[20] used mean thumb pressure measured by electronic weight scales at 20,150 mm Hg (right) and 1911 mm Hg (left) administered by one person. Kashanian and Shahali[34] and El Hamid et al.[36] did not explain if the pressure used was adapted for

Table 3
Individual acupressure study findings – pain VAS scores and mode of birth.

	Chung et al. (2003)	Lee et al. (2004)	Kashanian and Shahali (2010)	Hjelmstedt et al. (2010)	Hamidzadeh et al. (2012)	El Hamid et al. (2012)	Ingram et al. (2005)
First stage of labour Mean VAS pain score	Decreased immediately after intervention in active phase of first stage ($p = 0.041$) Decreased in latent phase ($p = 0.51$ NS)	Decreased at all-time points after intervention SP6 Immediately after intervention ($p = 0.012$) 30 mins ($p = 0.021$) 60 mins ($p = 0.012$)	Decreased immediately after intervention SP6 ($p = 0.003$)	Decreased at all-time points after intervention SP6 Immediately after invention ($p < 0.001$) 30, 60, 120 mins ($p < 0.05$)	Decreased immediately after intervention LI4 Immediately after ($p < 0.001$) 20 mins ($p < 0.001$) 60 mins ($p < 0.001$) 120 mins ($p < 0.001$)	Decreased at all-time points after invention SP6 Immediately after ($p = 0.004$) 30 mins ($p = 0.002$) 60 mins ($p = 0.02$) 120 mins ($p = 0.03$)	–
Mode of birth	–	–	–	Increased vaginal birth rate in intervention group (NS) SP6 = 77.5% Placebo = 67.1% Standard care = 60.6%	Both intervention and control group had 92% normal vaginal birth rate	–	Decreased CS rate in acupressure group ($p = 0.60$ NS) Acupressure: SP6, LIV4, GB21 = 9.1% Control group = 11.8%

Mins, minutes; VAS, Visual Analogue Scale; NS, not statistically significant; CS, caesarean section; SP6, Spleen 6; LI4, Large Intestine 4; BL67, Bladder 67; GB21, Gall Bladder 21.

Table 4
Risk of bias.[29]

	Chung et al. (2003)	Lee et al. (2004)	Kashanian and Shahali (2010)	Hjelmstedt et al. (2010)	Hamidzadeh et al. (2012)	El Hamid et al. (2012)	Ingram et al. (2005)
Powered sample	–	–	–	✓	–	–	–
Randomisation	✓	✓	✓	✓	✓	*?Unclear*	–
Random sequence (selection bias)	Coin toss	Randomisation tables	Computer generated: block	Computer generated	Computer generated: block	Randomly allocated	–
Allocation concealment (selection bias)	✓ Sequentially numbered	*?Unclear*	✓ Sealed envelopes	✓ Sealed envelopes	*?Unclear*	*?Unclear*	Non-randomised trial
Blinding (performance/ detection bias)	*?Unclear* Drs blind to group allocation	Double blind: participants and assessors blind to group allocation	Un-blinded	Single blind: data collector blind to group allocation	Single blind: data collector blind to group allocation	Un-blinded	Un-blinded
Placebo group	–	✓	✓	✓	✓	–	–
Standard care	✓	–	–	✓	–	✓	✓
Intervention described	✓	✓	✓	✓	✓		✓
Treatment consistency	✓	✓	✓	✓	✓		✓
All outcome data reported	✓	✓	✓	✓	✓		✓
Incomplete outcome data (attrition bias)	✓	✓	✓	✓	✓		✓
Selective reporting (reporting bias)	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported	*?Unclear* No discussion section in article	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported		✓ All pre-specified outcomes reported
Study protocol provided	×	×	×	×	×		×
Consort Flowchart	×	×	×	✓	×		×

Legend: ✓, no identified bias; ×, not included; ?unclear, insufficient information to determine bias; –, not applicable.

Table 5
Acupoint locations.

Spleen 6 (SP6): 4 finger-widths above the medial malleous in the soft tissue at the posterior border of tibia.	**Gall Bladder 21 (GB21)**: mid-point between Cervical 7 and acromion process.
Large Intestine 4 (LI4): dorsum of the hand between 1st and 2nd metacarpal bone, between thumb and index finger	**Bladder 67 (BL67)** dorsum of the 5th toe, lateral aspect at corner base of nail just off the nail.

each participant's pain threshold or measured by electronic weight scales.

4.6. Duration of acupressure

There was slight variation in the duration of time assigned to the bilateral acupressure intervention for the six studies on labouring women (Table 1). One study administered sustained pressure on the acupoint during each contraction over a period of 20 min and four studies used a period of 30 min. Chung et al.[19] administered acupressure over a time period of 20 min with five cycles of 1-min duration (10 s pressure, then 2 s of rest) on each acupoint (4 points i.e. left and right hand LI4, and left and right foot BL67).

4.7. Initiation of labour

One study (Ingram et al., 2005) examined the effect of acupressure on the initiation of labour for women at 40 weeks gestation. The non-randomised controlled trial found that women experiencing a post-dates pregnancy who used acupressure were significantly more likely to labour spontaneously than those who did not ($p = 0.038$).[33]

4.8. Duration of labour

Of the seven studies, five examined the impact of acupressure on duration of labour and/or birth outcomes. Two studies[19,34] reported only on the duration of first stage of labour, two[20,22] reported on the duration of first and second stage of labour, and one study[36] reported on the three stages of labour. All five studies on the use of acupressure for decreasing labour duration found a shortened first stage of labour in the intervention group compared to placebo or no intervention/standard care. The mean length of first stage labour ranged from 2.44 to 6.33 h/min in the intervention groups compared to 3.09–7.21 h/min for placebo and 8.45–9.45 h/min for standard care (Table 2).[19,20,22,34,36]

4.9. Measures of pain in labour

Although pain in labour is not part of this review, all six studies conducted during labour reported on pain levels using a Visual Analogue Scale [VAS] (Table 3).[19,20,22,34–36] The VAS has been shown to have high validity and reliability in pain quantification.[43] The studies varied widely in how often the pain scores were repeated in relation to the intervention. A statistically significant decrease in pain was experienced by participants, immediately after the intervention and each measurement period thereafter, compared to placebo or standard care.[19,20,22,34–36]

A comparison of results from the six studies on acupressure during labour elicited many statistically significant findings and are summarised in Tables 2 and 3.

4.10. Risk of bias in included studies

Table 4 provides the risk of bias assessment of the included studies. Based on the six domains at study and outcome levels: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias[32]: no study was at low risk of bias on all domains.

5. Discussion

The increasing presence of complementary and alternative medicines (CAMs) and therapies such as acupressure in the maternity care setting highlights the need for such therapies to be evidence-based and for any safety issues to be assessed and addressed.[44] A systematic review provides a retrospective, criteria-based approach for summarising research findings.[45,46] By applying the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) 27-step checklist to the trials under review we were able to use predetermined standards and uniform criteria to evaluate the selected trials and potential bias in the quality assessment process.[45,46]

Publication bias was minimised with a comprehensive search. However, a recognised limitation of our review is the exclusion of eight, non-English translated studies (two Korean and six Iranian) due to lack of funding for translation.[47–54] Based on the abstracts, many were clinical trials comparing either or both acupressure points SP6 and LI4.

5.1. Effect of acupressure on initiation and labour duration

There was only one study examining the use of acupressure for initiating spontaneous labour.[33] This controlled trial showed women who used acupressure were more likely to commence spontaneous labour compared to women who did not however. There were no studies found on using acupressure to augment prolonged labour. These are two areas that require further investigation with an appropriately powered RCT.

All five studies on the use of acupressure for decreasing labour duration found a statistically significant effect for acupressure compared to placebo or no intervention/standard care in the first stage of labour.[19,20,22,34,36] Of the three studies of acupressure for shortening second stage of labour, only two found a significant effect using acupressure compared to placebo. Although not the focus of this review, six studies assessed the use of acupressure in relation to labour pain. A statistically significant decrease in pain was experienced by participants, immediately after the intervention and each measurement period thereafter, compared to placebo or standard care.[19,20,22,34–36]

5.2. Study protocols

The systematic review documented variation in the duration and amount of pressure used in the trials. Many studies included placebo to control for potential bias. Using the CONSORT checklist, the items most commonly missing included: step 1a (identification as RCT in title); step 7 (how the sample size was determined); and steps 8, 9, 10 (details of randomisation procedure).[37] One study did stratify for parity but did not analyse or report on the effect.[22] Only one study determined sample size and power and utilised a CONSORT diagram to outline the study process.[35]

It is unclear whether the treatment protocols used in the trials are generalisable to how acupressure is usually practised in labour as there is limited literature published in this area.[25] Based on the

studies reviewed and findings, it is recommended that future study protocols include the following: bilateral sustained acupressure on the acupoints Spleen 6 and/or Large Intestine 4, during contractions, for a total duration of 30 min, in 'early' established labour i.e. 3–4 cm cervical dilatation, and assess the outcomes of all stages of labour duration and pain relief in order to improve the comparability of studies.

5.3. Quality of included studies

Increasingly, researchers have used the RCT design to meet the gold standard for testing the effectiveness of an acupressure intervention. It is recognised that well conducted RCTs are more likely to have internal validity than non-randomised studies and thus accurately estimate the causal effects of interventions.[55] There has been an improvement in the quality and reporting of acupressure studies in maternity care in terms of study design, randomisation processes and data analysis. This may have been due to the various study authors' expanding knowledge of research generally and increased awareness of a number of research guidelines such as the CONSORT and TREND statements employed in this review.[37,38,56]

A weakness of a number of the acupressure trials in this review continues to be the omission of clinical outcomes related to safety such as emergency caesarean section, neonatal Apgar scores and admission to neonatal intensive care. A recent Cochrane meta-analysis[57] of acupuncture and acupressure for pain management in labour did not reveal any link between the use of acupressure and adverse events: no increase in emergency caesarean section or impact on Apgar scores between acupressure, placebo and control groups.[57] However, the Cochrane review included only four acupressure studies available at the time of review.[19,20,34,35]

6. Conclusion and implications for clinical practice

Based on the findings of this systematic review acupressure may be associated with shortening the duration of first stage of labour but the impact of acupressure on influencing the onset of spontaneous labour in women who are postdates and augmentation of labour, remains unknown. The limitation is the small number of studies included in this review and their methodological weaknesses; therefore the findings must be interpreted with caution.

The studies on the use of acupressure for labour duration appear to be improving in quantity and quality but there is much room for improvement. Midwives and acupressure practitioners are encouraged to undertake future research using the CONSORT guidelines for comprehensive reporting, and include data on neonatal outcomes and the effects on analgesia requirements in institutions with and without an epidural service.[57] This review identified only one non-randomised controlled study exploring the use of acupressure for initiating spontaneous onset of labour and reducing the rate of medical/surgical induction of labour. There is a need for further appropriately powered studies to examine the use of acupressure to initiate spontaneous labour or 'labour priming' especially for post-date pregnancy. More supporting evidence of efficacy needs to be produced before acupressure can be recommended for clinical practice for initiating onset of labour and shortening labour duration.

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Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

LM is currently undertaking a PhD which involves the evaluation of acupressure for induction of labour and labour duration. The other authors are also LM's PhD supervisors. LM performed the data collection; LM and MF independently reviewed each paper. JA and MF made critical revisions to the paper for important intellectual content.

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2.9 Additional studies published since the 2015 systematic review on the impact of acupressure

2.9.1 Acupressure for initiating labour/uterine contractions

Since publication of the systematic review (2015), a further four RCTs have been published between 2015 and 2017 investigating the use of acupressure and acupressure/shiatsu for post-date pregnancy (Gregson et al. 2015; Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017). The four RCTs were evaluated to determine their contribution to the evidence base by applying the CONSORT RCT guidelines checklist for non-pharmacological treatment (NPT) (Boutron et al. 2008) and the methodological bias tool by the Cochrane Collaboration (Higgins et al. 2011). The RCTs were of varying quality, with many failing to comply with the CONSORT requirements and featuring a range of methodological biases, as shown in tables 2.3–2.6. Compliance with the NPT checklist is discussed for each RCT in the following section.

A total of 718 women were recruited to the four studies; 130 women in a UK study (Gregson et al. 2015), and three studies in Iran (recruiting 150, 288 and 150 women, respectively) (Torkzahrani et al. 2015; Batool et al. 2015; Torkzahrani et al. 2017). Three studies recruited only nulliparous women (Gregson et al. 2015;

Torkzahrani et al. 2015; Torkzahrani et al. 2017), and one study recruited both nulliparous and multiparous women (Batool et al. 2015). In all four studies, non-labouring women were recruited either at 39–40 weeks' gestation (Torkzahrani et al. 2015; Torkzahrani et al. 2017), 40 weeks and greater (Batool et al. 2015) or 41 completed weeks (Gregson et al. 2015). Three studies describe attaining ethical approval from a named ethics committee (Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017), and the fourth mentions a local ethics committee (Gregson et al. 2015). All four studies mention obtaining participants' informed written consent.

As shown in Table 2.3, each of the four studies used different acupressure points: SP6 acupoint only (Torkzahrani et al. 2015); SP6 and LI4 (Gregson et al. 2015); SP6, LI4 and GB21 (Batool et al. 2015); and SP6, BL32 and BL60 (Torkzahrani et al. 2017). With regard to the control group, two studies compared acupressure with standard or routine care (Torkzahrani et al. 2015; Batool et al. 2015), whereas two studies compared acupressure with sham (Gregson et al. 2015; Torkzahrani et al. 2017). The sham involved applying pressure to ineffective areas. Three studies compared acupressure administration from the researcher with self-administration by the woman (Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017).

The aim of the UK study was to determine if acupressure would shorten the treatment to commencement-of-labour interval (Gregson et al. 2015). The study found no statistically significant difference between the two groups ($p = 0.19$) in treatment to commencement of labour. Labour induction was more common in the acupressure group compared with the sham group (41% v. 24%, $p = 0.004$) (Gregson et al. 2015). As shown in tables 2.3 and 2.6, this publication describes most of the features recommended in the CONSORT RCT NPT checklist (Boutron et al. 2008). However, it does not include the duration and amount of pressure applied to the points, other than stating that 20 intermittent presses were repeated four times a day. In addition, the publication fails to include details of the number of women who were eligible, invited and declined to participate. Not all outcome measures are included in the findings as are outlined in the methods (i.e., analgesia use, labour duration and neonatal intensive care unit admission). The authors conclude that the use of acupressure (LI4 and SP6) to induce labour

for nulliparous women does not appear to be effective, and that 'sham treatment' appears to be more successful (Gregson et al. 2015). However, there was a statistically significant difference ($p = 0.02$) with a higher mean Bishop score (i.e., ripened cervix) for the sham acupressure group on entry into the study, which may have increased the rate of spontaneous labour onset and resulted in fewer labour inductions in this group ($p = 0.04$) (Gregson et al. 2015). The authors downplay this significant difference in the discussion section, stating that the difference was unlikely to affect the results in a major way (Gregson et al. 2015).

The second identified RCT was conducted in Iran with the aim to determine whether acupressure (SP6) influenced the primary outcome of cervical ripening (Torkzahrani et al. 2015). All features as per the CONSORT RCT checklist are described (Table 2.3 and 2.6). A significant difference in Bishop score and cervical ripening at 48 hours with the acupressure by researcher group ($p < 0.021$) and the self-administered acupressure group ($p < 0.007$) compared with routine care was found (Torkzahrani et al. 2015). A statistically significant difference between the two acupressure groups and routine care on admission to hospital was found ($p < 0.02$), but no difference between groups at 96 hours (Torkzahrani et al. 2015). This study is more robust than Gregson et al.'s (2015), as there was no difference in the mean Bishop score of participants in each group at the study's commencement, thus providing a comparable baseline for each group and more credible results.

The third RCT, also conducted in Iran, intended to establish if shiatsu/acupressure has an effect on labour induction for post-date pregnancy (Batool et al. 2015). There was an increased use of oxytocin ($p < 0.001$), use of analgesia ($p < 0.001$) and fetal distress ($p < 0.001$) in the control group when compared with the two intervention groups (Batool et al. 2015). At recruitment, the Bishop score differed, with a mean score of 4.3 in the intervention groups and 5.5 in the control group. While spontaneous labour onset was increased in the intervention group, the level of significance is not provided, as shown in Table 2.3. Most of the features as per the CONSORT RCT checklist are described (tables 2.3 and 2.6). However, the publication does not include the gestation of the post-date participants when the initial acupressure/shiatsu was attended, or note if an additional session was required for participants in the intervention

groups; further, there is no sub-analysis of the two intervention groups. The authors question their study findings, as the control group had a higher mean Bishop score on study entry and shorter mean labour duration, but reduced spontaneous labour initiation compared with the acupressure/shiatsu groups (Batool et al. 2015). The shorter mean labour duration for the control group could be explained by the higher Bishop score at study entry. The authors suggest that follow-up visits and stripping of the membranes may have assisted the outcome in the intervention group (Batool et al. 2015), yet membrane sweeping is not identified for either group in the methods or findings section of the article.

The fourth RCT, also from Iran, aimed to evaluate the effect of acupressure on the initiation of spontaneous labour (Torkzahrani et al. 2017). Table 2.3 outlines the three acupressure procedures. All features as per the CONSORT RCT checklist are described (tables 2.3 and 2.6). Similar to Torkzahrani's previous study (Torkzahrani et al. 2015), participants were examined 48 hours and 96 hours after the commencement of the intervention and at the time of hospitalisation (Torkzahrani et al. 2017). There were no differences in any baseline characteristics, including cervical Bishop score or BMI. No significant differences were found for spontaneous initiation of labour at 48 hours after commencing ($p = 0.464$), at 96 hours ($p = 0.111$) and at time of hospitalisation ($p = 0.897$) (Table 2.3). The authors conclude that 'acupressure was not effective in stimulating spontaneous birth or reducing the rate of caesarean section when compared to sham acupressure or usual care groups' (Torkzahrani et al. 2017, p. 50). They identify the small sample size ($n = 150$) as a study limitation; however, the calculated sample size was 162 and 162 women were enrolled, with 150 completing the study (Torkzahrani et al. 2017). Twelve participants were lost, either to follow-up ($n = 8$), birthing at another hospital ($n = 3$) or withdrawing from the study ($n = 1$). The authors include participants' fear of fetal complications as a limitation, but do not address this issue in the introduction, findings or discussion sections of the article.

When attempting to analyse current studies that aim to determine if acupressure has an effect on initiating labour contractions, it soon becomes apparent that each study uses a different study protocol—different acupressure points, duration of pressure, duration of total intervention and study participants' gestation (at

term and post date). These differences make it difficult to determine the effective dose and combination of acupressure points to initiate spontaneous labour for post-date pregnancies. To determine the effective dosage of acupressure further research is required with a standardised protocol for participants based on available evidence or if not available, expert opinion.

2.9.2 Acupressure for labour duration and/or pain relief

Since the publication of Mollart, Adam and Foureur's (2015) systematic review, a further nine studies have explored the use of acupressure during labour: five on the use of acupressure and its effect on labour duration (Akbarzadeh et al. 2016; Dabiri & Shahi 2014; Deepak & Chopra 2013; Mafetoni & Shimo 2015; Yesilcicek Calik & Komurcu 2014) and four on acupressure and delivery outcomes and labour pain (Akbarzadeh et al. 2013; Akbarzadeh et al. 2014; Akbarzadeh, Masoundi, Jowkar et al. 2015a; Akbarzadeh, Moradi, Jowkar, Zare, & Hadianfard 2015b). One study has compared the effect of acupressure points (LI4 and KID 1) on pain intensity in labour (Kaviani et al. 2015), and was therefore not included in this update. Tables 2.3–2.6 provide a summary of the nine studies.

A meta-analysis of the effect of acupressure on duration of labour and mode of delivery was published in 2016 (Makvandi et al. 2016). A total of 13 studies are included, with the primary outcomes being labour duration and mode of delivery. The meta-analysis features all acupressure studies on labour duration and pain identified in the systematic review (Mollart, Adam & Foureur 2015) and in this section (2.9.2). The analysis found that acupressure decreased the duration of the active phase of labour by 1.3 hours (95% CI –1.738 to –0.882; $p < 0.001$), and the second stage of labour by 5.8 minutes (95% CI –1.615 to –0.807; $p < 0.001$) (Makvandi et al. 2016). Acupressure also increased the chance of vaginal birth compared with placebo/no intervention (OR 2.329, 95%CI 1.348 to 4.024; $p = 0.005$) (Makvandi et al. 2016). This 2016 article identifies a number of limitations to the meta-analysis: publication bias, quality of RCTs and significant heterogeneity between studies (Makvandi et al. 2016). The meta-analysis supports our systematic review findings that acupressure has a role in reducing labour duration and identifies the potential to reduce CS operation rates (Makvandi et al. 2016; Mollart, Adam & Foureur 2015).

2.10 Chapter summary

Chapter 2 has highlighted the current concerns with post-date pregnancy, labour induction and increasing medical intervention, and the prevalence, characteristics and determinants of self-help strategies and CAM use in pregnancy and for initiating labour onset. This chapter has included the results of the published systematic review and more recent studies indicating that acupressure appears to have an effect on duration of first stage of labour and pain in labour. The international studies on acupressure for labour priming and during labour found women were interested in participating in the trials and using acupressure. However, there is a gap in knowledge about Australian women's use of acupressure for post-dates and in labour and further research is warranted. The use of acupressure for initiating labour needs to be evaluated in the Australian context with an FRCT to determine the effective dosage of acupressure as well as acceptability, recruitment, practicality and adaptability of this modality. To be able to determine these aspects of feasibility, participants and health professionals' (midwives and doctors) attitudes and views of CAM and experiences with RCTs of CAM efficacy need to be explored via qualitative methods. The next chapter provides the justification for the design of this project and methods used for the FRCT.

Table 2.2: Studies of effect of acupressure on labour initiation (2015 – April 2017)

	Gregson et al. 2015	Torkzahrani et al. 2015	Batool et al. 2015	Torkzahrani et al. 2017
Inclusion criteria				
Nulliparous/multipara	Nulliparas only	Nulliparas only	✓	Nulliparas only
Singleton pregnancy	✓	✓	✓	✓
Term gestation	41/40	39–41/40	40/40+	39–40
Low-risk pregnancy	✓	✓	✓	✓
Active labour (cervix dilatation)	*Not in labour*	*Nil Bishop score <4*	*Not in labour, Cx less 3 cm*	*Bishop score <4 Not in labour*
No augmentation	-	-	-	
No IV oxytocin	-	-	-	
No analgesia	-	-	-	
Membrane status	Intact	Intact	Intact	
Group allocation				
Standard care		N = 50	N = 144	N = 50
Placebo	Sham (n = 60) Patella and olecranon			Sham (n = 50) 3 ineffective points—hands and legs
Intervention acupressure	SP6 + LI4 n = 70	SP6 by researcher (n = 50) SP6 by woman (n = 50)	GL21 + SP6 + LI4 (n = 144)	SP + BL32 + BL60 (n = 50) Researcher: every other day 9–11 am, Woman: 9–11 am and 3–5 pm
Intervention/duration	Initial: 20 intermittent press points *(duration unknown)*; woman: repeat 4 times/day	Total 20 mins on right leg: 2 mins pressure and 2 mins rest, every 24 hrs, 9–11 am	30 secs on each point, once by researcher	Total 30 mins: 1 min pressure, 1 min rest, repeat = each acupoint 5 mins
Research question/Outcomes measured				
Bishop score—study entry	✓	✓		✓
Bishop score on admission	✓	✓	✓	
Cervical dilation on admission				
Labour onset	✓	✓	✓	✓
1st-stage duration			✓#	
2nd-stage duration			✓#	
3rd-stage duration			✓#	
Total labour duration			✓	
Pain (VAS score)				
Mode of Birth	✓		✓	✓
Augmentation—IV oxytocin	✓		✓	

 # data collected but not included in study article.

	Gregson et al. 2015	Torkzahrani et al. 2015	Batool et al. 2015	Torkzahrani et al. 2017
Mean Bishop score on study commencement (SD)	Acupressure SP6 + LI4 = 3.4 (2.2) compared with Sham = 4.3 (2.3), **p = 0.02**	Equal to or less than 4 NS between 3 groups (p = 0.464)		No difference in Bishop score between 3 groups at commencement (p=.508)
Bishop score: 48 hrs after study commencement	–	Increased Bishop score in SP6 groups: SP6 by researcher p = 0.021 SP6 by woman p = 0.007		
Mean Bishop score (SD)	–	SP6 by researcher = 4.88 (1.83), SP6 by woman = 5.12 (1.92), Standard care = 4.06 (1.59)		
Bishop score 96 hrs after study commencement **Mean Bishop score (SD)**	– –	Bishop score higher in acupressure groups = 0.95 NS SP6 by researcher = 5.08 (1.77), SP6 by woman = 5.25 (1.75), Standard care = 5.04 (1.96)		
Bishop score on admission for IOL or spont. onset	–	Increased Bishop score in SP6 groups p < 0.02 (ANOVA)	Mean Bishop score 4.3 in intervention group compared with 5.5 in control	
Mean Bishop score (SD)	–	SP6 by researcher = 5.95 (2.02), SP6 by woman = 6.02 (1.68), Standard care = 5.02 (2.03)		
Requirement for labour induction, n (%)	IOL higher rate in acupressure 28 (41) compared with sham group 14 (24) p = 0.04	–	Fewer women in intervention group (78/144, 54.5%) required augmentation than in control (134/144, 93.1%) p < .001	
Labour onset	No difference in timing from intervention start to labour start between acupressure and sham groups (p = 0.19)		More women in intervention group (82/144, 56.9%) started labour spontaneously than in control (12/144, 8.3%)	No difference interval from procedure to birth among 3 groups (p = .565)
Total labour duration ***Mean duration hrs mins***	– –		– No difference in mean labour duration p > .05	
Mode of birth, n (%)	No difference in mode of birth p = 0.90 NS		No difference in mode of birth p < .207	No difference in mode of birth p = .726

ANOVA = analysis of variance; BL67 = bladder 67; CS = caesarean section; GB21 = gall bladder 21; hrs = hours; IOL = induction of labour; LI4 = large intestine 4; mins = minutes; – = not applicable; NS = not statistically significant; SD = standard deviation; secs = seconds;SP6 = spleen 6.

Table 2.3: Studies of effect of acupressure on labour duration and pain (2015 – April 2017)

	Akbarzadeh et al. 2013	**Deepak et al. 2013**	**Calik et al. 2014**	**Dabiri & Shahi 2014**	**Kaviani et al. 2015**	**Mafetoni & Shimo 2015**	**Akbarzadeh, Moradi, Jowkar, et al. 2015**	**Akbarzadeh et al. 2014–2016~**
Inclusion criteria								
Nulliparous/ Multipara	Nulliparas only	Nulliparas only	Nulliparas only	✓	Nulliparas only	✓	Nulliparas only	✓
Singleton pregnancy	✓	✓	✓	✓	✓	✓	✓	✓
Term gestation	✓	34–41 wks	✓	✓	✓	✓	✓	✓
Low-risk pregnancy	✓	✓	✓	✓	✓	✓	✓	✓
Active labour (cervix dilatation)	3–4 cm	3 cm	2 cm	4–5 cm	3–4 cm	4 cm	3–4 cm	4 cm
No augmentation	✓			✓			✓	✓
No IV oxytocin	✓			✓			✓	✓
No analgesia			✓	✓	✓		No epidural	
Membrane status			Intact					
Group allocation								
Standard care	–	N = 30	N = 50	N = 49	N = 26	N = 52		N = 50
Placebo	Touch SP6 n = 50	–	–	Touch LI4 n = 50	–	Touch SP6 n = 52	Touch GB21 n = 50	Doula care n = 50
Intervention acupressure	1. SP6 x 1 @ 3–4 cm n = 50 2. SP6 x 2 @ 3–4 cm & 7–8 cm n = 50	GB21 + LI4+ SP6 + Bl60 + KID1 + buttock point n = 30	SP6 n = 50	LI4 n = 50	1. KID1 n = 26 2. LI4 n = 26	SP6 n = 52	1. GB21 x 1 @ 3–4 cm n = 50 2. GB21 x 2 @ 3–4 cm & 7–8 cm	BL32 n = 50
Intervention/duration	20 mins during contractions; 30 secs pressure & 30 secs rest	30 mins at 3 cm and 7 cm *(unknown if during contractions)*	During contractions: 35 times at 2–3 cm, 10 at 5–6 cm, 10 at 8–9 cm	30 mins during contractions: 1 min pressure & 1 min rest	10 mins during contractions at 3–4 cm, 7–8 cm & 2nd stage	20 mins during contractions	20 mins during contractions: 30 secs pressure & 30 secs rest	30 mins during contractions at 3–4 cm & 7–8 cm

Research question/outcome measured								
Onset of labour		✓				✓		
1st stage duration	✓	✓	✓	✓			✓	✓
2nd stage duration	✓		✓				✓	✓
3rd stage duration								
Total labour duration			✓			✓		
Pain (VAS score)	✓	✓	✓	✓	✓		✓	✓
Mode of birth	✓	✓		✓		✓	✓	✓
Augmentation—IV oxytocin		✓				✓		
Anxiety level (VAS)								✓ Spielberger
Postnatal recall memory								

~: 3 articles combined of same study

Table 2.4: Individual acupressure study findings on labour duration (updated April 2017)

	Akbarzadeh et al. 2013	Deepak et al. 2013	Calik et al. 2014	Dabiri & Shahi 2015	Mafetoni & Shimo 2015	Akbarzadeh, Morandi, Jowkar et al. 2015	Akbarzadeh et al. 2014-2016~
1st-stage duration	Shorter in the both acupressure groups p = 0.001	Shorter in acupressure group p = 0.001	Shorter in the intervention SP6 group p < 0.000	No difference between intervention (LI4), touch or standard care (p = 0.942)	–	Shorter in the intervention GB21 groups *(? Or GB21 x 2*) than touch p < 0.001	Shorter in the acupressure and doula/ support care compared with standard care p < 0.001 *(Data not provided if difference between acupressure and doula groups)*
***Mean duration hrs, mins, secs (SD*)**	SP6 x 1 = 3.06 (1.02) SP6 x 2 = 3.04 (1.08) Placebo/touch = 3.61 (0.67)	Acupressure = 696.87mins (187.19) Standard care = 860.17mins (1.66.57)	SP6 = 3.75 (SD?) Standard care = 5.33 (SD?)	*Data not provided in article*	–	1. GB21 x 1 = 3.06 (1.02hrs) 2. GB21 x 2 = 2.86 (1.08hrs) 3. Touch = 3.61 (0.67hrs)	BL32 = 161.7mins (37.3) Doula = 157.0 mins (29.5) Standard care = 281.0 mins (79.8)
2nd-stage duration	Shorter in the acupressure groups p = 0.44 NS	–	Shorter in the intervention SP6 group p = 0.002	–	–	Shorter in intervention groups NS p = 0.44	Shorter in the acupressure and doula/support care compared with standard care p < 0.001 *(Data not provided if difference between acupressure and doula groups)*
Mean duration mins, secs (SD)	SP6 x 1 = 36.68 (12.63) SP6 x 2 = 37.15.1 Placebo = 40.44 (20.13)	–	SP6 = 15.0 (SD?) Standard care = 20.0 (SD?)	–	–	1. GB21 x 1 = 36.72 (12.63mins) 2. GB21 x 2 = 37.45 (15.1mins) 3. Touch = 40.44 (20.13mins)	BL32 = 56.2mins (31.4) Doula = 58.9mins (25.8) Standard care = 128.4min (44.9)
3rd-stage duration	–	–	–	–	–		
Mean duration mins, secs (SD)	–	–	–	–	–		
Total labour duration	–	–	Shorter in intervention SP6 group p < 0.0001	–	Shorter in SP6 group p < 0.016		
Mean duration hrs, mins (SD):	–	–		–			

 # Mean difference in duration of labour stage; BL67 = bladder 67; GB21 = gall bladder 21; hrs = hours; LI4 = large intestine 4; mins = minutes; – = not applicable ; NS = not statistically significant; SD = standard deviation; secs = seconds;SP6 = spleen 6; ~3 articles of same study by same authors.

Table 2.5: Methodology bias—acupressure studies on labour duration and pain (updated April 2017)

	Gregson et al. 2015	**Torkzahrani et al. 2015**	**Batool et al. 2015**	**Torkzahrani et al. 2017**
Powered sample	✓	✓	✓	✓
Randomisation	✓	✓	✓	✓
Random sequence (selection bias)	Computer generated	Randomised table	Randomised table	Computer generated
Allocation concealment (selection bias)	✓ Sealed sequential envelopes	*? unclear*	*? unclear*	*? unclear*
Blinding (performance/ detection bias)	Single blind: investigators and participant blind to allocation	Un-blinded		Double blind
Placebo group	✓ (sham)			✓ (sham)
Standard care		✓	✓	✓
Intervention described Treatment consistency	*? Unclear on intervention duration* ✓	✓ ✓	✓	✓
All outcome data reported	× not all included	✓	✓	✓
Incomplete outcome data (attrition bias)	× (*attrition not reported*)	✓	✓	✓
Selective reporting (reporting bias)	× Not all pre-specified outcomes reported	✓ All pre-specified outcomes reported	✓ Outcomes reported but p value not presented for all outcomes	✓
CONSORT flowchart	×	✓	×	✓
Study protocol provided	×	Included in article	Included in article	Included in article

Legend: ✓ = no identified bias; – = not applicable; × = not included; ? unclear = insufficient information to determine bias.

Table 2.5: Methodology bias (cont'd)

	Akbarzadeh et al. 2013 *SP6*	**Deepak et al. 2013**	**Calik& Komurcu 2014**	**Dabiri & Shahi 2015**	**Mafetoni& Shimo 2015**	**Akbarzadeh et al. 2015–*GB21***	**Akbarzadeh et al. 2014–2016~*BL32***
Powered sample	✓	×	✓	As per Similar studies	✓	× Convenience (150)	✓
Randomisation	?	✓	✓	✓	✓	✓	✓
Random sequence (selection bias)	Not randomised—purposive	Lottery method	✓ 2-part block-	Randomly allocated-	Randomisation list	Randomisation table	Randomisation table
Allocation concealment (selection bias)	✓ Sequential draw	*? unclear*	✓ Sealed sequential envelopes	×	×	× Sequential draw	× Stratified block randomisation
Blinding (performance/ detection bias)	Single blind: participants unaware of other interventions	Un-blinded	Single blind: stated *? unclear*	Single blind: stated *? unclear*	Double blind: participants and carers blind to intervention group	Un-blinded	*? unclear* *? un-blinded*
Placebo group	✓			✓	✓	✓	✓ (Doula/support)
Standard care		✓	✓	✓	✓		✓
Intervention described	✓	*? unclear*	✓	✓	*? unclear*	✓	✓
Treatment consistency	✓	✓	✓	✓	✓	✓	✓
All outcome data reported	✓	*? unclear* *Mode of delivery not reported*	✓	*? unclear*	✓	✓ *(satisfaction reported but not included in method)*	✓
Incomplete outcome data (attrition bias)	✓	✓ *(?no attrition)*	✓	*? unclear*	✓	*? unclear* *(?no attrition)*	*? unclear* *(?no attrition)*
Selective reporting (reporting bias)	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported	✓ All pre-specified outcomes reported	✓ *(sub-analysis for intervention groups not included)*	✓ *(sub-analysis for intervention groups not included)*
CONSORT flowchart	×	×	✓	✓	✓	×	×
Study protocol provided	×	×	×	×	×	×	×

Legend: ✓ = no identified bias; – = not applicable; × = not included; ? unclear = insufficient information to determine bias.

STUDY 1

Chapter 3: Study design and method

3.1 Chapter overview

This chapter provides the rationale for using a sequential mixed-methods study design with two sequential studies, Study 1 and Study 2. Study 1 includes an FRCT of acupressure for women who are post-date together with a survey of trial participants and focus groups with healthcare staff at the trial setting. Study 2 is a national survey of Australian midwives about their practices, knowledge, referral patterns, attitudes and views, and personal use of CAM.

This chapter explains the reason why an FRCT was chosen for Study 1 rather than a pilot study. It also presents the RCT protocol, the data-collection methods and the analysis for the subsequent, related qualitative studies in Study 1. Study 2 arose following the analysis of Study 1 data that raised questions about the feasibility of RCTs in this area related to midwives' experiences of CAM and acupressure in particular. Therefore, the detailed design of Study 2 is presented in a separate and subsequent chapter (6) that follows the analysis and discussion of Study 1 in chapters 4 and 5.

3.2 Rationale for the sequential mixed-methods study design

Until recently, qualitative (QUAL) and quantitative (QUAN) research, which have roots in the different 'world views' of constructivism and logical empiricism, have been presented as competing paradigms (Pluye et al. 2009; Teddlie & Tashakkori 2009). Constructivism is most frequently associated with inductive (QUAL) studies of context-bound information leading to patterns or theories that help explain a phenomenon, whereas logical empiricism is most frequently associated with deductive (QUAN) studies of logic, where theories and hypotheses are tested in a cause-and-effect order (Creswell 1994; Pluye et al. 2009; Teddlie & Tashakkori 2009). Only since the 1960s has the model of combining the approaches been introduced (Johnson & Onwuegbuzie 2004; Teddlie & Tashakkori 2009).

Mixed methodology involves philosophical assumptions that guide the direction of collecting and analysing data, and the mixture of the two approaches. Its logic

of inquiry includes the use of induction (or discovering patterns), deduction or reasoning (testing theories and hypotheses) and abduction (uncovering and relying on the best of a set of explanations for understanding one's results) (Bishop & Holmes 2013; Johnson & Onwuegbuzie 2004). The complementary approach of combining the two different research paradigms facilitates a wider breadth and depth of understanding (Pluye et al. 2009).

3.2.1 Mixed model and mixed methods

Mixed-methods research focuses on the 'collecting, analysing, and interpreting of both quantitative and qualitative data in a single study or in a series of studies that investigate the same underlying phenomenon' (Leech & Onwuegbuzie 2007, p. 276). The philosophical orientation most often associated with mixed methods is pragmatism (Teddlie & Tashakkori 2009, p. 7). Teddlie and Tashakkori (2009) define pragmatism as follows:

> a deconstruction paradigm that debunks concepts as 'truth' or 'reality' and focuses instead on 'what works' as the truth regarding the research questions under investigation. Pragmatism rejects the either/or choices associated with the paradigm wars, advocates for the use of mixed methods in research, and acknowledges that the values of the researcher play a large role in interpretation of results (p. 8).

