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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.