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A pilot randomised controlled trial (RCT) investigating the effectiveness of reflexology for managing pregnancy low back and/or pelvic pain

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ABSTRACT

Many pregnant women with low back and/or pelvic pain (LBPP) use pain medications to manage this pain, much of which is self-prescribed and potentially harmful. Therefore, there is a need to find effective nonpharmacological treatments for the condition. Reflexology has previously been shown to help nonspecific low back pain. Therefore; a pilot RCT was conducted investigating reflexology in the management of pregnancy-LBPP. 90 primiparous women were randomised to either usual care, a reflexology or footbath intervention. Primary outcome measures were; the Pain Visual Analogue Scale (VAS). 64 women completed the RCT; retention rates for the reflexology group were 80%, usual care group 83.33% and footbath group 50%. The reflexology group demonstrated a Clinically Important Change (CIC) in pain frequency (1.64 cm). Results indicate it is feasible to conduct an RCT in this area, although a footbath is an unsuitable sham treatment. Reflexology may help manage pregnancy-LBPP; however a fully powered trial is needed to confirm this.

1. Introduction

Low back pain is typically experienced by over two thirds of pregnant women and pelvic pain by almost one fifth [1]. Low back and/or pelvic pain (LBPP) can have significant consequences on women's health and well-being, affecting their ability to walk, sleep, work and increasing their risk of depression [2–4].

Low back and pelvic pain are frequently considered together due to pregnant women's inability to distinguish between the two and the limited clinical tests available for health professionals to distinguish between them [5]. Currently, there is no clinical guideline for managing the problem and this has led to pregnant women using a wide range of treatment strategies, some of which may pose health risks to the fetus. A recent survey indicated that most women with pregnancy-LBPP use pain medications much of which is self-prescribed [6]. This is concerning particularly as pregnant women are recommended to avoid pain medications where possible and advised only to use medications under health professional supervision. In this survey it was revealed that opiates were among the most frequently used pain medications for pregnancy-LBPP, even though these drugs have been shown to have specific risks to the health of the mother such as dependence as well as increasing the risk of spina bifida for the baby [7,8]. These findings suggest the need for more research into potential non-pharmacological management strategies for pregnancy -LBPP.

Complementary and Alternative Medicine (CAM) is popular with pregnant women for managing a range of pregnancy ailments including LBPP. Pregnant women report various reasons for making their decision to use CAM these include; a desire to increase control over the child bearing experience and the belief that these treatments offer a safer alternative to pharmacological treatments [9,10]. Pregnant women's belief in these treatments is evident in the fact that the majority of CAM is self-funded with only a few maternity hospitals offering such provisions. There are many forms of CAM which pregnant women chose to use, popular choices include osteopathy, chiropractic and reflexology [6]. Despite the popularity of CAM and its use for pregnancy LBPP, research into the use of CAM for managing pregnancy-LBPP is restricted. A recent

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systematic review on CAM in the management of pregnancy- LBPP found limited evidence to support CAM use for this pregnancy complaint, due to lack of available studies in the area, studies with small sample sizes and other methodological issues [11]. This review identified a small number of studies using acupuncture, osteopathy and chiropractic treatments but none on reflexology.

Reflexology is a CAM therapy which can be defined as:

"The use of a sophisticated system of touch, usually on the feet … ..in which the area being massaged is thought to correspond to a map of the whole body," [12].

Despite the fact that reflexology has not been investigated for managing pregnancy LBPP it has been reported to be a popular choice of CAM for pregnant women. Further to this, of the few maternity hospitals in the United Kingdom which offer CAM treatments for pregnancy complaints reflexology is one of the most frequently provided treatments [6,13].