Johnson and Onwuegbuzie (2004) describe the two major types of mixed-methods research: *mixed model*, which combines qualitative and quantitative approaches within or across the stages of the research process, and *mixed method*, which includes a quantitative phase and a qualitative phase in an overall research study. It is also possible to design a study that includes both mixed-model and mixed-methods design features (Johnson & Onwuegbuzie 2004; Teddlie & Tashakkori 2009). However, the time order of the QUAL and QUAN phases is another important dimension, and the phases can be carried out concurrently or sequentially (Leech & Onwuegbuzie 2009).

3.2.2 Sequential mixed-methods design

In a sequential mixed-methods design, the QUAN and QUAL approaches of the study/research occur in chronological order. Questions or procedures (sampling

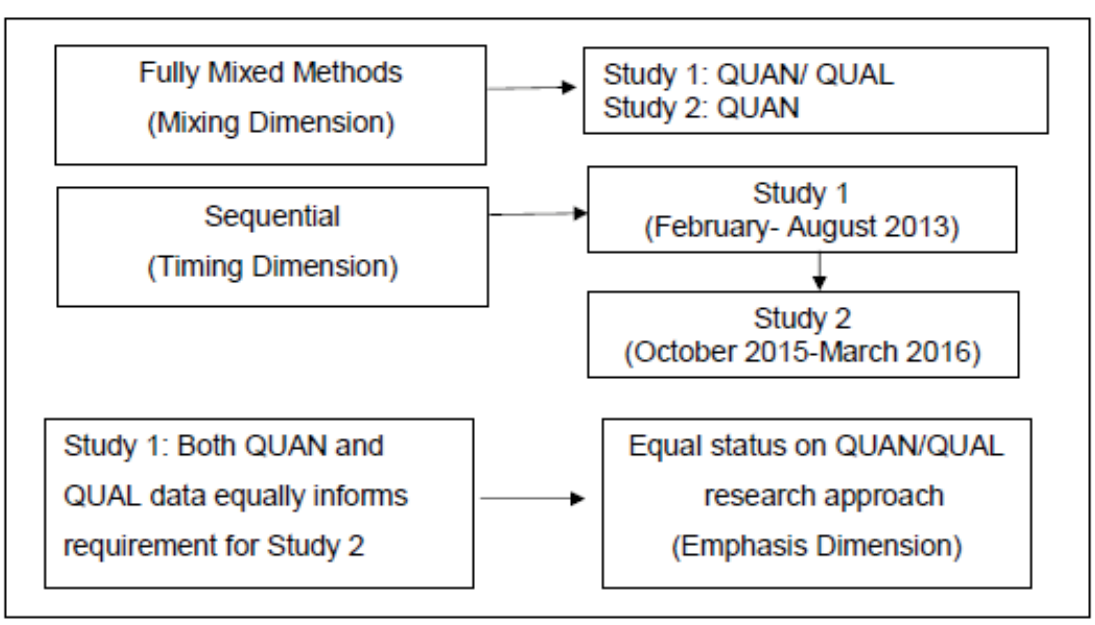
or data collection) of one strand emerge from or are dependent on the previous strand and may evolve as the study unfolds (Teddlie & Tashakkori 2009). Leech and Onwuegbuzie (2009) outline eight mixed-methods research designs based on three dimensions: a) level of mixing (partial versus full), b) time orientation (concurrent versus sequential) and c) weight on research approach (equal weight versus dominant status on QUAN/QUAL research approach).

Figure 3.1 defines this PhD project as a 'fully fixed sequential equal status' design that involves

> conducting a study that mixes qualitative and quantitative research within one or more of, or across the stages of the research process. In this design, the quantitative and qualitative phases occur sequentially at one or more stages or across the stages. Both elements are given approximately equal weight (Leech & Onwuegbuzie 2009, p. 271).

The project comprises Study 1 (mixed model) and Study 2 (quantitative).

Figure 3.1: PhD project—sequential mixed-methods design (after Leech & Onwuegbuzie 2009, p. 273)



Researchers have started to include qualitative research methods into RCTs and feasibility studies to improve the investigators' understanding of CAM interventions and participants' experiences and produce more comprehensive accounts of this complex phenomena (Bishop & Holmes 2013; Fonteyn and

Bauer-Wu 2005; Fox et al. 2013). Incorporating qualitative data and analysis into my study aims to increase understanding of trial feasibility using acupressure in real life and real time, and will identify the burdens (and benefits) of this intervention while potentially gaining information that might not otherwise be known (Fonteyn & Bauer-Wu 2005; Smith, Pirotta & Kilbreath 2014).

3.2.3 Feasibility RCT compared with pilot study

At the time of designing Study 1, only one published study investigating the use of acupressure points for initiating spontaneous labour onset was identified: a quality improvement project conducted in the UK (Ingram et al. 2005). Studies exploring the use of acupressure for labour duration and pain had been conducted in Egypt, Iran, India, Korea and Taiwan. No studies had been conducted in Australia. Study 1 was thus the first time a study on primigravid women to be undertaken in Australia in a public hospital setting. A decision needed to be made regarding whether to conduct a pilot or feasibility study.

Piloting a design is usually undertaken when the researcher wants to test study procedures, validate study tools, calculate the sample size for an RCT or undertake the first phase of a substantive study (Arain et al. 2010). However, Arnold et al. (2009) further define the pilot design into three distinct areas:

> *pilot work* as any background research that informs a future study; *pilot study* refers to studies with a specific hypothesis, objective, and methodology; and *pilot trial* refers to a stand-alone pilot study that includes a randomization procedure (p. S69).

It is recommended that researchers be aware of the different requirements of pilot studies and feasibility studies and report appropriately (Arain et al. 2010). An FRCT design is usually chosen when there is a need to determine eight key attributes of any proposed intervention. These attributes include acceptability (how participants react to the intervention), demand/recruitment (whether there is a demand for this type of intervention in this population), implementation/practicality (how easy or difficult it is to fully implement the intervention given the constraints of the setting) and adaptability/integration of this modality incorporating study participants' and health professionals' experiences (as outlined in Table 3.1 below) (Bowen et al. 2009). A feasibility trial

need not have a primary outcome and a power calculation is not normally undertaken, since it aims for limited-efficacy testing with a convenience sample and intermediate outcomes. Instead, the sample size should be adequate to estimate the eight focus areas to the necessary degree of precision (National Institute for Health Research [NIHR] 2017). Efficacy is the extent to which an intervention produces the expected result under ideal circumstances such as RCTs with a homogenous patient population (Witt 2011, Kim 2013) whereas 'effectiveness' assesses the intervention when provided in 'real life' or under usual circumstances of health care practice (Kim 2013).

Table 3.1: Feasibility study focus areas (Source: Bowen et al. 2009)

Focus area	Outcome
Acceptability	How recipients react to the intervention.
Demand	Estimated use of intervention in defined population/setting.
Implementation	Extent, likelihood intervention will be fully implemented as planned.
Practicality	Extent intervention can be provided with constraints, e.g., resources, time, etc.
Adaptation	Changing content or procedures appropriate to new population/setting.
Integration	Level of system change needed to integrate intervention into existing infrastructure/program/service.
Exploration	Potential success of already successful intervention with a different population/setting.
Limited-efficacy testing	Convenience sample with intermediate rather than final outcomes, with shorter follow-up periods or limited statistical power.

After reviewing the components of feasibility and pilot studies, I decided to choose a feasibility study design for the Study 1 RCT to answer the question, can this study be done in an Australian maternity setting? (NIHR 2017). Further, the eight areas of focus would address several gaps in current knowledge about the use of CAM and acupressure in maternity care and would best meet Study 1 objectives. Therefore, I designed a study protocol for an FRCT that is detailed in the following section.

3.3 Study 1 protocol: RCT feasibility study

3.3.1 Aim and objectives

To determine the feasibility of conducting an Australian trial of acupressure, a CAM modality, focusing on acupressure for post-date pregnancy (PR.E.P.A.RE: PRimgravidas Experiencing Post-date pregnancy Acupressure REsearch).

Study 1 addresses three of the four project objectives:

1. to undertake an FRCT on the efficacy of acupressure to initiate spontaneous labour onset for primigravid women experiencing post-date pregnancy
2. to explore participant women's views of acupressure, CAM and RCTs to increase understanding of the feasibility of RCTs in this area
3. to explore participant health professionals' views of acupressure, CAM and RCTs to increase understanding of the feasibility of RCTs in this area.

3.3.2 Study design

A mixed-methods study design was implemented and comprised an two-arm blinded RCT, a survey of trial participants and focus groups with maternity healthcare professionals. A FRCT design was chosen to address the eight focus areas of acceptability (how participants react to the acupressure), demand/recruitment (whether there is a demand for acupressure in this population), implementation/practicality (how easy or difficult it is to fully implement acupressure given the constraints of the setting) and adaptability/integration of this CAM modality incorporating study participants' and health professionals' experiences (Bowen et al. 2009).

3.3.3 Study setting

The study setting was two regional hospitals in one local health district (LHD) with a combined annual birth rate of approximately 2,900. The main hospital, with a birth rate of 2,600 per annum, was a level five maternity service (birthing from 32 weeks' gestation) with an eight-room birthing unit, 28-bed inpatient maternity ward, four-bed day assessment unit (DAU), special care nursery and antenatal clinics (Health System Planning and Investment 2017). The antenatal care

options available included high-risk obstetric clinics, midwife antenatal clinics (MAC), a community team midwives program (CMP), midwifery group practice (MGP) and a GP antenatal shared care program (Health System Planning and Investment 2017). The subsidiary hospital featured an outreach antenatal clinic for women requiring or wishing to birth at the main hospital, a high-risk obstetric clinic and a MAC. The women accessing the midwifery models of care (MAC, CMP and MGP) are considered normal risk—that is, with some risk factors (Australian College of Midwives [ACM] risk code A/B), but not requiring ongoing obstetric antenatal care (ACM risk code C) (ACM 2014). In Study 1, there was a stable midwifery workforce within the MGP (n = 10) and CMP (n = 10) compared rotating staff to the MAC (n = 10). Most of the midwives (80%) working in the midwifery care models had completed a one-day competency-based acupressure workshop (2010-2013). A guideline on the use of acupressure was approved by the maternity services policies and procedure committee in November 2011 prior to the commencement of the trial and endorsed by the health district policy and procedure committee in July 2012.

3.3.4 Study population

All eligible women receiving care at the study sites were invited to participate.

The inclusion criteria were as follows:

- primigravid women of gestation ≥ 41 weeks, with a singleton pregnancy
- cephalic presentation
- English speaking
- ≥ 18 years
- receiving antenatal care within a midwifery model of care (as per NSW PD 2010_022 Maternity—National Midwifery Guidelines for Consultation and Referral).

The exclusion criteria were as follows:

- women with a strong preference for using acupressure
- women experiencing regular uterine contractions (established labour)
- contra-indication for vaginal birth
- women who did not speak or read English

- women with an intellectual or mental impairment
- women who were highly dependent on medical care, required specialist medical/obstetric consultation and would usually have medical intervention prior to 41 weeks' gestation.

3.3.5 Sample size

It was estimated that a sample size of 60 women would be sufficient to provide data to address the feasibility study aims. It is recommended that a feasibility study have an adequate sample size to estimate the critical parameters (Table 3.1) (Bowen et al. 2009). Although a feasibility study usually aims for limited-efficacy testing with a convenience sample and intermediate outcomes, this feasibility RCT would also aim to calculate an effect size for a future, appropriately powered RCT. As funding was limited a pragmatic decision to cease recruitment was made when 44 women had been recruited (22 in each group), as this number was deemed sufficient to address the feasibility study aims.

3.3.6 Recruitment protocol

At the 40-week$^{(+/-\ 2days)}$ antenatal visit, the midwife identified if the woman met the eligibility criteria (as above) and was provided with a project information sheet, consent form and revocation of consent form (Appendix 3 and 4). The midwife informed the research assistant (RA) of the date and time of the next appointment for each woman who had received the project information.

At the 41-week antenatal visit, the RA approached the woman to ask if she received the information and whether she was interested in participating. After an eligibility check, consenting women were randomised using a remote internet-based randomisation/allocation service. The staff providing clinical care were unaware (blinded) of group allocation unless the participant disclosed study participation.

For the 40- and 41-week visits, 'usual care' included the following: blood pressure assessment, abdominal examination, fetal heart rate and assessment for any risk factors. The midwife also offers a vaginal examination and a 'strip and stretch' and provided appropriate information on 'natural strategies' for initiating labour, excluding acupressure.

If allocated to usual antenatal care, the participant was advised of her next clinic/DAU appointment at approximately 40 weeks plus 10 days$^{(+/-2\ days)}$ for an induction assessment, and an induction date was given (by 40 weeks and 14 days) as per local procedure PR2010_268. Maternal and fetal induction assessment included abdominal palpation, vaginal examination to determine Bishop score and electronic fetal monitoring (CTG).

Participants randomised to the intervention received information, education and instruction in the use of acupressure for three points by the midwife/RA (Figure 1). The participant was also advised of the next clinic/DAU appointment at approximately 40 weeks and 10 days$^{(+/-\ 2\ days)}$ for an induction assessment, and an induction date was given (by 40 weeks and 14 days) as per local procedure. Maternal and fetal induction assessment included abdominal palpation, vaginal examination to determine Bishop score and CTG.

3.3.7 Intervention protocol

The acupressure protocol and dosage (duration and frequency) was developed based on the literature review by the principle investigator (LM) and in consultation with Debra Betts, an internationally recognised leader in acupuncture and acupressure (Betts 2003).

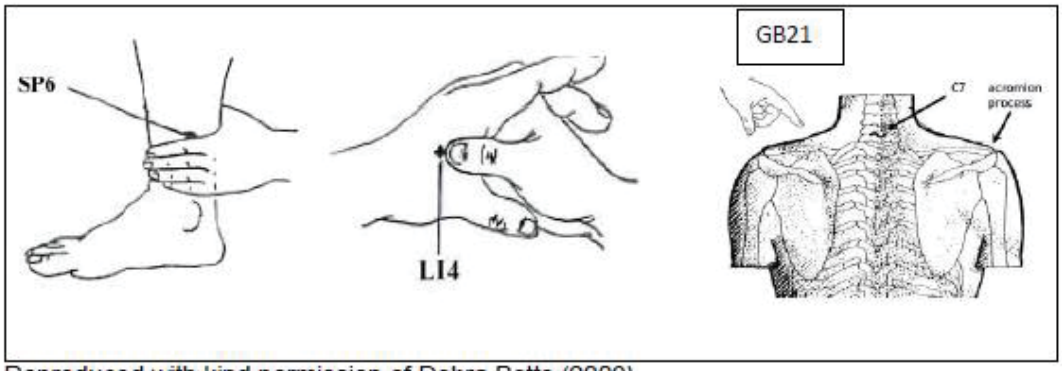
The woman and her partner/support person were shown the three bilateral points: SP6 (lower leg), LI4 (hand) and GB21 (shoulder) (see Figure 3.2). They were instructed on how to apply sustained bilateral pressure using thumb or finger for:

- two minutes on point SP6 (lower leg) followed by two minutes on LI4 (hand) every two hours during the day
- two minutes on point GB21 (shoulder point) twice a day (morning and evening).

The woman also received a written instruction sheet with diagrams showing the location of the points and descriptions of the timing and frequency of use (Appendix 5). A diary sheet was provided to the woman to record her use of acupressure and the points on a daily basis from recruitment (40 weeks and 7 days$^{(+/-\ 2\ days)}$) to commencement of labour, either spontaneous or medically/surgically induced (40 weeks and 10–14 days) (Appendix 6). The RA

contacted the woman one to two days after the 41-week antenatal visit to discuss the use of the acupressure points and to ask if further education was required.

Figure 3.2: FRCT acupressure points SP6, LI4 and GB21



Reproduced with kind permission of Debra Betts (2003)

3.4 Data collection

3.4.1 Clinical outcomes

Data were obtained from the hospital obstetric database (ObstetriX) and clinical records, including:

- demographic information, including age, model of care and past medical and surgical history
- clinical outcome measures for labour and birth, including labour onset (spontaneous or labour induction), timeframe from commenced use of points to labour commencement, type of delivery, length of labour and analgesia and other pain-relief options used.

3.4.2 Participant survey

A self-completed participant survey was provided to the women (either while they were in hospital or posted to their home address) to explore their experiences of the care received and opportunities for decision-making, their experience of participating in a randomised trial and being randomised and the use of any natural strategies to 'induce' labour. For woman randomised to the acupressure intervention, the participants completed questions on compliance with using the three points during pregnancy, if they were also used during labour and any partner involvement with the acupressure points. The women were asked to

return their completed diary sheet with their survey for review of compliance with intervention protocol. The survey is located in Appendix 7.

3.4.3 Focus group with health professionals

Four focus groups were conducted to examine the views of maternity service healthcare professionals towards the acceptability of acupressure and their views on the RCT. The focus groups used purposive sampling of healthcare professionals at the study sites to achieve participation from (and, therefore, the opinions of) both midwives and doctors. Flyers were distributed and displayed in the staff tearoom and an invitation letter sent by internal mail to all obstetric staff and midwives working in antenatal care (MAC, CMP, and MGP).

Prior to the commencement of the focus groups, written consent was obtained from the healthcare professional participants (Appendix 8 and 9). The independent facilitator provided a focus for the discussion by posing structured questions relating to participants' views on CAM in general, acupressure use in maternity specifically and the FRCT. The discussions were triggered by these questions, and the midwives and medical staff were encouraged to be open and reflective in sharing their views and insights. The location of the focus group sessions was chosen on the basis of suitability to the participants and to ensure confidentiality and privacy. The duration of the sessions did not exceed one hour. Each focus group was digitally recorded. The trigger questions for the focus groups are located in Appendix 10.

Focus groups were chosen using structured questions so participants could explore a range of opinions, beliefs and understandings about CAM and the acupressure RCT (Carey and Ashbury 2016; Ryan, Gandha, Culbertson and Carlson 2014). Since scoping structured approach assumes information sought is of opinions that are basically stable, data analysis focuses primarily on verbal content and not analysing participant's interactions (Ryan et al 2014). Due to limited funding it was not possible to conduce individual interviews with midwives and doctors. It is recognised that the focus group method may have resulted in some silencing of participants who may have had alternative views to those presented.

3.4.4 Data analysis

The Statistical Package for Social Science (SPSS) V.19.0 was used for data analysis in consultation with a statistician. Demographic and women's survey data were analysed using univariate descriptive analysis. Multivariate analyses were used to test for differences between the groups of women. Categorical data were analysed using Chi Square and Fisher's exact test (because of the small sample size). These data were analysed using odds ratio and 95% confidence intervals (CI). T-tests analysed normally distributed categorical and continuous data to compare means between the two groups of women reported as 95% CI. All levels of significance are reported as $p < 0.05$. Data analysed by a statistician was blinded to group allocation.

Qualitative questionnaire data were collated and content analysed by counting the number of participant comments in each response category (Sandelowski 2000). Thematic analysis of the transcripts was undertaken using the method described as fundamental or generic qualitative description (Caelli, Ray & Mill 2003; Merriam 2014; Sandelowski 2000), which aims to discover and understand a phenomenon or the perspectives of people involved that is low inference with themes generated from the data itself (Merriam 2014; Sandelowski 2000).

Two researchers (LM and MF) read the transcripts, generated initial codes from the data and then compared codes so that the analysis was reflexive and interactive. Codes were then grouped into themes and continuously modified to accommodate new data and new insights (Sandelowski 2000). Quotations were selected to illustrate the themes because they accurately reflected the experiences of a number of health professionals, or because they represented examples of a different perspective or experience.

3.4.5 Ethical issues

3.4.5.1 Participant discontinuation

Women were able to withdraw from the study at any time using a *Revocation of Consent Form*, but no women took up this option (Appendix 4).

3.4.5.2 Safety

Any serious adverse event would be given a Severity Assessment Code consistent with incident monitoring in NSW (NSW Health 2009) and reviewed by the LHD Maternity Clinical Risk Management Committee (MCRMC). The MCRMC includes representation from risk management, obstetrics and gynaecology and the clinical governance unit. The membership is independent of the trial investigators.

3.4.5.3 Security/privacy

Allocation concealment was assured by using a remote, internet-based computerised allocation service (Sealed Envelope). The RA registered the women's initials and dates of birth, and the computer program informed the RA of group allocation and provided the woman with a study number that was recorded in the trial register and log book.

All information was stored in locked filing cabinets and on password-protected computers and external hard drives that were disconnected daily and stored in the principal researcher's locked office, accessible only by the principal researchers and RA. The names and identifying features of people and places were removed from all data used for analysis. No identifying information will be used in written reports, presentations and publications. All information will be stored for seven years after the study's completion and the publication of the findings. The data files will then be shredded, destroyed and deleted.

3.4.5.4 Ethical approval

Human Research Ethics Committee (HREC) approval for two sites was provided by the Northern Sydney Local Health District HREC (1209-293M) (Appendix 1 and 2). Research governance approval for two hospital study sites was also obtained (SSA 1209-307M; 1210-354M) (Appendix 1 and 2).

3.5 Chapter summary

Chapter 3 has provided the rationale for using a sequential mixed-methods study design with two sequential studies, Study 1 and Study 2. The chapter has described the rationale for Study 1 design and outlined the Study 1 protocol, including the data-collection and analysis methods that address the three

objectives via an FRCT, participant survey and health professional focus groups. The next two chapters contain the two publications arising from Study 1; the next chapter presents the FRCT.

Chapter 4: Study 1—FRCT results

4.1 Chapter overview

This chapter presents the quantitative findings of the PR.E.P.A.RE FRCT (Publication 2). The trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: 12613000145707). The CONSORT guidelines were used to ensure that the study design was robust (Boutron et al. 2008). The feasibility questions addressed in Publication 2 are acceptability (recruitment), practicality and adaptability. The qualitative findings of Study 1 are reported in Chapter 5.

4.2 Publication 2: FRCT

The FRCT is a paper published as follows:

Mollart, L. (LM), Skinner, V. (VS) & Foureur, M. (MF). 2016, '**A feasibility randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy**', *Midwifery,* vol. 36, pp. 21–27. DOI: 10.1016/j.midw.2016.02.020.

The reader will thus find that the background material and study protocol have already been addressed in the previous chapters, and is therefore invited to go directly to the 'Findings' subheading of the publication.

NOTE: Since the release of Publication 2, the CONSORT statement has been extended to feasibility and pilot studies (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane, Lancaster & PAFS Consensus Group 2016).

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A feasibility randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy

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ABSTRACT

Objective: this Australian feasibility study aimed to determine; the willingness of women experiencing a post-date pregnancy to participate in a randomised controlled trial (RCT) of acupressure and compliance with the study protocol. The study also aimed to determine the effect size of the primary outcome in order to calculate a sample size for a future appropriately powered RCT.
Design: a two-arm randomised controlled trial. Staff providing clinical care were blinded to group allocation unless the participant disclosed study participation.
Setting: maternity services at two outer metropolitan public hospitals in New South Wales, Australia
Participants: sixty seven healthy primigravid women experiencing a singleton cephalic pregnancy at 40 weeks ± 2 days gestation were assessed as eligible to participate and were provided with study information.
Intervention: both groups received standard clinical care, with the intervention group also receiving verbal and written instructions on the self-administration of three acupoints (Spleen 6, Large Intestine 4, and Gall Bladder 21) to be used until spontaneous or induced labour began.
Measurements: assessment of feasibility included determining recruitment rate and acceptability of an RCT for a CAM modality, and acupressure treatment compliance, via participant surveys. The primary clinical outcome was spontaneous onset of labour.
Findings: from the 67 women eligible during the timeframe for the study, 44 women (65.6%) agreed to participate and were randomised. There was no statistically significant difference in rate of spontaneous onset of labour (50% acupressure vs 41% control). Twenty nine participant surveys were returned (65.9%). In the intervention group there was a high compliance with the acupressure protocol (83%) and the use of the three acupoints (94%).
Conclusions and implications for practice: this feasibility study revealed that pregnant women are interested in the use of CAM, and acupressure in particular, for the initiation of labour. Most women found it acceptable to be randomised to receive the intervention. While the 9% difference in the primary outcome was not statistically significant it is the best estimate of the treatment effect for calculating a sample size of 994 for a future RCT with 80% power, alpha 0.05.
Trial registration: Australia and New Zealand Clinical Trials Register (ANZCTR): ANZCTR:12613000145707.

Introduction

In an area such as Complementary and Alternative Medicine (CAM), which is endeavouring to establish scientific credibility, randomised, controlled trials (RCTs) are an important methodology to use in order to establish causal relationships. However few RCTs in this area appear to have considered the relevance of establishing whether an intervention study can actually be

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0266-6138/

conducted successfully (Hawk et al., 2002; Do et al., 2011). Feasibility studies are therefore conducted before fully powered RCTs, in order to answer the question, "Can this study be done?", and to estimate important parameters for designing robust studies. This is of particular relevance when there are few previously published RCTs or limited existing data about the use of specific interventions (Fonteyn and Bauer-Wu, 2005; Bowen et al., 2009; Arain et al., 2010). One area where little data exists concerns the use of CAM modalities for increasing the likelihood of spontaneous onset of labour in women whose pregnancy has progressed beyond the due date.

Increasing rates of pharmaceutically induced labour and operative birth have been reported in the UK, US, Canada and Australia since the early 1990s (MacDorman et al., 2008; Mealing et al., 2009; Ehrenthal et al., 2010; Leduc et al., 2013; Stock et al., 2013). Concerns over rates of induced labour led to an Australian government policy recommendation that the number of women who embark on a labour and/or go into labour, spontaneously, needs to increase and the number of labour interventions needs to decrease (NSW Ministry of Health, 2010). The discovery of a non-pharmacological, non-invasive technique to stimulate uterine contractions which is simple, safe, effective and without serious side effects may prove beneficial for both mother and infant, especially in areas where pharmacological pain relief may not be available. Acupressure is one technique that has been trialled for this purpose.

Acupuncture and acupressure/shiatsu techniques use the same meridian points on the body, however acupuncture uses needle stimulation on the meridian points whereas acupressure/shiatsu uses firm thumb or finger pressure, which is less invasive and does not require an acupuncturist (Kolster and Waskowiak, 2007). Shiatsu also includes gentle exercises and massage in the treatment session (Tiran and Mack, 2000). These three techniques are based on the traditional Chinese medicine (TCM) philosophy that meridians or pathways flow through the body, enhancing blood flow, nourishing tissue, and facilitating normal functions of the body (Chung et al., 2003; Betts, 2006). A systematic review of randomised controlled trials (RCT) of labour induction and acupuncture (not acupressure or shiatsu) found that fewer women receiving acupuncture required cervical ripening prior to labour induction compared to women receiving standard care (Smith et al., 2011). Since the same meridian points are stimulated, it may be possible that acupressure could serve the same purpose with the advantage that women or their partners could apply it themselves.

A search of the literature using the search terms, 'acupressure', 'induction of labour', 'labour onset', and 'post-date pregnancy', helped to locate six international RCTs that have examined the effect of acupressure on already established labour, uterine contractions, labour duration and pain level (Chung et al., 2003; Lee et al., 2004; Heidari et al., 2008; Hjelmstedt et al., 2010; Kashanian and Shahali, 2010; El Hamid et al., 2013). All six studies found a shortened first stage of labour and a decrease in the labour pain score compared to placebo or standard care (Mollart et al., 2015). One pilot audit that examined the effects of shiatsu on initiation of uterine contractions for women experiencing post-date pregnancy was also located (Ingram et al., 2005). This UK study recruited 132 multiparous and primiparous women at 40 weeks gestation, 66 of whom were instructed to use three acupoints (Spleen 6, Large Intestine 4 and Gall Bladder 21) as often as they wanted, together with breathing exercises until the onset of labour (Ingram et al., 2005). The remaining 76 women received standard care. Of those women who used all three acupoints (n=41/66), 100% laboured spontaneously compared to women who used less than three acupoints and subsequently required surgical/medical induction of labour (Ingram et al., 2005). Overall, women who used acupoints (n=66) compared to women who did not (n=76), were significantly more likely to labour spontaneously ($\chi^2$4.28, p=0.038). There was no difference in adverse outcomes for mothers or babies (Ingram et al., 2005). Major limitations of this study are the use of the non-randomised design, analysis not being stratified by parity and the use of 40 weeks as the point of recruitment, which is not post-term. There is a need for a robust RCT with a standard protocol describing duration and frequency of use of the three acupoints in women who are at more than 40 weeks gestation.

Additionally, there have been few published studies investigating the pregnant woman's experience of complementary and alternative medicines and/or therapies (CAM) using the RCT design (Mollart, 2003; Mitchell and Allen, 2008; Do et al., 2011). Williams and Mitchell (2007) acknowledged the importance of involving key stakeholders such as women accessing services and health professionals, to explore the acceptability and implications of providing CAM in mainstream care (Williams and Mitchell, 2007). Our study builds on the current limited evidence by providing a rigorous study protocol focusing on primigravidae, a participant survey and health professional focus groups. This paper reports on the findings of the feasibility RCT, treatment fidelity and on women's willingness to be randomised to receive acupressure.

Aims

This Australian feasibility study aimed to determine: the willingness of women experiencing a post-date pregnancy to participate in a randomised controlled trial of acupressure; compliance with the study protocol and to estimate a sample size for a future appropriately powered study. Health professional's views on the trial and the use of CAM in maternity care were also assessed and will be reported in a separate publication.

Study design and methods

This study was conducted between 13 February to 30 August 2013 using a two arm blinded RCT design, to compare the experiences and outcomes for primigravid women experiencing a post-date pregnancy using three acupressure points, compared with those who had standard antenatal care. The staff providing clinical care were unaware (blinded) of group allocation unless the participant disclosed study participation. Data were analysed by a statistician blinded to group allocation.

The intervention protocol was developed based on the three acupoints used in Ingram et al. (2005) study. Expert advice from Debra Betts, an internationally recognised expert in perinatal acupuncture and acupressure (Betts, 2003, 2006) supported the use of the three acupoints and recommended the pressure duration and frequency of application. The midwife research assistant (MRA) attended a one-day competency based workshop on acupressure and was assessed as competent. All women were asked to complete a self-administered survey following the birth and up to 10 days post partum. The intervention group also completed an acupressure protocol compliance assessment (daily diary).

Study population

All eligible women at two outer metropolitan public hospitals in New South Wales, Australia were invited to participate.

Sample size

It was estimated that a sample size of 60 women (30 in each group) would be sufficient to provide data to address the

feasibility study aims (Hertzog, 2008; Arain et al., 2010). It is recommended that a feasibility study have an adequate sample size to estimate the critical parameters such as acceptability, recruitment, practicality, and adaptability (Bowen et al., 2009; Arain et al., 2010).

Control and intervention groups

Control: standard care

Women randomly allocated to the control group received standard clinical antenatal care at either of the two study sites. Each woman was advised of her next clinic/ Day Assessment Unit (DAU) appointment at approximately 40 weeks+10 days ($\pm$2 days) for a maternal and fetal assessment that included abdominal palpation, vaginal examination to determine cervical favourability for induction of labour (Bishop Score), and fetal heart pattern (electronic monitoring). This assessment determined the method of medical induction and set an induction date before 40 weeks and 14 days.

Intervention: standard care plus acupressure

In addition to standard care, women randomly allocated to the intervention group received verbal and written information on the self-administration of acupressure to three acupoints Spleen 6 [SP6 – lower leg], Large Intestine 4 [LI4 – hand] and Gall Bladder 21 [GB21 – shoulder] (see Fig. 1). The participants were asked to apply sustained bilateral pressure using thumb or finger for:

- 2 minutes on point SP6 (right/ left) followed by 2 minutes on LI4 (right/left) every 2 hours during the day; and
- 2 minutes on point GB21 (right/left) twice a day (morning and evening).

The MRA demonstrated, on the participant, the acupoints and level of pressure that results in a feeling of numbness, warmth, tingling, or a buzzing sensation (known as Deju) (Betts, 2006). The participant was then asked to locate the acupoints and self-apply pressure whilst being observed by the MRA. An acupressure diary sheet was provided for the women to record acupoints used on a daily basis from recruitment (40 weeks+5 days) to the commencement of labour i.e. spontaneous or medically induced at 40 weeks+11–14 days. A CD with short videos demonstrating the acupressure and location of the three acupoints was also supplied. The women were contacted one to two days after recruitment to discuss compliance and if further education was required.

Inclusion criteria

Women who fulfilled the following conditions were included: healthy primigravid woman of gestation $\geq$40 weeks+5days with a singleton pregnancy; cephalic fetal presentation; English speaking; $\geq$18 years; and receiving midwifery-led antenatal care.

Exclusion criteria

Participants who met any of the following criteria were excluded: wanting to use or currently using acupressure (due to concern of crossover after randomisation); experiencing regular uterine contractions; any contra-indications for vaginal birth; and highly dependent on medical care/requiring specialist medical/ obstetric consultation and likely to have medical intervention prior to 41 completed weeks of gestation

Trial recruitment

The MRA accessed the clinic appointment books and hospital obstetric database (ObstetriX) to determine the eligibility of women to participate, identified their next clinic appointment and placed the study information package (information sheet, consent form and revocation of consent form) in the woman's records ready for her next antenatal visit.

Between 39 and 40 weeks gestation each eligible woman received verbal and written information on the study. At 40 weeks+5–7days visit, the MRA obtained written consent if the woman agreed to participate. Once written consent was obtained, the woman's details were entered into the trial register and the remote, computer generated randomisation allocation service was contacted for allocation to group.

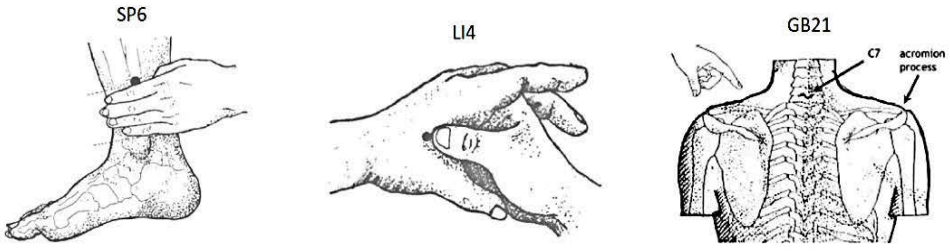
Group allocation

Allocation concealment was assured by using a remote internet-based allocation service. The MRA provided the woman's hospital medical record number and eligibility criteria, the allocation service randomised the woman based on a block size of four and immediately provided the group allocation. After the MRA received confirmation of the woman's group allocation and study number, the woman was informed of her group allocation. If allocated to the intervention group, the MRA provided the woman with the acupressure information as outlined previously. Participant demographic details, date of randomisation, group allocation, and date of demonstrating acupressure techniques were kept in the Trial Register.

Data collection

Clinical data

The majority of clinical data required for the study were routinely collected and available in hospital records. The hospital's maternity data manager, who was blinded to the participants' allocation, extracted the following information from the hospital



Reproduced with kind permission of Debra Betts (2003)

Fig. 1. Acupressure points SP6, LI4 and GB21. Reproduced with kind permission of Betts (2003).

obstetric database (ObstetriX): (1) Demographic information including maternal age, model of midwifery care, and past obstetric, medical and surgical history (these variables are the same as used in previous studies of acupressure to ensure comparability); and (2) Clinical outcome measures for labour and birth including onset of labour (spontaneous or induced), analgesia and any other pain relief options used, and mode of birth.

Analysis

Categorical data were analysed using χ^2 and Fisher's exact test (due to the small sample size) and results are reported as odds ratios and 95% confidence intervals. *T*-tests were used to analyse normally distributed continuous data. All levels of significance are reported as $p < 0.05$. Data were analysed using the Statistical Package for Social Science V21.0 (SPSS).

Ethical aspects

Human Research Ethics Committee (HREC) approval for two sites was provided by the Northern Sydney Local Health District HREC (1209–293M). Research governance approval for two hospital study sites was also obtained (SSA 1209–307M; 1210–354M).

Data safety and monitoring

A Data and Adverse Event Monitoring Committee (DAVMC) assessed any serious adverse events.

Findings

Eighty (80) nulliparous women at 40 weeks+5 days gestation were identified as eligible for the study. Thirteen women were not recruited, as seven women birthed prior to being contacted by the MRA (40 weeks+5days to 40 weeks+6 days), and six women were unable to be contacted. From the remaining 67 eligible

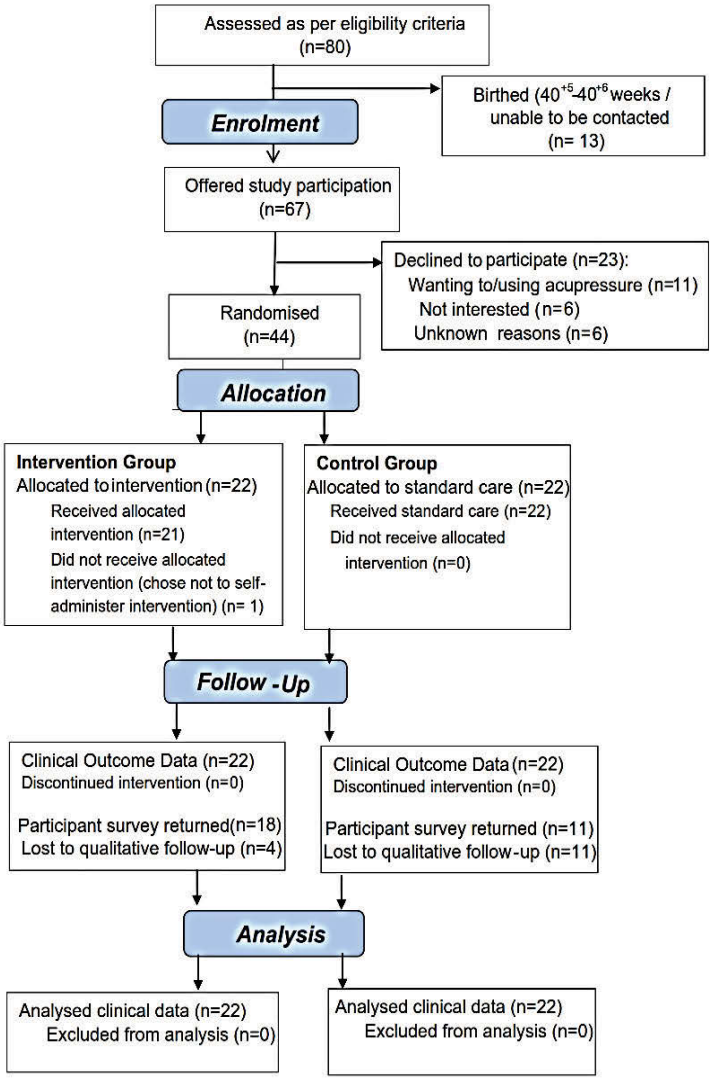


Fig. 2. Flow of participants through the feasibility trial.

