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A pilot randomised controlled trial exploring the effects of antenatal reflexology on labour outcomes

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Objective: to investigate the effects of antenatal reflexology on labour outcomes. Design: secondary analysis of a pilot three-armed randomised controlled trial conducted between July 2012 and September 2013. Setting: a large UK inner city hospital maternity department. Participants: ninety primiparous women with a singleton pregnancy experiencing low back and / or pelvic girdle pain. Interventions: six weekly 30-minute reflexology treatments compared to sham (footbath) treatments or usual Low back pain antenatal care only. Pelvic girdle pain Measurements: labour outcome data including labour onset, duration of the second stage of labour, epidural Clinical Trial and Entonox usage, and mode of delivery. Participant feedback was collected prior to each treatment. Findings: labour outcomes were collected for 61 women (95.3%) who completed the study. The second stage of labour duration data, available for 42 women (62.5%) who had vaginal births, showed a mean reduction of 44 minutes in the reflexology group (73.56 minutes; SD= 53.78) compared to the usual care (117.92 minutes; SD=56.15) (p < 0.05) and footbath groups (117.4 minutes; SD=68.54) (p=0.08). No adverse effects were reported. Key conclusions: in this trial antenatal reflexology reduced labour duration for primiparous women who had experienced low back and/ or pelvic girdle pain during their pregnancy, compared with usual care and footbaths Implications for practice: reflexology is suitable for use during pregnancy, is safe and enjoyable and may reduce labour duration. Midwives may wish to recommend reflexology to promote normal childbirth and facilitate women centred care. Trial registration: this trial was listed with the International Standard Randomised Controlled Trial Number Register (ISRCTN26607527).

1. Introduction

The National Institute of Health and Care Excellence (NICE) (2016) states, that from the start of the second stage of labour, nulliparous women should be expected to give birth within three hours, and within two hours for multiparous women. If labour has not progressed adequately within one hour for primiparous women or within 30 minutes for multiparas, labour is diagnosed as delayed and should be

referred to an obstetrician for a possible instrumental delivery or caesarean section (NICE, 2016). Cheng et al. (2014) examined labour duration in a cohort of 42,262 women and reported a second stage of labour duration of 197 minutes for nulliparous women and 81 minutes for multiparous mothers. The effect on labour duration in response to intra-natal reflexology has been investigated by several authors. However, labour is a highly emotional and dynamic situation and may not be an ideal time for reflexology sessions to take place for the

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labouring women, health care professionals, or reflexologists. Most maternity complementary and alternative medicine (CAM) research has focused on intrapartum use with few studies investigating birth outcomes for antenatal use or employing a randomised controlled trial design (Mollart et al., 2015; Steel et al., 2015). Therefore, more research into the effects of reflexology during pregnancy, and the subsequent effect on labour, is worthy of investigation.

1.1. Background

Reflexology is a specialist massage whereby controlled pressure is applied to specific points, mainly on the feet. Known as the reflexes, each point is believed to correspond to particular structures or organs of the body (Poole et al., 2007). By applying pressure to the reflexes practitioners aim to promote homeostasis and, as a result, restore and maintain physiological and psychological health and wellbeing (McVicar et al., 2007; Poole et al., 2007; Özdemir et al., 2013). To date minimal research has been carried out investigating its use during pregnancy. Concerns regarding the safety to mother and child, particularly during early gestation, appear to be a key factor (Tiran, 2006; Wang et al., 2008). Indeed, NICE (2017) recommends that pregnant women should be informed that few CAM therapies have been established as being safe and effective during pregnancy, therefore, they, should not consider them without risks and use them as little as possible during pregnancy. However, the guidance goes on to say that women's decisions should be respected, even when contrary to the views of the healthcare professional (NICE, 2017). Kalder et al. (2011) reported that the pregnant women in their study were not concerned about adverse effects and perceived reflexology to be beneficial to themselves and to their unborn baby. Anecdotal evidence suggests that reflexology may be useful for encouraging the onset of labour, and shortening the duration of labour. In fact, it is recommended and used for this purpose by midwives in the UK (Motha and McGrath, 1993; McNeill et al., 2006; Tiran, 2006).

In a randomised controlled trial (RCT) involving 120 nulliparous women Dolatian et al. (2011) compared one 40-minute reflexology treatment during active labour with emotional support and usual care and found a significant reduction in mean labour duration in favour of the intervention group $(25.18 \pm \text{SD}=17.24 \text{ minutes}$ for reflexology; $47.63 \pm \text{SD}=2.087 \text{ minutes}$ for emotional support and $55.63 \pm$ SD=27.29 minutes for usual care). Moghimi-Hanjani et al. (2015) also reported a reduction in second stage of labour duration using a similar protocol involving 80 nulliparous participants in a two-armed RCT.