Furthermore, there is evidence of effectiveness for reflexology for managing non-specific low back pain (LBP) [14,15]. A pilot RCT of 15 adults, with LBP randomised to reflexology or sham reflexology found a median reduction of 1.9 cm on the pain VAS in the reflexology group compared to an increase of 0.1 cm in the sham group at the end of the intervention [14]. In a double blind RCT randomising 50 female and male nurses with LBP to a reflexology or non-specific massage intervention found that those in the reflexology group had a significantly higher reduction in the intensity of their pain compared to those in the non-specific massage group [15].

The evidence of effectiveness for reflexology in managing non-specific LBP, its non-pharmacological nature combined with the popularity of this treatment in the pregnant population indicated potential merit in researching this treatment for pregnancy- LBPP.

Therefore, this study set out to determine if it was possible to conduct an RCT investigating the effectiveness of reflexology as an addition to usual care for pregnancy LBPP. The study objectives were to investigate recruitment, compliance and retention rates along with the logistics of providing the interventions in a maternity setting and the sensitivity of the outcomes measures (OM's) to detect changes.

2. Materials and methods

2.1. Inclusion/exclusion criteria

Ethical approval was received from the Office of Research Ethics Northern Ireland in July 2012 (reference number 12/NI/0052). Table 1 shows study inclusion and exclusion criteria (next page).

2.2. Recruitment

Women were recruited from ante-natal clinics in the Ulster Maternity Unit, in Northern Ireland between July 2012 and September 2013 which has an annual birth rate of approximately 4000. Women meeting the inclusion criteria were identified by the midwife, at 20–22 weeks gestation when they attended for a foetal anomaly scan. The LBPP inclusion criterion was applied later as participation didn't begin until a later gestation. Therefore, women were invited to take part in the RCT at 20–22 weeks irrespective of whether they had LBPP at this time point or not. Inviting women even if they did not have LBPP was seen as an important way to ensure that all eligible women could participate in the study, given that it was possible for women to develop LBPP between the initial invitation to participate (20–22 weeks) and active participation in the RCT (26–29weeks). Only inviting women who had LBPP at 20–22weeks could have severely reduced recruitment to this study and given that the average number of week's gestation at the time of onset of pregnancy-LBPP has been reported to be 22 weeks, many women may not have been experiencing LBPP at 20–22 weeks when they were initially invited to participate in the RCT but may have developed this pain later in their pregnancy [16].

At the initial recruitment point women were provided with a verbal overview, patient information sheet and consent form by the researcher. Interested women contacted the researcher before 29 weeks gestation and were screened for eligibility over the telephone by the researcher.

2.3. Randomisation

At 26–29 weeks gestation women attended the hospital for their first study appointment, completing baseline outcome measures (OM's), a paper-based physiotherapy questionnaire, and urinalysis. Before randomisation participants indicated expectations of helpfulness for reflexology and footbaths for reducing pregnancy-LBPP. Women were then given a sequentially, numbered opaque sealed, envelope containing details of their group allocation. The randomization schedule was drawn up using computer generated block randomization before study commencement by an independent statistician. To conceal the intervention under investigation the research study was referred to as "The CAM in Pregnancy Trial".

Women in the study continued to receive the usual care for pregnancy-LBPP provided within the maternity unit. Usual care participants received no additional intervention during the study; however they were offered a free reflexology treatment after the study period.

Table 1
RCT inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
First time pregnant women	Women pregnant with more than one baby
≥18 years of age	Smokers
Presence of low back pain and/or pelvic pain (assessed prior to active participation)	Women with neurological diseases
26-29 weeks gestation	Deep Vein Thrombosis (DVT) sufferers
Able to understand written and verbal English	Fungal foot infections or verrucae
	Currently using CAM therapies
	Placenta Previa Grade 3 or 4
	Already participating in a research study
	Any serious spinal pathology e.g. cancer, Cauda Equina, infection in the spine?
	Previous road traffic accident
	Previous surgery to the hip, back or pelvic region
	Inflammatory arthritis
	Diabetes/Gestational diabetes
	Cardiac related problems
	Women whom the midwife deems unable to participate