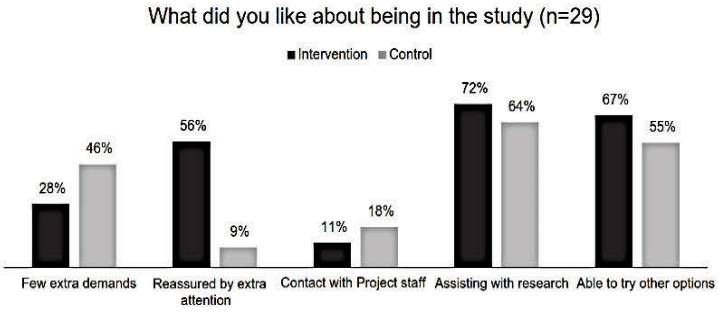


Fig. 3. Involvement in a randomised controlled trial.

women, 23 declined to participate because 11 preferred to use, or had already started to use acupressure and 12 women were not interested (n=6/12) or reason unknown (n=6/12). As a result of the decline to participate rate, recruitment was stopped once 44 women had been randomised, 22 to the intervention group and 22 to the control group (Fig. 2). It was decided by the authors that there were sufficient participants to address the feasibility parameters such as acceptability, practicality, adaptability and recruitment.

Demographics

Baseline characteristics of study participants were similar between groups (Table 1). Participants' ages ranged between 19 and 39 years, gestation at time of birth between 40 weeks and 6 days to 40 weeks and 14 days and Body Mass Index (BMI) ranged between 20 and 36.

Recruitment and acceptability

Twenty nine participant postnatal surveys were returned (65.9%) with 18 from the acupressure group (82%) and 11 from the control group (50%). The majority of women in both groups would agree to participate in the study again if presented with the opportunity (94% acupressure; 82% control).

Four women (36%) randomised to the control group disliked being randomised with the following comments:

> *I was excited to participate in this study but very disappointed when I wasn't selected & felt let down*
>
> *Didn't experience much as didn't get selected, was just info I could go through and discuss. Thought it should be something available to all without being random if consent given*

One woman in the acupressure group disliked being randomised and she clarified her answer by commenting *'I was lucky to be in the acupressure group. I would have been disappointed if I was in the control group'.*

Table 1
Participant baseline characteristics.

	Acupressure N=22	Control N=22	p Value
Caucasian N (%)	22 (100)	21 (95.5)	–
Mean Age (SD)	27 (5.23)	27 (6.02)	0.939
Mean BMI (SD)	25.46 (4.14)	28.72 (5.75)	0.037*
Mean Gestation at birth-days (SD)	290.6 (1.78)	290.4 (2.17)	0.707

* Statistically significant.

Involvement in a RCT

The women commented on what they liked about being in the study as shown in Fig. 3. Many women in both groups liked assisting with research and liked having other options available to start labour. Some of the women in the acupressure group explained:

> feeling like I was doing something empowering,
>
> being able to try non-drug/non-invasive options,
>
> I'm glad some natural options are available to try help bring on labour.

One woman in the control group commented

> Made no difference or anything only extra thing would be this survey. Not sure how I help with the survey.

Practicality and adaptability

For the 18 responders in the intervention/acupressure group, 100% found they had received enough information on the use and location of the three acupressure points. Compliance was high with 15/18 women (83%) using the acupoints as per study protocol, and 16/17 (94%) using all three acupoints (one woman did not complete this question). Only one woman did not use the points at all as she found it "too time consuming". Thirteen women (72%) returned their completed acupressure diary which provides a level of validation of survey responses indicating the frequency of stimulating the acupoints had occurred as per the protocol. Compliance with the study protocol indicated a range of one (1) day to five (5) days of using the acupoints before commencing spontaneous labour or having labour induced. Seven of the 18 survey responders (39%) in this group had a preference for particular acupressure points with two women preferring SP6 [inner leg], two preferring GB21 [shoulder point], two preferring SP6 and GB21 and one preferring LI4 [hand point]. Comments included:

> *Inner leg was effective for use on yourself, Shoulder GB21 required birthing partner*
>
> *Preferred shoulder and hand as I found it practically impossible to find the right point on my leg.*

Most women found that using acupressure made them feel actively involved in their care (78%) and more than half (66.7%) found that their partner helped with the acupressure and felt more involved in the care:

> SP6 was very comfortable and my husband often did the pressure for this point which was nice.

Table 2
Clinical outcomes.

	Acupressure N=22(%)	Control N=22(%)	p Value	OR; 95% CI
Primary outcome				
Spontaneous onset of labour	11(50)	9(40.9)	0.37	1.44; 0.44–4.76
Mode of Birth				
Vaginal Birth	15(68.2)	18(81.8)	0.48*	0.48; 0.12–1.94
Pain relief in 1st stage labour	N=20(%)	N=21(%)		
No analgesia/anaesthesia	2(10)	3(14.3)	0.02*	0.33; .067–1.65
Analgesia (N202 ± Narcotic)	8(40)	7(33.3)	0.10	1.23; 0.35–4.36
Epidural (± other pain relief)	10(50)	11(53.4)	0.02	0.91; 0.27–3.01
Mean Birth weight (SD)	3779(449.7)	3662.7(511.8)	0.43	–
Apgar < 7 at 5 minutes	1	0	–	–
Admission to SCN	3(13.6)	5(22.7)	0.43*	0.54; 0.11–2.6

* Fisher's exact.

Clinical outcome data

Clinical outcome data were available for all 44 women. Analyses of clinical outcomes are presented in Table 2. Eleven women (11/22=50%) in the acupressure intervention group experienced spontaneous onset of labour compared to nine women (9/22=41%) in the control group, however this difference did not reach statistical significance ($p=0.37$, OR 1.4, 95% CI 0.44–4.76). There was no statistically significant difference in the rate of vaginal births ($p=0.48$, OR 0.48, 95% CI 0.12–1.94). There was one neonatal death in the acupressure group after medical induction of labour. The DAVMC and the investigative root cause analysis (RCA) team did not find acupressure as a contributing factor.

Discussion

Our study was able to determine that an RCT of this intervention is feasible with Australian women experiencing a post-date pregnancy. The study protocol was found to be practical. The duration and frequency of using the three acupoints was based on expert advice (DB) to ensure the acupressure dose/duration was not too short as the therapeutic effect of acupressure on stimulating labour is uncertain and the women may need to use acupressure for up to seven days. The UK audit study suggested that the pregnant women apply pressure to the same three acupoints as often as the woman wanted but did not suggest how often the women should use the acupoints or the duration of pressure on each point (Ingram et al., 2005). The women in our study found the protocol of two hourly application for two minutes each time acceptable with a high rate of compliance with nearly all acupressure group women using the three acupressure points.

Excluding women who wanted to use acupressure or who were already using acupressure when invited to participate influenced the recruitment rate. The preference for using acupressure could be due to the already established use of acupressure in clinical practice at the hospital sites where the research was conducted. This aspect needs to be considered for future studies and may require the use of sites where acupressure is not included as currently accepted midwifery practice.

Some women were disappointed at being randomised into the control group but were willing to participate for research purposes. These findings are similar to an Australian CAM study conducted by Smith and Coyle (2006). Disappointment by control group members has been reported in other CAM RCTs and suggests that trial designs with 'empty glass' control arms may be less than satisfactory (Smith and Coyle, 2006; Mackereth et al., 2014). A recommendation for future research is to have a randomisation arm using a placebo acupoint that is not known to initiate uterine contractions but has some beneficial effects and is easily accessible for self-administration such as: Lung 7 (action: letting go of grief, worry) on the arm, above the wrist; Stomach 36 (action: increases stamina/reduces fatigue, tiredness) near outer knee, or DU20 (action: lift up- emotional and physical) on top of head (Betts, 2006; Cross, 2010). It is recommended that the non-therapeutic points be situated near the selected active acupoints to achieve proper blinding while taking care that they avoid being on the same meridian as the true intervention (i.e. Large Intestine, Spleen and Gall Bladder) (Tan et al., 2015).

A strength of the study but at the same time a potential limitation was the prevalence of acupressure use in the clinical practice of midwives at the two study sites prior to conducting the study. This may have contributed to the number of women wanting to use acupressure and declining to participate in the trial. However knowledge and/or awareness of CAM and acupressure may have also contributed to the acceptability of the study in these settings.

A recognised limitation of our feasibility study is the small sample size with the result that the study was underpowered to detect statistically significant differences between groups. The 9% difference in the spontaneous onset of labour was not statistically significant and may have occurred by chance but we suggest it can be regarded as the best estimate of the effect of acupressure for increasing the onset of spontaneous labour in post-date women; an effect that can be used to calculate the sample size for a future appropriately powered study. Using our data, the sample size we have calculated would be 994 primigravid, post-date women (80% power, alpha 0.05, allowing for a 1% cross-over) (https://www.sealedenvelope.com/power/binary-superiority).

Conclusion

This was the first Australian and international feasibility RCT on the use of acupressure for primigravid women experiencing a postdate pregnancy. Acupressure was applied as an intervention to initiate uterine contractions to increase spontaneous onset of labour and potentially decrease pharmaceutically induced labour and subsequent operative birth. The study demonstrated acupressure and the acupressure study protocol were acceptable to women as was participation in an RCT and completing questionnaires. Compliance with the acupressure regime was high although challenges with women agreeing to be randomised were identified.

Although this study was unable to demonstrate a statistically significant effect of acupressure for the initiation of labour, the effect size obtained has enabled the calculation of a sample size for a future RCT and the study adds to the body of knowledge about the use of CAM in maternity care. It would be prudent that a future study be undertaken at a hospital site where the acupressure modality is not already entrenched into clinical practice.

Conflict of interest statement

The authors declare they have no competing interests.

Authors' contributions

LM, VS, MF: All have contributed to the design and development of the study protocol. LM, VS performed the statistical analysis. MF is the supervisor for this research. LM developed the draft manuscript, VS and MF critically reviewed and revised the draft manuscript. All authors read and approved the final manuscript.

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There was a statistically significant difference in BMI between groups (Table 1) however we were unable to determine whether this difference influenced the lack of difference in outcomes.

4.3 Chapter summary

This chapter has presented the quantitative findings of the PR.E.P.A.RE FRCT contained in Publication 2. The findings address four of the eight feasibility focus areas. For 'acceptability', the publication has discovered that most women in the study were happy to participate in a randomised trial with high compliance with the acupressure protocol. It is acknowledged there was a low return rate in control group participant surveys (50%) therefore results need to be viewed with caution. However, the low return rate may reflect disappointment at not being randomized to receive acupressure so speaks to the acceptability of this modality. Nevertheless, researchers need to consider a range of methods of obtaining

information from postnatal participants that will yield a high response rate when designing future studies.

There was also a high level of interest in this particular population of women, as acupressure was already a well-established part of maternity care at the study sites, thus addressing the 'demand' focus area (Publication 2, p. 26). Publication 2 has also highlighted and addressed 'practicality' in that the intervention was relatively easy to apply with minimal increase in resources—women randomised to the acupressure group found the intervention simple to apply and, since they applied it themselves, it was readily integrated into existing clinical practice. Publication2 has also partially addressed the focus area of 'adaptability', with the study protocol adapted from the UK study (Ingram et al. 2005) to the Australian maternity setting without difficulty. The protocol also required that participants were primigravida only; that the intervention include two acupoints to be used every two hours during the day and one acupoint twice daily; and that a high percentage of midwives were trained in acupressure at study sites. Further aspects of feasibility not addressed by the RCT were any assessment of the participants' and health professionals' experiences of being involved in an RCT and the experience of acupressure itself. The next chapter presents these findings in the form of Publication 3, which comprehensively addresses the feasibility focus areas at a local level.

Chapter 5: FRCT—participants' and health professionals' perceptions of CAM and participation in the acupressure trial

5.1 Chapter overview

This chapter presents the findings of the post-birth questionnaire completed by 29 women participating in the FRCT, as well as the findings from four focus groups with doctors and midwives at the research sites.

The findings have been published as follows:

Mollart, L., Adams, J. & Foureur, M. 2016, '**Pregnant women and health professional's perceptions of complementary alternative medicine, and participation in a randomised controlled trial of acupressure for labour onset**' *Complementary Therapies in Clinical Practice*, vol. 24, August, pp. 167–73. DOI:10.1016/j.ctcp.2016.06.007.

The reader will thus find that the background material has already been addressed in the previous chapters, and is therefore invited to go directly to section 2.2.1 of this publication, 'Participants', which provides participant details.

5.2 Publication 3

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Pregnant women and health professional's perceptions of complementary alternative medicine, and participation in a randomised controlled trial of acupressure for labour onset

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ABSTRACT

Feasibility randomised controlled trials of complementary medicine are important to evaluate acceptability and practicality. This study examined participants' and health professionals' perceptions of CAM and participation in a feasibility RCT of acupressure for labour onset.

Methods: A qualitative study incorporated within an RCT. Data were collected from postnatal women via questionnaires and health professionals via focus groups.

Results: Four themes emerged from the women's views: "Using CAM to start labour", "Feeling empowered through action", "Desiring randomisation to acupressure group", and "Welcoming the opportunity to assist in research". Five themes emerged from the health professionals' views: "Personal awareness and attitudes towards CAM"; "Supporting and empowering women"; "Complements the wellness model of pregnancy and childbirth"; "Need for evidenced based practice"; and "Randomisation 'doing it on the sly'".

Conclusions: Themes from the groups were similar. The study protocol will be refined with a placebo group to improve equipoise with a powered RCT planned.

1. Introduction

There is an emerging body of literature on the use of complementary and alternative medicine (CAM) during pregnancy [1–11]. Pregnant and birthing women have been identified as substantial CAM users internationally and in Australia [2–6,12,13]. Research in Australia shows vitamins/herbs, massage, meditation/yoga and aromatherapy are the most popular CAM used by pregnant women [5,12,13]. None of the aforementioned Australian exploratory studies included acupressure as a CAM option whereas at least three international studies have reported acupressure use by pregnant women [2,14,15]. There is a gap in the literature describing pregnant women's views on acupressure and their experiences of using acupressure in a research context.

A number of studies have reported on midwives' and obstetricians' perceptions of CAM. Many obstetricians have a positive attitude towards specific CAM, view CAM as a useful supplement to regular medicine and refer patients to specific CAM practitioners for massage, yoga, meditation and acupuncture [13,16,17]. It has also been recognised by both midwives and obstetricians that there is a need to establish a scientific basis for CAM and provide additional professional education in CAM to enable more understanding of the possible risks to pregnant women [13,17–20]. Meanwhile, midwives are highly likely to offer CAM options to women as studies suggest they view CAM as an alternative aid to reducing medical invention, and as a means of empowering and increasing the autonomy of women in their care [19,21,22]. Although Australian studies have explored both midwives' and obstetricians' views on the use of CAM in pregnancy [13,21,23,24] only one study has investigated women's or health professionals' perceptions of participation in randomised controlled trials (RCT) of CAM interventions [25].

This study focuses on Acupressure, a widely used CAM intervention. Acupressure uses firm thumb or finger pressure on

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meridian points which is based on the traditional Chinese medicine (TCM) philosophy that meridians or pathways flow through the body, enhancing blood flow, nourishing tissue, and facilitating normal functions of the body [26,27]. International RCTs have investigated the use of acupressure for initiating labour [25,28,29] and labour duration and pain relief [30–34], yet none explored the participants' views on CAM or their views on participating in an RCT of acupressure. One study briefly reported on the woman's experience of discomfort while receiving acupressure compared to sham acupressure [25]. This gap in RCT participant's and health professional's perceptions limits our understanding of the suitability and acceptability of an acupressure intervention for women experiencing a post-date pregnancy.

Incorporating qualitative methods to gain participants' and health professionals' perceptions in feasibility RCTs, aims to ensure the research considers acceptability, demand, implementation, and practicality of interventions [35]. Involving key stakeholders such as women and health professionals, enables an exploration of the acceptability of participating in an RCT and the implications of providing CAM in mainstream maternity care [36]. This study aimed to explore women's views on participating in an RCT, and the acceptability and use of Acupressure and other CAM techniques for a postdate pregnancy; as well as exploring health professionals' views on the use of CAM and Acupressure in a research context in maternity care.

2. Methods

A mixed methods study including a blinded, feasibility RCT (FRCT) together with a participant questionnaire and focus groups with care providers, was conducted between February and July 2013 in two Australian outer metropolitan maternity units. The FRCT aimed to determine whether an acupressure intervention increased the likelihood of spontaneous onset of labour in women experiencing a post-date pregnancy (i.e. a pregnancy continuing after 40 completed weeks or 280 days gestation from the first day of the last menstrual period). The post-birth, participant questionnaire aimed to explore the views of women relating to: participation in a RCT of acupressure; CAM use in late pregnancy; and to examine intervention protocol compliance. Following completion of the FRCT, focus groups with care providers aimed to explore views and perceptions towards CAM generally and in maternity care in particular.

2.1. Recruitment

Healthy primigravid women were invited to participate in the FRCT. Eligibility criteria included pregnancy gestation ≥40 weeks^{+5days}, singleton pregnancy, cephalic fetal presentation, English speaking, ≥18 years of age and receiving midwifery-led antenatal care. Women were excluded if they were experiencing regular uterine contractions; were considered highly dependent on medical care/requiring specialist medical/obstetric consultation; likely to have medical intervention prior to 41 weeks gestation; had any contra-indications for vaginal birth; and were currently using acupressure or had a strong preference to use acupressure.

Purposive sampling of health professionals was used to achieve broad participation and views of both midwives and senior obstetric doctors providing antenatal care for women participating in the FRCT. Information flyers were displayed in the staff tea-rooms and an invitation letter was sent by internal mail to all eligible senior obstetric staff (n = 8) and midwives (n = 27) working in antenatal care i.e. antenatal clinics, midwife clinics, team and caseload midwifery models.

2.2. Randomisation of pregnant women

Consenting women were randomised into standard antenatal care or, standard care plus acupressure using three acupressure points at set intervals, until the onset of labour. At randomisation to the intervention group women received an initial acupressure treatment, plus further demonstration and information on self-administration of the three acupressure points according to the study protocol (bilateral pressure on Spleen 6 and Large Intestine 4 for 2 min every 2 h during the day; and Gall Bladder 21 for 2 min twice a day i.e. morning and night). Staff providing clinical care were unaware (blinded) of group allocation unless disclosed by the participant. Outcome data were collected from a hospital database, by a midwife, blinded to group allocation. The FRCT including treatment protocol, sample size and analysis has been described in a separate publication [37].

2.2.1. Participants

Forty four women agreed to participate. Of these, 29 completed a post-birth questionnaire (response rate 65.9%). In the health professional group, 20 of the 27 invited midwives and 5 (four female and one male) of the 8 invited senior obstetric doctors providing antenatal care to women in the trial agreed to participate in five focus groups conducted in June 2013. There were a total of five focus group sessions conducted with four groups of midwives and one group of doctors. This sample size was deemed to be sufficient to address the feasibility parameters of acceptability, practicality, adaptability and recruitment and for qualitative analysis [38].

Human Research Ethics Committee (HREC) approval for two sites was provided by the relevant authorities (1209-293M; SSA 1209-307M; 1210-354M). Trial Registration: ANZCTR:12613000145707.

2.2.1.1. Development of the woman' questionnaire. The questionnaire was purposively developed by the authors with a total of 32 questions: 10 open-ended, 4 closed-ended, 3 multiple choice and 15 Likert scaled questions to enable participants to report on their experience of the care received, opportunities for decision-making, experience of participating in a randomised controlled trial and being randomised, and the use of any natural strategies to 'induce' labour. The findings of this component of the questionnaire are the focus of this article. Those women randomised to the acupressure intervention completed additional questions on compliance with the study protocol (published in a related article [37]. The questionnaire was piloted with ten pregnant women and minor changes were made to ensure the questions were logical and clear to the average adult reader. Women received the self-administered questionnaire and reply paid envelope whilst in the postnatal ward, or via surface mail (up to 10 days post-birth).

2.2.1.2. Health professional focus groups. To examine the views and perceptions of health professionals, focus group sessions of up to 1 h duration were conducted at the completion of the FRCT. All focus groups were facilitated by a midwife research assistant and used a semi-structured format with five questions exploring health professionals' knowledge of CAM modalities; personal views towards the use of CAM in pregnancy; knowledge of acupressure and CAM in a research context; perceptions of evaluating and researching acupressure in a RCT; and implementing CAM modalities in the maternity clinical setting more generally. Informed written consent was obtained prior to each focus group. Each focus group session was digitally recorded and fully transcribed.

2.3. Data analysis

Patient demographic and questionnaire data were analysed using descriptive and univariate descriptive analyses. Qualitative questionnaire data were collated and content analysed by counting the number of participant comments in each response category [39]. Thematic analysis of the transcripts was undertaken using the method described as fundamental or generic qualitative description [39–41] which aims to discover and understand a phenomenon or the perspectives of people involved, that is low inference with themes generated from the data itself [39,40].

Two research team members (LM and MF) read the transcripts and generated initial codes from the data and then compared so that the analysis was reflexive and interactive. Codes were grouped into themes and were continuously modified to accommodate new data and new insights [39]. Quotations were selected to illustrate the themes because they reflected accurately the experiences of a number of health professionals or because they were examples of a different perspective or experience.

3. Results

3.1. Womens' perspectives

Except for a significant difference in Body Mass Index (BMI), baseline characteristics of the FRCT participants (n = 44) were similar between control and intervention groups and all women were experiencing a normal risk pregnancy and receiving midwifery-led care. Women were aged between 19 and 39 years (p = 0.939), gestation at the time of the baby's birth was similar between groups at 40 weeks and 6 days, up to 40 weeks and 14 days (p = 0.707) and BMI ranged between 20 and 36 (p = 0.037).

Twenty nine of 44 women returned questionnaires (66%) with, 11/22 from the standard care/control group (50%) and 18/22 from the intervention (82%). Thematic analysis of surveys revealed four themes: "Using CAM options to start labour", "Feeling empowered through action", "Desiring randomisation to acupressure/intervention group", and "Welcoming the opportunity to assist in research". Each theme is described below with illustrative quotations from the women.

3.1.1. Using CAM options to start labour

Most of the 29 women who responded from either arm of the FRCT (83% Intervention [n = 15/18], 73% standard care group [n = 8/11]) used other self-help and CAM strategies to assist in the onset of labour.

Many women in both groups indicated they used either a single or a combination of strategies including nipple stimulation, reflexology, acupuncture, evening primrose oil, raspberry leaf tea, sexual intercourse and fruit dates (Fig. 1). It was apparent also that other CAM options were recommended by attending midwives.

> "I really appreciated the help given by midwives. I was very anxious when I went overdue. Reassurance by midwives and the tips how to induce labour occupied me. I was trying all means to go into labour." (Intervention)

> "I tried the other things suggested but still had to be admitted for induction." (Standard care)

Five women didn't use CAM or self-help options with one woman commenting:

> "I wish there was more communication for first time mums. I was wanting more help, explanations etc." (Standard care)

3.1.2. Feeling empowered through action

Most women from both groups liked being involved in the study (88.8% Intervention [n = 16/18] and 91% control group [n = 10/11]). Most intervention group respondents found using acupressure made them feel actively involved in their care (78%, n = 14/18) with some describing a feeling of empowerment through their participation in the FRCT: "Felt empowered to take action re: my health".

More than half (66.7%) of the intervention group women found their partner helped with the acupressure and also felt more involved in the care thereby increasing the partnership between the couple and feelings of active involvement and being in control.

Women randomised to the intervention group were keen to use acupressure revealing high compliance with the study regime i.e. 83% of participants 'always' or 'almost always' used the acupressure

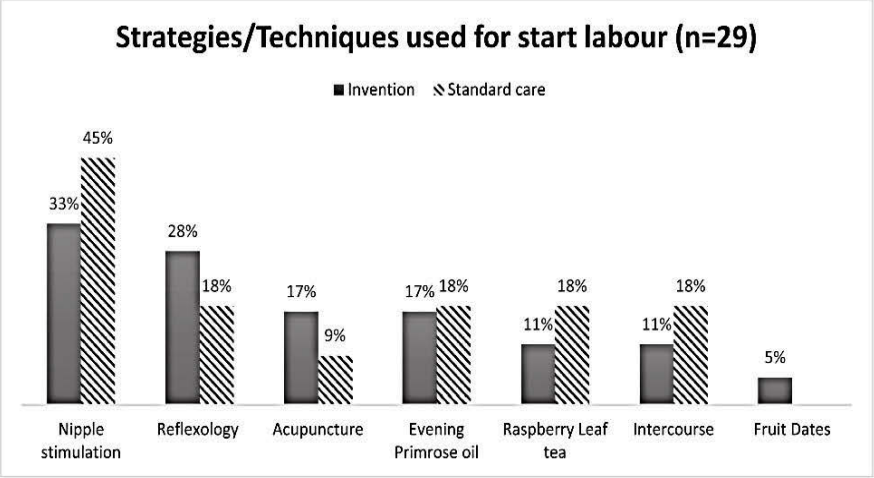

Fig. 1. Use of CAM and Self-help strategies by study participants.

points (ie 2nd hourly during the day) with a range of one day up to five [5] days before commencing spontaneous labour or having labour induced.

"I was randomised into the acupressure group and followed the prescription of acupressure diligently. We also used points in labour" (Intervention)

Only one woman did not use the points at all as she found it too time consuming.

3.1.3. Desiring randomisation to intervention group

Four women in the standard care group were disappointed in not being randomised into the intervention (acupressure) group with comments:

"Unfortunately I was not chosen to take part in the acupressure."

"I wanted the information about acupressure … I was looking forward to the acupressure"

"I was disappointed I got randomised to normal care so there was no difference to me at all"

Two women in the standard care/control group revealed that they also used acupressure during the trial. This finding was echoed in the words of one woman in the intervention group who commented:

"It was good I got accepted into the study [intervention group] but even if I wasn't I was going to do the acupressure points anyway".

3.1.4. Welcoming the opportunity to assist in research

Most women in the intervention group (72.2%, n = 13/18) believed they were 'assisting in research to help other women' compared to the standard care group (64%, n = 7/11). The majority of women in both groups (95% intervention [n = 17/18] and 82% standard care [n = 9/11]) would agree to participate in a similar study again.

"I wasn't overly concerned either way. Just happy to help and keen to try anything to start labouring naturally" (Intervention)

"I felt lucky to be part of this study" (Intervention)

"A quick process & glad to be a part of research" (Standard care)

3.2. Midwives' and obstetric doctors' perceptions

Analysis of health professionals' perceptions of CAM use in maternity services and the acupressure FRCT for post-date pregnancy revealed five themes: "personal awareness and attitudes towards CAM"; "supporting and empowering women"; "complements the wellness model of pregnancy and childbirth"; "need for evidenced based practice"; and "randomisation and 'doing it on the sly'".

3.2.1. Personal awareness and attitudes towards CAM

The midwives and doctors reported an awareness of CAM with massage, acupuncture, aromatherapy, chiropractic, osteopathy, reflexology, and herbs, the most frequent modalities mentioned.

Most of the midwives and one doctor expressed positive attitudes towards the use of CAM in general, and in the treatment of pregnancy related conditions.

"I have been using a few points in labour. I mean initially I started using them postnatally I thought it would be easier way to do it, to make the milk flow and now I use a fair few in labour" (Midwife)

"Yeah, well we use aromatherapy all the time and we use visualisation and relaxation …" (Midwife)

"… using aromatherapy and the patient was quite relaxed and according to her … didn't require as m[uch] pain relief as she thought. I think most of the time it depends on the background, about her expectations …. But if it works for her, to settle, why not" (Doctor)

Two doctors expressed more neutral attitudes towards CAM.

"I guess the thing about it is not supported by as much evidence as mainstream … so for that reason I guess I don't think … I don't have an opinion that it particularly works very well. Although but some things in medicine like … chronic pelvic pain, and things where they maybe have already tried everything that medicine has to offer then things like acupuncture may have some benefit" *(Doctor)*

3.2.2. Supporting and empowering women

Midwives viewed acupressure as having the potential to provide increased choices for women experiencing a post-dates pregnancy. Women were thought to be accepting of the study as it enabled them to be in control and empowered by actively managing their own "care".

"It also gives women something they can do for themselves, to help the situation, doesn't it … It empowers them … as opposed to coming to us for all the answers" (Midwife)

"It gives them a chance to feel like they're doing something to influence their outcome sometimes even if it doesn't work as well that they have made an effort" (Midwife)

"I saw one of the midwives in birth centre, she was doing some pressure points on her [woman's] toes and according to her it works in labour and a lot of midwives were doing the same training …. everyone saw her doing the pressure, and everyone was interested in that. That … [woman] had a normal birth but [I] don't know if it [was] because of the pressure point … Whether, what's happened is the pressure, the woman is happy."(Doctor)

3.2.3. Complements the wellness model of pregnancy and childbirth

The FRCT of acupressure and the use of CAM strategies generally were seen by the midwives as complementing the wellness model of midwifery care and normalising pregnancy and birth. There were no comments from the doctors relating to this theme.

"It takes them back to nature that's what I like about it. It takes it back to the yin and the yang and the energy and stuff and its says yeah it's a wellness not an illness" (Midwife)

" it's a positive and makes them feel really good about themselves … it releases stress and makes them feel nice and personally I think we'd be mad not to use them every day in our practice" (Midwife)

3.2.4. Need for evidence based practice

Although information sessions, including current research, were conducted with the midwives and doctors prior to the commencement of the FRCT, ten midwives (50%) and none of the doctors participating in the focus groups were familiar with research or evidence of acupressure for labour onset and labour pain relief.

> "I've looked at some of the studies as well that have been used for acupressure and have mixed results, some are favourable and some are inconclusive. There's quite a bit of research out there" (Midwife)

> "Most of the success or not success I would expect is based on anecdotal reports rather than evidence. I haven't seen any evidence …. There will be cases [that] I don't know of, that may back that up" (Doctor)

Most of the midwives and all of the doctors thought a randomised controlled trial was necessary to evaluate acupressure to demonstrate safety and efficacy.

> "I think it needs to be a randomised trial and I think it needs to have adequate numbers. I think that the drawback in a lot of research projects [is] that the numbers are not big enough to come to a proper conclusion" (Midwife)

> "I think it's good. I think we need to know so if people do ask us about it we have something to back it up. I think if we want to try and bring this [acupressure] in, I think we need to have some idea if it works and the safety … or harm. I'm 100% for it." (Doctor)

3.2.5. Randomisation and 'doing it on the sly'

Midwives perceived randomisation as challenging due to women's interest in CAM and desire for acupressure specifically. There was concern that women were not being honest about not using acupressure when randomised to standard care. None of the doctors considered this an issue; however one doctor questioned the compliance of women with the acupressure protocol.

> "So I think a big problem with this particular trial might be- that a lot of women out there know about acupressure and irrespective of [when] they say they won't use [it], in the general population they[re] going to use it anyway – so it's going to be tricky to weed out the ones that have done it on the sly" (Midwife)

> "How do we know people are doing it [acupressure]? It's difficult with labour and inductions and that sort of things, because the end result is going to happen anyway. So you need a good, well designed study that going to look at whether it's the acupressure that did it or whether the patient was going to go into labour anyway … (Doctor)

4. Discussion

This is the first study to report the perceptions and experiences of trial participants and health professionals on the use of CAM options in pregnancy and participation in an RCT of acupressure for post-date pregnancy. The themes identified in this study highlight the similarities in how pregnant women and midwives and obstetric doctors perceived participation in a CAM RCT and using acupressure, as the intervention. For pregnant women and their families, going over the 'due' date (post-dates) can be an emotionally charged time. The theme from the women *Using CAM options to start labour* emerged strongly with many women in the study keen to try alternative or 'natural' methods to start labour rather than be medically/surgically induced [22,42]. In our study, many of the women used self-help strategies and CAM to 'bring labour on' such as nipple stimulation, sexual intercourse, reflexology, acupuncture, and herbs. Our findings are similar to a study of 23 Australian women with most using self-help strategies such as nipple stimulation, exercise, intercourse, acupuncture and raspberry leaf [43]. Whereas, Chaudhry et al. (2011) found USA women using very few strategies like acupuncture (1.9%) or herbal preparations (1%) with a preference for walking/exercise (43%), intercourse (22.9%), spicy food (11%) and nipple stimulation (7.5%) [44]. Few studies have specifically investigated women's use of self-help and/or CAM strategies to initiate spontaneous labour in a post-date pregnancy [43] and further research into this area is needed.

The health professionals theme of *personal awareness and attitudes towards CAM* highlighted the expanding qualitative evidence exploring midwives', and to a lesser degree doctors' attitudes towards CAM use in the maternity setting [13,21–24,45,46]. In our study the midwives were accepting and supportive of acupressure use in a RCT. This highlighted the midwives acknowledgement of the ability of CAM modalities such as acupressure to increase women's choice and options that complement the wellness model of pregnancy and birth. The female doctors in the study, although less expressive than the midwives, also supported woman's choice to use CAM, if the woman felt it was helpful. These findings are similar to other studies on maternity service health professionals' views on CAM [13,22,23]. A study of Australian doctors and midwives found more women health professionals (midwives and obstetricians) than male obstetricians agreed that CAM is a useful supplement to medicine [13]. Midwifery and CAM philosophy share a holistic world view and the concept that benefit can be gained from supporting rather than overriding natural physiological processes to keep birth normal [22,47].

Similarities arose between the womens' identified theme of *Using CAM options to start labour* and *Feeling empowered through action* and the health professionals' themes of *Supporting and Empowering women* and *Complements the Wellness model of pregnancy and childbirth.* The women viewed the opportunity to participate in a RCT using acupressure and ability to use CAM strategies as enabling them to feel empowered, having choice and being actively involved in their care. These findings are supported by studies in the United Kingdom [48] and Australia [49]. Warriner and colleagues found the use of CAM in pregnancy was seen by women as a component of supporting their health and wellbeing by actively participating, in contrast to assuming a passive, compliant and obedient role, traditionally ascribed to patients [48].

A similarity occurred with womens' theme of *Welcoming the opportunity to assist in research* and the staff's theme of *Need for evidence-based practice.* In our study, some women were disappointed in being randomised into the control group but were willing to participate for research purposes. The findings are similar to Australian studies conducted on acupuncture and infertility [50,51]. The staff theme of *Randomisation and 'doing it on the sly'* merges with the women's theme of *Desiring randomisation to intervention group.* Some staff thought women allocated to the control group would use acupressure 'on the sly' which would contravene the study protocol. Two women randomised to the control group did indicate that they used acupressure during the study. One woman in the intervention group was honest in saying she would have used acupressure even if she was randomised into the control group. Disappointment by control group women has been reported in other CAM RCTs and suggests that trial designs

with 'empty glass' control arms may be less than satisfactory [50,52]. We recommend that in order to improve equipoise (the assumption that one intervention is not better than another) [53], a future study should use placebo acupoints that are not known to initiate uterine contractions, may have some beneficial effects and are easily accessible for self-administration such as Lung 7 on arm above the wrist (letting go-worry), Stomach 36 near the outer knee(stamina-tiredness), or DU20 on top of the head (lift up-emotional/physical) [27,54].

The clinicians' support of CAM strategies was moderated by the necessity to evaluate CAM/acupressure to demonstrate safety and efficacy, balanced within an evidence based framework [13,21,23]. The participants and health professionals support and acceptance of acupressure may resonate with others however such findings cannot be generalised. A potential limitation is that acupressure was embedded into the clinical practice of the midwives of the hospital sites prior to conducting the study and this may have contributed to the number of women wanting to use acupressure and declining to participate in the trial. The knowledge and/or awareness of CAM and acupressure may have contributed to the acceptability of the study at the hospital sites.

5. Conclusion

The perceptions of the majority of women and midwives about CAM, specifically acupressure, were positive and to a lesser degree were similar to perceptions of CAM held by the doctors. Women and health professionals identified similar themes or features when asked about their experience of participating in a RCT. Clinicians were accepting and supportive of this modality, within an evidence based framework. Based on the womens' and health professionals' themes relating to the desire to be randomised to the intervention group and non-compliance with the control group, the acupressure RCT study protocol will be refined with the inclusion of a placebo arm using non-therapeutic acupoints and additional testing in an appropriately powered randomised controlled trial.

Authors contributions

LM, MF, JA: All have contributed to the design and development of the study protocol. LM and MF read the transcripts and completed the thematic analysis. LM prepared the initial draft of the manuscript. MF and JA are the supervisors for this research. All authors critically reviewed the content and approved the final version.

Conflict of interest statement

The authors declare they have no competing interests.

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5.3 Is it feasible to conduct an acupressure RCT for post-date pregnancy?

The findings of Study 1, the FRCT, suggest that it is indeed feasible to conduct an acupressure RCT for post-date pregnancy in Australia. Further, the FRCT identifies important aspects of future trial protocols in this area that require refinement. The quantitative and qualitative findings from the RCT, participants' survey and health professionals' focus groups address the three objectives:

1. undertake an FRCT on the efficacy of acupressure to initiate spontaneous labour onset for primigravid women experiencing post-date pregnancy
2. explore participant women's views of acupressure, CAM and RCTs to increase understanding of the feasibility
3. explore participant health professionals' views of acupressure, CAM and RCTs to increase understanding of the feasibility of RCTs in this area.

Study 1 addresses the eight focus areas of a feasibility study: acceptance, demand, implementation, adaptation, practicality, integration, expansion and limited-efficacy testing (Bowen et al. 2009). The following section discusses each of these focus areas to reflect on issues to be addressed in future studies.

5.3.1 Acceptability of the intervention (acupressure)

The 'acceptability' component of feasibility seeks to determine how recipients react to the intervention. Of the 67 women invited to participate in the acupressure RCT, most (65.7%) were interested and agreed to participate. Of the 23 women who declined to participate in the RCT, 11 wanted to use or were currently using acupressure, which indicates that in this population, acupressure is acceptable. In addition, two participants who were randomised to the control group (routine care) also used acupressure, again indicating its acceptability. Compliance with the study protocol was high, with 83% of women in the acupressure group using the acupoints for up to five days until labour onset or induction.

