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, acceptability of an RCT for Acupressure, a CAM modality, and 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.

Keywords: Acupressure; postdates pregnancy, labour onset, uterine contractions; pilot RCT

Introduction

In an area such as Complementary and Alternative Medicine (CAM) which is endeavouring to establish scientific credibility, randomised controlled trials are an important methodology however few consider the relevance of establishing whether an intervention study can actually be conducted successfully (Hawk *et al.* 2002; Do *et al.* 2011). Feasibility studies are conducted before full powered studies in order to answer the question “Can this study be done?” and to estimate important parameters for designing robust randomised controlled trials when there are few previously published studies or limited existing data using a specific intervention technique (Fonteyn & Bauer-Wu 2005; Bowen *et al.* 2009; Arain *et al.* 2010).

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). Recent Australian government policy recommended 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 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. 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 & Waskowiak 2007). Shiatsu also includes gentle exercises and massage in the treatment session (Tiran & 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).

A search of the literature using the search terms, 'acupressure', 'induction of labour', 'labour onset', and 'post-date pregnancy', was able 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 & Shahali 2010; El Hamid *et al.* 2013). All six studies found a shortened first stage of labour and a decrease in 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 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 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 & 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 & 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 related 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 the Ingram *et al* study (Ingram *et al.* 2005). Expert advice from Debra Betts, an internationally recognised expert in perinatal acupuncture and acupressure (Betts 2003; Betts 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 postpartum. 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 40wks+10 days $^{(+/-2\ days)}$ for a maternal and fetal assessment that included abdominal palpation, vaginal examination to determine cervical favorability 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], Gall Bladder 21 [GB21 -shoulder] (see Figure 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 commencement of labour i.e. spontaneous or medically induced at 40 weeks$^{+11\text{-}14\ days}$. 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 ≥40 weeks^{+5days} with a singleton pregnancy; cephalic fetal presentation; English speaking; ≥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 39-40 weeks gestation each eligible woman received verbal and written information on the study. At 40 weeks$^{+5\text{-}7days}$ 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 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 Chi Square 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 (40weeks^{+5days} to 40weeks^{+6days}), and six women were unable to be contacted. From the remaining 67 eligible 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 (Figure 2). It was determined by the authors 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 40weeks and 6 days to 40 weeks and 14 days and Body Mass Index (BMI) ranged between 20 and 36.

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

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".*

Involvement in a RCT

The women commented on what they liked about being in the study as shown in Figure 3. Many women in both groups liked assisting with research and liked having other options available to bring on 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%) used 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 using acupressure made them feel actively involved in their care (78%) and more than half (66.7%) found 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*".

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 birth (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.

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*	XXX 2.68-12-.92
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

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 the pregnant women apply pressure to the same three acupoints as often as the woman wanted but did not determine how often the women used 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 wanting 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 et al., (Smith & 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 & Coyle 2006; Mackereth *et al.* 2014). Consideration should be given to innovative trial designs such as block randomisation or the Zelen technique that permits randomisation prior to recruitment (Mitchell & Allen 2008).

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 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 is 994 primigravid, post-date women (80% power, alpha 0.05, allowing for a 1% cross-over) would be required (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 were participation in a 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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