However, in an RCT involving 88 nulliparous participants, mean labour duration was not significantly reduced following two, one-hour reflexology treatments during active labour $(40.54 \pm$ SD=12.49 minutes), compared usual $(43.63 \pm$ to care SD=14.79 minutes) (Valiani et al., 2010). However, it is important to note that the control group participants in this study received oxytocin during the active phase of labour which may have shortened labour duration in this group, leading to no significant difference between the intervention and control groups. Research by Mirzaei et al. (2010) and Jenabi et al. (2012) reported no difference in duration of labour between usual care and reflexology groups. In their studies each involving 70 nulliparous women in active labour, they compared one 20-minute and one 30-minute reflexology treatment focused on stimulating the uterus reflex, with a sham reflexology treatment to another area of the foot. However, as noted by Witt and Schützler (2013), when comparing active CAM treatments with sham treatments the placebo effect of the sham may lead to positive beneficial health effects, thus, leading to small, non-significant differences in effect size.

Two studies have investigated the effect of antenatal reflexology on the duration of the second stage of labour. In a cohort study with no control group, the average labour duration was 16 minutes for 37 women (58%) (Motha and McGrath,1993). A retrospective study found no difference between reflexology (n=50) and control (n=100) participants for labour duration (mean=8 hours 46 minutes \pm SD=3 hours 47 minutes) (McNeill et al., 2006). However, variations in the number and timing of treatments and the small sample sizes limit the applicability of the findings.

Information of treatment routines were reported by three authors (Valiani et al., 2010; Dolatian et al., 2011; Moghimi-Hanjani et al., 2015). Each author stated that they first performed massage on the feet followed by a specific reflexology routine. Dolatian et al. (2011) and Moghimi-Hanjani et al. (2015) reported focusing specifically on the pituitary gland, solar plexus and reproductive organs. However, Valiani et al. (2010) provided a detailed routine consisting of general reflexology and stimulation of specific reflex points for labour pain. Dolatian et al. (2011) was the only author to provide a foot map indicating reflex points stimulated. Details about reflex points stimulated, duration of treatment or setting in which it took place may have had a profound effect on the treatment benefits and expectations experienced by women and the overall treatment outcomes. Such information is important to compare findings between studies and develop effective reflexology protocols based on patient requirements.

No adverse events were reported for any of the above studies with three stating that there were no negative effects either during labour or pregnancy (McNeill et al., 2006; Dolatian et al., 2011; Moghimi-Hanjani et al., 2015). However, the limited evidence available indicates that reflexology received antenatally may influence labour and birth outcomes and, therefore, there is a need to investigate how pregnant and labouring women respond following reflexology received during pregnancy.

1.2. Aims

The aim of this part of the study was to test how reflexology affected labour outcomes in a sample of primiparous women suffering from pregnancy related low back and/ or pelvic girdle pain who had experienced a six-week reflexology or sham (footbath) intervention added to usual antenatal care in the third trimester of their pregnancy, compared with women who received usual antenatal care alone.

2. Study design and methods

This pilot study was registered with the International Standard Randomised Controlled Trial Registry (ISRCTN26607527). Women were recruited from the maternity outpatient unit of a large inner city hospital maternity unit between July 2012 and September 2013, with all follow up data collected by February 2014. This secondary analysis was derived from a larger pilot RCT known as 'The CAM (Complementary and Alternative Medicine) in Pregnancy Study' and included pregnant, primiparous women with a singleton pregnancy experiencing pregnancy related low back and / or pelvic girdle pain (LBPGP). It involved a three-armed pilot randomised controlled design to test the proposed methodology for delivering 30 minutes of reflexology or a 30-minute footbath, plus usual antenatal care, and collection of relevant outcomes. The primary aim was to collect information regarding feasibility and outcomes associated with providing reflexology to manage LBPGP during pregnancy. The findings have been reported in an earlier publication (Close et al., 2015; Close et al., 2016).

2.1. Participants

The majority of the exclusion criteria were related to the primary focus of the RCT which was to investigate LBPGP. Therefore, first time pregnant women only were recruited to control for any previous experiences of LBPGP during pregnancy. Women carrying more than one baby were excluded as there is some evidence that such women may be at higher risk of developing LBPGP (Mens et al., 1996). Smokers were also excluded as smoking can affect salivary analysis which was carried out as part of biochemical analysis conducted during Download English Version:

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