5.3.1.1 Acceptance of randomisation

Twenty-three women (23/67) declined to participate in the RCT. Six were not interested, six provided no reason and 11 women were already using or wanting to use acupressure, and thus did not want to risk not being randomised to the acupressure intervention group. Most women in both groups would agree to participate in an RCT of acupressure if presented with the opportunity (94% intervention, 82% control). According to the questionnaire responses, four women in the control group disliked being randomised compared with one woman in the intervention group. In this small sample randomisation, acupressure appeared to be acceptable for the majority of women. In settings where acupressure is not the usual practice and, therefore, where equipoise may be more apparent, randomisation may be even more acceptable.

5.3.2 Demand

This aspect of feasibility considers the estimated use of the intervention in a defined population or setting. There was a perceived high use of acupressure by the women in this study and at the study sites. Midwives positively discussed acupressure, with many from different models of care discussing acupressure with women from 39 weeks' gestation. In settings where acupressure is not the usual practice, demand may be limited, which may affect the feasibility of future studies.

5.3.3 Implementation

The ‘implementation’ area of feasibility considers the extent or likelihood that the intervention will be fully implemented as planned. Since acupressure had been successfully incorporated into clinical practice in this setting for some time prior to the study, it is reasonable to assume that acupressure would be fully implemented in any future RCT. Since the completion of this study, acupressure has continued to be an accepted practice and used in daily clinical practice at the study sites. In future studies, care should be taken to measure intervention fidelity to ensure that the acupressure was implemented as planned. This could be undertaken through observation or diary records or interviewing participants about how and when the acupressure was applied.

5.3.4 Adaptation

The ‘adaptation’ feature of feasibility is reviewing or changing the content or procedures appropriate to a new population or setting. At the time of developing the RCT protocol, only one study had been published on the use of acupressure for stimulating labour onset (Ingram et al. 2005). The framework of this quality project was adapted for the FRCT by using the same three acupoints, but a more robust and standardised ‘dosage’ regime for these acupoints was developed: SP6 and LI4 for two minutes every two hours during the day, and GB21 twice a day, morning and night. Further, to ensure high compliance with the intervention protocol, an acupoint diary was developed for women to complete. A further adaptation was that the eligibility criteria were more clearly defined, with only primigravid women to be recruited at 40 weeks and 5 days’ gestation.

5.3.5 Practicality

The ‘practicality’ or extent to which an intervention can be provided within constraints is another aspect of feasibility. For our RCT, we recommended that midwives be trained in acupressure via a four-hour workshop showing them how to provide women with accurate information on acupressure, and to be able to demonstrate the acupoints to women allocated to the intervention group. In relation to time constraints, as in all research projects, additional time was required for staff information sessions about the study and for training staff to discuss and provide verbal and written information on the research to ensure that

valid, informed consent was obtained. In this study, an additional 10 minutes (approximately) were required for the RA/midwifery staff to demonstrate and explain the acupoints to the intervention group participants. There was no equipment required other than a printer to provide a two-page acupressure information sheet and a diary page for intervention participants. An extra resource given to each intervention group participant was a CD containing short videos on the three acupoints in an attempt to improve compliance. Although this CD was not expensive (fewer than $1AUD each), its usefulness was not evaluated.

5.3.6 Integration

This study also considered the feasibility element of 'integration', or the level of system change needed to integrate an intervention into existing infrastructure, program or service. As previously mentioned for 'acceptance', acupressure was incorporated into the midwives' clinical practice prior to the study, as an accepted practice, system or program change was not required at study sites (midwives attended acupressure workshops 2010-2012). However, a different challenge not envisaged was ensuring that midwives did not discuss or recommend acupressure to all primigravid women while the study was being undertaken to allow for recruitment of women who were not using or wanting to use acupressure (study inclusion criteria). Integration may be a challenge in settings where acupressure is not the usual practice or an accepted therapy, or where training of many midwives is required.

5.3.7 Expansion

This aspect of feasibility considers the potential success of an already successful intervention with a different population or setting. Based on the RCTs cited in Chapter 2, both in the Systematic review and further studies since, and the clinical outcomes of our small RCT, acupressure appears to be a safe (based on clinical outcomes of maternal and neonatal morbidity and mortality) and acceptable invention, and an 'easy-to-learn' technique for staff and women/partners/support persons. There is a potential for expansion and implementation at other maternity services, especially in rural and remote areas, at birth centres or for home births, where there are low technology requirements and minimal staff to educate in acupressure.

5.3.8 Limited-efficacy testing

Most feasibility studies use convenience samples with intermediate rather than final outcomes, with shorter follow-up periods or limited statistical power (Bowen et al. 2009). We chose to undertake an RCT to evaluate pregnant women's acceptance of randomisation to acupressure or routine/usual antenatal care. Our FRCT, although not fully powered, evaluated a number of outcomes: clinical outcomes included spontaneous labour onset, mode of birth and intervention rates; behavioural outcomes included participants' and health professionals' views and attitudes towards acupressure, CAM and RCTs. We had a very short follow-up period, with women completing a questionnaire in the immediate postnatal period (up to five days after giving birth) to reduce recall bias. Although not required with a feasibility study, we were able to determine the sample size for a future, appropriately powered RCT (n = 994, 80% power, alpha 0.05, allowing for a 1% cross-over) to be able to detect a 9% difference in spontaneous labour onset for the acupressure group.

5.4 Raising a new question

During reflection on the analysis of the midwives' focus group, it appeared that midwives who personally used CAM seemed to be more inclined to discuss and recommend it to women. For example, some of the midwives said:

> I am [a] person who seeks them [CAM] out occasionally for myself for my own health benefits so I'm quite happy to talk about them.

> I use them [CAM] and I offer them all the time.

However, midwives who had not used CAM themselves or knew little about it were less inclined to discuss or recommend CAM to women:

> I am not the sort that seeks them [CAM] out so I probably don't promote them as well as I could.

> I don't know a lot about acupressure, what's it all about … I don't want to teach them [women] the wrong thing.

> From my point of view, I need to learn more about complementary therapies to be able to give more information to the women. I can give them a sheet of paper but I want to learn more to be able to do it.

These findings are supported by Hall et al.'s (2013b) grounded theory study, which found that some midwives rely on their personal, experiential understanding for making recommendations: 'I tend to recommend things if I've used them myself [in practice] and found them to be beneficial' (Hall, Griffiths & McKenna 2013b, p. 805). Upon reflection, it became apparent that increasing understanding of midwives' attitudes towards, knowledge of and skills in CAM would also contribute to the feasibility of trials in this area. Previous studies have recommended that future research needs to be done at a national level to assess midwives' attitudes and views on CAM (Adams et al. 2011; Adams & Steel 2012; Hall, McKenna & Griffiths 2013). Therefore, to address these recommendations and the findings of this feasibility study, a survey of midwives at a national level was undertaken as Study 2.

5.5 Study 1 summary

Chapters 4 and 5 have provided the quantitative and qualitative findings of Study 1, addressed three of the four objectives of this project and assessed the feasibility of conducting an acupressure trial for post-date pregnancy at a local level. Study 1 findings suggest that acupressure is an acceptable intervention for primigravid women experiencing a post-date pregnancy, and a CAM trial is feasible in a maternity setting at a local level in Australia. However, a major challenge identified when conducting this study was that acupressure was embedded in the midwives' clinical practice at the study sites, which may have influenced the attitudes of the staff and the women, some of whom wanted to use acupressure and were less agreeable to enrolling in an RCT. This insight suggests that a further study should be conducted in a unit where acupressure is not the normal practice.

The next chapter describes Study 2, which aims to address the project's fourth objective: to conduct a national survey of Australian midwives to explore their beliefs, knowledge, skills and training in CAM and acupressure and to increase

understanding of the feasibility of conducting trials in the use of acupressure and CAM modalities during pregnancy and birth in the Australian maternity setting.

STUDY 2

Chapter 6: Study 2—national survey of Australian midwives

6.1 Chapter overview

Women have identified health professionals such as midwives, nurses, GPs and obstetricians as a source of information about CAM and self-help strategies during pregnancy and for labour induction (Chaudhry, Fischer & Schaffir 2011; Gatward et al. 2010). Over the past 15 years, there has been a marked increase in the number of international studies on the referral practices and/or professional use of CAM by midwives and nurse-midwives during pregnancy and/or labour (Adams 2006; Bayles 2007; Gaffney & Smith 2004a; Harding & Foureur 2009; Hastings-Tolsma & Terada 2009; Neri et al. 2017; Samuels et al. 2010). However, it appears that none of these studies consider the midwives' own personal use of CAM or how this personal use might influence what CAM options are discussed or recommended to women. During Study 1, through the FRCT and health professional focus groups, it became apparent that the midwife participants who personally used CAM appeared more likely to discuss and recommend CAM to pregnant women (Mollart, Adams & Foureur 2016). These findings, together with the apparent gap in the literature, led to this project's fourth objective:

4. To conduct a national survey of Australian midwives to explore their personal use, beliefs, knowledge, skills and training in CAM and acupressure to increase understanding of the feasibility of conducting trials in using acupressure and CAM modalities during pregnancy and birth.

6.2 Literature review

To inform the design of the national survey, a search was undertaken to determine if the following six questions had previously been considered in the international or Australian literature:

1. Do Australian midwives personally use CAM, including during their own pregnancy/ies?

2. Does personal use of CAM influence Australian midwives' discussion of CAM with pregnant women or their referral of women to CAM practitioners?
3. What CAM and self-help modalities do Australian midwives discuss with and recommend to women experiencing a post-date pregnancy?
4. What CAM practitioners do Australian midwives recommend to women experiencing a post-date pregnancy?
5. What are Australian midwives' attitudes, beliefs and views towards CAM?
6. What knowledge, skills and training in CAM do Australian midwives have?

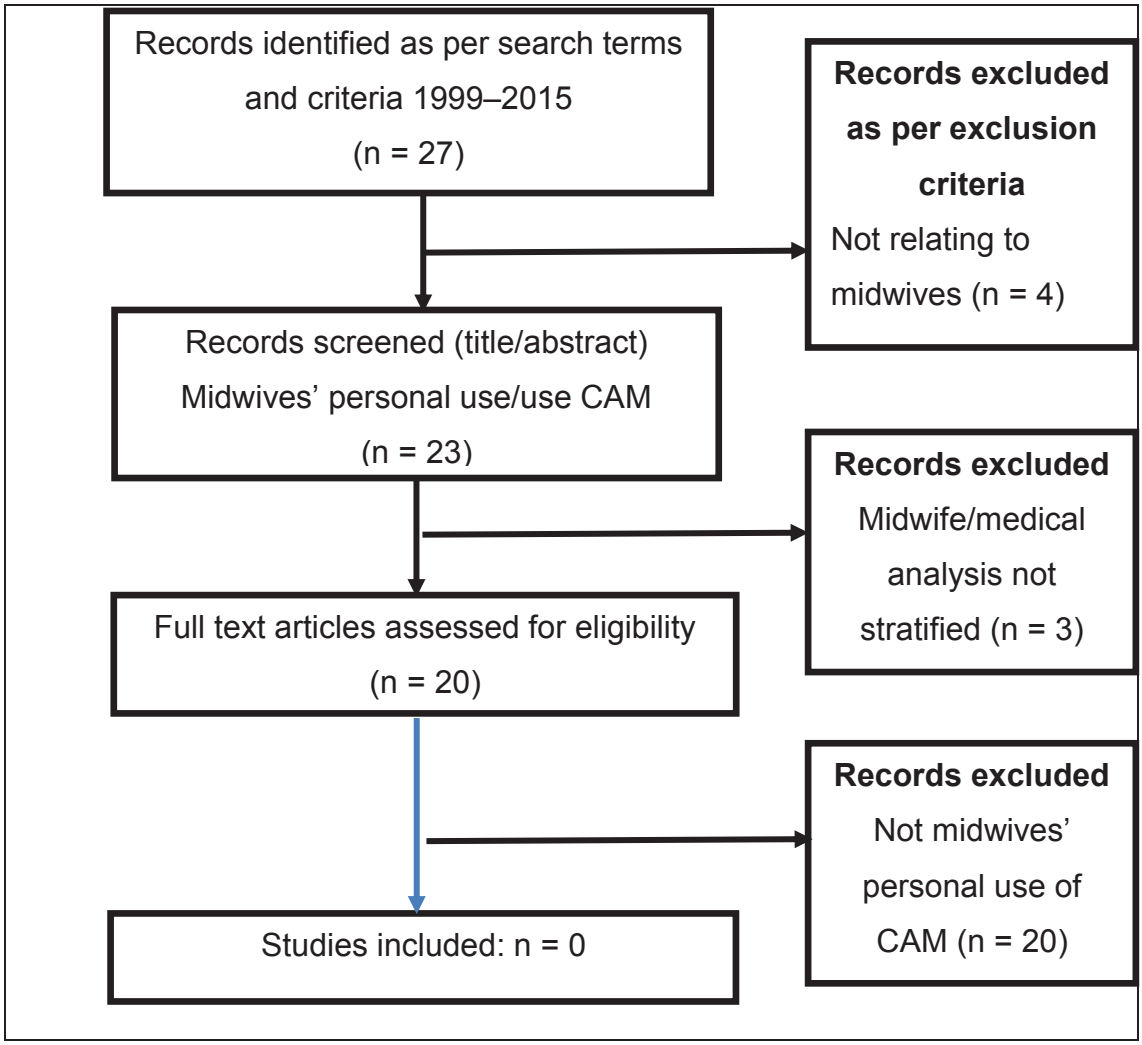
6.2.1 Locating literature on midwives' personal use of CAM and effect on clinical practice

A literature search was undertaken via MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Collaboration, AMED (Allied and Complementary Medicine), Proquest and Science Direct using the search terms 'midwives, midwife, midwifery, personal use, use, complementary alternative medicine, complementary alternative therapies, complementary treatments'. All identified titles and abstracts were assessed via search terms. Twenty-seven articles were located and their abstracts reviewed. If the abstract did not provide sufficient information, the full paper was retrieved and examined prior to making a final decision regarding inclusion. The references of the retrieved articles were checked to identify any additional studies.

As shown in Figure 6.1, within the 27 studies located using these key search terms and databases, no studies were found that focused on midwives' personal use of CAM. Two studies were of Australian nurses' personal use of CAM (Shorofi & Arbon 2017; Wilkinson & Simpson 2002) and two included non-nurses/midwives (Bradshaw et al. 2015; Johnson et al. 2012). Also excluded were three studies that explored health professionals' use of and attitudes towards CAM where a separate analysis for midwives was not available (Munstedt, Brenken & Kalder 2009; Stewart et al. 2014; Wiebelitz et al. 2009). After retrieving the full text articles of the remaining 20 studies, none were considered relevant. Therefore, midwives' personal use of CAM and whether

personal use influences what is recommended to women has clearly been under-researched both in Australia and worldwide, so further study is warranted.

Figure 6.1: Flowchart of the literature search—midwives' personal use of CAM



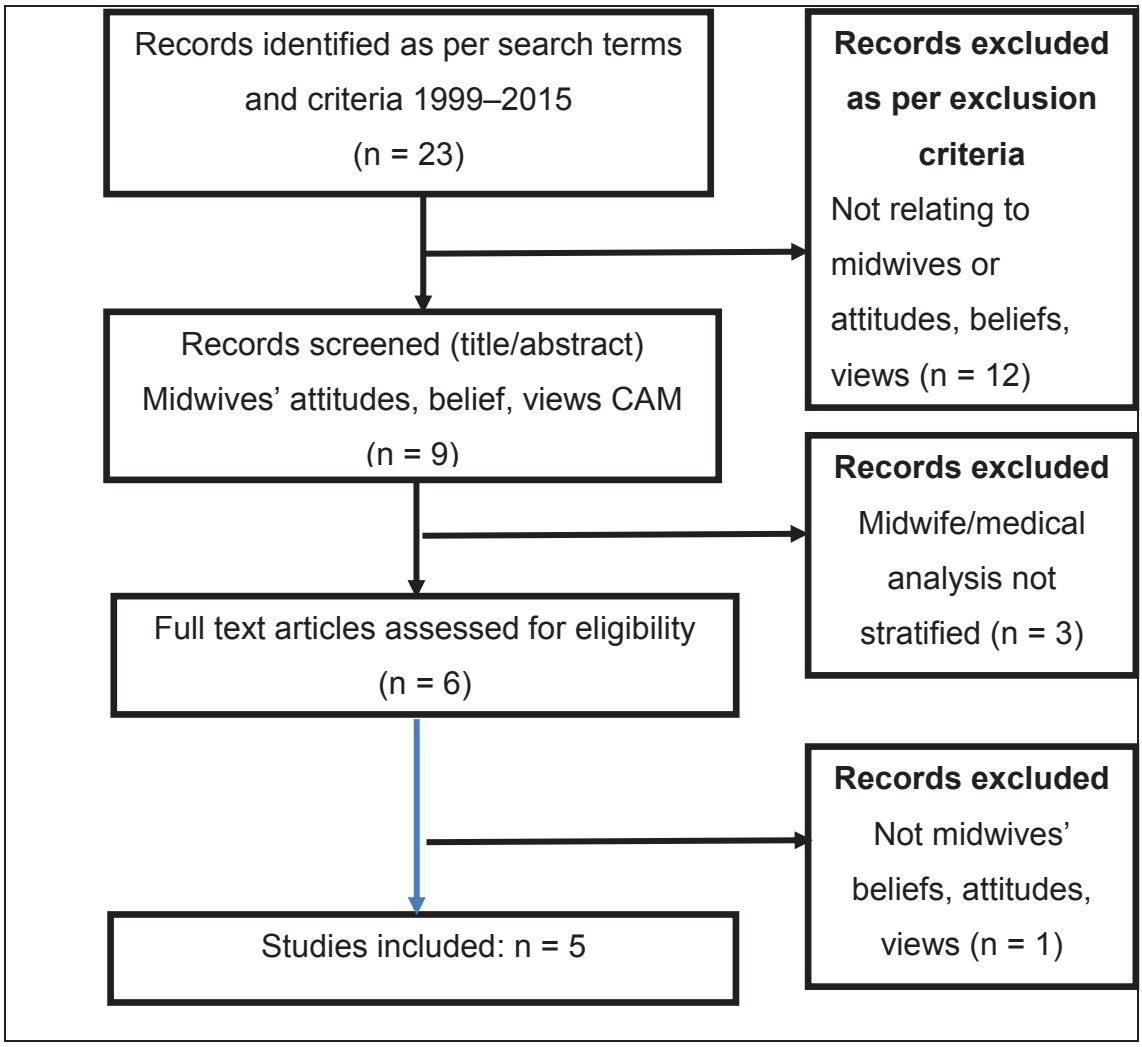
6.2.2 Literature exploring midwives' attitudes, beliefs and views of CAM

Several studies have found that midwives perceive CAM as an alternative or complement to conventional medicine, a possible aid to reducing medical intervention and a means to empowering women and increasing their autonomy (Adams 2006; Adams et al. 2011; Hall, Griffiths & McKenna 2013a; Harding & Foureur 2009; Neri et al. 2017).

A search of the literature using the search terms 'midwives, midwife, midwifery, complementary alternative medicine, complementary alternative therapies, attitudes, beliefs, views' was conducted, as outlined in section 6.2.1. Figure 6.2 presents a flowchart revealing that 23 studies were initially identified, with 18

excluded (those not relating to midwives or attitudes, beliefs, views [n = 12]; not original research [n = 2]; midwife/medical analysis not stratified [n = 3]). In addition, one study with Italian midwives was excluded because although the title of the article stated 'midwives' attitudes towards complementary and alternative medicine', the article did not report on the midwives' attitudes towards CAM, but only described the CAM options recommended to women and reasons why, and level of CAM training midwives had undertaken (Neri et al. 2017). Finally, five studies were found that focused on analysing midwives' attitudes and views towards CAM (Gaffney & Smith 2004a; Hall, Griffiths & McKenna 2012; Harding & Foureur 2009; Koc, Topatan & Saglam 2012; Samuels et al. 2010). Two studies were from Australia (Gaffney & Smith 2004a; Hall, Griffiths & McKenna 2012), and one each was from New Zealand/Canada (Harding & Foureur 2009), Turkey (Koc, Topatan & Saglam 2012) and Israel (Samuels et al. 2010). Table 6.1 presents a summary of the studies, and the following section presents a critique of the studies.

Figure 6.2 Flowchart of the literature search process—midwives' attitudes and beliefs about CAM



One of the first studies exploring midwives' views and attitudes towards CAM was conducted over 10 years ago, with 145 midwives and 70 obstetricians from South Australia (SA) (Gaffney & Smith 2004a) (Table 6.1). Midwives in this study had a positive view of CAM, perceived it as natural and effective in stimulating the body's natural healing power ($p < 0.001$) and did not consider it a threat to public health ($p < 0.001$) (Gaffney & Smith 2004a). Overall, the studied midwives had a more positive view of CAM than obstetricians ($p < 0.001$), although both groups had similar positive views on the safety of specific CAM modalities during pregnancy, such as acupuncture, hypnosis, massage, meditation and yoga (Gaffney & Smith 2004a).

A random sample of 171 New Zealand and 172 Canadian midwives explored how midwives in primary midwifery practice in these two countries use and view CAM

(Harding & Foureur 2009) (Table 6.1). Most midwives from both countries agreed with the statements that CAM supports normal birth (76.2%), is an essential part of midwifery (71.5%) and enhances midwifery care (78%), and is often used to avoid medical intervention (81.4%). However, the Canadian midwives demonstrated stronger disagreement with the statement that 'CAM are not considered an intervention' compared with the New Zealand midwives ($p = 0.001$) (Harding & Foureur 2009). The authors suggest the lack of equipoise, 'where we are prepared to acknowledge that we do not know whether CAM interventions make a difference or not to the outcome' (Harding & Foureur 2009, p. 12), together with the belief in CAM efficacy identified in their study, may result in low interest and support for CAM research among midwives.

A survey of 173 Israeli nurse-midwives using the validated CAM Health Belief Questionnaire (CHBQ) found that the majority of respondents strongly agreed with many of the fundamental tenets of CAM: belief in the existence of an underlying energy/life force, the concept of self-healing, the importance of integrating patients' expectations, health beliefs and values into the patient care process (Samuels et al. 2010) (Table 6.1). More than half of the midwives agreed with the statement that 'CAM stimulate the body's natural therapeutic powers' (57%), and the majority (85.3%) did not agree that 'CAM poses a threat to public health' (Samuels et al. 2010). The advantage of using this validated tool is the internal consistency of the measure (Cronbach's alpha 0.81) for the midwifery setting (Samuels et al. 2010), and it has also been used with other health professional groups, such as medicine (Lie & Boker 2004; Riccard & Skelton 2008), dentistry and pharmacy (Jakovljevic et al. 2013).

The fourth study of 129 Turkish midwives (Koc, Topatan & Saglam 2012) (Table 6.1) found that more than half (58.9%) suggested a range of CAM methods to pregnant women. Of those, 61.2% thought CAM would be beneficial, 61.2% thought medical therapy and CAM were useful during pregnancy, 47.3% suggested CAM to women who did not use medicine during pregnancy, 30.2% suggested it for psychological relief and 61.2% thought CAM methods may have side effects during pregnancy (Koc, Topatan & Saglam 2012). The authors report that the majority of midwives held positive views of CAM (Koc, Topatan & Saglam 2012). This assumption appears to be based on the high percentage of

respondents agreeing with the statement ‘CAM is beneficial’ and recommending CAM methods to pregnant women, rather than reporting on a direct question posed to the midwives. Most of this article focused on midwives’ discussion of CAM with women and professional use of CAM rather than an in-depth investigation of midwives’ attitudes to CAM.

The fifth and final study located was a grounded theory study of 25 midwives in Victoria, Australia to explore their attitudes and behaviours towards CAM (Hall, Griffiths & McKenna 2012) (Table 6.1). The core category of ‘managing conflict’, with midwives negotiating conflicting expectations with hospital bureaucracy (culture and policies), their medical and midwifery colleagues and childbearing women (divergence between women persisting with CAM in opposition to midwife’s judgement). Strategies used by participants when they experienced conflicting expectations were ‘legitimising CAM’ with midwifery and CAM as natural allies characterised by the principles of holism, highlighting the women’s autonomy to promote CAM practices and endorsing complementary rather than alternative; and ‘protecting themselves’ by concealing their support of CAM from colleagues, referring women interested in CAM to other clinicians or CAM practitioners or avoiding discussion of CAM with women and highlighting medical expertise (Hall, Griffiths & McKenna 2012). A key revelation from this study was that midwives’ documentation of CAM occurred in an ad hoc fashion, or midwives avoided documenting CAM use to evade scrutiny. As one said: ‘I can’t even write it down … because it might be heresy you know, it might be witchcraft!’ (Hall, Griffiths & McKenna 2012, p. 249).

Table 6.1 Studies exploring midwives' attitudes and views towards CAM

Study	Focus	Participants	Key Findings
Gaffney & Smith 2004a	Attitudes of midwives (and obstetricians) towards CAM during pregnancy	Random sample of SA midwives—members of the ACM (n = 370); All 93 obstetricians—members of the SA branch of Royal Australian and New Zealand College of Obstetricians and Gynaecologists (n = 93) Purposively developed postal questionnaire	• Response rate 78%(145/370 midwives, 70/93 obstetricians) • CAM stimulating the body's natural healing power: 65% agree/strongly agree ($p < .001$) • CAM as a threat to public health: 91.1% strongly disagree/disagree ($p < .001$) • CAM not tested in a scientific manner should be discouraged: 25.9% agree/strongly agree, 40% undecided • CAM in most cases because of placebo effect: 57% disagree/strongly disagree, 37.8% undecided.
Harding & Foureur 2009	The role of CAM in contemporary midwifery practice in New Zealand and Canada	New Zealand (n = 383) and Canadian (265) midwives: Random sample of midwives from New Zealand, and 2 provinces in Canada Purposively developed postal questionnaire	• Response rate 53% (171 NZ, 172 Canada) • CAM supports normal birth (76.2%) • CAM essential part of midwifery (71.5%) • CAM enhances midwifery care (78%) • CAM often used to avoid medical intervention (81.4%).
Samuels et al. 2010	Evaluate the use of and attitudes of nurse-midwives towards CAM	Israeli midwives at 5 medical centres: n = 238 Purposive sample Questionnaire used validated tool CAM CHBQ	• Response rate 72.7% (173/238) • CAM stimulate the body's natural therapeutic powers: 57% strongly agree • CAM poses a threat to public health: 85.3% disagree • Need to discourage treatments that have not been scientifically proven: 47.6% disagree • CAM are no more than placebo effect: 61.1% disagree.

Koc, Topatan & Saglam 2012	CAM modalities used and views towards CAM	Turkish midwives in family health centres: n = 159 Purposive sample Purposively developed postal questionnaire	• Response rate 81% (129/159) • 61.2% thought CAM would be beneficial • 61.2% thought medical therapy and CAM methods were useful during pregnancy • 61.2% thought CAM methods may have side effects during pregnancy.
Hall et al 2012b	Midwives' attitudes and Beliefs towards CAM	Midwives (n = 25) from 4 hospitals in Victoria, Australia Purposive sample Semi-structured interviews Grounded theory study Sub-group (n = 9) non-participant observation	• Category concept: 'Managing the conflicts' • Strategies employed by participants when they '*experienced conflicting and perspectives expectations* (between hospital bureaucracy, work culture, their colleagues and childbearing women) included: ○ *'Legitimising CAM'* and ○ '*Protecting themselves'.*

There are few studies on midwives' beliefs, attitudes and/or views of CAM on a national scale. Each of the five located studies used a different survey tool, which makes it difficult to compare findings with future studies. Only one study used a validated tool, the CHBQ (Lie & Boker 2004). Therefore, one of the Study 2 objectives is to evaluate the personal views and attitudes of midwives in Australia towards CAM using the validated CHBQ.

6.2.3 Professional guidance to support midwives' CAM practice

Formal professional guidance to support midwives' use of CAM in clinical practice may be provided in a number of ways—for example, through undergraduate or postgraduate education provided, qualified experts in the field and legislative/policy support.

Many Australian national and state nursing and midwifery organisations have developed a range of guidelines, policies and position statements outlining important factors when incorporating CAM into midwifery practice. A common recommendation is that any employing facility should have written policies and

protocols to support midwives (Australian Nursing Federation 2008; NSW Nurses and Midwives Board 2006; Nursing and Midwifery Board of the Northern Territory 2004; Nursing Board of Tasmania 2005; Nursing Board of Victoria 2006; Nurses Board of Western Australia 2003; Royal College of Nursing Australia 2004). However, since the introduction of the Australian Health Practitioners Regulation Agency and the Nursing and Midwifery Board of Australia (NMBA) in 2011, many of these documents no longer exist or have not been updated. Currently, in 2017, there is no Australian national document to provide guidance for midwives in the use of CAM in clinical practice.

The current NSW Nurses and Midwives Association (NSWNMA) policy acknowledges that using a range of complementary therapies may enhance the health and wellbeing of individuals, and that each person has the right, wherever possible, to the healthcare of their choice (NSWNMA 2014). The policy outlines that nurses and midwives 'must maintain a current knowledge base and are responsible for ongoing education in their chosen areas of practice, including those who practise complementary and alternative therapies' (p. 1) (NSWNMA 2014). This policy is linked to the NSW Nurses and Midwives Board (NSWNMB) Practice Standards, *Complementary Therapies in Nursing and Midwifery Practice*, originally developed in 1996, updated in 2006 and still available online (http://www.nmb.nsw.gov.au/Complementary-Therapies/default.aspx). The NSWNMB document also acknowledges that nursing and midwifery practice has always included a range of therapeutic approaches and interventions. In addition to maintaining a current knowledge base, nurses and midwives must observe the Code of Professional Conduct at all times (NSWNMB 2006). Both documents clearly state that nurses and midwives in NSW must document the practice of CAM in a patient's notes and that each nurse/midwife is responsible for evaluating whether their qualifications, education and/or experience in the use of a CAM modality can provide a level of competence appropriate for using that skill in patient care (NSWNMA 2014; NSWNMB 2006).

Literature exploring midwifery and medical professional guidance and clinical guidelines or protocols on the use of CAM in clinical practice is very limited. In a 2012 Australian study, a self-selecting sample of 53 midwives attending two maternity care conferences completed a questionnaire about CAM (Diezel et al.

2013). Forty-three percent of respondents did not have a clear understanding of the legal implications of recommending or using CAM within their clinical practice (Diezel et al. 2013). Three-quarters (67%) of respondents felt that they understood their workplace policies regarding the referral and use of CAM as part of their scope of practice (Diezel et al. 2013). A noticeable limitation of this published article is the lack of explanation relating to sample size—that is, the number of conference attendees at each conference, the number of questionnaires distributed or whether the sample was representative of all Australian midwives.

There is a challenge in providing sufficient direction through a guideline or protocol while maintaining flexibility to enable midwives to make appropriate individualised clinical care decisions rather than mandating a strict policy (Hall, McKenna & Griffiths 2013). Because of the lack of literature exploring legal implications of midwives' recognised scope of practice including CAM and organisational policies or procedures to support midwives incorporating CAM into their clinical practice, this area of inquiry is in urgent need of further research. Study 2's national study thus includes two questions exploring this issue: were midwives aware of hospital policy on CAM, and if they felt supported by the organisation to use/recommend CAM (see Appendix 13 for the full questionnaire).

6.2.4 Midwives and CAM education and training

Despite the proliferation of research into CAM in relation to midwifery practice and maternity care, the number of studies investigating midwives' level of training in the field of CAM is only slowly increasing. Eight studies conducted between 2000 and 2017 were located during the literature search, and all but one used a survey design with populations responding ranging from 27 to 343. One study used a grounded theory methodology with 25 midwife participants. The available evidence indicates that although midwives frequently discuss and recommend CAM to pregnant women, many have no formal education or qualifications in this field (Hall, McKenna & Griffiths 2013; Hastings-Tolsma & Terada 2009). Education is broadly defined as the process of learning, especially in a school or college, or the knowledge attained from this, whereas 'training' is the process of learning the skills needed to undertake a particular activity, which may take the

form of an in-service, lecture or informal learning setting ('Training' 2016). Seven studies were found that related to midwives and their training and/or education in CAM (Allaire et al. 2000; Harding & Foureur 2009; Hastings-Tolsma & Terada 2009; Munoz-Selles, Vallas-Segales & Goberna-Tricas 2013; Neri et al. 2017; Stewart et al. 2014; Wiebelitz et al. 2009); these are reviewed in the following section. An additional study was found that, although it did not focus on midwives and CAM education, did include this topic area (Hall, Griffiths & McKenna 2013c). Of the eight studies, two were conducted in the US (Allaire et al.2000; Hastings-Tolsma & Terada 2009), with one each from New Zealand/Canada (Harding & Foureur 2009), Germany (Wiebelitz et al. 2009), Spain (Munoz-Selles, Vallas-Segales & Goberna-Tricas 2013), Scotland (Stewart et al. 2014), Australia (Hall, Griffiths & McKenna 2013c) and Italy (Neri et al. 2017). An early survey of 82 North Carolina nurse-midwives identifies that 41.5% reported receiving formal training in different CAM modalities such as herbal medicine, massage, acupressure, homeopathy and therapeutic touch (Allaire et al. 2000). Twenty-nine (46.7%) had received some CAM education during their nurse-midwife training, with the most common being herbal medicine, massage, acupressure, mind–body interventions, homeopathy, therapeutic touch and acupuncture (Allaire et al. 2000). Most respondents (93.9%) recommended CAM to pregnant women, with the five most commonly cited forms being herbal medicine, massage, acupressure, homeopathy and therapeutic touch. The survey was sent to all 120 certificated nurse-midwives in North Carolina and achieved an impressive 68.3% response rate (Allaire et al. 2000). Two potential limitations of this study are that only midwives interested in CAM completed the survey, and that the sample was confined to one US state. The authors acknowledge these limitations and recommend that future studies on a national or population level should be undertaken.

In their study of 343 midwives from New Zealand (n = 171) and Canada (n = 172), Harding and Foureur (2009) reveal that many midwives recommended CAM to pregnant women (71.95%), but only half of the respondents from both countries (51.6%, 341) had learnt about CAM from workshops, courses, seminars or educational programs (Harding & Foureur 2009). Of those, only 10.4% identified as having obtained formal certification or licensure in modalities such as

homeopathy, acupuncture and herbal medicine. More New Zealand midwives (17%) indicated obtaining certification than Canadian midwives (4%) ($p < .001$) (Harding & Foureur 2009). It was worrying that 95% of respondents had learnt about CAM from discussions with other midwives. This raises the question of potential misinformation provided to women and their families and highlights the need to include CAM education in undergraduate programs.

Professional use and knowledge/training in CAM was explored in a survey of 500 randomly selected midwives from six US regions (Hastings-Tolsma & Terada 2009). A total of 227 midwives (45.4%) responded, with the majority (78%) reporting using CAM such as herbs (85%), massage (53.9%) acupressure (50%), music (39.9%) and guided imagery (39.3%) in their midwifery practice. Under half of respondents (41%) had completed a formal course in a CAM modality, although the articles gives no information about the particular CAM education these participants had completed. Other sources of knowledge identified include self-study/workshops (24.7%, n = 44), workshops/lectures (6.2%, n = 11), self-help/observation (20.2%, n = 36), self-study only (16.3%, n = 29), preceptor only (4.5%, n = 8), or other (22.5%, n = 40). Many respondents (63.5%) did not have specific CAM content in their basic nurse-midwife program. Nearly all respondents (90.4%) believed that CAM belongs in midwifery practice. I agree with the authors' comment that there are no other health-related therapies used with such frequency where clinicians are not expected to have baseline knowledge and understanding (Hastings-Tolsma & Terada 2009). Mainstreaming CAM into midwifery education is thus an important strategy to ensure that midwives have sufficient knowledge and information to offer women competent advice.

A survey of 246 German student midwives and 63 midwifery lecturers on CAM use in clinical practice and level of CAM training (Wiebelitz et al. 2009) found that irrespective of their degree of professional experience, nearly all (95%) rated their CAM education as inadequate. This study identifies midwives as the teachers of CAM in most cases (teaching acupuncture, homeopathy, phytotherapy, hydrotherapy), with doctors teaching only a few topics ($p < .001$). The authors reveal that student midwives and registered midwives did not receive any support

in teaching and applying their CAM knowledge when caring for pregnant women (Wiebelitz et al. 2009).

Munoz-Selles, Vallas-Segales and Goberna-Tricas (2013) surveyed 237 Spanish midwives working in 28 hospitals in the region of Catalonia Spain on their level of CAM training and use of CAM (Munoz-Selles, Vallas-Segales & Goberna-Tricas 2013). Nearly all (90%) midwives were trained in some form of CAM, but only 30% had attended training after their initial midwifery education. The most common CAM modalities in which midwives had received training were massage (47.6%), guided imagery (42.6%), hypnotherapy (37.1%), homeopathy (30.4%), music therapy (27.4%), reflex therapy/reflexology (25.3%) and yoga (17.3%), with the least common being acupuncture (9.0%) and acupressure (8%) (Munoz-Selles, Vallas-Segales & Goberna-Tricas 2013). The total number of CAM modalities in which the midwives were trained correlated negatively with age ($p < 0.001$) and with the years in which midwives had been working at the hospital ($p = 0.036$) (Munoz-Selles, Vallas-Segales & Goberna-Tricas 2013). Unfortunately, the authors do not provide details on what length of training or level of CAM training the midwives had undertaken.

Stewart et al. (2014) surveyed CAM practice and CAM training of Scottish midwives ($n = 77$) and obstetricians ($n = 40$). Only a third of respondents (32.5%) recommended the use of CAM with pregnant women, and midwives were more likely to recommend CAM ($p = 0.038$) than obstetricians (Stewart et al. 2014). Many respondents did not recommend CAM because of their lack of training (75.9%). Most respondents (76.1%) agreed that all health professionals should be taught about CAM during their undergraduate curriculum, with an emphasis on evidence (Stewart et al. 2014).

The most recent study surveyed midwives from the Emilia-Romagna region of Italy on their CAM knowledge and training, with 147 participating from a possible 525 invited (28% response rate) (Neri et al. 2017). Nearly all midwives who responded (90%) advised women about the use of CAM during pregnancy, with just under half (47%) having received CAM training through private education, 30% from their employing hospital and 20% from their university (Neri et al. 2017). The article does not report the level of CAM education and the percentage of midwives trained. Most of the respondents (70%) wished for the opportunity to

acquire CAM education during their undergraduate program, while 30% preferred post-degree education (Neri et al. 2017).

