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Massage or music for pain relief in labour: A pilot randomised placebo controlled trial

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Abstract

Research on massage therapy for maternal pain and anxiety in labour is currently limited to four small trials. Each used different massage techniques, at different frequencies and durations, and relaxation techniques were included in three trials. Given the need to investigate massage interventions that complement maternal neurophysiological adaptations to labour and birth pain(s), we designed a pilot randomised controlled trial (RCT) to test the effects of a massage programme practised during physiological changes in pain threshold, from late pregnancy to birth, on women's reported pain, measured by a visual analogue scale (VAS) at 90 min following birth. To control for the potential bias of the possible effects of support offered within preparation for the intervention group, the study included 3 arms – intervention (massage programme with relaxation techniques), placebo (music with relaxation techniques) and control (usual care). The placebo offered a non-pharmacological coping strategy, to ensure that use of massage was the only difference between intervention and placebo groups. There was a trend towards slightly lower mean pain scores in the intervention group but these differences were not statistically significant. No differences were found in use of pharmacological analgesia, need for augmentation or mode of delivery. There was a trend towards more positive views of labour preparedness and sense of control in the intervention and placebo groups, compared with the control group. These findings suggest that regular massage with relaxation techniques from late pregnancy to birth is an acceptable coping strategy that merits a large trial with sufficient power to detect differences in reported pain as a primary outcome measure.
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Keywords: Massage; Self-reported labour pain; Pharmacological analgesia; Birth outcomes

1. Introduction

Little evidence is available on complementary therapies for pain relief in labour, although research has grown on the possible modes of action of non-pharmacological treatments, for different types of pain (Uvnas-Moberg et al., 1993; Lund et al., 2002; Ramnero et al., 2002; Yang et al., 2006; Chao et al., 2007; Maeda et al., 2007; Hantoushzadeh et al., 2007). To-date, adequate trials have been conducted only on acupuncture and hypnosis for labour and birth pain(s); massage trials have not been sufficiently large or well-designed to provide reliable evidence (Smith et al., 2006; Hantoushzadeh et al., 2007).

Four trials have been conducted on massage in labour (Field et al., 1997; Chang et al., 2002; Yildirim and Sahin, 2004; Khodakarami et al., 2006). The first involved 28 women randomly assigned to coaching in relaxation

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breathing techniques alone, or with massage, in a US hospital (Field et al., 1997). The intervention group received 20 min of head, shoulder/back, hand and foot massage, hourly for 5 h, from the latent phase of labour. Outcomes included reduced anxiety, depressed mood and pain, length of labour and postnatal depression.

The second compared 30 women randomly allocated to 60 min massage with relaxation breathing techniques, in the latent, active and transitional phases of labour, with 30 women assigned to usual hospital care, in Taiwan (Chang et al., 2002). Massage included abdominal effleurage, sacral pressure, shoulder and back kneading performed for 30 min by the primary researcher and repeated for 30 min by the partner. Outcomes included significantly lower pain measured by nurse-rated present behavioural intensity scale and lower anxiety.

The third compared 20 mothers assigned non randomly to massage and relaxation breathing techniques performed by a nurse, with 20 women assigned to routine monitoring, in Istanbul (Yildirim and Sahin, 2004). The intervention used upper/lower back massage, self administered abdominal massage and continuous nursing support. Pain perception measured by a visual analogue scale (VAS) was significantly lower. Mothers also reported lower levels of fear and anxiety, and more positive birth experiences.

The fourth compared 30 women randomly allocated to back/limb massage with 30 women allocated to usual hospital care, in Tehran (Khodakarami et al., 2006). The intervention was undertaken by the attending midwife and pain was measured by a VAS. Preliminary findings included shorter labours, less medical interventions, reduced pain perception and use of pharmacological analgesia.

Methodological problems with existing trials include heterogeneous treatments and variable inclusion of relaxation breathing techniques; inadequate reporting of training and experience of professionals undertaking massage and levels of social support. Information on social support is essential for massage interventions in labour, since the presence of a trusted companion reduces pharmacological analgesia and obstetric interventions (Hodnett et al., 2003).