A grounded theory study conducted in Victoria, Australia with 25 midwives from four hospitals (Hall, Griffiths & McKenna 2013b; Hall, Griffiths & McKenna 2013c) found that when midwives engage in the process of determining the role of CAM, a number of strategies were used, including 'seeking professional knowledge'. Hall, Griffiths and McKenna (2013b, 2013c) found that some participants (eight) had undertaken CAM education in reflexology, massage, aromatherapy, reiki and relaxation therapies (Hall, Griffiths & McKenna 2013c). However, 18 midwives had no formal CAM education, and accessed academic and online resources to gain knowledge of CAM modalities to provide information to pregnant women about CAM and share their knowledge with colleagues (Hall, Griffiths & McKenna 2013b). Many midwives felt that their knowledge on CAM was inadequate, and that this affected their ability to facilitate women's informed decision-making and possibly restricted their own clinical practice (Hall, Griffiths & McKenna 2013c). This was the first study to introduce non-rational ways of knowing derived from experiential and intuitive understanding, which is important for midwives who promote CAM use in the perinatal period (Hall, Griffiths & McKenna 2013c). In addition to these subjective judgements, the authors highlight the need for improved CAM education for midwives.

6.2.4.1 CAM education opportunities

As an indication of how acceptable CAM has become to the general population, and specifically for women of childbearing age, some universities now offer CAM familiarisation courses as part of undergraduate nursing (Booth-Laforce et al. 2010; Cornman, Carr & Heitkemper 2006) and medical (Brokaw et al. 2002; Templeman, Robinson & McKenna 2015) programs. The other option is inter-professional education on CAM (Netherwood & Derham 2014; Steel et al. 2014b). In some countries, such as Israel (Samuels et al. 2010), midwives are exposed to courses in the efficacy and safety of CAM in their undergraduate program or, in the UK, as a specific midwifery degree (Tiran 2011), although the effect of this education has not been studied.

In 2003, the Australian Government released an expert committee report identifying the need for health professionals to have reliable CAM information (Expert Committee on Complementary Medicine in the Health System 2003). In 2013, 102 Australian nurse/midwifery university course coordinators were surveyed on CAM course inclusion and resource allocation, political support and philosophical concerns (Diezel et al. 2014). The study found that the amount of CAM teaching in Australian universities varied, but that more midwifery courses included CAM education than nursing courses. CAM's inclusion in tertiary–level programs may be influenced by political support, despite interest from students and patients and the growing body of evidence (Diezel et al. 2014). This study was published as a conference abstract, and further publication of the findings has not occurred; this is disappointing as there are very few studies in this research area.

It has been recognised by midwives and previous studies that there needs to be a scientific basis for CAM and additional professional education in CAM to enable more understanding of its possible risks to pregnant women (Adams et al. 2011; Gaffney & Smith 2004a; Munstedt, Brenken & Kalder 2009; Stewart et al. 2014; Tiran 2006). Other than Hall et al.'s (2103) grounded theory study, no further research has examined midwives' CAM education and training in Australia; further research is thus necessary.

6.2.5 Summary of the literature

This literature review has identified a knowledge gap in three specific areas: midwives' personal use of CAM and its potential influence on discussing and recommending CAM to women and especially women experiencing a post-date pregnancy; midwives' beliefs, attitudes and/or views towards CAM on a national scale, using a validated tool; and Australian midwives' levels of training and education in CAM modalities. The need for further research on a national scale was identified by all studies included in this literature review, since the sample size in each case was small and potentially non-representative, despite the similarities of the findings. Importantly, these aspects of midwives' relationships with CAM must be further understood as part of the feasibility of undertaking robust RCTs of acupressure for post-date pregnancy, or indeed any other CAM modality, in the Australian maternity setting.

Feasibility may be affected by a lack of formal education or skills in CAM, negative views of CAM or lack of legislative/policy or organisational support of CAM use in maternity care and midwifery practice. Therefore, a national survey of Australian midwives exploring these issues is well justified. Study 2, described in the next section, addresses the project's fourth objective:

4. to conduct a national survey of Australian midwives to explore their beliefs, knowledge, skills and training in CAM and acupressure to increase understanding of the feasibility of conducting trials in using acupressure and CAM modalities during pregnancy and birth.

6.3 Study 2: design and methods

6.3.1 Study design

This was a descriptive study that used an anonymous, national survey of registered midwives in Australia.

6.3.2 Aims

The study's two aims are as follows:

1. to investigate Australian midwives':
    a) discussions and recommendations for CAM and self-help strategies for women with post-date pregnancy, in particular to explore if acupressure is one of the included modalities
    b) referral of women with post-date pregnancy to CAM practitioners
    c) personal use of CAM, including acupressure including during their own pregnancies
    d) attitudes, beliefs and views of CAM
    e) training and education in the use of CAM, including acupressure
2. to explore the influence of the midwife's personal use of CAM on the their discussions/recommendation of CAM to women during the continuum of perinatal care.

6.3.3 Study population

There are an estimated 15,000 practising midwives in Australia, based on Health Workforce Australia data for 2011 (Australian Institute of Health and Welfare

[AIHW] 2012). A national convenience sample was obtained from the registered midwife members of the ACM, who received the ACM e-bulletin in the 2015–2016 financial year. The e-bulletin is distributed to 3,552 registered midwives in all states and territories of Australia which accounts for 35.5% of the midwifery workforce.

The sample size required for the study to have sufficient statistical power (i.e., 5% margin of error and 95% confidence) was 375 participants (Dean, Sullivan & Soe 2014). Recent online surveys inviting Australian midwives to participate in research have had response rates ranging from 6.8% (Biro et al. 2013) to 19% (Lee, Martensson & Kildea 2012). Therefore, to improve the response rate for the Study 2 online survey, two recruitment options were provided.

6.3.4 Recruitment

Following ethics approval (UTS HREC 2015000614) (Appendix 11), the research invitation was distributed via two methods. First, a research invitation was sent to all ACM members via the ACM weekly e-bulletin (Appendix 12). The research invitation advertisement, with a link to the SurveyMonkey questionnaire, was included in two regular e-bulletins approximately four weeks apart (November – December 2015). Regular e-bulletins contain a mix of news articles and research participation invitations for any number of different studies. Because of a low response rate to these advertisements for participation, the research invitation was re-sent twice as a dedicated e-bulletin, again four weeks apart (January – February 2016). A ‘dedicated e-bulletin’ means this was the only research project described in the bulletin.

Second, the survey was distributed to 160/450 registered midwives attending a national ACM conference held in Queensland in October 2015. The information sheet, survey and pre-paid self-addressed envelope were provided to attendees when they visited the PR.E.P.A.RE (Study 1) poster in the poster display area at the conference. The attendees placed the completed surveys into a return box (also next to the PR.E.P.A.RE poster stand) and received a raffle ticket for a $50 prize (candles and bath salts) drawn at the conference closing session.

6.3.5 Survey tool

A comprehensive questionnaire was developed by the research team based on the reviewed literature (Gaffney & Smith 2004a; Hall, McKenna & Griffiths 2012b; Harding & Foureur 2009; Hunt et al. 2010; Samuels et al. 2010; Shorofi & Arbon 2010; Wilkinson & Simpson 2002), as well as the first author's relevant CAM experiences with clinical midwives and study findings from focus groups conducted with local midwives regarding CAM. The full survey tool is located in Appendix 13.

The survey tool consists of 32 questions within four sections. The first section (Q1–10) focuses on the respondent's demographics, including professional qualifications and workplace setting. The second section (Q11–20) features questions relating to the midwives' clinical practice of discussing and recommending CAM and self-help options to pregnant women with a post-date pregnancy as well as suggested CAM practitioners; confidence and knowledge of CAM and self-help options; specific CAM/self-help options recommended to women for a post-date pregnancy; reasons for or views on why CAM/self-help options are discussed/recommended to women; and the support level at the midwives' organisations and the existence of CAM procedures/guidelines.

The third section (Q21–28) seeks the midwives' personal views and beliefs regarding CAM and their own use of CAM for general health and their own pregnancy/ies. This third section includes the CHBQ, which comprises three segments: demographic data, CAM Needs Assessment and attitudes to CAM (Samuels et al. 2010). Only the validated third segment of the CHBQ was incorporated into the survey tool. This segment consists of 10 items and examines respondents' attitudes towards CAM using a 7-point, Likert-type rating scale (in which 1 equals 'absolutely disagree' and 7 equals 'absolutely agree'). Higher scores for 1–5 and 9–10 items indicate more favourable attitudes towards CAM. Items 6–8 are worded negatively to minimise the acquiescence response set, requiring the scores of each question to be reversed prior to data analysis (Samuels et al. 2010). The CHBQ has been trialled with a variety of healthcare professional and students, including those in medicine (Lie & Boker 2004) dentistry and pharmacy (Jakovljevic et al. 2013; Riccard & Skelton 2008), and nurse-midwives (Samuels et al. 2010). The internal consistency of the CHBQ

(using a Cronbach's alpha) was found to be 0.75 (Lie & Boker 2004) and 0.81 (Samuels et al. 2010).

The fourth and last section (Q29–32) concentrates on the midwives' levels of education and training in CAM, including the specific CAM modalities. The questions were scored using multiple-choice tick-box options or statements scored using 5-point Likert-type rating scales (in which 1 = strongly disagree, 4 = strongly agree and 5 = unsure) for the four sections excluding the CHBQ. The final open-ended question (Q32) invites participants to include any further comments.

The survey tool was pilot-tested with five midwives (non-ACM members) for clarity, completion time and overall ease of administration. Minor revisions were made to the questionnaire based on the pilot testing. The web-based questionnaire was developed and designed using a secure, commercially available internet platform called SurveyMonkey (http://www.surveymonkey.com).

6.3.6 Data analysis

The respondents entered their electronic responses directly into SurveyMonkey; the responses to the surveys completed at the ACM National Conference were entered manually by the primary author (LM). The tools built into SurveyMonkey were used for simple descriptive statistics as well as individual-level data. Survey data were then imported into SPSS V23.0 for further analysis. Statistical analysis included descriptive statistics, chi-square and logistic regression. The level of significance was set as $p < 0.05$. Within the regression analysis, discussing self-help/CAM and recommending self-help/CAM were treated as dependent variables; age, years as a midwife and personal and professional use of CAM were treated as independent variables. Age and years as a midwife were analysed separately. To undertake logistic regression analysis for the midwives' personal views on CAM, the six questions were each re-coded into two categorical variables of 0 = disagree–strongly disagree and 1 = agree–strongly agree. The 'unsure' answers were not analysed.

In addition, the national survey findings were compared with previous midwifery studies using the CHBQ tool (Gaffney & Smith 2004a; Samuels et al. 2010). As

Gaffney and Smith (2004a) only use the last five of the 10 item statements (6–10) and present the data as percentages and numbers, whereas Samuels et al. (2010) present the findings of the 10 item statements using means and standard deviations, the comparison was undertaken against each of these studies as separate analyses.

6.3.7 Ethical issues

The ethical considerations for using online surveys such as Survey Monkey included ensuring that the responses were anonymous by choosing the option to collect computer IP addresses was switched to 'No'; that confidentiality was maintained by not using a shared account; and that consent was implied by completion of the survey, with information on the first survey 'page' following the pattern of a paper-based information sheet and including researcher contact details, reasons for the research and participants' right to withdraw at any point by exiting the survey (see Appendix 13) (British Psychological Society 2007). Data were entered on a question-by-question basis so that if a participant suspended the survey or lost their internet connection, any entered data would not be lost; at their next login, a participant would automatically be re-directed to the last question they completed.

All hard copies of data were stored in a locked filing cabinet, on password-protected computers and on external hard drives that were disconnected daily and stored in the locked office of the principal researcher, and only accessible by same. Any names and identifying features of people and places were removed from any data used for analysis. No identifying information was used in written reports, presentations and publications.

All researchers who had coordinating roles on this project have many years' experience in publishing research findings derived from hospital settings and are trained in data security and research ethics. All information will be stored for seven years after the study's completion and publication of the findings. The data files will then be shredded, destroyed and deleted.

6.4 Chapter summary

This chapter has presented a literature review examining the available evidence on midwives' personal use of CAM; attitudes, beliefs and views towards CAM;

education and training in CAM; and professional guidance on using CAM in clinical practice. Based on the limited studies and identified gaps, there is a strong rationale for undertaking a national survey of midwives in Australia to explore the previously mentioned aspects of the literature review. A survey tool was developed for this purpose based on this review and the findings from Study 1, particularly the focus group with midwives involved at the research sites as well as the principal researcher's personal experience over many years of working with midwives around the issue of CAM and acupressure.

The chapter has also presented the design of Study 2, outlining the aims, objectives and methodology of the national survey. The next chapter is the first of three (7, 8 and 9) that describe the findings of this national survey. Chapter 7 presents the findings as described in Publication 4, which explores the effect of midwives' personal use of CAM in terms of discussing and recommending CAM to pregnant women experiencing a post-date pregnancy.

Chapter 7: National survey—midwives discussing and recommending CAM to pregnant women and effect of personal use of CAM on clinical practice

This chapter presents the findings of the national survey, focusing on the relationship between midwives' discussion and recommendation of CAM and self-help strategies for post-date pregnancy, and the effect of midwives' personal use of CAM and their practice in relation to pregnant women.

The findings have been published as follows:

Mollart, L. (LM), Skinner, V. (VS,) Adams, J. (JA) & Foureur, M. (MF). 2018, '**Midwives' personal use of complementary and alternative medicine (CAM) influences their recommendations to women experiencing a post-date pregnancy**', *Women and Birth* vol. 31, no. 1, pp.44-51. DOI: 10.1016/j.wombi.2017.06.014.

The reader will find that the background material and study protocol have already been addressed in the previous chapters and is therefore invited to go directly to the subheading 'Findings' of Publication 4.

7.1 Publication 4

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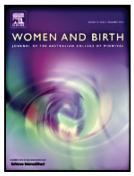

Midwives' personal use of complementary and alternative medicine (CAM) influences their recommendations to women experiencing a post-date pregnancy

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ABSTRACT

Complementary and Alternative Medicine (CAM) have increasingly been used by pregnant women with a steady rise in interest by midwives. Literature describing CAM and self-help options midwives recommend to women experiencing a post-date pregnancy is sparse. This study aimed to investigate if Australian midwives' personal CAM use impacts on discussions and recommendations of CAM/Self-help strategies.

Methodology/design: A survey of a national midwifery association midwifery members (n = 3,552) was undertaken at a midwifery conference (October 2015) and via e-bulletins (November 2015–March 2016). The self-administered survey included questions on what self-help and CAM strategies midwives discuss and recommend to women with a post-date pregnancy, midwives' confidence levels on discussing or recommending CAM, midwives' own personal use of CAM.

Findings: A total of 571 registered midwives completed the survey (16%). Demographics (age, years as a midwife, state of residence) reflected Australian midwives and the midwifery association membership. Most respondents discuss (91.2%) and recommend (88.6%) self-help/CAM strategies to women with a post-date pregnancy. The top five CAM recommended were Acupuncture (65.7%), Acupressure (58.1%), Raspberry Leaf (52.5%), Massage (38.9%) and Hypnosis/Calmbirthing/Hypnobirthing (35.7%). Midwives were more likely to discuss strategies if they personally used CAM ($p < .001$), were younger ($p < .001$) or had worked less years as midwives ($p = .004$). Midwives were more likely to recommend strategies if they used CAM in their own pregnancies ($p = .001$).

Conclusion: Midwives' personal use of CAM influenced their discussions and recommendations of CAM/self-help strategies to women experiencing a post-date pregnancy. This study has implications for inclusion of CAM in midwifery education curricula.

Statement of significance

Problem or issue

Little is known about midwives' personal use of complementary and alternative medicine (CAM) and the impact this has on midwives' discussion and recommendation of CAM/self-help strategies to pregnant women with a post-date pregnancy.

What is already known

CAM is increasingly used by pregnant women. Referral practices and/or professional use of CAM by midwives during pregnancy varies between studies.

What this paper adds

Evidence that most midwife survey respondents discuss and recommend self-help/CAM strategies to pregnant women at

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term. Midwives who are younger, less years as a midwife, and have personally used CAM are more likely to discuss and recommend self-help/CAM with pregnant women experiencing a post-date pregnancy.

1. Introduction

Women are taking proactive measures when experiencing a pregnancy past the due date by using self-help and complementary and alternative medicine/techniques to stimulate uterine contractions and induce spontaneous labour.[1–5] Post-date pregnancy is a pregnancy continuing past the expected date of birth (40 weeks gestation).[6] Self-help strategies are natural options administered or ingested by the pregnant woman enabling them to actively participate in their own care. Self-help strategies require time and commitment from the woman as the options may take several days to produce results.[7] Systematic reviews of the self-help strategies of sexual intercourse, ingestion of spicy foods or castor oil found little evidence to support their use in post-date pregnancy, however nipple/breast stimulation appears beneficial in reducing the number of women not in labour after 72 h.[8–10]

Complementary and Alternative Medicine (CAM) is difficult to define as more techniques become mainstream however, a current definition is "a group of diverse medical and health care systems, practices and products that are not generally considered part of conventional (western) medicine" (p.1).[11] The CAM techniques used by women vary with limited research to support their use.[7,12] Specific herbs such as evening primrose oil,[13] raspberry leaf [14,15] and blue cohosh [16] as well as date fruit[17,18] have been examined to determine their effect on labour induction and contractions. Other CAM modalities investigated to stimulate uterine contractions and induce labour include homoeopathic remedies,[19] reflexology,[20] shiatsu/acupressure[21–23] and acupuncture.[24,25]

Women have identified health professionals such as midwives, nurses, general practitioners and obstetricians as a source of information about CAM and self-help strategies during pregnancy and for labour induction.[1,3] In the past 15 years, there has been a marked increase in the number of international studies on the referral practices and/or professional use of CAM by midwives and nurse-midwives during pregnancy and/or labour.[13,26–29] Research suggests midwives are highly likely to offer CAM options to women due to midwives holding a view of CAM as an alternative aid to reduce medical invention, to empower women in their care and as a means of increasing women's autonomy.[13,26,30]

None of the afore mentioned studies consider the midwives' own personal use of CAM or how personal use might influence what is offered to women. During our previously published study it was apparent that midwives who personally used CAM were more likely to discuss and recommend CAM to pregnant women.[31] There is a scarcity of studies examining health professionals' personal use of CAM with only one study identified of Australian nurses' personal use of CAM.[32] As such, there is a significant gap in the literature regarding midwives' personal use of CAM and the relationship with self-help and CAM options midwives recommend to pregnant women, especially in a post-date pregnancy.

2. Method

2.1. Participants

The population invited to participate in this study were registered midwives who were current members of the Australian College of Midwives (ACM) in all states and territories of Australia (n = 3552) and who received the weekly ACM e-bulletin, since this provided an accessible, national sampling frame (pers. comm. ACM May 2017). The sample size required for the study to have sufficient statistical power i.e. 5% margin of error and 95% confidence was calculated at 375 participants.[33]

2.2. Recruitment

Following University Ethics Committee approval (UTS HREC 2015000614), the research invitation was distributed via two methods. Since recent online surveys inviting Australian midwives

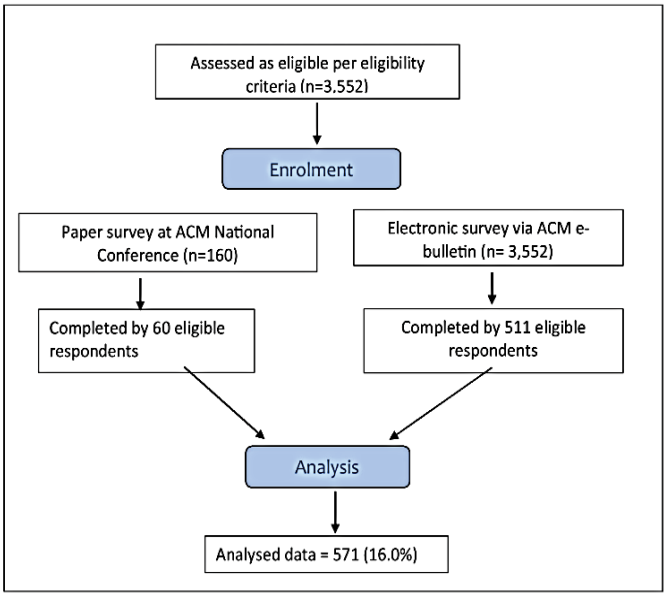

Fig. 1. Flowchart of eligible respondents.

to participate in research have had a response rate of 6.8%[34] to 19%,[35] two recruitment strategies were utilised. Firstly, the survey was distributed to eligible participants attending a national midwifery conference (October 2015). The information sheet, survey and pre-paid self-addressed envelope were provided to attendees when visiting the poster display area of the conference. Attendees placed the completed surveys into a return box and received a raffle ticket for a $50 prize which was drawn at the conference closing session. A total of 160 surveys were distributed.

Secondly, a research invitation was electronically sent to all eligible participants via the ACM weekly e-bulletin with a short information section and a link to a SurveyMonkey questionnaire. The e-bulletin was emailed twice within the weekly general e-bulletin and again twice as a dedicated e-bulletin, approximately 4 weeks apart to increase the response rate. As the researchers did not collect information on email or Internet Protocol (IP) addresses, it is possible that participants may have completed the survey more than once, however we regard this as unlikely. The information sheet and electronic invitation detailed the purpose of the study, the inclusion criteria and highlighted that participation was voluntary. No formal consent process was required.

2.3. Survey tool

A comprehensive survey was developed by the research team, based on the literature, the combined 90 years of midwifery clinical experience of three authors, extensive CAM research and policy expertise of one author and study findings from focus groups conducted with local midwives regarding CAM.[31] The survey used multiple-choice and likert-type rating scale questions for the four (4) sections: respondent's demographics; discussion with and recommendations to women about five self-help and 23 CAM options, and referral to CAM practitioners; midwife's personal views and belief and own use of 23 CAM options; and midwife's personal training and education in CAM. The survey also included the 'Complementary and Alternative Medicine Health Belief Questionnaire' (CHBQ)[27] consisting of ten questions. CHBQ response options were presented along a 7-point Likert-type rating scale for each item. Higher scores indicate more favorable attitudes toward CAM. The construct validity of the CHBQ has been verified by its repeated use in studies of primary care physicians, pediatricians, nurse-midwives, and obstetricians.[36] The findings from the sections on midwives' training and education and the CHBQ questions will be published in subsequent papers.

The survey was pilot-tested by five midwives (non-ACM members) for clarity, time to complete and overall ease of administration. Minor revisions to the survey were made based on the pilot testing. The web-based survey was developed and designed using a secure, commercially available internet platform called SurveyMonkey™ (www.surveymonkey.com).

2.4. Data analysis

Electronic responses were entered directly into SurveyMonkey by the respondents and the surveys completed at the ACM National Conference were entered manually by the primary author (LM). The tools built into SurveyMonkey™ were used for simple descriptive statistics as well as individual-level data. Survey data were then imported into the Statistical Package for Social Science V23.0 (SPSS) for further analysis. Statistical analysis included descriptive statistics, chi-square and logistic regression. The level of significance was set as $p < 0.05$. Within the regression analysis, discussing self-help/CAM and recommending self-help/CAM, were treated as dependent variables; age, years as a midwife, personal and professional use of CAM were treated as independent variables. Age and years as a midwife were analysed separately.

3. Results

The survey was completed by 571 eligible participants, which represents a response rate of 16.0% (Fig. 1). Not all questions in the survey were answered by all respondents therefore percentages are given for the actual number of responses. The demographic data are representative of midwives for ACM membership and registered midwives in Australia, based on available data[37,38] (Tables 1 and 2). Demographic data are shown in Tables 1 and 2. More than half of respondents indicated they worked in all areas of maternity care (Table 1).

3.1. Midwives discuss and recommend self-help and CAM strategies

Most participants (520, 91.1%) sometimes/always discuss self-help and CAM strategies with women experiencing a post-date pregnancy, 47 (8.2%) never/not very often discuss these topics and 4 (0.7%) did not respond to this question. A substantial proportion of participants (505, 88.4%) recommended self-help and CAM strategies, 62 (10.9%) did not and four (0.7%) did not complete. The 62 participants who answered the question in the negative, selected multiple reasons as indicated in Table 3.

Of the 485 participants (84.9%) completing this question, 270 participants (55.7%) would discuss post-date self-help and/or CAM strategies with women prior to 40 weeks gestation and then onwards. Two hundred and fifteen (44.3%) participants would discuss from 40+ weeks and onward.

As described in Tables 4a and 4b, in separate analyses, midwives were significantly more likely to discuss self-help ($p < 0.001$) and CAM ($p < 0.001$) when they were confident in having the knowledge to discuss and recommend these strategies with women.

The top five self-help strategies recommended by participants for women experiencing a post-date pregnancy were sexual intercourse (83.2%), exercise e.g. walking, swimming (82.3%), nipple stimulation (79.0%), followed by eating spicy foods (16.8%) and castor oil (5.8%).

Table 5 displays the specific CAM strategies recommended by participants for women experiencing a post-date pregnancy with the top five strategies being Acupuncture (65.7%), Acupressure (58.1%), Raspberry Leaf (52.5%), Massage (38.9%) and Hypnosis/Calmbirthing/Hypnobirthing (35.7%).

A total of 315 (55.2%) respondents would refer a woman experiencing a post-date pregnancy to a CAM practitioner. Of those respondents, the top five practitioners being Acupuncturist (89.8%), Calmbirthing/Hypnotherapist (54%), Massage therapist (44.4%), Reflexologist (35.2%) and Naturopath (33%).

3.2. Personal use of CAM

Four hundred and fifty-nine (80.4%) participants have used CAM strategies for their own personal use with many participants choosing multiple modalities. The top five CAM strategies used for own personal health and wellbeing were Massage (80.0%), Acupuncture (66.6%), Aromatherapy (66.6%), Chiropractic/Osteopathy (59.5%) and Acupressure (55.7%) (Table 5). The majority (416/457, 91%) of participants found their own personal experience with CAM as a positive or very positive experience.

Nearly half of the participants (267, 46.8%) had used CAM strategies in their own pregnancy/ies, 130 (22.8%) participants did not use CAM and 174 (30.5%) answered not applicable. The top five CAM strategies used by participants in their own pregnancy/ies were Raspberry Leaf Tea/Tablet (55.8%), Massage (47.2%), Aromatherapy (43.8%), Acupuncture (38.6%) and Acupressure (36.3%) (Table 5).

Table 1
Demographic characteristics of respondents compared with national available data.

Respondents		Survey N = 571 N (%)	National Data §# %	
Age§	18–24	9 (1.6)	Under 25	2.2
	25–34	64 (11.2)		13.1
	35–44	112 (19.6)		16.2
	45–54	203 (35.6)		30.6
	55–64	162 (28.4)		32
	65–74	18 (3.2)		5.6
	75 and older	3 (0.5)		0.2
Gender#	Female	555 (97.2)		98.6
	Male	16 (2.8)		1.4
Ethnicity#	Indigenous Australian	7 (1.2)		1
	White/Caucasian/European	546 (95.6)		–
	Asian/Pacific Islander	10 (1.8)	–	–
	Indian	1 (0.2)		–
	Black/African American	3 (0.5)		–
	Other	4 (0.7)		–
Highest qualification	Hospital Certificate	69 (12.1)		–
	Graduate Certificate	44 (7.7)		–
	Diploma	23 (4.0)		–
	BA Midwifery	116 (20.3)		–
	BA Nursing	27 (4.7)		–
	Graduate Diploma	130 (22.8)		–
	Masters	147 (25.7)		–
	PhD	15 (2.6)		
Employment status#	Full-time	222 (38.9)		57.6 FTE
	Part-time	271 (47.5)		–
	Casual	51 (8.9)		–
	Not working/Retired/Studying/on Leave	27 (4.7)		
Work Setting#	Public Hospital	430 (75.3)	Hospitals	45FTE
	Private Hospital	25 (4.4)	(Public/Private)	
	Public/Private Hospital	2 (.4)		
	Private Midwifery Practice/Homebirth	26 (4.6)	Private Practice	1.0FTE
	Indigenous Services	6 (1.1)		
	University/Education/Research	41 (7.2)	Tertiary Ed	1.5FTE
	Community Health Centre	20 (3.5)	Community	4.0FTE
	Other	21 (3.6)		
Years as a registered midwife	Less than 1 year	24 (4.2)		–
	1–5 yrs	77 (13.5)		–
	6–10 yrs	86 (15.1)		–
	11–15 yrs	62 (10.9)		–
	16–20 yrs	51 (8.9)		–
	21–25 yrs	56 (9.8)		–
	More than 25 yrs	215 (37.7)		
Main clinical area#	All areas of maternity care	334 (58.5)		–
	Antenatal	38 (6.7)		6 FTE
	Intrapartum	57 (10.0)		14 FTE
	Postnatal	34 (6.0)		15.2 FTE
	Nursery (SCN/NICU)	7 (1.2)		3.8 FTE
	Group Practice/Caseload	18 (3.2)		9.5 FTE
	Non-clinical/education/management/research	56 (9.8)		6.1FTE
	Not currently working in maternity clinical area	14 (2.5)		–
	Other	13 (2.3)		3FTE

Legend: §Nursing and Midwifery Board Australia (NMBA) Data 2015 for Nurses and Midwives; #Australian (AIHW) National Health Workforce Data Set: Nurses and Midwives 2015 (N = 23801); FTE: Full Time Equivalent per 100,000 population; ~data not available.

Table 2
Respondents as per ACM membership and NMBA by Australian state and territory.

State of residency	Survey participants N = 571 % (n)	RM ACM members by state and territory 2015–2016 % (n = 3552)	Nursing and Midwifery Board of Australia (NMBA) Midwives by state/territory 2015 %
New South Wales (NSW)	31.5 (180)	29.2	21.7
Queensland	23.3 (133)	23.8	16.7
Victoria	19.4 (111)	19.7	29.8
South Australia	7.9 (45)	8.2	14.4
Tasmania	1.9 (11)	2.3	0.4
Western Australia	9.1 (52)	10.6	10.1
Australian Capital Territory (ACT)	4.2 (24)	3.1	2.9
Northern Territory	2.6 (15)	2.7	1.7

Table 3
Reasons for not recommending self-help and CAM strategies (n = 62).

	% (n)
I do not have the knowledge of CAM to confidently discuss with women	41.9 (26)
I do not have training in CAM to confidently discuss with women	40.3 (25)
Self-help and CAM strategies are not evidence based	27.4 (17)
I do not believe the strategies are effective	12.9 (8)

Multiple reasons selected by 62 respondents.

Table 4a
Midwives' confidence in knowledge when discussing self-help/CAM strategies to women with a post-date pregnancy.

	Discuss self-help/CAM N (%)	X^2 ∞
Confident in knowledge to discuss self-help strategies (n = 492)		
Yes- confident/very confident	442 (89.8)	<0.001
Not confident	50 (10.2)	<0.001
Confident in knowledge to discuss CAM (n = 471)		
Yes- confident	345 (73.2)	<0.001
Not confident	126 (26.8)	<0.001

∞Pearson's Chi-square.

Table 4b
Midwives confidence in knowledge when recommending self-help/CAM strategies to women.

	Recommend self-help/CAM. N (%)	X^2 ∞
Confident in knowledge to discuss self-help strategies (n = 480)		
Yes- confident/very confident	438 (91.2)	<0.001
Not confident	42 (8.8)	<0.001
Confident in knowledge to discuss CAM (n = 460)		
Yes- confident	341 (74.1)	<0.001
Not confident	119 (25.9)	<0.001

3.3. Discuss/recommend self-help and CAM strategies to women

The statistically significant results of the logistic regression analysis show that midwives were more likely to discuss self-help/CAM strategies if they had personally used CAM ($p < 0.001$), were younger ($p < 0.001$) and/or had worked less years as registered midwives ($p = 0.004$) (Table 6). Also, midwives were more likely to discuss self-help/CAM strategies if they provided CAM to women in the perinatal period ($p = 0.026$), were younger ($p = 0.001$) and/or had less years as a registered midwife ($p = 0.008$) (Table 7).

Midwives were more likely to recommend self-help/CAM strategies if they had personally used CAM ($p < 0.001$), were younger ($p < 0.001$) and had less years registered as midwives ($p < 0.001$) than those midwives who were not likely to recommend CAM (Table 8). Also, midwives were more likely to recommend self-help/CAM strategies if they have used CAM in their own pregnancies ($p = 0.001$) and were younger ($p = 0.029$) (Table 9).

4. Discussion

This is the first national survey of Australian midwives examining their clinical practice in relation to self-help and CAM strategies for women experiencing a post-date pregnancy. This is also the first time Australian midwives have been asked about use of CAM strategies in their personal life and pregnancy/ies on a national scale. The response rate of 571 registered midwives was well above the required sample size of 375 for 5% margin of error and 95% confidence. This study achieved a response rate (16%) similar to other online surveys conducted with Australian midwives,[34,35] and is representative of midwives registered in Australia.[37] A potential limitation of the study was that the sample was self-selected and it is possible only midwives who were interested in CAM may have responded to the survey. However, there were 48 participants (8.1%) who completed the survey who reported never discussing CAM strategies with women in their care, did not have knowledge and education on CAM and did not use CAM for personal use.

Table 5
CAM strategies: recommended for post-date pregnancy, midwives' personal use and use in own pregnancy.

CAM strategy	Recommended to women by participants N = 571, N (%)	Personal Use by Participants N = 459, N (%)	Personal use in own pregnancy N = 267 N (%)
Acupuncture	**385 (65.7)**	**307 (66.6)**	**103 (38.6)**
Acupressure	**332 (58.1)**	**257 (55.7)**	**97 (36.3)**
Raspberry Leaf (tea or tablet)	**300 (52.5)**	156 (33.8)	**149 (55.8)**
Massage	**222 (38.9)**	**367 (80.0)**	**126 (47.2)**
Hypnosis (Calmbirthing, Hypnobirthing)	**204 (35.7)**	105 (22.9)	60 (22.5)
Aromatherapy	170 (29.8)	**307 (66.6)**	**117 (43.8)**
Chiropractic/osteopathic	#	**273 (59.5)**	79 (29.6)
Reflexology	201 (35.2)	173 (37.5)	45 (16.9)
Imagery techniques	175 (30.6)	184 (40.1)	82 (30.7)
Evening primrose oil	132 (23.1)	111 (24.2)	37 (13.9)
Yoga	128 (22.4)	13 (2.2)	7 (2.6)
Meditation	120 (21.0)	&	&
Date fruit	93 (16.3)	#	#
Homoeopathic remedies	83 (14.5)	171 (37.3)	64 (24.0)
Bowen therapy	41 (7.2)	12 (2.1)	#
Reiki/therapeutic touch	39 (6.8)	94 (20.5)	12 (4.5)
Bach flower remedies	27 (4.7)	127 (27.5)	40 (15.0)
Shiatsu	23 (4.0)	56 (12.1)	7 (2.6)
Blue Cohosh	14 (2.5)	#	#
Traditional Chinese Medicine (TCM)	#	134 (29.2)	23 (8.6)

= this CAM option was not included in the survey section; & = meditation included with imagery techniques.

Table 6
Discussing self-help/CAM with women experiencing a post-date pregnancy related to midwife's CAM personal use, age and years registered as a midwife.

N = 506	B	S.E	Wald	Sig.	Exp (β)	95% CI for Exp(B)	
						Lower	Upper
Midwives CAM Personal use	2.154	0.401	28.866	0.000	8.617	#3.928 *3.754	18.906 17.528
Constant- age	4.232	1.041	16.511	0.000	68.829		
Constant- years as RM	2.047	0.557	13.481	0.000	7.744		
Age#	−0.067	0.019	12.785	0.000	0.935	0.902	0.970
Years as RM*	−0.068	0.024	8.054	0.005	0.935	0.892	0.979

(B = Correlation Co-efficient; SE = Standard Error; Wald = z^2; Sig = $p > 0.05$; Exp(B) = odds ratio; CI = Confidence Interval; # = age and * = years as RM were analysed separately).

Table 7
Discussing self-help/CAM with women experiencing a post-date pregnancy related to midwives providing CAM to women during the perinatal period, age and years as a midwife.

N = 504	B	S.E	Wald	Sig.	Exp (β)	95% CI for Exp(B)	
						Lower	Upper
Midwives provide CAM to women	0.905	0.405	5.006	0.025	2.473	#1.119 *1.119	5.464 5.385
Constant- age	4.926	1.065	21.694	0.000	142.880		
Constant- years as RM	2.913	0.586	24.711	0.000	18.403		
Age#	−0.061	0.018	11.027	0.001	0.941	0.908	0.975
Years as RM*	−0.061	0.023	6.861	0.009	0.941	0.899	0.985

(B = Correlation Co-efficient; SE = Standard Error; Wald = z^2; Sig = $p > 0.05$; Exp(B) = odds ratio; CI = Confidence Interval; # = age and * = years as RM were analysed separately).

Table 8
Recommending self-help/CAM with women experiencing a post-date pregnancy related to midwives using CAM, age and years registered as a midwife.

N = 506	B	S.E	Wald	Sig.	Exp (B)	95% CI for Exp(B)	
						Lower	Upper
Midwives CAM Personal use	1.698	0.386	19.342	0.000	5.465	#2.564 *2.451	11.648 10.706
Constant- age	4.798	0.968	24.566	0.000	121.251		
Constant- years as RM	2.213	0.528	17.572	0.000	9.139		
Age group#	−0.078	0.017	20.828	0.000	0.925	0.895	0.957
Years as RM*	−0.076	0.021	12.763	0.000	0.927	0.889	0.966

B = Correlation Co-efficient; SE = Standard Error; Wald = z^2; Sig = $p > 0.05$; Exp(B) = odds ratio; CI = Confidence Interval; # = age and * = years as RM were analysed separately).
B = Correlation Co-efficient; SE = Standard Error; Wald = z^2; Sig = $p > 0.05$; Exp(B) = odds ratio; CI = Confidence Interval; # = age and * = years as RM were analysed separately).

Table 9
Recommending self-help/CAM to women experiencing a post-date pregnancy related to midwives using CAM for own personal pregnancy/ies and age.

N = 397	B	S.E	Wald	Sig.	Exp (B)	95% CI for Exp(B)	
						Lower	Upper
Midwives using CAM in own pregnancy/ies	1.227	0.373	10.825	0.001	3.411	1.642	7.086
Constant	3.799	1.191	10.183	0.001	44.674		
Age group#	−0.043	0.021	4.384	0.036	0.958	0.920	0.997

B = Correlation Co-efficient; SE = Standard Error; Wald = z^2; Sig = $p > 0.05$; Exp(B) = odds ratio; CI = Confidence Interval; # = age and * = years as RM were analysed separately).

Most international and Australian studies have focused on CAM use during pregnancy relating to pregnant women's perspectives and use.[39,40] The most commonly used CAM options by pregnant women in Australian studies varies with the most popular being massage, vitamins and minerals, meditation, yoga, aromatherapy, herbal medicine (raspberry leaf) and Chinese medicine.[4,39,41] A potential limitation of these studies has been the limited checklist of CAM options from which participants can choose.[42] For this reason, our study offered 23 CAM modalities from which participants could choose.

A number of CAM modalities and self-help strategies have been used by women in order to naturally induce labour rather than having a medical/surgical induction. In our study, the top five self-help strategies recommended by midwives for post-date pregnancy were sexual intercourse (83.2%), exercise e.g. walking, swimming (82.3%), nipple stimulation (79.0%), followed by eating spicy foods (16.8%) and castor oil (5.8%); and CAM strategies were acupuncture (65.5%), acupressure (58%), raspberry leaf (52.3%), massage (39.2%) and hypnosis/Calmbirthing/Hypnobirthing (35.4%). Our findings are similar to the qualitative study of Australian women by Gatward et al. that found women use self-help/CAM strategies such as nipple stimulation (94.4%), exercise (83.3%), sexual intercourse (77.8%), acupuncture (27%) and raspberry leaf (61%) to stimulate contractions for a post-date pregnancy.[1] Whereas, Chaudhry et al. found USA women used very few strategies like acupuncture (1.9%) or herbal preparations (1%) with a preference for self-help options like walking/exercise (43%), intercourse (22.9%), spicy food (11%) and nipple stimulation (7.5%)

to self-induce labour.[3] Kozhimannnil et al. also reported on USA women's use of self-help strategies with findings similar to Chaudhry et al. with the average gestation reported as 39 weeks.[2]

Many respondents (55.2%) refer women with a post-date pregnancy to a CAM practitioner. This referral rate is similar to other Australian and international studies on referral rates to a CAM practitioner in pregnancy which ranged from 59% to 94%.[13,27–29] However, previous studies have not examined midwives' practice of discussing, recommending or referring women to CAM for a post-date pregnancy.

As this is the first study examining midwives' use of CAM in their personal lives and in their own pregnancies we are unable to compare our findings to other studies as only one study was found which included midwives, obstetricians and anaesthetists collectively.[43] Participants in our study were more likely to discuss and recommend self-help/CAM strategies if they had personally used CAM, were younger and/or had worked less years as registered midwives. Also, our study shows there is a statistically significant relationship between recommending self-help/CAM strategies to women experiencing a postdate pregnancy and midwives' personal use of CAM in their own pregnancy/ies. This is not an unexpected finding as most midwives are women[37] and the research shows that women generally and pregnant women specifically are high users of CAM. Midwives as women as well as their philosophy of midwifery are attracted to CAM with the potential to increase autonomy, control and decision-making.[13,30]

Our study found a similarity between the top five CAM strategies discussed and recommended to pregnant women and personally used by midwives including raspberry leaf and aromatherapy. It is important to remember that not all CAM modalities are intrinsically safe and midwives need to be aware of the potential benefits and risks, and the lack of quality studies.[44] Midwives have the opportunity to direct women to the National Centre for Complementary and Integrated Health (NCCIH) website which provides consumers with research-based CAM information on the more commonly used therapies.[45] However it is important for all health practitioners to remember and consider when reviewing CAM risk and safety that the 'lack of scientific verification does not equate to lack of benefit, it simply means more research is needed before specific conclusions regarding clinical recommendations can be made' (p145).[12]

It is concerning that a quarter of respondents in our study were not confident in their knowledge of CAM modalities yet 26.9% discussed and 25.9% recommended CAM options to pregnant women. As pregnant women are high users of CAM techniques, midwives need to have the confidence and knowledge to discuss CAM in an evidence-based approach. Therefore, health professional and midwifery education programs in particular, need to incorporate content that addresses commonly used CAM modalities in pregnancy including existing safety and efficacy data. Other studies have identified that although midwives frequently communicate with pregnant women regarding the use of CAM, many have no formal education in this area.[28,30] Due to word limit, further findings on midwives' training and education relating to CAM will be published in a future paper.

5. Conclusion

Increasingly as midwives work within their full scope of practice and as autonomous practitioners, they have the ability to influence pregnant women's attitudes and behaviours regarding the use of self-help and CAM techniques when wanting to induce labour. Despite the need to interpret the findings with caution, self-help and CAM techniques appear to be widely discussed and recommended by Australian midwives with women experiencing a post-date pregnancy. The level of discussion and recommendation of techniques was dependent on the midwives' age, years as a registered midwife and personal use of CAM modalities. It was interesting to note that the midwives' personal use during their own pregnancy did impact on recommending CAM options to pregnant women. We have been able to identify that further studies are warranted into Australian midwives' level of training and education in CAM modalities at an undergraduate and postgraduate level.

Authors' contributions

LM, MF, JA: have contributed to the design and development of the study protocol. LM and VS performed the statistical data analysis. LM prepared the initial draft of the manuscript. MF and JA are the supervisors for this research. All authors critically reviewed the content and approved the final version.

Conflict of interest

The authors declare they have no competing interests.

Ethical statement

I wish to submit our research paper **"Midwives' personal use of complementary and alternative medicine (CAM) influences recommendations of CAM to women experiencing a post-date pregnancy"** as subscription publication.

The study was conducted with approval from the University of Technology Sydney Human Ethics and Research Committee (UTS HERC 2015000614) on the 8th October 2015.

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7.2 Chapter summary

This national survey has found that a representative sample of Australian midwives discuss and recommend a range of CAM or self-help options to women experiencing a post-date pregnancy. Over 80% of the midwife respondents had personally used CAM modalities and found receiving CAM a positive experience. Midwives who personally used CAM in their own life were also more likely to have conversations with pregnant women about CAM modalities. Midwives who were younger and had worked fewer years in midwifery were significantly more likely to either use or recommend CAM to women. In addressing the limitations of previous studies in this area, this study provided an extensive range of CAM and self-help options for the midwife respondents to consider in relation to post-date pregnancy. As a consequence, this study found that the top five options recommended to women were acupuncture, acupressure, raspberry leaf, massage and hypnosis-based programs such as Calmbirth® or Hypnobirthing®. These were the same CAM modalities the midwives themselves had used. The

survey also explored midwives' beliefs and attitudes towards CAM and its use in post-date pregnancy. The next chapter presents the results of this aspect of the study.

Chapter 8: National survey—midwives' beliefs and attitudes to CAM

8.1 Chapter overview

The review of the literature presented in Chapter 6 that explored midwives' beliefs, attitudes and views towards CAM located five relevant studies worldwide (Gaffney & Smith 2004a; Hall, Griffiths & McKenna 2012; Harding & Foureur 2009; Koc, Topatan & Saglam 2012; Samuels et al. 2010). Several of these allude to a philosophical synergy between midwifery and CAM, an area that needs further exploration. The national survey of Australian midwives explored midwives' beliefs and attitudes through questions 18, 21 and 22. This chapter presents the findings of the analysis of these questions describing midwives' views of CAM and organisational support for CAM use in maternity care, and discusses the findings.

The second part of the chapter details the findings of Q21, the validated CHBQ (Appendix 13). This discussion includes a comparison with the only two studies of midwives using the CHBQ: an Australian study by Gaffney and Smith (2004a) and an Israeli study by Samuels et al. (2010).

8.2 Midwives' personal views of CAM

Not all questions were answered by all 571 respondents—therefore, means and percentages are given for the actual number of responses. For the six statements on midwives' personal views on CAM (Q22, Appendix 13), 501–505 midwives responded. As shown in Table 8.1, most respondents strongly agree/agreed with each of the six statements in this section of the survey.

Table 8.1: Midwives' personal views of CAM

Q22	Statements	*Strongly disagree/ Disagree % (n)*	*Neither/ Unsure % (n)*	*Strongly agree/ Agree % (n)*
1	CAM is an important aspect of my own/family healthcare (n = 505)	15.4 (88)	3.4 (19)	**81.2** (398)
2	Women should have the right to choose between conventional treatments and CAM strategies in healthcare (n = 504)	2.1 (12)	4.6 (22)	**93.3** (470)
3	Women should be adequately informed about the CAM strategies that can be used safely in pregnancy (n = 504)	0.7 (4)	2.9 (14)	**96.4** (486)
4	CAM strategies can be used as a complement in conventional healthcare (n = 504)	1.4 (8)	3.8 (18)	**94.8** (478)
5	All midwives **should have the knowledge** on commonly used CAM used during the perinatal period (n = 505)	2.1 (12)	5.2 (25)	**92.7** (468)
6	All midwives should receive **education of CAM strategies during their undergraduate** curriculum (n = 501)	3.0 (17)	5.6 (26)	**91.4** (458)

There was a statistically significant relationship between midwives who answered positively to Statement 1 (*CAM is an important aspect of my own/family healthcare*) and midwives' who personally used CAM ($p < 0.000$), or used CAM in their own pregnancy/cies ($p < 0.000$) and had CAM training or qualifications ($p < 0.003$).

There was also a statistically significant relationship for Statement 6 (*All midwives should receive education of CAM strategies during their undergraduate curriculum*) and midwives who personally used CAM ($p < 0.007$). No other variables (age, years as a midwife, professional qualifications) were significantly related to any of the six statements. Interestingly, there was no significant relationship between midwives working in the education field (hospitals/universities, n = 53) and Statement 6 ($p = 0.141$). The logistic regression calculation tables for statements 1 and 6 are included in Appendix 14.1 and 14.2, respectively.

8.3 Midwives' views of organisational support for CAM

For the three statements on midwives' perception of organisational support for self-help/CAM strategies and local CAM guidelines/procedures, 525–527 (92–92.3%) midwives responded. As shown in Table 8.2, just under half of respondents (49.5%) strongly disagreed or disagreed and 44% strongly agreed or agreed with the statement, *My hospital or service has guidelines or procedures on the use of CAM*. It is interesting to note that 14.4% of respondents answered 'unsure' that they felt supported in their organisation to recommend self-help strategies and 11.6% were unsure they felt supported to recommend CAM strategies.

More respondents strongly agreed or agreed with the statement that they felt supported by their organisation to recommend self-help strategies (53.3%) compared with feeling supported by their organisation to recommend CAM strategies (47.6%) (as shown in Table 8.2).

Table 8.2: Support from organisations/services

Statements	***Strongly disagree/ Disagree % (n)***	***Unsure % (n)***	***Strongly agree/Agree % (n)***
My hospital/service has guidelines/procedures on the use of CAM (n = 525)	49.5 (260)	6.5 (34)	44.0 (231)
I feel supported in my organisation to recommend self-help strategies (n = 527)	32.3 (170)	14.4 (76)	53.3 (281)
I feel supported in my organisation to recommend CAM strategies (n = 525)	40.8 (214)	11.6 (61)	47.6 (250)

8.4 CBHQ

Only respondents who completed the 10 CHBQ questions were included in the mean score analysis. Most respondents absolutely agreed or agreed with many of the philosophical statements of CHBQ. As depicted in Table 8.3, midwives responded with high scores to the positively worded items 1–3, 5 and 9–10. Of interest is that nearly a fifth of midwives (18.6%) absolutely disagreed or

disagreed with Item 4, *A patient's symptoms should be regarded as a manifestation of a general imbalance or dysfunction affecting the whole body*. As for the negatively worded items (6–9), the majority of midwives disagreed or absolutely disagreed (scoring 1–3) with the statement that CAM poses a threat to public health (Item 6: 91.7%), with half of respondents disagreeing with the need to discourage treatments that have not been scientifically proven (Item 7: 58.7%), and the assumption that the effect of CAM is no more than a placebo effect (Item 8: 62.2%).

Table 8.3: CHBQ—frequency

	Item	Absolutely Disagree/ Disagree % (n)	Neither disagree/ agree % (n)	Absolutely Agree/ Agree % (n)
1	The physical and mental health are maintained by an underlying energy or vital force. (n = 498)	8.6 (43)	25.3 (126)	**66.1 (326)**
2	Health and disease are a reflection of balance between positive life-enhancing forces and negative destructive forces. (n = 494)	11.3 (56)	23.1 (114)	**65.6 (324)**
3	The body is essentially self-healing and the task of a healthcare provider is to assist in the healing process. (n = 500)	9.25 (46)	19.8 (99)	**71.0 (355)**
4	A patient's symptoms should be regarded as a manifestation of a general imbalance or dysfunction affecting the whole body. (n = 499)	18.6 (93)	24.2 (121)	**57.1 (285)**
5	A patient's expectations, health beliefs and values should be integrated into the patient care process. (n = 501)	2.6 (13)	1.8 (9)	**95.6 (479)**
6#	Complementary therapies are a threat to public health. (n = 503)	**91.7 (461)**	5.4 (27)	3.0 (15)
7#	Treatments not tested in a scientifically recognised manner should be discouraged. (n = 499)	**58.7 (293)**	21.6 (108)	19.7 (98)
8#	Effects of complementary therapies are usually the result of a placebo effect. (n = 500)	**62.2 (311)**	29.6 (148)	8.2 (41)
9	Complementary therapies include ideas and methods from which conventional medicine could benefit. (n = 500)	4.4 (22)	14.0 (70)	**81.6 (408)**
10	Most complementary therapies stimulate the body's natural therapeutic powers. (n = 500)	7.4 (37)	23.6 (118)	**69.0 (345)**

 # Q6,7,8 are worded negatively and answers are in the reverse

Table 8.4 displays the last five questions of the 10-question CHBQ and compares the findings of this national study with those of Gaffney and Smith (2004a), whose study was conducted in one state (SA). The comparison reveals similarities between both studies, especially for Item 6, *Complementary therapies are a*

threat to public health, with 91.7% of the national survey respondents and 91.1% of SA midwives strongly disagreeing or disagreeing; and for Item 10, *Most complementary therapies stimulate the body's natural therapeutic powers*, with 69% national survey midwives and 65% SA midwives strongly agreeing or agreeing.

Table 8.4 CHBQ national survey findings in relation to Q6–10 compared with Gaffney and Smith's (2004a) study

	Item	Absolutely Disagree/ Disagree % (n)	Neither disagree/ agree % (n)	Absolutely Agree/ Agree % (n)
6#	Complementary therapies are a threat to public health. (n = 503)	**91.7 (461)**	5.4 (27)	3.0 (15)
6	*Gaffney & Smith (n = 135)*	***91.1 (123)***	*6.7 (9)*	*2.2 (3)*
7#	Treatments not tested in a scientifically recognised manner should be discouraged. (n = 499)	**58.7 (293)**	21.6 (108)	19.7 (98)
7	*Gaffney & Smith (n = 135)*	***34.1 (46)***	*40.0 (54)*	*25.9 (35)*
8#	Effects of complementary therapies are usually the result of a placebo effect. (n = 500)	**62.2 (311)**	29.6 (148)	8.2 (41)
8	*Gaffney & Smith (n = 135)*	***57.0 (77)***	*37.8 (51)*	*5.2 (7)*
9	Complementary therapies include ideas and methods from which conventional medicine could benefit. (n = 500)	4.4 (22)	14.0 (70)	**81.6 (408)**
9	*Gaffney & Smith 2004 (n = 135)*	*0.7 (1)*	*7.4 (10)*	***91.8 (124)***
10	Most complementary therapies stimulate the body's natural therapeutic powers. (n = 500)	7.4 (37)	23.6 (118)	**69.0 (345)**
10	*Gaffney & Smith 2004 (n = 124)*	*2.2 (3)*	*32.6 (33)*	***65.0 (88)***

 # Q6,7,8 are worded negatively and answers are in the reverse

Table 8.5 displays the national survey findings as mean scores and compares them with data obtained from the CHBQ scores recorded by 173 Israeli midwives in Samuels et al.'s (2010) study. All positively framed questions (items 1–5, 9–10) had mean scores greater than 5 (i.e., strong agreement) except for Item 4, *A patient's symptoms should be regarded as a manifestation of a general imbalance or dysfunction affecting the whole body*, which had a high mean score

of 4.8, with 18.6% of respondents disagreeing and 24.2% indecisive. Conversely, the three negatively framed questions (items 6–8) had lower scores, indicating less endorsement of these negative statements. A total CHBQ mean score of 45.43 (SD 6.53) was calculated, with a range of 14–67 (possible range 7–70).

Table 8.5: CHBQ mean score compared with the findings of Samuels et al. (2010)

Item	CHBQ	National survey Mean (SD)	*Samuels et al. (2010) n = 173* Mean (SD)
1	Physical and mental health are maintained by an underlying energy or vital force. (n = 498)	5.3 (1.51)	5.33 (1.90)
2	Health and disease are a reflection of balance between positive life-enhancing forces and negative destructive forces. (n = 494)	5.1 (1.57)	5.41 (1.71)
3	The body is essentially self-healing and the task of a healthcare provider is to assist in the healing process. (n = 500)	5.3 (1.49)	5.75 (1.56)
4	A patient's symptoms should be regarded as a manifestation of a general imbalance or dysfunction affecting the whole body. (n = 499)	4.8 (1.62)	5.43 (1.55)
5	A patient's expectations, health beliefs and values should be integrated into the patient care process. (n = 501)	6.2 (1.06)	6.21 (1.29)
6#	Complementary therapies are a threat to public health. (n = 503)	1.8 (1.11)	1.68 (1.34)
7#	Treatments not tested in a scientifically recognised manner should be discouraged. (n = 499)	3.2 (1.58)	3.17 (2.10)
8#	Effects of complementary therapies are usually the result of a placebo effect. (n = 500)	2.9 (1.36)	2.57 (1.77)
9	Complementary therapies include ideas and methods from which conventional medicine could benefit. (n = 500)	5.6 (1.24)	5.87 (1.46)
10	Most complementary therapies stimulate the body's natural therapeutic powers. (n = 500)	5.2 (1.35)	5.49 (1.59)

1 = absolutely disagree, 3 = agree, 4 = neither disagree/agree, 5 = agree, 7 = absolutely agree.

 # Q6, 7, 8 are worded negatively and answers are in the reverse.

8.5 Discussion

Midwives may have a particular viewpoint or belief, but this may not be consistent with their behaviour or clinical practice, since their behaviour may be more circumscribed than their attitudes or beliefs because of organisation or policy constraints (Bourgeault & Hirschkorn 2008; Hall, Griffiths & McKenna 2012). In light of this variant, it is necessary to not only examine what midwives practice—that is, discussing and recommending CAM or referring women to a CAM practitioner—but also to discover what midwives' views and beliefs are about CAM that underpin their philosophy and practice. Most Australian midwife national survey respondents agreed with the fundamental principles/ideologies of CAM (Table 8.1), which align with the concept of woman-centred care, such as women having the right to choose, being adequately informed about the CAM strategies that can be used safely in pregnancy and that their expectations, health beliefs and values should be integrated into the patient care process (Pairman & McAra-Couper 2015).

This national study findings was consistent with others, revealing that midwives have a positive view of CAM and perceive it as beneficial, natural and effective in stimulating the body's natural healing power, and that they do not view CAM as a threat to public health (Gaffney & Smith 2004a; Harding & Foureur 2009; Koc, Topatan & Saglam 2012). In the South Australian study, Gaffney and Smith (2004a) used the last five of the 10 questions from the CHBQ tool. A comparison between the national survey findings and the Gaffney and Smith (2004a) study was undertaken for these five questions (described in Table 8.4). Although the national study had a large and nationally representative sample of midwives and was conducted 12 years later than the South Australian study, the comparison of findings shows that Australian midwives' beliefs and views of CAM have remained relatively unchanged.

Comparing the national survey findings of the CHBQ with the Samuels et al.'s (2010) study reveals very similar CHBQ mean scores (see Table 8.7) except for Item 4, *A patient's symptoms should be regarded as a manifestation of a general imbalance or dysfunction affecting the whole body*. For this item, the mean score for Australian midwives was lower than for Israeli midwives (Table 8.5). A reason

for this difference could be that Australian midwives do not have a strong 'belief' in this statement. Belief is defined as the 'acceptance, trust, faith or confidence feeling that something exists or is true' ('Training' 2016).

For our study on Australian midwives and Samuels et al.'s (2010) study of Israeli midwives, the CHBQ mean scores for the positively worded items (1–4) were similar, yet higher than those of medical students (Lie & Boker 2004). Respectively, for the negatively worded items (6–8), Australian and Israeli midwives' mean scores were lower than those of medical students (4.1–5.5) (Lie & Boker 2004). The variation of mean scores between midwifery and medical health professionals may reflect the variations between the medical philosophy (focus on illness and disease) and the midwifery social philosophy (focus on wellness and normal process). Obstetric and midwifery ideology are different and opposing: arguably, the obstetric medical paradigm views childbirth as risky and aims to control the process, whereas midwifery and CAM share a holistic approach and assert that benefit can be gained from supporting natural physiology (Adams 2006; Hall, Griffiths & McKenna 2012).

Although midwives may have strong personal beliefs about CAM, they may feel the need to curb their enthusiasm for CAM modalities, either directly by concealing their support of CAM in the presence of an unsupportive obstetrician or colleague, and/or indirectly within the context of hospital policies by not documenting their use of CAM (Bourgeault & Hirschkorn 2008; Hall, Griffiths & McKenna 2012). It is concerning that in Study 2, over half (51.6%) of respondents were unsure or felt unsupported by their organisation to recommend CAM strategies to women. Also of concern is that nearly half (49.5%) of respondents believed that their hospital/service did not have guidelines/procedures on the use of CAM to support or guide midwifery clinical practice; however, at the same time, nearly all respondents discussed (91.1%) and recommended (88.4%) CAM/self-help options to pregnant women. Several previous studies have identified the need for guidelines on CAM modalities that provide the necessary guidance and regulation for midwives, but that maintain sufficient flexibility to enable midwives to make appropriate clinical decisions and support individualised care (Diezel et al. 2013; Hall, McKenna & Griffiths 2012a; Hall, McKenna & Griffiths 2013;

Hastings-Tolsma & Terada 2009; Kenyon 2009). This is an identified need with which the findings of this national Australian study concur.

8.6 Chapter summary

This chapter has detailed the findings of the Australian national midwife survey in relation to midwives' attitudes and beliefs about CAM using the validated CHBQ. The findings were compared with two similar studies: one conducted on a sample of midwives in one Australian state (Gaffney & Smith 2004a), and the other on a sample of Israeli midwives (Samuels et al. 2010). A majority of midwife respondents strongly agreed or agreed with the fundamental philosophical statements of CAM and woman-centred care. Midwives' positive attitudes and beliefs towards CAM address the 'acceptability' component of feasibility, which seeks to determine how recipients react to the intervention and, to some degree, the 'implementation' area, which considers the extent or likelihood that the intervention will be fully implemented as planned.

The survey reveals that that midwives believed their hospital/service did not have guidelines/procedures on the use of CAM to support or guide midwifery clinical practice, even though nearly all respondents had conversations with pregnant women about CAM/self-help options. This component of the study confirms the need for clearly defined and supportive clinical guidelines on CAM for midwives. Since many midwives are discussing and recommending CAM, it is therefore important to know the level of training and education midwives have received in this field. The next chapter presents the national midwife survey findings on midwives' level of training and education relating to CAM, generally and in relation to specific CAM modalities.

Chapter 9: National survey—midwives' education and training in CAM

9.1 Chapter overview

This chapter describes and discusses the findings of the national survey focusing on midwives' CAM training and education (Appendix 13, section 4). The fourth section of the survey includes two segments addressing the level of midwives' education or training and the specific CAM modality in which they had received education or training. The findings of each segment are detailed in the following sections, beginning with the level of CAM training/education.

9.2 Level of midwives' CAM training/education

A total of 401 midwives (70.2%) completed the question on whether they had attended specific CAM training based on the level of education they had received (Appendix 13, Q31). Seventy-six midwives (19.0%) had not received any CAM education or training, but were interested in gaining more knowledge in CAM, and only 15 midwives (3.7%) were not interested and did not wish to learn about CAM. As indicated in Table 9.1, the remaining 310 midwives nominated many different levels of CAM education and training, which were influenced by the number of different CAM modalities and courses they had accessed. A small number of midwives nominated that they had attended a competency workshop (n = 5) or a CAM workshop/course (n = 7) during their undergraduate program. There was not a targeted yes/no question on completed/attended CAM education/training in the survey, which affected the analysis and ability to accurately calculate a denominator, as many midwives who selected self-learning as their level of training also responded to attending workshops and courses for specific CAM modalities.

Table 9.1 Midwives' level of CAM education and/or training (n = 310)[#]

Level of CAM education and training	N = 310[#]	(%)
1. Certificate/diploma	72	(23.2)
2. Competency workshop	119	(38.4)
3. Workshop or course (not competency based)	113	(36.5)
4. In undergraduate program	51	(16.5)
5. Self-learning	160	(51.6)

[#] *multiple responses were possible from 310 respondents*

In the second segment of this question, 310 respondents who had completed CAM education (as per Table 9.1) could choose their appropriate education level on a specific CAM modality from the 20 CAM options provided. Many midwives responded to multiple CAM options and varying levels of training/education, as displayed in Table 9.2. The top five CAM modalities were acupressure (66.5%), aromatherapy (60.3%), massage (45.5%), reflexology (37.7%) and hypnosis/Calmbirth®/Hypnobirth® (26.1%). Most of the midwives had undertaken workshops without an associated competency assessment.

Table 9.2 CAM modalities and education level[#] accessed by midwives

CAM Education/training	Certificate/ diploma n (%)	Workshop/course competency n (%)	Workshop—no competency n (%)	Total (n = 310) n (%)
Acupressure	9 (4.4)	62 (30.1)	135 (65.5)	206 (66.5)
Aromatherapy	14 (7.5)	29 (15.5)	144 (77.0)	187 (60.3)
Acupuncture	5 (10.0)	9 (18.0)	36 (72.0)	50 (16.1)
Ayurveda medicine	15 (71.4)	2 (9.5)	4 (19.0)	21 (6.8)
Bach flower remedies	10 (20.4)	8 (16.3)	31 (63.3)	49 (15.8)
Herbal medicine	15 (29.4)	3 (5.9)	33 (64.7)	51 (16.5)
Hypnosis/ Calmbirth®/ Hypnobirth®	10 (12.3)	17 (21.0)	54 (66.7)	81 (26.1)
Homeopathy	8 (13.3)	7 (11.7)	45 (75.0)	60 (19.4)
Iridology	4 (19.0)	5 (23.8)	12 (57.1)	21 (6.8)
Kinesiology	3 (14.3)	6 (28.6)	12 (57.1)	21 (6.8)
Massage	37 (26.2)	14 (9.9)	90 (63.9)	141 (45.5)
Naturopathy	10 (25)	1 (2.5)	29 (72.5)	40 (12.9)
Reiki	13 (22.8)	14 (24.6)	30 (52.6)	57 (18.4)
Reflexology	19 (16.2)	38 (32.5)	60 (51.3)	117 (37.7)
Shiatsu	5 (20.0)	3 (12.0)	17 (68.0)	25 (8.1)
Spiritual healing	1 (3.4)	4 (13.8)	24 (82.8)	29 (9.4)
Touch therapy	2 (5.1)	6 (15.4)	31 (79.5)	39 (12.6)
TCM	3 (17.6)	2 (11.8)	12 (70.6)	17 (5.5)
Yoga	8 (11.0)	8 (11.0)	57 (78.0)	73 (23.5)
Other	–	21 (100)	–	21 (6.8)

#Multiple responses selected by respondents

Midwives with a CAM certificate or diploma were more likely to discuss ($p = 0.045$) or recommend CAM/self-help strategies ($p = 0.001$) and recommend women experiencing a post-date pregnancy to a CAM practitioner ($p < 0.000$) than midwives without a CAM qualification (Table 9.3). Further, midwives who had completed a CAM certificate or diploma were more likely to use CAM

modalities for their own health and wellbeing (p = 0.001) and in their own pregnancy/ies (p < 0.000) compared with midwives without a CAM certificate or diploma (Table 9.3).

Table 9.3: Midwives' with a CAM certificate/diploma and professional and personal use of CAM

	Midwives with a CAM qualification (certificate/diploma) N =~ (%)	**Midwives without CAM qualification N =~ (%)**	**P value****
Q11. Discusses CAM/self-help strategies to women experiencing a post-date pregnancy	70/72 (97.2)	450/495 (90.9)	0.045#
Q12. Recommends CAM/self-help strategies to women experiencing a post-date pregnancy	71/72 (98.6)	434/495 (87.6)	0.001#
Q15b. Confident in knowledge to discuss CAM with pregnant women	61/68 (89.7)	291/446(65.2)	0.000
Q19. Recommends visit to CAM practitioner to pregnant women	59/69 (85.5)	256/458 (55.9)	0.000
Q29. Provides CAM to women during the perinatal period	69/72 (95.8)	366/432 (84.7)	0.01
Q23. Midwife uses CAM for personal use	72/72 (100)	387/434 (89.2)	0.001#
Q27. Midwife uses CAM in own pregnancy	47/53 (88.7)	220/344 (64.0)	0.000

*~Different dominator for each question; ** χ^2 analysis of CAM qualification for each question separately*

#Fisher's exact test (as one cell < 5).

Midwives who had completed CAM training by attending a competency-based workshop (p < 0.000) or workshop/course (p = 0.004) were more confident or very confident in their CAM knowledge to discuss CAM strategies with women than midwives who had not completed CAM training/education (Table 9.4).

Table 9.4: Midwives' confidence in CAM knowledge to discuss CAM with pregnant women and CAM levels of training/education

	Confident in CAM knowledge to discuss CAM with pregnant women n = ~ (%)	**Not confident in CAM knowledge n =~ (%)**	**P value***
CAM knowledge by completing a CAM competency workshop	98/113 (86.7)	254/401 (63.3)	0.000
CAM knowledge by completing a CAM workshop or course (not competency based)	85/106 (80.2)	267/408 (65.4)	0.004
CAM knowledge gained in undergraduate degree	34/49 (69.4)	318/365 (68.4)	0.886 NS
CAM knowledge by self-learning	102/151 (79.5)	250/363 (68.9)	0.769 NS

*~Different dominator for each question; *p value represents χ^2 analysis of CAM education for each question separately. NS = not significant.*

9.3 Discussion

This study has identified Australian midwives' CAM education and training on a national level. Based on available evidence from a literature view of midwives' support of CAM, Hall, McKenna and Griffiths (2012b) report that although midwives frequently interact with pregnant women regarding the use of CAM, many have no formal education in the field, with most (61%) learning about CAM from private study (Hall, McKenna & Griffiths 2012a). This was not the case in this Australian national survey, where many midwives had completed CAM education either at certificate/diploma level (23.2%), at a competency-based workshop (38.4%) or at a workshop/course (36.5%) level. There was also a significant correlation between midwives receiving CAM education and having the confidence to discuss CAM options with pregnant women compared with midwives who had not received CAM education. It is important to acknowledge that the studies in Hall, McKenna and Griffiths's (2012b) literature review were from New Zealand/Canada (Harding & Foureur 2009), Germany (Wiebelitz et al. 2009) and the US (Allaire et al. 2000), not Australia. These national survey

findings thus provide new information on midwives' levels of CAM education and training in Australia.

A limitation of the national survey is that it failed to ask midwives if they had continued to update their CAM knowledge and skills. In NSW, a current policy prepared by a professional association advises midwives to be responsible for their ongoing education if their clinical practice includes CAM (NSW Nurses and Midwives Association 2014). Other than in NSW, there are no other current national or state-based guidelines, protocols or policies in Australia that outline a midwife's responsibility for CAM education and ongoing professional development.

This national survey found that Australian midwives are interested in learning about a wide variety of CAM modalities, and that many have accessed this learning at a variety of education and training levels. Despite the fact that the Australian Government released an expert committee report in 2003 identifying the need for health professionals to have reliable CAM information, only a small number (n = 51) of survey respondents had received basic CAM education during their undergraduate degree (Expert Committee on Complementary Medicine in the Health System 2003). However, the survey also reveals that midwives who had received basic CAM education in their undergraduate program did not feel confident in their knowledge to discuss CAM with pregnant women and wanted to learn more about CAM. These findings support those of Wiebelitz et al. (2009), who found in a German study of 63 midwifery teachers and 246 midwifery students that nearly all (95%) rated the amount of CAM teaching in the undergraduate program as inadequate (Wiebelitz et al. 2009). The national survey did not explore the depth or extent of CAM education in the midwifery undergraduate curriculum; this area thus needs further research.

9.4 Chapter summary

During the perinatal period (pregnancy, childbirth and postnatal period), women rely on advice from health professionals, including midwives (Frawley et al. 2014; Frawley et al. 2015b). Ensuring that evidence-based information on CAM modalities is part of undergraduate and postgraduate midwifery education programs would improve midwives' confidence and knowledge in terms of

discussing and interacting with women about CAM. CAM education could also reduce any potential risk, such as interactions between herbal supplements and prescribed medications (Hall, McKenna & Griffiths 2013). The call continues for midwifery education institutions to introduce relevant mandatory courses in all aspects of CAM. The absence of CAM knowledge and skills training in the education of health professionals has not been widely investigated, thus warranting further research (Abedzadeh Kalahroudi 2014; Adams et al. 2011; Gaffney & Smith 2004a; Hall, McKenna & Griffiths 2013; Hastings-Tolsma & Vincent 2013; Mollart et al. 2018; Tiran 2006).

The next and final chapter synthesises the eight feasibility areas addressing the project aim, discusses the research strengths and limitations and presents recommendations for midwifery education, professional support and key components of a future RCT on using acupressure for primigravid women experiencing a post-date pregnancy.

Chapter 10: Discussion and conclusion

'The important thing is not to stop questioning' – Albert Einstein

10.1 Chapter overview

This chapter synthesises the body of work constituting the sequential mixed-methods study exploring the feasibility of conducting an RCT of acupressure for women experiencing post-date pregnancy. This work contains important insights for contemporary maternity care and midwifery education in Australia. Two studies were undertaken with data collected from four sources: an FRCT, an RCT participant survey and health professional focus groups at the research sites, together with a survey of a nationally representative sample of Australian midwives to investigate their practices, beliefs, knowledge and education regarding CAM generally, and particularly acupressure, for post-date pregnancy.

This research ascertains that it is feasible to conduct a well-designed RCT in the Australian setting, since there is a demand for alternative methods of addressing the issue of post-date pregnancy, and support from midwives across the country for the use of acupressure, specifically. There appears to be a high level of interest from women in using acupressure when 'going overdue', although the small sample size in this study precludes generalising this finding. Support from obstetricians involved in the study was evident but, again, the number of participants was small.

The chapter begins by establishing the links between the two studies and the four publications, which address the eight aspects of the feasibility of conducting a robust RCT of acupressure for post-date pregnancy in Australia. It then turns to the project strengths and limitations. Finally, it proposes three recommendations from the findings: for a distinct CAM module to be included in midwifery undergraduate curricula; for the development of a national position statement on CAM and midwifery practice in Australia; and the key components for a future robust RCT.

10.2 Links between Study 1 and Study 2

The four published manuscripts build upon each other and are linked. Publication 1 offers a systematic review of existing studies of acupressure to initiate spontaneous labour onset as well as its effect on labour duration and pain (Publication 1: Chapter 2, section 2.8). This systematic review reveals a gap in the evidence for use of acupressure for women experiencing a post-date pregnancy. Additionally, none of the acupressure studies had been undertaken in Australia, so it was not possible to determine if the existing evidence could be easily translated to Australian healthcare settings.

Therefore, Study 1 was designed to address this gap in knowledge through meeting three of the four project objectives:

1. to undertake an FRCT on the efficacy of acupressure to initiate spontaneous labour onset for primigravid women experiencing post-date pregnancy
2. to explore participant women's views of acupressure, CAM and RCTs to increase understanding of the feasibility of an acupressure RCT
3. to explore participant health professionals' views of acupressure, CAM and RCTs.

The next two publications address the three Study 1 objectives and provide evidence of feasibility. Publication 2 (Chapter 4, section 4.2) reports the quantitative findings of the FRCT in relation to the feasibility focus areas of acceptance, demand, implementation, practicality, integration and expansion. Based on the study findings, to achieve a 9% clinically significant difference in spontaneous labour onset for primigravid women experiencing a post-date pregnancy between an acupressure group and standard care group, a sample size of 994 women (80% power, alpha 0.05, allowing for a 1% cross-over) would be required for an appropriately powered RCT (http://www.sealedenvelope.com/power/binary-superiority). Publication 3 (Chapter 5) provides the qualitative findings describing the woman participants' and health professionals' views of acupressure and CAM in general and their views of the FRCT and of being randomised to a trial. This publication also addresses the feasibility focus areas of acceptance, demand and practicality.

Both publications offer valuable insights into the feasibility of conducting an RCT at a local level. The identified limitations include the challenge of undertaking an RCT on acupressure at study sites where acupressure was an accepted CAM option already embedded into midwives' clinical practice. In this setting, information on acupressure was routinely provided to all pregnant women in late pregnancy, even though it was not based on evidence of efficacy but rather a belief that it might work. This may have increased midwives' willingness to recruit women to the study and for women to join the study in the hope of receiving acupressure. Alternatively, this may have stopped some midwives from recruiting women to the study, if they believed that all women should have access to an intervention that may be therapeutic. Similarly, women who had already received information about acupressure may not want to risk being randomised to the control group. To increase equipoise among both midwives and women in any future RCT, it would be best to choose research sites where acupressure is not a routinely offered intervention in post-date pregnancy.

Further insights emerged from reflection on the health professional focus groups, indicating that midwives who had used CAM in their personal life appeared to discuss and recommend CAM options to pregnant women more than midwives who had not used CAM. If this local finding was echoed across the country, I considered that feasibility may be affected. For example, if a study site was selected where few midwives had personally used CAM, recruitment may not be as successful as in the FRCT reported here. Therefore, the second study was designed to explore, on a national level, midwives' beliefs, knowledge, skills and training in CAM and acupressure, but also to make additional contributions to the understanding of feasibility.

Publication 4 (Chapter 7) provides the first of the findings of the national survey of Australian midwives. It reveals CAM and acupressure, in particular for post-date pregnancy, were acceptable to Australian midwives. Many Australian midwives currently discuss and recommend CAM and self-help techniques to women experiencing a post-date pregnancy. The second important finding from the survey is that midwives' age, years practising as a midwife and personal use of CAM influenced their conversations with women about CAM (Mollart et al. 2018). These findings need to be considered when designing future RCTs in this

area. Understanding what proportion of midwives at study sites personally use CAM may yield additional insights to explain study findings.

10.3 Feasibility of conducting an acupressure RCT

This next section synthesises the findings of the two studies by examining the eight feasibility areas of acceptance, demand, implementation, practicality, adaptation, integration, expansion and testing (Bowen et al. 2009), and compares the findings with those of other, similar studies.

10.3.1 Acceptance and demand

10.3.1.1 Acceptance of the intervention

As detailed in Chapter 4, the women experiencing a post-date pregnancy were interested in acupressure and willing to participate in the RCT and use the three acupoints. There was high compliance with the acupressure protocol by the intervention group women, who applied acupressure to GL21 twice a day, and to SP6 and LI every two hours each day for up to five or seven days, as evidenced by those completing their acupressure diary. These findings are supported by Gregson et al.'s (2015) acupressure study, which reports that women experiencing a post-date pregnancy were pleased to have something positive to do that could potentially start labour before they were induced by medical or surgical means (Gregson et al. 2015).

A small number of Australian RCTs with pregnant women have used a range of CAM modalities, such as acupuncture for post-date pregnancy (Smith et al. 2008), raspberry leaf for labour (Simpson et al. 2001) and moxibustion for breech presentation (Do et al. 2011). Smith et al. (2008) found that of the 450 women declining the acupuncture study, 22% feared needles and 33% were not interested in acupuncture and had other reasons, such as having a first baby and feeling anxious or not wanting to be randomised (Smith et al. 2008). The acupuncture study also imposed an extra burden on all participants, who were required to visit the study site for insertion of true or sham acupuncture needles. However, the acupressure FRCT found that only a small number of women were not interested in participating. The non-invasive nature of acupressure, which can also be self-administered, may explain the difference in *acceptance* to participate.

When undertaking a CAM RCT, it is important to consider the cultural/ethnic *acceptability* of any proposed intervention in the Australian maternity setting. In Study 1, culture was not explored, as the 44 participants were 99.8% caucasian. In Study 2, nearly all midwives (95.6%) identified as caucasian/European/white, with the remaining 4.4% from a variety of other cultures and ethnic backgrounds (1.8% Asian/Pacific Islander, 1.2% Indigenous Australian, 0.5% Black/African American and 0.2% Indian). Ethnicity was not found to be significant in any of the national survey findings. Since previous acupressure RCTs have been conducted in a wide variety of countries and ethnically diverse populations, including Egypt, Iran, India, Taiwan, Korea and the UK (Akbarzadeh et al. 2013b; Chang et al. 2004; Dabiri & Shahi 2014; Deepak & Chopra 2013; Gregson et al. 2015; Hjelmstedt et al. 2010; Kaviani et al. 2015; Lee, Chang & Kang 2004; Mafetoni & Shimo 2015; Batool et al. 2015; Torkzahrani et al. 2017), it would appear that ethnicity will not affect the feasibility of future trials in this area.

10.3.1.2 Acceptance of randomisation

Previous studies have identified that some women dislike being randomised, as they perceive that they may miss out on what they regard as a desirable CAM option (Smith et al. 2008; Tooher, Middleton & Crowther 2008). The South Australian acupuncture RCT of 364 women with post-term pregnancy found that 14–15% of participants in both groups (true and sham) disliked being randomised, which may influence their decision to participate in a future RCT (Smith et al. 2008). While Study 1 had a much smaller sample size than that of Smith et al. (2008), four women in the control group (36%) disliked being randomised compared with only one woman in the acupressure group (5.5%). This may have been because acupressure was seen as desirable and women were disappointed to not receive it. A feasibility RCT on the use of moxibustion for women with fetal breech presentation in NSW also found that 11/39 (28%) women declined to participate, including five who refused randomisation (Do et al. 2011). A limitation of previous RCTs on acupressure to stimulate labour onset is the failure to obtain participants' views about participating in the study or being randomised in this new area of research (Gregson et al. 2015; Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017). These are important aspects of feasibility. Future research must account for these identified challenges when

conducting a CAM RCT with pregnant women who may not be interested in the study or intervention, who may consider the intervention or trial participation too time consuming or who want the intervention and do not want to be randomised to a control group (Do et al. 2011; Mollart, Adams & Foureur 2016; Smith et al. 2008). Therefore, Zelen RCT design should be considered for the future study and has the advantage that, before providing consent, a woman will know whether an experimental treatment is to be used. Any loss of statistical efficiency can be overcome by increased numbers (Zelen 1979).

10.3.1.3 Acceptance by staff

The evidence in the literature reviews presented in previous chapters found midwives worldwide are very supportive of CAM. Australian evidence of midwives' views of CAM was limited to two studies conducted at a state level (SA and Victoria), which may not be representative of all Australian midwives (Gaffney & Smith 2004a; Hall, Griffiths & McKenna 2012). However, the findings of the national survey in Study 2 reveal that a large percentage of Australian midwives are supportive of CAM, particularly acupressure. Study 2 also shows that most midwives have conversations with women in their last few weeks of pregnancy about a range of CAM and self-help options for addressing a post-date pregnancy (Mollart et al. 2018), and hold positive views towards CAM and CAM use in pregnancy, including acupressure (Chapter 8). These findings provide evidence of Australian midwives' *acceptance* of acupressure and other CAM modalities, and underpin the feasibility of undertaking an RCT on acupressure for women experiencing a post-date pregnancy. One further aspect of feasibility not addressed in Gregson et al.'s (2015) study and Study 1 is the issue of personal equipoise, where midwives involved in an RCT may have a preference or are certain about the overall benefit offered by acupressure (Cook & Sheets 2011). The lack of equipoise may influence recruitment in a future RCT if midwives suggest that acupressure is beneficial; as a result, women may decline randomisation. This potential influence is addressed as a key component in a future RCT, outlined in section 10.5.3.

Over the past 10 years, there has been evidence of increasing acceptance of CAM by obstetricians, many of whom have a positive attitude towards specific CAM, view CAM as a useful supplement to regular medicine and refer patients to

specific CAM practitioners for chiropractic, acupuncture, hypnotherapy and meditation therapy. However, obstetricians also view some CAM modalities, such as herbal medicine, as potentially harmful (Furlow et al. 2008; Gaffney & Smith 2004a; Munstedt, Brenken & Kalder 2009). Study 1 focus group findings relating to obstetricians' views on CAM differ from those of the studies cited above, as the five participating obstetricians were less supportive of CAM than the midwives. The obstetricians believed that RCTs on acupressure were necessary to address safety and efficiency, although acknowledged that they were unaware of the many RCTs conducted on acupressure in labour (Mollart, Adams & Foureur 2016). Midwives in the FRCT and the literature review (Chapter 6) also acknowledged the need for establishing a scientific basis for using CAM (Adams et al. 2011; Gaffney & Smith 2004a; Munstedt, Brenken & Kalder 2009; Stewart et al. 2014; Tiran 2006), which further supports the feasibility of any future RCTs in this area. Since the focus groups in Study 1 only included five obstetricians, the views of other obstetricians across Australia should be sought. In future studies, including obstetricians who believe evidence of CAM efficacy needs to be established will enable positive support for trials and ensure feasibility.

10.3.1.4 Demand

As explored in the literature review in Chapter 2, there is a high demand for and use of a wide range of CAM modalities by childbearing women overseas and in Australia. The lack of evidence available to estimate the *demand* for acupressure by childbearing women in Australia formed the basis for the Study 1 FRCT and participant survey, and the Study 2 national survey of midwives, who are mostly female, on their personal use of acupressure for general wellbeing and pregnancy.

As detailed in section 10.3.1, acupressure was highly used and in *demand* by the pregnant women invited to participate and those who participated in Study 1. Eleven women declined to participate, as they wanted to or were already using acupressure. Further, the national survey reveals that acupressure was one of the top five CAM modalities used by midwives for their personal general health and wellbeing and in their own pregnancy/ies. Therefore, in Australia, it is apparent that acupressure is in *demand*. Other studies exploring the use of acupressure to stimulate labour onset do not report on the number of women who

declined to participate because of wanting to or already using acupressure (Gregson et al. 2015; Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017). It may not be feasible to conduct RCTs on the use of acupressure for post-date pregnancy where demand may be limited, such as in settings where pregnant women are not interested in acupressure or where there is little information on acupressure available to pregnant women. To determine the demand for, or pregnant woman's use of or interest in, acupressure in pregnancy or childbirth, future studies in Australia and overseas should include acupressure as a CAM option.

10.3.2 Implementation and practicality

A supportive research culture is an important factor that can influence the successful implementation of a trial (Smith & Coyle 2006). The RA in Study 1 was an experienced midwife, of a similar age and gender to the women invited to and participating in the trial and committed to the research project. Women with a post-date pregnancy can experience stressful emotions; therefore, the study aimed to provide a caring and empathetic research environment in addition to midwifery care. This supportive environment may have contributed to high compliance in the acupressure arm and low drop-out rates, as the majority of Study 1 participants felt they were helping with research and that their role was valued. This finding is supported by other studies, which have shown that most pregnant women like helping with research and would agree to take part in a trial if asked again (Smith et al. 2008; Do et al. 2011). The focus groups and national survey indicate that midwives are also very supportive and accepting of acupressure and CAM in general. Based on these findings, a future RCT on acupressure would be well supported by pregnant women and midwives within a caring research environment.

Another feasibility area to consider is the extent to which an intervention can be provided within existing constraints, called *practicality* by Bowen et al. (2009). Existing constraints include financial and staff resources, staff training and time required to recruit women and demonstrate acupoints (Bowen et al. 2009). Section 5.3.5 outlines the additional resources required to implement Study 1. The advantage of an acupressure study is the minimal training (four-hour workshop) the midwives required to be able to accurately demonstrate the

acupoints to the woman and her partner compared with acupuncture studies, which require trained acupuncturists (Smith et al. 2008). The acupressure FRCT required minimal resources, equipment and cost (CD and two-page handout) compared with trials by Do et al. (2011), which supplied participants with moxi sticks for 10 days, and by Smith et al. (2008), which required employing qualified acupuncturists and acupuncture needles. Future studies on acupressure for post-date pregnancy compared with medical/surgical labour induction should consider assessing cost effectiveness.

10.3.3 Adaptation and integration

The focus area of *adaption* explores the requirement or ability to change procedures to ensure they are appropriate to a new population or setting, and *integration*, which is the level of system change needed to integrate the intervention into an existing program or service (Bowen et al. 2009). Cardini et al. (2005) attempted to replicate their successful RCT on the use of moxibustion for breech presentation in China to a different population setting (Italy), but discontinued the study after two years of recruiting 123 women, fewer than half of the planned sample size of 260. The authors identify possible ethnic, social and cultural challenges of transferability, with 24 women declining to participate because of fearing the treatment, and low compliance with the intervention protocol, as the Italian women complained about the treatment being unpleasant (Cardini et al. 2005).

The FRCT protocol was adapted from the quality project undertaken by Ingram et al. (2005) and provided a more robust standardised regime: only primigravid women were eligible to participate, which enabled a homogenous analysis; self-administration of the acupressure at home reduced the burden for participants; and the standardised ‘dose’ of acupoints was to be administered by all women in the intervention arm (SP6 and LI4) for two minutes every two hours during the day, and GB21 twice a day (morning and evening). An acupoint point diary was also developed for the women to complete, which may have assisted in the high level of compliance in the intervention group.

Since this FRCT was completed, four more studies have been conducted in this area, although each has varied in the acupoints used, pressure and dosage

(Gregson et al. 2015; Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017). This highlights the importance of a well-defined, consistently used robust study protocol in any future acupressure RCT.

10.3.3.1 Integration

Undertaking an acupressure RCT may be difficult at rural hospitals, where system change is needed to *integrate* acupressure into an existing program or service. Most rural hospitals in Australia rely on antenatal shared care with GPs, the dominant model of care, and there is little opportunity to have pregnancy care with midwives in antenatal clinic or caseload/group practices, especially when women are experiencing a post-date pregnancy (Commonwealth of Australia 2009; Quinn et al. 2013). Burns et al. (2007) also identified this issue when conducting a pilot RCT on aromatherapy in labour in Italy. The authors note that their lower than expected recruitment rate was the result of a fragmented maternity care system, with no access to a midwifery antenatal service (Burns et al. 2007). Difficulties with *integration* may also be the present in private hospitals where midwives do not have sufficient access to pregnant women, as midwives may not meet women until they arrive in labour or are booked for labour induction. It is more feasible to undertake an acupressure RCT in a publicly funded urban, regional or metropolitan hospital. The feasibility components of *adaptability* and *integration* are more likely to be met where pregnancy care is provided by midwives with opportunities to interact with women who are post-date or approaching their due date to discuss and recruit women to the RCT.

10.3.4 Expansion

There is vast potential to *expand* and implement an acupressure RCT at maternity services where the service capability does not permit medical interventions such as labour induction (Health System Planning and Investment 2017), or for women choosing to birth in a birth centre or at home. The advantages of conducting an acupressure RCT are that it is easy for staff and women/partners/support persons to learn how to locate and use the acupoints, and that acupressure has low technology requirements, as no equipment is required compared with medical/surgical induction. If the study was conducted in

an ethnically diverse population, then translation of the information material and acupressure protocol would need to be undertaken.

10.3.5 Limited-efficacy testing

Although feasibility studies can use a convenience sample, Study 1 used a mixed-methods FRCT design to evaluate a number of clinical and behavioural outcomes. This included exploring participants' and health professional's views and attitudes towards acupressure, CAM and randomisation, which enhanced our understanding of a complex issue (Campbell et al. 2007). There are challenges identified with undertaking a standalone RCT of a CAM modality, as it dissects the modality in a reductionist manner and fails to take into account complementary medicine's holistic nature, which is tailored to the individual's needs; these factors potentially lead to invalid evaluation (Dooley 2006; Mason, Tovey & Long 2002).

Two further aspects of a CAM RCT must be carefully considered in terms of feasibility: 1) the use of a placebo or sham for complex interventions, which may lead to false negative results (Dooley 2006); and 2) focusing on only one aspect (such as post-date pregnancy) without acknowledging the mind–body–spirit connection (reaction to the situation or state of mind) (Cook& Sheets 2011; Dooley 2006; Mason, Tovey & Long 2002). As outlined in Chapter 2, some acupressure studies have used a 'control group' of correct SP6 location, but without applying pressure (Lee, Chang & Kang 2004), while others have used sham points, which are not true acupressure/acupuncture points (Gregson et al. 2015). In addition, some of the placebo/sham acupressure studies informed participants that either treatment could alleviate their labour pain (Lee, Chang & Kang 2004), while other studies may not have provided information to the participants about the efficacy of either the sham/placebo or the intervention (Dabiri & Shahi 2014; Hamidzadeh et al. 2012; Kashanian & Shahali 2010). In many countries, including Australia, women can access information on the well-known acupressure points used to initiate labour onset via websites and YouTube videos (https://acupuncture.rhizome.net.nz/; https://www.youtube.com/watch?v=wnEcLSHTI0s&t=8s; https://www.youtube.com/watch?v=hS8FzLx74PU) (Abeshouse & Young 2010; Betts 2017; Carol 2009). A potential challenge for a future trial is not only that

many women are aware of recommended acupoints, but that suggesting to these women that sham or non-effective acupoints are as effective as true acupoints is ethically untenable. Women need to be informed that current evidence is not available to confirm which, if any, acupoints are known to have an effect on initiating labour, despite the information that may be provided on the internet (Chen & Johnson 2009; Linde & Dincer 2004).

For the second challenge when conducting a CAM RCT and attempting to consider the mind–body–spirit connection, a mixed-methods design should be used. In recent times, CAM has become recognised as an adjunct to orthodox or Western medicine. In 2014, the National Centre for Complementary Alternative Medicine changed its name to the National Centre for Complementary and Integrated Health to encourage conventional and complementary practitioners to work together to 'integrate' their approaches (NCCIH 2011). The concept of complementary and integrated health can be encouraged with midwives, doctors and CAM practitioners working together on research designed to examine the effectiveness of CAM interventions. There is enormous value in using a health service research approach, including epidemiology and sociology perspectives, to elicit the more elusive experiential outcomes of participants and health professionals relating to acupressure use during pregnancy and childbirth. To address these two challenges, the key components proposed for a fully powered RCT are discussed in section 10.5.3.

10.4 Strengths and limitations

The strengths of this sequential mixed-methods project are many. Study 1 is the first RCT conducted in Australia on the use of acupressure for primigravid women experiencing a post-date pregnancy. The FRCT represents a rich source of data on many aspects of this area of interest, as it not only included a carefully prescribed intervention protocol, but also assessed the clinical obstetric outcomes together with the women's and health professionals' perspectives on the trial. This mixed-methods approach has been identified by Campbell et al. (2007) as the best framework for designing and evaluating complex interventions (Campbell et al. 2007).

Another strength of the project is the contribution to understanding the broader issues of feasibility for an RCT of acupressure provided by Study 2. This is the only study worldwide that has used a nationally representative sample of midwives to investigate their personal use of acupressure and other CAM modalities for health and wellbeing generally and during pregnancy and to explore midwives' views and beliefs about CAM, their education and training in acupressure and other CAM modalities and the effect of these factors on their clinical practice. The national survey offers evidence of strong support from the midwifery profession in Australia for undertaking research into CAM, such as acupressure use for post-date pregnancy.

A number of limitations have already been highlighted and considered in the published manuscripts that form the results chapters of this thesis, and earlier in this chapter. In summary, the limitations include the particular circumstances of the FRCT study sites, where acupressure was an already accepted CAM option embedded into the clinical practice of the midwives who provided information on CAM options to all pregnant women in late pregnancy; the small number of women FRCT participants who completed the survey investigating their views of participating in a trial and the acceptability of the acupressure intervention; and the small number of staff that participated in the focus groups. While providing valid and important insights into the components of feasibility, these aspects of the FRCT may limit generalisability of the findings. There were two main limitations of the national survey, including the low response rate of 16%, although this was calculated as sufficiently large enough to be representative; and the understanding that only midwives interested in CAM may have responded to the survey.

10.5 Recommendations

A number of recommendations arise from this project and are outlined below. The three major recommendations include featuring CAM topics in undergraduate and postgraduate midwifery education; developing a national position statement on midwifery and CAM; and the essential components of a future appropriately powered RCT.

10.5.1 CAM and midwifery education

The Study 2 findings support those of other researchers who have recommended that undergraduate midwifery programs in Australia need to include a module on CAM based on current evidence. The module should cover the most commonly used CAM during pregnancy; the perceived benefits and risks of each CAM; safety issues when CAM are used in pregnancy; and best practice relating to giving women information to ensure informed decision-making and appropriate documentation (Abedzadeh Kalahroudi 2014; Hall, McKenna & Griffiths 2013; Hastings-Tolsma & Vincent 2013).

The Australian National Competency Standards for Midwives (NMBA 2006) cover four domains in providing women-centred care: legal and professional practice, midwifery knowledge and practice, midwifery as primary health care and ethical and reflective practice. The midwifery competency standard framework is focused on the woman's individual unique needs, recognises the woman's self-determination in terms of choice and control and asserts that care is holistic, addressing the woman's social, emotional, physical, psychological, spiritual and cultural needs and expectations (NMBA 2006). To ensure that midwives are able to fulfil these essential competencies and act in the best interest of the woman, students and registered midwives need adequate knowledge of the risks and benefits of any proposed treatment and should be able to canvas all safe options (Hall, McKenna & Griffiths 2013).

10.5.2 National position statement on CAM and midwifery

The national survey found most respondents discussed and recommended CAM and self-help strategies to pregnant women, although many were unsure if their organisation or service had guidelines supporting the provision of CAM in clinical practice. This creates a dilemma for clinicians, as current research and guidelines recommend that midwives and doctors ask women about their use of CAM early in pregnancy and on admission to hospital to assess any safety risk (Australian Medical Association 2012; NSW Nurses and Midwives Association 2014; Royal College of Midwives 2014; Thompson 2013). Assessing potential CAM and prescribed medication interactions or any increased risk is not possible if midwives and doctors have had no education in CAM and possess no knowledge of the CAM modalities women are using.

As discussed in the literature review (section 6.2.3), only one state in Australia (NSW) currently provides professional guidance for midwives on CAM, as the other state board policies or position statements about CAM have been rescinded following the merging of state authorities into a national registration body in 2010. There is thus an urgent need for a national Australian position statement or guideline to be developed and published by either the NMBA or the ACM. Such a document could be based on the UK Royal College of Midwives' position statement on complementary therapies and natural remedies (Royal College of Midwives 2014). A national statement or guideline would assist and support Australian midwives and ensure that they are able to adhere to the national competency standards, code of ethics and code of professional practice.

10.5.3 Powered RCT on acupressure for women experiencing post-date pregnancy

Many areas for future research have emerged from this body of work, although the project's aim was to determine the feasibility of conducting an Australian trial of acupressure for post-date pregnancy. Therefore, this section focuses on describing the factors necessary to implement and conduct a powered RCT on acupressure in an Australian maternity care setting.

Research has shown that acupressure has an effect on cervical ripening prior to labour, labour duration and pain relief in labour, and cannot be disregarded as a placebo response (Makvandi et al. 2016; Mollart, Adam & Foureur 2015). As yet, the research has not definitively shown that acupressure has a significant effect on stimulating uterine contractions and spontaneous labour onset. Based on the six published studies in this field (Gregson et al. 2015; Ingram et al. 2005; Mollart, Skinner & Foureur 2016; Batool et al. 2015; Torkzahrani et al. 2015; Torkzahrani et al. 2017), research has not yet been able to determine the correct dosage of acupressure needed to be effective, and further studies are thus warranted. In addition, the six studies have focused on the acupoints that have been known to effect the physical aspect of uterine contractions and pain relief (SP6, GB21, LI4, BL32, BL60); no studies have considered the woman's possible feelings of fear or anxiety about labour and how these feelings may affect her physiology (Mollart, Skinner & Foureur 2016). Future acupressure research must include acupoints (such as Liver 3, Kidney 1) that have an influence on calming (reducing release

of adrenaline and increasing oxytocin), as primigravid women may feel fear and anxiety as they approach childbirth and potential medical intervention (Fenwick et al. 2009; Nilsson & Lundgren 2009).

When designing a future, appropriately powered, randomised placebo-controlled trial, a number of criteria need to be met: 1) to detect a 9% clinically significant difference in spontaneous labour onset for the acupressure group compared with standard care, a sample size of 994 women (80% power, alpha 0.05, allowing for a 1% cross-over) is required; 2) a rigorous study protocol with three acupoints, as per the FRCT requirements described in this thesis; 3) Bishop score assessed by vaginal examination at randomisation (40 weeks and 5 days) and again at 40 weeks and 10 days, or at the time of medical/surgical induction to compare changes in cervical ripening; and 4) a three-arm study with an intervention, control and placebo group. The placebo group would be shown one calming acupoint (i.e., Liver 3 and/or Kidney 1) to detect if fear/anxiety can influence onset of spontaneous labour onset. Alternatively, the placebo arm could include three sham points that are non-therapeutic, but situated near the selected active acupoints to achieve proper blinding, while taking care to avoid being on the same meridian as the true intervention (i.e., Large Intestine, Spleen and Gall Bladder) (Tan et al. 2015).

Any future RCT should have a mixed-methods design that includes health professionals' and women's perspectives, beliefs and attitudes towards acupressure and other forms of CAM, and compliance with the intervention protocol. The proposed RCT site/s would be at hospitals that are supportive of acupressure, but where acupressure is not currently integrated into the midwives' clinical practice. In this case, the unit of randomisation would be individual women. An alternative would be to undertake the trial using hospitals as the unit of randomisation. However, a multi-site RCT would be required to recruit the required sample size of 994 primigravid women experiencing a pregnancy at 40 weeks and 5 days in a reasonable timeframe, as the incidence of Australian women birthing at 41 weeks gestation is approximately 14% (Li et al. 2011), and for primigravida approximately 23% (Patterson et al. 2011).

10.6 Conclusion

It is important to undertake research and increase the body of knowledge on the efficacy and effectiveness of CAM modalities such as acupressure. This mixed-methods research project has contributed further insights into the use of CAM generally but, in particular, has determined the feasibility of conducting an RCT on acupressure in the Australian maternity setting. Feasibility studies are often not conducted or seem unimportant, but they can provide valuable insights and answer questions such as 'does a new study have the potential to succeed?' or 'should we proceed with the proposed research idea?'. Feasibility studies can elucidate any specific validity threats and possibly avoid costly mistakes in a future RCT. As has occurred in other studies, failure to identify the key issues and barriers may have resulted in the study stopping prior to completion because of a lack of interest in the CAM option by the particular population group or non-compliance with the study protocol. This project has also been able to identify the key protocol components required to conduct a robust RCT.

It is clear that midwives and pregnant women are interested in and more than willing to use acupressure, thus providing a strong impetus for further research in this area. Establishing the effectiveness and efficacy of acupressure for increasing the likelihood of spontaneous labour onset for women experiencing a post-date pregnancy has yet to be undertaken. Acupressure is a safe, non-invasive, easy-to-learn and low-cost intervention that has the potential to change the maternity experience for many women and babies.

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Appendices

Appendix 1: Study 1—PR.E.P.A.RE HREC approval

06 February 2013

Ms Lyndall Mollart
Maternity Services
Gosford Hospital
PO Box 361 Gosford
NSW 2250

Dear Ms Mollart,

1209-293M: *A randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy: A pilot study. Ms Lyndall Mollart, Dr Virginia Skinner, Prof Maralyn Foureur, Dr Mutayyab Shah, Ms Debra Betts*

SPONSOR ACRONYM: PREPARE

Thank you for providing additional information as requested on **30 January 2013** by the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC). Following a review of the additional information provided and the HREC Executive have determined that the proposal meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). The HREC Executive is pleased to advise that your study has now granted scientific and ethical approval.

The documentation included in the approval is as follows:

- National Ethics Application Form, locked code AU/1/AA8E010
- PREPARE Study Protocol, version 2, dated 1/2/2013

- Information Sheet-Women and Consent Form, version 2, dated 1/2/2013
- PREPARE Study Questionnaire, version 2, dated 30/1/2013
- Participant's Acupressure Diary, version 2, dated 2/1/2013

It is noted that the approval covers the following NSW Health sites:

- Gosford Hospital
- Wyong Hospital

It is noted that the study has been assessed by the HREC for ethical and scientific review ONLY and that clearance on the Site Specific aspects of the trial (local sign-off s, legal documentation etc.) MUST be obtained from the above listed sites prior to commencement of research. Each site has different requirements; NSW Area Health Service sites require submission and approval of a Site Specific Assessment (SSA), which can be completed at: *www.ethicsform.org.au.* Please contact the local site for advice on what will be required.

The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia,* and in line with NSLHD HREC policy, the Chief Investigator is responsible to ensure that:

1. ***The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.***
2. ***The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines. Please refer to the Research Office website.***
3. ***Proposed amendments to the research protocol or conduct of the research that may affect the ethical acceptability of the project are submitted to the HREC on an amendment form (including any relevant attachments). For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each of the sites so that they can notify their Research Governance Officer.***
4. ***Proposed changes to the personnel involved in the study are submitted to the HREC on a Change in Personnel Form (accompanied by the investigator's CV where applicable).***
5. ***The HREC must be provided with an annual progress report for the study by the 31st***

October each year. For multi-centre studies the Chief Investigator should submit to the Lead HREC on behalf of all sites.

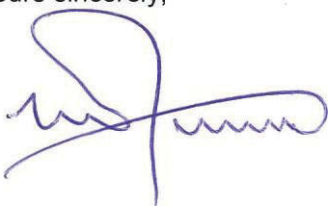
6. ***The HREC must also be provided with a final report upon completion of the study. For multi-centre studies the Chief Investigator should notify the Lead HREC and the investigators at each site should notify the relevant Research Governance Officer.***
7. ***The HREC must be notified, giving reasons if the project is discontinued at a site before the expected date of completion.***

Please refer to the NSLHD Research Office website to access forms such as the amendment form, Annual/Final Report Form, Change in Personnel Form and Serious Adverse Event Guidelines and Forms;

Internet: http://www.northernsydneyresearch.comu

HREC approval is valid for five (5) years from the date of the approval letter. Your approval will therefore expire on the 06 February 2018. Your first progress report is due on the 31st October 2013.

Yours sincerely,



Professor Stewart Dunn/ Dr Liz Newton

Co-Chairperson

Health
Northern Sydney
Local Health District

Research Office Kolling Building,
Level 13 Royal North Shore Hospital
St Leonards NSW 2065
Tel (02) 9926 4590 Fax (02) 9926 6179

2 February 2013

Ms Lyndall Mollart
Maternity Services
Gosford Hospital
PO Box 361
Gosford 2250

Dear Ms Mollart,

1210-354M : *A randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy: A pilot study., Ms Lyndall Mollart,*

I am pleased to inform you that on the **12 February 2013,** the delegate of the Chief Executive authorised the Site Specific Assessment for the above study on behalf of Northern Sydney Local Health District (NSLHD).

It is noted that the approval covers the following NSW Health site:

- Gosford Hospital

The documentation included in the approval is as follows:

- National Ethics Application Form dated 9 August 2012
- HREC approval letter dated 6 February 2013
- Site Specific Assessment application form dated 9 August 2012
- PREPARE Study Protocol version 2 dated 1 February 2013
- Information Sheet – Women and Consent Form dated 30 January 2013
- Participant's Acupressure Diary version 2 dated 2 February 2013

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSLHD HREC policy, the Chief Investigator is responsible to ensure that:

1. ***The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.***
2. ***The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines. Please refer to the Research Office website.***
3. ***Proposed amendments to the research protocol or conduct of the research that may affect the ethical acceptability of the project are submitted to the HREC on an amendment form (including any relevant attachments). For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each of the sites so that they can notify their Research Governance Officer.***
4. ***Proposed changes to the personnel involved in the study are submitted to the HREC on a Change in Personnel Form (accompanied by the investigator's CV where applicable).***
5. ***The HREC must be provided with an annual progress report for the study by the 31st October each year. For multi-centre studies the Chief Investigator should submit to the Lead HREC on behalf of all sites. The annual report acknowledgment from the Lead HREC should be submitted to the Research Governance Officer.***
6. ***The HREC must be provided with a final report upon completion of the study. For multi-centre studies the Chief Investigator should notify the Lead HREC and the investigators at each site should notify the relevant Research Governance Officer.***
7. ***The HREC must be notified, giving reasons if the project is discontinued at a site before the expected date of completion.***

Site Authorisation remains valid until the HREC approval associated with this project expires. It is therefore noted that the Ethics approval for this project will expire on 6 February 2018. Should you require an extension an amendment form should be submitted to the approving HREC. Once approved by the Lead HREC you will need to notify the Research Governance Officer.

Yours sincerely,

Kylie Becker

Governance Officer

RESEARCH OFFICE

NORTHERN SYDNEY CENTRAL COAST HEALTH

AURED NEAF REF: *HREC/12/HAWKE/281* NSLHD REF NO: 1209-293M

Health
Northern Sydney
Local Health District

Research Office Kolling Building,
Level 13 Royal North Shore Hospital
St Leonards NSW 2065
Tel (02) 9926 4590 Fax (02) 9926 6179

12 February 2013

Ms Lyndall Mollart
Maternity Services
Gosford Hospital
PO Box 361
Gosford 2250

Dear Ms Mollart,

1209-307M : *A randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy: A pilot study., Ms Lyndall Mollart,*

I am pleased to inform you that on the **12 February 2013,** the delegate of the Chief Executive authorised the Site Specific Assessment for the above study on behalf of Northern Sydney Local Health District (NSLHD).

It is noted that the approval covers the following NSW Health site:

- Wyong Hospital

The documentation included in the approval is as follows:

- National Ethics Application Form dated 9 August 2012
- HREC approval letter dated 6 February 2013
- Site Specific Assessment application form dated 9 August 2012
- PREPARE Study Protocol version 2 dated 1 February 2013
- Information Sheet – Women and Consent Form dated 30 January 2013
- Participant's Acupressure Diary version 2 dated 2 February 2013

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSLHD HREC policy, the Chief Investigator is responsible to ensure that:

1. ***The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.***
2. ***The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines. Please refer to the Research Office website.***
3. ***Proposed amendments to the research protocol or conduct of the research that may affect the ethical acceptability of the project are submitted to the HREC on an amendment form (including any relevant attachments). For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each of the sites so that they can notify their Research Governance Officer.***
4. ***Proposed changes to the personnel involved in the study are submitted to the HREC on a Change in Personnel Form (accompanied by the investigator's CV where applicable).***
5. ***The HREC must be provided with an annual progress report for the study by the 31st October each year. For multi-centre studies the Chief Investigator should submit to the Lead HREC on behalf of all sites. The annual report acknowledgment from the Lead HREC should be submitted to the Research Governance Officer.***
6. ***The HREC must be provided with a final report upon completion of the study. For multi-centre studies the Chief Investigator should notify the Lead HREC and the investigators at each site should notify the relevant Research Governance Officer.***
7. ***The HREC must be notified, giving reasons if the project is discontinued at a site before the expected date of completion.***

Site Authorisation remains valid until the HREC approval associated with this project expires. It is therefore noted that the Ethics approval for this project will expire on 6 February 2018. Should you require an extension an amendment form should be submitted to the approving HREC. Once approved by the Lead HREC you will need to notify the Research Governance Officer.

Yours sincerely,

Kylie Becker

Governance Officer

RESEARCH OFFICE

NORTHERN SYDNEY CENTRAL COAST HEALTH

AURED NEAF REF: *HREC/12/HAWKE/281* NSLHD REF NO: 1210-354M

Appendix 2: Study 1—amendment PREPARE HREC approval

16 July 2013

Ms Lyndall Mollart
Maternity Services
Gosford Hospital
PO Box 361
Gosford, NSW 2250

Dear Ms Mollart,

1209-293M: *A randomised controlled trial of acupressure to assist spontaneous labour for primigravid women experiencing a post-date pregnancy: A pilot study*

Investigators: Ms Lyndall Mollart, Dr Maralyn Foureur, Dr Mutayyab Shah, Dr Virginia Skinner, Debra Betts, Gloria Albert

Thank you for your application dated **28th February 2013,** requesting approval for an amendment from the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC). Following a review of the information provided the HREC Executive have determined that the proposed amendments meet the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that your amendment for the protocol on the above study has now been approved.

Description of amendment:

- Addition of qualitative analysis by including focus groups with staff (midwives and medical officers) to examine the acceptability of acupressure in healthcare practice and their views on the

Randomised Control Trial (RCT).

The updated amendment involves the following documentation:

- Protocol version 3, dated 22 February 2013
- Participant Information and Consent Form (PICF) - Staff, version 1, dated 22 February 2013

The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

In order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia,* and in line with NSLHD HREC policy, may I remind you that it is the Chief Investigator's responsibility and a condition of approval, to ensure that:

1. ***The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.***
2. ***The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines. Please refer to the Research Office website.***
3. ***Proposed amendments to the research protocol or conduct of the research that may affect the ethical acceptability of the project are submitted to the HREC on an amendment form (including any relevant attachments). For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each of the sites so that they can notify their Research Governance Officer.***
4. ***Proposed changes to the personnel involved in the study are submitted to the HREC on a Change in Personnel Form (accompanied by the investigator' s CV where applicable).***
5. ***The HREC must be provided with an annual progress report for the study by the 31st October each year. For multi-centre***

studies the Chief Investigator should submit to the Lead HREC on behalf of all sites.

6. ***The HREC must also be provided with a final report upon completion of the study. For multi-centre studies the Chief Investigator should notify the Lead HREC and the investigators at each site should notify the relevant Research Governance Officer.***
7. ***The HREC must be notified, giving reasons if the project is discontinued at a site before the expected date of completion.***

Please refer to the NSLHDS Research Office website to access forms such as the amendment form, Annual /Final Report Form, Change in Personnel Form and Serious Adverse Event Guidelines and Forms;

Internet: http://www.northern sydneyresearch.com.au

Please note that for studies approved prior to 1 June 2011 HREC approval is valid for four (4) years from the date of the original ethics approval letter for the study. HREC approval is valid for five (5) years from the date of the original ethics approval letter for the studies approved from 1 June 2011.

Yours sincerely,

DR LIZ NEWTON

Co-Chairperson

Northern Sydney LOCAL HEALTH DISTRICT HUMAN RESEARCH ETHICS COMMITTEE

AURED NEAF REF: *HREC/12/HAWKE/281*

NSLHD REF NO: 1209-293M

Appendix 3: Study 1—participant information sheet

INFORMATION SHEET—Women
PR.E.P.A.RE: Primigravidas Experiencing Post-date and Acupressure Research

Invitation

You are invited to participate in a research study into the use of acupressure for women experiencing their first pregnancy (primigravidas) from 41 weeks of pregnancy.

The study is being conducted by:

- Lyndall Mollart, Clinical Midwifery Consultant Antenatal Services, Women's, Children's and Family Health Division, Central Coast Local Health District (CCLHD)
- Dr Mutayyab Shah, Director of Obstetrics and Gynaecology, Women's, Children's and Family Health Division, CCLDH
- Dr Maralyn Foureur, Professor of Midwifery, Centre for Midwifery, Child and Family Health
- University of Technology Sydney.
- Dr Virginia Skinner, Program Convenor of the Bachelor of Midwifery Programme, The University of Newcastle.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose of this study is to investigate the impact of using specific acupressure points on the onset of spontaneous labour for women experiencing their first pregnancy (primigravidas) from 41 weeks of pregnancy.

In Australia, concerns have been raised about rising caesarean section (CS) rates and the associated cost increase in terms of health for mothers and babies. One of the main contributors to the overall CS rate is women having a medical induction of labour rather than spontaneous onset of uterine contractions and labour. International studies have found that specific acupressure points have

safely assisted in effective uterine contractions with pregnant women, and shortened the length of labour. We don't know if acupressure will initiate contractions and labour for women experiencing postdates pregnancy. This can only be determined by conducting a randomised controlled trial. So, will be the first randomised controlled trial that focuses on first time mothers experiencing pregnancy at 41 weeks (or past the due date) using three specific acupressure points to initiate spontaneous labour.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because you have been identified as a potential participant due to you being a woman experiencing your first term pregnancy, you are over the age of 18 years, you have no other complicating factors (e.g. Twins, etc.) therefore are considered low risk and eligible for midwifery care in this pregnancy, you are approaching (or you are at) 41 weeks of pregnancy. You are proficient in English (spoken and written) and are currently having care at Gosford or Wyong Hospital and have no strong preference as to whether or not I receive information or use acupressure.

3. What does this study involve?

When you attend your antenatal visit at approximately 41 weeks gestation, a project midwife will discuss the research and the process with you. If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will be randomised to either usual antenatal care or usual care and acupressure point use. If allocated to usual antenatal care, the midwife will advise you of your next appointment. If you are allocated to usual care and acupressure group, you will receive education and information from the attending midwife, on three specific acupressure points (location and frequency of use) for self-administration of these acupressure points at home. The midwife will also advise you of your next appointment.

No matter which group you are in, after giving birth, you will receive a survey either during your hospital stay or posted to your home address. The survey includes questions on your experience with the care you received and being involved in a research study. For women allocated to the acupressure group, there is a section regarding the information you received about the acupressure

points, and whether or not you used the acupressure points during pregnancy and labour.

The research team will also access information from your maternity notes about your pregnancy, labour and birth and the early postnatal period. All of this information is already collected at every birth and is available in hospital records.

What does 'randomised trial' mean?

Sometimes we don't know the best way of treating women with a particular condition so comparisons need to be made between different treatments or techniques. To do this, study participants are put into groups and given different treatments/techniques, and the results are compared to see whether one treatment/technique is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the researcher nor the study participant can decide which treatment/technique the participant receives.

4. What are the risks associated with this study?

It may be that you find reflecting on the care you received distressing to you. If this happens, we can arrange counselling and support through the hospital.

5. Will I benefit from this study?

We cannot guarantee or promise that you will personally receive any benefits from this project. In previous studies however, participants have experienced benefits from having an opportunity to participate and express their views and opinions on the care they received. We trust that similar benefits will be produced in this present study.

6. What happens if I don't want to take part in the study?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the care and treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you decide to later withdraw from this project, please formally notify the research midwife. You should make clear whether your withdrawal means already collected data needs to be destroyed, or whether your withdrawal only pertains to future data collection and participation.

7. How will my confidentiality be protected?

Any information obtained in connection with this project and that can identify you will remain confidential. Only the research team will have access to your personal details. We will use a code number to identify you. All records containing personal information will remain confidential and no information that could lead to your identification will be made public. It will only be disclosed with your permission as required by law.

We plan to publish the findings. In any publication, information will be provided in such a way that you cannot be identified. Original materials will be stored in a password-protected computer and in locked filing cabinets. No one other than the researchers listed on this project will have access to the data. Each one of these researchers on this study fully understands the obligation to adhere to full confidentiality. All data and personal information will be stored, accessed and used in accordance with Commonwealth Privacy Laws and the *NSW Health records and Information Act 2002*, as well as in accordance with Central Coast Local Health District policy.

8. What should I do if I want to discuss this study further before I decide?

When you have read this information, the midwife or research assistant will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the principal researcher Ms Lyndall Mollart on 02 4320 2461 or 0434323322.

9. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by Northern Sydney Coast HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 8106 and quote *HREC* NEAF 1209-293.

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

Appendix 4: Study 1—participant consent form

Patient Label here

CONSENT FORM—Women

PR.E.P.A.RE: PRimgravidas Experiencing Post-date and Acupressure Research

1. I,.....
of.....
agree to participate as a subject in the study described in the participant information statement attached to this form.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Central Coast Local Health District.
5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Ms Lyndall Mollart on telephone 02 43202461 or 0434323322, who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the, Research Governance Officer (02 9926 4590) or Email: research@nsccahs.health.nsw.gov.au and quote the reference number NEAF 1209-293M.

Signature of Participant	Please PRINT name	Date
Signature of Midwife	Please PRINT name	Date

PR.E.P.A.RE: PRimgravidas **E**xperiencing **P**ost-date and **A**cupressure **Re**search

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the *Central Coast Local Health District, or my midwifery or medical attendants*.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to Ms Lyndall Mollart CMC, Antenatal Services, Maternity Services, Women's Children and Family Health, CCLHD.

Appendix 5: Study 1—intervention group acupressure information sheet

Participant Acupressure Information Sheet

PR.E.P.A.RE: PRimgravidas **E**xperiencing **P**ost-date and **A**cupressure **RE**search

SPLEEN 6 (SP 6)

This point is located using four of the woman's finger widths above the tip of the shin bone on the inside of the ankle. This area will often be tender and the point is found when you slide your finger off the edge of the tibia bone, towards the inside of the leg. It is useful to press on the tibia when first locating this point as pressing on this bone produces a very different sensation from the acupressure point.

Acupressure technique

- **2 minutes on each leg every 2 hours during the day**
- Apply direct pressure with index finger or thumb.

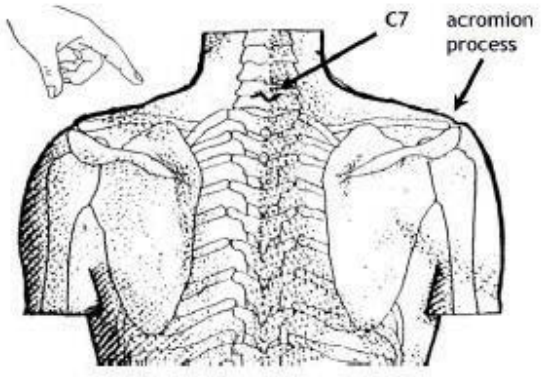
LARGE INTESTINE 4 (LI 4)

This point is found between the first and second metacarpal bones (the bones of the thumb and first finger). It lies at the highest point formed when the thumb is brought to rest against the index finger.

Acupressure technique

- **2 minutes on each hand every 2 hours during the day**
- Apply firm pressure with thumb. This acupressure point has a dull achy feeling when located correctly.

GALL BLADDER 21 (GB 21)



When you draw an imaginary line between the bony prominence of the neck (C7), and the top of the shoulder joint (the acromion process), this point lies midway along this curved line, at the highest point of the shoulder muscle.

It will feel tender with a numbing/ buzzing/ warming sensation (this sensation varies with individuals). The sensation is stronger on this point than any other points along this line.

Acupressure technique

- **Each shoulder point—2 minutes in the morning and 2 minutes in the afternoon/evening.**
- Apply firm downwards pressure with thumb or knuckle. Pressure needs to come from the arms rather than the thumb joint—otherwise people will end up with very sore thumbs.

Appendix 6: Study 1—intervention group: acupressure diary

Participant's Acupressure Diary Sheet

PR.E.P.A.RE: PRimgravidas **E**xperiencing **P**ost-date and **A**cupressure **RE**search

You can use this Diary sheet to keep a record on how often you use the acupressure points—tick the boxes as you go. The times in the first column are an example only. You can start any time in the morning.

- Spleen 6 (SP6)—inner leg point: each leg —for 2 minutes, every 2 hours during the day
- Large Intestine (LI4)—hand point: each hand- for 2 minutes, every 2 hours during the day
- Gall Bladder 21 (GB21)- mid-shoulder point: each shoulder- for 2 minutes in the morning, 2 minutes in the evening. You can do both shoulder points at the same time if you can (total of 2 minutes).

	DAY 1			DAY 2			DAY 3			DAY 4			DAY 5			DAY 6			DAY 7			Day 8		
Times eg	SP6	LI4	GB 21	SP6	LI4	GB 21	SP6	LI 4	GB 21	SP6	LI4	GB21	SP 6	LI4	GB21	SP6	LI4	GB21	SP6	LI 4	GB 21	SP6	LI 4	GB 21
8am																								
10am																								
12md																								
2pm																								
4pm																								
6pm																								
8pm																								

Please return with your postnatal questionnaire

Appendix 7: Study 1—PR.E.P.A.RE woman's survey

PR.E.P.A.RE (PRimgravidas Experiencing Post-date and Acupressure Research

We are interested in your experience in the PREPARE study during you recent pregnancy. To assist us with our research please take the time to fill out the following survey. You will not be identified in any part of the research

How to fill in the questionnaire

Most of the questions can be answered by ☑ - putting a tick in the box next to the answer that best applies to you.

Other questions can be answered by circling ONE number between 1 and 7. In the following question 1 means "Very poor" and 7 means "Very good" while 4 is a value in between meaning "Good in some ways, poor in others".

PART 1: ANTENATAL CARE

1.1 Who was responsible for your antenatal care?

Midwife Antenatal Clinic (MAC)	☐
Gosford Midwifery Group Practice (MGP)	☐
Wyong Midwifery Group Practice (MGP)	☐
Community Midwives Program (CMP)	☐
Other (specify_____)	☐
Don't know/can't remember	☐

1.2 Pregnancy Care

	Very Poor						Very good
	1	**2**	**3**	**4**	**5**	**6**	**7**
a. Generally, how would you describe your care during the pregnancy?	☐	☐	☐	☐	☐	☐	☐

1.3 Some of the things women have said about their CARE in PREGNANCY are listed below. We would like to know whether you would say the same things about your care.

Please circle ONE number on EACH line to show whether you agree or disagree. If the statement is not applicable, go to the next one.

	Disagree strongly						Agree strongly
	1	2	3	4	5	6	7
a. I was always given an active say in decisions about my care in pregnancy	☐	☐	☐	☐	☐	☐	☐
b. I always felt my worries, anxiety or concerns about the pregnancy and the baby were taken seriously by the midwives	☐	☐	☐	☐	☐	☐	☐
c. I always felt my worries, anxiety or concerns about the pregnancy and the baby were taken seriously by the doctors	☐	☐	☐	☐	☐	☐	☐
d. The midwives provided reassurance when I needed it.	☐	☐	☐	☐	☐	☐	☐

1.4 Please describe any things about your pregnancy care that you are…

a. Particularly happy with

_____

_____

b. Particularly unhappy with

_____

_____

PART 2: STUDY PARTICIPATION

Tick in the box next to the answer that best applies to you.

2.1 The following questions are about your general experiences as a participant in this study.

	Disagree strongly						Agree strongly
	1	2	3	4	5	6	7
a. During the 40 and 41 week antenatal visits I was given time to ask questions and/or discuss the study	☐	☐	☐	☐	☐	☐	☐
b. I was given enough information or explanations about the study	☐	☐	☐	☐	☐	☐	☐
c. The information about the study was explained to me in a way I could understand	☐	☐	☐	☐	☐	☐	☐

2.2 What did you <u>like</u> about being in the study? (You can tick more than 1 answer)

Few additional demands were made upon my time	☐
I was reassured by the extra attention to my health	☐
There was nothing I liked	☐
My contact with project staff	☐
Assisting with research to help others like me	☐
Being able to try other options in my care	☐
Other: _____	☐

2.2a Comments

2.3 What did you dislike about being in the study? (you can tick more than 1 answer)

Extra demands were made upon my time	☐
I felt more anxious about my health and my baby's health	☐
My contact with project staff	☐
There was nothing I disliked	☐
Being randomised	☐
Having to use acupressure points	☐
Other: _____	☐

2.3a Comments

2.4 If time went suddenly backwards and you had to do it all over again, would you agree to participate in this research study?

No, definitely	☐
No, possibly	☐
I'm not sure	☐
Yes, possibly	☐
Yes, definitely	☐

2.5 Did you use any strategies/techniques to start your contractions?

Yes	☐
No	☐

2.6 If yes, what strategies/techniques did you use? (You can tick more than 1box)

Nipple stimulation	☐
Reflexology	☐
Acupuncture	☐
Evening primrose oil	☐
Vaginal examination 'strip and stretch'	☐
Acupressure (randomised to acupressure group)	☐
Acupressure (but not randomised to acupressure group)	☐
Other: _____	☐

2.7 Please comment on your experience in being randomised in this study?

If you were randomised into usual antenatal care, thank you for completing this survey.

Please read the mailing instructions on the last page

If you were randomised into the usual care plus acupressure,

please continue onto the next page

PART 3: USING ACUPRESSURE POINTS

3.1 Tick in the box next to the answer that best applies to you

	Disagree strongly						Agree strongly
	1	**2**	**3**	**4**	**5**	**6**	**7**
a. Overall, I was given sufficient information on the use of the 3 acupressure points?	☐	☐	☐	☐	☐	☐	☐
b. I was given sufficient information on the location of the 3 acupressure points	☐	☐	☐	☐	☐	☐	☐
c. I was given sufficient information on the timing and duration when using the 3 acupressure points	☐	☐	☐	☐	☐	☐	☐

3.2.A. Did you use the acupressure points as often as recommended on the Acupressure Information Sheet?

Yes, always	☐
Yes, almost always	☐
Sometimes	☐
No, almost never	☐
No, not at all	☐

3.2B. If 'not at all' or 'almost never', could you please explain:

_____

_____

3.3 Did you use the three acupressure points (Inner leg SP6, Hand LI4, Shoulder GB21)**?**

Yes, always	☐
Yes, almost always	☐
Sometimes	☐
No, almost never	☐

No, not at all	☐

3.3.B. If 'not at all' or 'almost never', could you please explain:

_____
_____

3.4.A Did you have a preference for any particular acupressure point (Inner leg SP6, Hand LI4, Shoulder GB21)?

Yes	☐
No	☐

3.4.B. If 'Yes', could you please explain:

_____
_____

3.5 Tick in the box next to the answer that best applies to you

	Disagree strongly						Agree strongly
	1	**2**	**3**	**4**	**5**	**6**	**7**
a. Being able to use acupressure made me feel actively involved in my care	☐	☐	☐	☐	☐	☐	☐
b. My partner helped with the acupressure and felt more involved in my care	☐	☐	☐	☐	☐	☐	☐

3.6.A. Did you use any of the acupressure points in labour (Inner leg SP6, Hand LI4, Shoulder GB21)?

Yes	☐
No	☐

3.6 B. If 'Yes', could you please explain:

_____
_____

3.7 Please provide any further comment on your experience using acupressure points?

_____
_____

Thank you very much for completing this questionnaire. We are very grateful for the time and trouble you have taken.

If you have any questions or concerns you can contact the PREPARE Project Coordinator:

Lyndall Mollart 02 43202461

Please return this questionnaire in the reply paid envelope.

If you have misplaced the envelope please mail the questionnaire to:

PREPARE Team
Gosford Antenatal Clinic
C/- Gosford Outpatient Department
Gosford Hospital
PO Box 361 GOSFORD NSW 2250.

Appendix 8: Study 1—staff information sheet

INFORMATION SHEET – STAFF

PR.E.P.A.RE: Primigravidas **E**xperiencing **P**ost-date and **A**cupressure **RE**search

Invitation

You are invited to participate in a research study investigating the use of acupressure for women experiencing their first term pregnancy (primigravidas) from 41 weeks of pregnancy.

The study is being conducted by:

- Lyndall Mollart, Clinical Midwifery Consultant Antenatal Services, Women's, Children's and Family Health Division, Central Coast Local Health District (CCLHD)
- Dr Mutayyab Shah, Director of Obstetrics and Gynaecology, Women's, Children's and Family Health Division, CCLDH
- Dr Maralyn Foureur, Professor of Midwifery, Centre for Midwifery, Child and Family Health
- University of Technology Sydney.
- Dr Virginia Skinner, Program Convenor of the Bachelor of Midwifery Programme, The University of Newcastle.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose of this study is to investigate the impact of using specific acupressure points on the onset of spontaneous labour for women experiencing their first term pregnancy from 41 weeks of pregnancy.

In Australia, concerns have been raised about rising caesarean section (CS) rates and the associated cost increase in terms of health for mothers and babies. One of the main contributors to the overall CS rate is women having a medical induction of labour rather than awaiting the spontaneous onset of uterine contractions and labour. International studies have found that specific

acupressure and/or acupuncture points have safely initiated or assisted in effective uterine contractions with pregnant women, and shortened the length of labour. This will be the first Australian and international randomised controlled trial that focuses on first time mothers experiencing pregnancy at 41 weeks (or past the due date) using three specific acupressure points to initiate spontaneous labour.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because you are a health professional (midwife or obstetric medical officer) employed by Central Coast Local Health District and are currently involved in providing antenatal care for women accessing the maternity services. We are interested in your view as a health professional on the pilot study.

3. What does this involve?

You are invited to attend a focus group to explore health professionals' views towards complementary and alternative therapies in mainstream medicine and in the treatment of pregnancy related conditions, and health professionals' views on the randomisation controlled trial of acupressure. There will be four or five focus groups held to enable the maximum number of health professionals to be involved. The focus groups will be conducted by an independent facilitator. The location of the focus groups will be chosen on the basis of suitability to the participants and to ensure confidentiality and privacy. The duration of the session will not exceed one hour. Each focus group will be digitally recorded.

4. Will I benefit from this study?

This study aims to further knowledge of this complementary therapy and may improve future care and management of post-date pregnancy and induction of labour, however it may not directly benefit you.

5. What happens if I don't want to take part in the study?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not disadvantage you in any way and will not affect your current or future employment.

If you decide to later withdraw from this project, please formally notify the research midwife. You should make clear whether your withdrawal means already collected data needs to be destroyed, or whether your withdrawal only pertains to future data collection and participation.

6. How will my confidentiality be protected?

Any information obtained in connection with this project and that can identify you will remain confidential. Only the research team will have access to your personal details. All records containing personal information will remain confidential and no information that could lead to your identification will be made public. It will only be disclosed with your permission as required by law.

We plan to publish the findings. In any publication, information will be provided in such a way that you cannot be identified. Original materials will be stored in a password protected computer and in locked filing cabinets. No one other than the researchers listed on this project will have access to the data. Each one of these researchers on this study fully understands the obligation to adhere to full confidentiality. All data and personal information will be stored, accessed and used in accordance with Commonwealth Privacy Laws and the *NSW Health records and Information Act 2002*, as well as in accordance with Central Coast Local Health District policy.

7. What should I do if I want to discuss this study further before I decide?

When you have read this information, the research assistant will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the principal researcher Ms Lyndall Mollart on 02 4320 2461 or 0434323322.

8. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by Northern Sydney HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote *HREC* NEAF 1209-293M.

Thank you for taking the time to consider this study.

If you wish to take part please sign the attached consent form.

This information sheet is for you to keep.

Appendix 9: Study 1—staff consent form

CONSENT FORM—STAFF

PR.E.P.A.RE: PRimgravidas **E**xperiencing **P**ost-date and **A**cupressure **Re**search

1. I,.....

   of.....

   agree to participate in the study described in the participant information statement attached to this form.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Central Coast Local Health District.
5. I agree that research data gathered from the results of the focus groups may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Ms Lyndall Mollart on telephone 02 43202461 or 0434323322, who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the, Research Governance Office, 02 9926 4590 or Email: research@nsccahs.health.nsw.gov.au and quote the reference number NEAF 1209-293M.

Signature of Participant Please PRINT name Date

Appendix 10: Study 1—staff focus group trigger questions

1. Can you explain your understanding of what is Complementary Therapies?
   OR What do you see/define as complementary therapies?

2. What are your personal views towards CAM in the treatment of pregnancy related conditions?

3. Do you know about any research on clinical application of acupressure or acupuncture for uterine contractions and labour?

4. What are your personal views about 'evaluating' (researching) acupressure in a clinical trial and randomisation?

Appendix 11: Study 2—ethics approval

From: Research.Ethics@uts.edu.au <Research.Ethics@uts.edu.au>
Sent: Thursday, 8 October 2015 10:34 AM
To: Lyndall Mollart; Maralyn Foureur; Jon Adams; Research Ethics;

Subject: UTS HREC Letter of Noting

Dear Applicant,
The Faculty has considered your Nil/Negligible Risk Declaration Form for your project titled, "National midwife survey on Complementary and Alternative Medicine (CAM) strategies for women with post-date pregnancy", and agree your research does not require review from the UTS Human Research Ethics Committee. Please keep a copy of your Declaration form on file to show you have considered risk.

For tracking purposes, you have been provided with an ethics application number, which is UTS HREC 2015000614.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of noting.

Instructions for saving the declaration form can be downloaded from:
http://www.research.uts.edu.au/policies/restricted/human/forms.html#instructions
To access this application, please follow the URLs below:

* if accessing within the UTS network:
http://rmprod.itd.uts.edu.au/RMENet/HOM001N.aspx
* if accessing outside of UTS network: https://remote.uts.edu.au, and click on "RMENet - ResearchMaster Enterprise" after logging in.

If you or anyone connected with this research have any queries please do not hesitate to contact Research.Ethics@uts.edu.au

Yours sincerely,

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee
C/- Research & Innovation Office
University of Technology, Sydney
E: Research.Ethics@uts.edu.au
I: http://www.research.uts.edu.au/policies/restricted/ethics.html
P: PO Box 123, BROADWAY NSW 2007
[Level 14, Building 1, Broadway Campus]
CB01.14.08.04

REF: E28

Appendix 12: Study 2—ACM e-bulletin—invitation for midwives to participate in study

1st National Survey of Australian Midwives on Complementary and Alternative Medicines (CAM) and Post-date pregnancy.

My name is Lyndall Mollart and I am a PhD student at University of Technology Sydney (UTS). My supervisors are Dr Maralyn Foureur and Dr Jon Adams.

You are invited to take part in the 1st national on-line survey on Australian midwives' clinical practice, knowledge and views on Complementary and Alternative Medicine/therapies (CAM); and what CAM and/or self-help strategies midwives recommend to women experiencing a post-date pregnancy.

Your participation is very important since a high response rate produces more credible results.

We ask that you complete the survey which takes 15–20 minutes—by 1st March 2016. You will find background information and directions for completing the survey on the first page. We look forward to receiving your response.

If you have already completed the survey—thank you for taking the time.

Follow the link to complete the survey:

https://www.surveymonkey.com/r/CAM-SurveyMidwives2015

You can change your mind at any time and stop completing the survey without consequences. As you are completing this survey via 'Surveymonkey' your responses are anonymous. The research team will not access your personal details—the computer IP address is switched to 'No' and consent is implied by completion of the survey.

If you have concerns about the research that you think I or my supervisor can help you with, please feel free to contact me on 0410422954.

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Officer on 02 9514 9772 or

Research.ethics@uts.edu.au and quote this number *(UTS HREC Approval Number: 20150000614)*.

Appendix 13: Study 2—national midwifery questionnaire

Post-dates Pregnancy and Use of Complementary and Alternative Medicines.
A National Survey of Australian Midwives

You are invited to participate in a survey of midwives' clinical practice, knowledge and views on Complementary and Alternative Medicine/therapies (CAM) generally; and what CAM and self-help strategies midwives recommend to women experiencing a **Post-dates Pregnancy**.

The study is being conducted by:

- Lyndall Mollart, PhD candidate, Centre for Midwifery, Child and Family Health, University of Technology Sydney.
- Dr Maralyn Foureur, Professor of Midwifery, Centre for Midwifery, Child and Family Health, University of Technology Sydney.
- Dr Jon Adams, Professor of Public Health and Director of Australian Research Centre in Complementary and Integrative Medicine, Faculty of Health, University of Technology Sydney

The purpose of this study is to investigate Australian midwives':

- Recommendations for CAM and self-help strategies for women with post-dates pregnancy
- Personal views and own personal use of CAM
- Knowledge and practice in the use of CAM in the perinatal period, and
- Training and education in the use of CAM

Why have I been invited to participate in this study?
As you are a member of the Australian College of Midwives (ACM), and a registered midwife or student midwife currently working in the maternity service sector in Australia, you are eligible to participate in this survey. Participation is voluntary. It is completely up to you whether or not you participate. You have the right to withdraw at any point by exiting the survey without completion. Whatever your decision, it will not affect your relationship with the Australian College of Midwives.

Anonymity
As you are completing this survey via 'Surveymonkey' your responses are anonymous. The research team will not access your personal details as these are confidential to ACM - the computer IP address is switched to 'No' and consent is implied by completion of the survey. This study has been approved by the University of Technology Sydney, Health Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Office on 95149772 and quote 2015000614. If you would like to know more at any stage, please do not hesitate to contact the principal researcher Ms Lyndall Mollart on 0410422965.

The survey has four sections: (each section takes about 5 minutes to complete)

1. Demographics
2. Discussing/recommending self-help and CAM strategies for women experiencing post-dates
3. Your personal views and use of CAM;
4. Your knowledge and professional skills in CAM.

Thank you for taking the time to consider this study. The completion of this survey (taking into consideration your personal reflection on practice, knowledge and skill) attracts one (1) hour of continuing professional development (CPD).

1

Post-dates Pregnancy and Use of Complementary and Alternative Medicines. A National Survey of Australian Midwives

1. Demographics

* 1. Are you female or male?

- ◯ Female
- ◯ Male

* 2. What is your age?

- ◯ 18 to 24
- ◯ 25 to 34
- ◯ 35 to 44
- ◯ 45 to 54
- ◯ 55 to 64
- ◯ 65 to 74
- ◯ 75 or older

* 3. What is your ethnicity? (Please select all that apply.)

- ☐ Indigenous Australian
- ☐ White / Caucasian/ European
- ☐ Asian / Pacific Islander
- ☐ Indian
- ☐ Black or African American
- ☐ Hispanic or Latino

Other (please specify)

* 4. How many years have you been a registered midwife?

- ◯ less than 1 year
- ◯ 1-5 years
- ◯ 6-10 years
- ◯ 11-15 years
- ◯ 16-20 years
- ◯ 21-25 years
- ◯ more than 25 years
- ◯ N/A

* 5. In what state/territory do you currently reside?

- ◯ NSW
- ◯ Queensland
- ◯ South Australia
- ◯ Victoria
- ◯ Northern Territory
- ◯ Western Australia
- ◯ Tasmania
- ◯ ACT

Other (please specify)

* 6. What is your highest professional qualification?

- ◯ Hospital certificate
- ◯ Ba Midwifery
- ◯ PhD
- ◯ Graduate Certificate
- ◯ Graduate Diploma
- ◯ Diploma
- ◯ Masters

* 7. Which of the following category best describes your current employment status?

- ◯ Working full-time
- ◯ Not working, not looking for work
- ◯ Working part-time
- ◯ Retired
- ◯ Working casual

Other (please specify)

* 8. What is your predominant work setting?

- ◯ Public Hospital
- ◯ Private Midwifery Practice/ Homebirth
- ◯ Private Hospital
- ◯ University (Education /Research)

Other (please specify)

* 9. What is your predominant area of work?

- ◯ All areas of maternity care
- ◯ Postnatal
- ◯ non-clinical/education/management/research
- ◯ Antenatal
- ◯ Nursery (SCN/NICU)
- ◯ Intrapartum
- ◯ Student Midwife
- ◯ not currently working in maternity setting
- ◯ Other (please specify)

* 10. What is the annual birth rate at your unit/service?

- ◯ less than 500
- ◯ 1500-1999
- ◯ 3000+
- ◯ 500- 999
- ◯ 2000- 2499
- ◯ Not applicable
- ◯ 1000-1499
- ◯ 2500-2999

Post-dates Pregnancy and Use of Complementary and Alternative Medicines. A National Survey of Australian Midwives

2. Self Help and CAM strategies for women experiencing post-dates pregnancy

This next section relates to your practice with pregnant women. If you are not currently working with pregnant women, please answer the questions as if you are. Post-dates pregnancy is any time after the Expected Date of Birthing (EDB/EDC).

* 11. When working with women with a post-date pregnancy, do you or would youdiscuss any self- help and Complementary Alternative (CAM) strategies?

- ◯ Yes, always
- ◯ Yes, almost always
- ◯ Yes, sometimes
- ◯ No, not very often
- ◯ No, never

* 12. Do you or would you recommend any self-help and CAM strategies to pregnant women with a post-date pregnancy?

- ◯ Yes, always
- ◯ Yes, almost always
- ◯ Yes, sometimes
- ◯ No, not very often
- ◯ No, almost never
- ◯ No, not at all

Post-dates Pregnancy and Use of Complementary and Alternative Medicines. A National Survey of Australian Midwives

2. Self Help and CAM strategies for women experiencing post-dates pregnancy

13. If no, please select one or more answer

- [ ] Self-help and CAM strategies are not evidenced based
- [ ] I don't believe the strategies are effective
- [ ] I don't have training in CAM strategies to confidently discuss with women
- [ ] I don't have the knowledge of CAM strategies to confidently discuss with women
- [ ] Women need to see a doctor to discuss self-help strategies

Post-dates Pregnancy and Use of Complementary and Alternative Medicines. A National Survey of Australian Midwives

2. Self Help and CAM strategies for women experiencing post-dates pregnancy

* 14. What gestation do you or would you discuss/recommend self-help and CAM strategies?

- ☐ Prior to 39 weeks
- ☐ 39-40weeks
- ☐ 40 weeks+1 days to 40 + 6 days
- ☐ 40 weeks +7 days onwards

* 15. How confident do you feel that you have the knowledge to discuss the various self-help and CAM strategies with women?

	Very unconfident	Unconfident	Confident	Very confident
Self-help strategies	○	○	○	○
CAM strategies	○	○	○	○

* 16. What self-help strategies do you/would you recommend specifically for post-dates?

- ☐ Exercise eg walking, swimming, yoga
- ☐ Nipple stimulation
- ☐ Sexual intercourse
- ☐ Eat spicy food
- ☐ Castor oil

* 17. What CAM strategies do you/would you recommend specifically for post-dates?

- ☐ Acupressure
- ☐ Acupuncture
- ☐ Aromatherapy
- ☐ Bach Flower essences
- ☐ Blue Cohosh
- ☐ Date Fruit
- ☐ Evening primrose oil
- ☐ Homoeopathic remedies
- ☐ Hypnosis (Calmbirthing, Hypnobirthing)
- ☐ Other (please specify)
- ☐ Imagery techniques/ Meditation
- ☐ Massage
- ☐ Meditation
- ☐ Raspberry Leaf (tea or tablet)
- ☐ Reflexology
- ☐ Reiki/Therapeutic Touch
- ☐ Shiatsu
- ☐ Yoga

* 18. What are the reasons you discuss or recommend self-help and/or CAM strategies? (select a answer per statement)

	Strongly disagree	Disagree	Agree	Strongly agree
Self-help/CAM doesn't do any harm	◯	◯	◯	◯
Self-help/CAM maybe helpful to prevent medical induction of labour	◯	◯	◯	◯
Anecdotal evidence supports self-help/CAM	◯	◯	◯	◯
There is research supporting strategies I recommend	◯	◯	◯	◯
Women are more empowered using Self-help/CAM strategies	◯	◯	◯	◯
Self-help/CAM strategies can be safer than medical induction of labour	◯	◯	◯	◯
Self- help/CAM allows women to have more options to choose from	◯	◯	◯	◯
Women ask, so I provide information on Self-help/CAM strategies	◯	◯	◯	◯
My hospital/service has guidelines/procedures on the use of CAM	◯	◯	◯	◯
I feel supported in my organisation to recommend self-help strategies	◯	◯	◯	◯
I feel supported in my organisation to recommend CAM strategies	◯	◯	◯	◯

19. Do you refer women to visit a CAM practitioner?

◯ Yes

◯ No

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2. Self Help and CAM strategies for women experiencing post-dates pregnancy

* 20. What CAM practitioner(s) do you recommend or refer women to specifically for post-dates?

- [ ] Massage Therapist
- [ ] Calmbirthing, Hypnobirthing Practitioner
- [ ] Acupuncturist
- [ ] Reflexologist
- [ ] Homoeopathist
- [ ] Naturopath
- [ ] Herbalist
- [ ] Aromatherapist
- [ ] Kinesiologist
- [ ] Reiki/Therapeutic Touch Practitioner
- [ ] Imagery techniques/Meditation Practitioner
- [ ] Shiatsu Practitioner
- [ ] Other (please specify)

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3. Your Personal views on and use of CAMs

This section relates to your personal views and beliefs on Complementary and Alternative Medicines/Therapies (CAMs).

* 21. Please rate your personal beliefs on the statements below (CHBQ):

	Absolutely Disagree	Somewhat disagree	Disagree	Neither Disagree or Agree	Agree	somewhat agree	Absolutely Agree
The physical and mental health are maintained by an underlying energy or vital force.	○	○	○	○	○	○	○
Health and disease are a reflection of balance between positive life enhancing and negative destructive forces.	○	○	○	○	○	○	○
The body is essentially self-healing and the task of a health care provider is to assist in the healing process.	○	○	○	○	○	○	○
A patient's symptoms should be regarded as a manifestation of general imbalance or dysfunction affecting the whole body.	○	○	○	○	○	○	○
A patients expectations, health beliefs and values should be integrated into the patient care process.	○	○	○	○	○	○	○
Complementary therapies are a threat to public health.	○	○	○	○	○	○	○
Treatments not tested in a scientifically recognised manner should be discouraged.	○	○	○	○	○	○	○
Effects of CAMs are usually the result of a placebo effect.	○	○	○	○	○	○	○
CAM include ideas and methods from which conventional medicine can benefit.	○	○	○	○	○	○	○
Most CAMs stimulate the body's natural therapeutic powers.	○	○	○	○	○	○	○

* 22. Please rate your personal views for the statements below:

	Absolutely Disagree	Somewhat disagree	Disagree	Neither Disagree or Agree	Agree	Somewhat agree	Absolutely Agree
CAM is an important aspect of my own/ family health care	◯	◯	◯	◯	◯	◯	◯
Women should have the right to choose between conventional treatment and CAM strategies in health care	◯	◯	◯	◯	◯	◯	◯
Women should be adequately informed about the CAM strategies that can used safely in pregnancy.	◯	◯	◯	◯	◯	◯	◯
CAM strategies can be used as a complement in conventional health care	◯	◯	◯	◯	◯	◯	◯
All midwives should have knowledge on commonly used CAM used during the perinatal period.	◯	◯	◯	◯	◯	◯	◯
All midwives should receive education of CAM strategies during their undergraduate curriculum	◯	◯	◯	◯	◯	◯	◯

* 23. Have you used CAM strategies for your personal use?

◯ Yes

◯ No

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3. Your Personal views on and use of CAMs

* 24. What CAM strategies have you personally used for your own personal health and wellbeing?

- ☐ Acupressure
- ☐ Aromatherapy/Essential oils
- ☐ Acupuncture
- ☐ Ayurveda medicine
- ☐ Bach Flower essences
- ☐ Chiropractic/Osteopathic
- ☐ Evening primrose oil
- ☐ Herbal medicine
- ☐ Hypnosis (Calmbirthing, Hypnobirthing)
- ☐ Homoeopathic remedies
- ☐ Imagery techniques/ Meditation
- ☐ Iridology
- ☐ Kinesiology
- ☐ Massage therapy
- ☐ Naturopathy
- ☐ Raspberry Leaf (tea or tablet)
- ☐ Reiki/Therapeutic Touch
- ☐ Reflexology
- ☐ Shiatsu
- ☐ Spiritual Healing
- ☐ Traditional Chinese Medicine (TCM)
- ☐ Other (please specify)

25. What has been your own personal experience with CAM strategies?

Very negative experience	Negative experience	not positive or negative	Positive experience	Very positive experience
○	○	○	○	○

26. What is your own personal view of CAM based on your experience?

Very negative view	Negative view	not positive or negative	Positive view	Very positive view
○	○	○	○	○

27. Have you used CAM strategies for your own pregnancy/ies?

○ Yes ○ No ○ N/A

3. Your Personal views on and use of CAMs

28. What CAM strategies have you personally used for your pregnancy/ies?

- ☐ Acupressure
- ☐ Aromatherapy/Essential oils
- ☐ Acupuncture
- ☐ Ayurveda medicine
- ☐ Bach Flower essences
- ☐ Chiropractic/Osteopathic
- ☐ Evening primrose oil
- ☐ Herbal medicine
- ☐ Hypnosis (Calmbirthing, Hypnobirthing)
- ☐ Homoeopathic remedies
- ☐ Imagery techniques/ Meditation
- ☐ Iridology
- ☐ Kinesiology
- ☐ Massage therapy
- ☐ Naturopathy
- ☐ Raspberry Leaf (tea or tablet)
- ☐ Reiki/Therapeutic Touch
- ☐ Reflexology
- ☐ Shiatsu
- ☐ Spiritual Healing
- ☐ Traditional Chinese Medicine (TCM)
- ☐ Other (please specify)

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4. Your professional skills in CAM

* 29. Do you mostly use CAM strategies for women during... (select answer/s that apply)

- ☐ Pregnancy
- ☐ Labour and birth
- ☐ Postnatal
- ☐ Equally throughout pregnancy, labour, birth and postnatal period

* 30. Have you received specific training in CAM? (select all that apply)

- ◯ Yes, recognised qualification e.g. certificate, diploma
- ◯ Yes, course/workshop- competency based
- ◯ Yes, course/workshop- no recognised qualification or competency
- ◯ No, but information was included in my nursing/midwifery training
- ◯ No, information gained through self study/reading
- ◯ No, but interested
- ◯ No, not interested

4. Your professional skills in CAM

31. Please select the specific training in CAM you have attended (select all that apply)

	workshop/course: no competency	workshop/course with competency	Recognised certificate/diploma
Acupressure	○	○	○
Aromatherapy/Essential oils	○	○	○
Acupuncture	○	○	○
Ayurveda medicine	○	○	○
Back Flower remedies	○	○	○
Herbal medicine	○	○	○
Hypnotherapy/Hypnosis	○	○	○
Homoeopathy	○	○	○
Iridology	○	○	○
Kinesiology	○	○	○
Massage Therapy	○	○	○
Naturopathy	○	○	○
Reiki	○	○	○
Reflexology	○	○	○
Shiatsu	○	○	○
Spiritual healing	○	○	○
Touch Therapy	○	○	○
Traditional Chinese Medicine (TCM)	○	○	○
Yoga	○	○	○

Other (please specify)

32. Any further comments

Appendix 14: Midwives' personal review of CAM (logistics regression)

17.1 Statement 1 and Q11 Discuss CAM/self-help strategies

	B	S.E.	Wald	df	Sig.	Exp(B)	95% Ci for EXP (B)	
							Lower	Upper
Statement 1	1.509	0.118	165.125	1	0.000	4.523		
Q23 Personal View CAM –	2.497	0.357	48.898	1	0.000	12.141	6.030	24.442
constant	-0.657	0.329	3.977	1	0.046	0.519		
Q27 Use of CAM in own pregnancy/ies	1.397	0.278	25.262	1	0.000	4.042	2.344	6.968
constant	0.718	0.193	13.854	1	0.000	2.050		
Q31 CAM training/ qualification	-.020	0.007	8.758	1	0.003	0.980	0.967	0.993
constant	3.156	0.597	27.988	1	0.000	23.476		

17.2 Statement 6 and Q23 midwives' personal use of CAM

	B	S.E.	Wald	df	Sig.	Exp(B)	95% Ci for EXP (B)	
							Lower	Upper
Statement 6								
Q23 Midwives' personal use CAM	1.499	.558	7.215	1	.007	4.476	1.500	13.363
constant	2.054	.475	18.700	1	0.000	7.800		