To improve the quality and replicability of research evidence, we designed a pilot RCT to test the feasibility and procedures for a larger trial, to investigate the effects of a massage programme with relaxation techniques, practised by women with their birth companions, from 36 weeks' and assisted by trained carers, following hospital admission for labour and birth.

2. Methods

In preparation for the present trial a feasibility study was undertaken on 35 women, to produce a detailed specification of the massage programme and test the procedures, processes, tools and measurements for the intervention arm of a future trial (Goldstone, 2000). Information was gathered relating to couples' responses to the programme during pregnancy and labour (McNabb et al., 2006). The feasibility study also provided a description of the environmental conditions on the labour ward, staff preparation and support needs, to run a successful trial (Haines and Kimber, 2005a,b).

This preliminary study highlighted the need to conduct a pilot trial, including three arms, to control for possible confounders such as social support, information and the active role of the partner. A pilot study was also required to fully test the comparison intervention in the third arm and the feasibility of recruiting women to be randomised to one of three options. We also needed to improve information on which our power calculations could be based, since existing information from the literature was limited.

Permission was obtained from Oxfordshire Research Ethics Committee to conduct a pilot RCT at the Horton Maternity Unit, Banbury; a consultant unit with an annual birth rate of 1560. The study commenced in December 2004 and recruitment finished in January 2006.

2.1. Population, sample and recruitment

Participants were women booked for care and birth at the unit during the study period. The exclusion criteria were: planned elective caesarean section, multiple pregnancy, existing medical problems that precluded the use of massage, previous use of the massage programme or a strong preference for a particular form of pain relief. Women who did not speak fluent English and those not intending to have a birth companion were also excluded.

The numbers for the trial were set at a pragmatic level and we anticipated that these would not be sufficient to show significant differences, unless the differences observed were far greater than anticipated from earlier research using the VAS to assess levels of labour pain (Capogna et al., 1996). It was calculated that 30 women in each arm would be sufficient to detect a reduction in VAS scores from 8.5 to 7.5 (SD 2) with 80% power and 5% significance (90 women in total).

Women received written information about the trial from sonographers at 20 weeks gestation to coincide with their anomaly scan. The trial was discussed again at 28 weeks by the midwife during a routine antenatal appointment. Between 30 and 35 weeks, the research midwife arranged an appointment to discuss the trial in detail for couples who were eligible and interested. At this appointment, women and their chosen birth partners received further information and had an opportunity to ask questions. Since blinding to such visibly

different options was impossible, information offered to women focused on complementary strategies for coping with pain. Lack of reliable evidence about what helps women to cope with labour was emphasised. None of the information stated or implied superiority of one strategy or form of care over another.

Once couples agreed to participate, the woman signed a consent form; filled out the initial Cambridge Birth Worry Scale and was then randomised (Green et al., 1990). Women were randomised to study groups by a computer based randomisation program supplied by the National Perinatal Epidemiology Unit (NPEU), University of Oxford. The randomisation program used minimisation to ensure balance between the groups for nulliparous and multiparous women. Following random allocation, the appropriate class was organised for those allocated to the intervention or placebo arm of the trial.

Women allocated to the intervention group (massage programme with relaxation techniques) attended a two and half hour class between 35 and 37 weeks gestation with their chosen birth companion. Massage techniques were taught by the midwife/therapist. The birth partner learnt to perform slow rhythmic long stroke massage movements using the flats of the hands. These strokes were combined with slow rhythmic breathing and performed primarily on the lower back and also the upper and lower limbs. The massaging hands move upwards during inspiration and downwards during expiration. The woman and her birth partner were taught to synchronise massage strokes with controlled breathing. The visualisation/mind mapping component was taught, by asking the woman to visualise/focus on the massaging hands. Participants were asked to practise the programme at least three evenings a week, for about 30–45 min, until 39 weeks and then a combination of techniques every evening, until hospital admission for labour/induction.

The placebo group (music with relaxation techniques) was included to control for the potential bias of the possible effects of the support offered within the antenatal preparation for the intervention group. The placebo offered an alternative non-pharmacological coping strategy, to ensure that the only difference between the intervention and placebo groups was the use of massage. The placebo class taught breathing and visualisation techniques, and music instead of massage. The woman and her birth partner were encouraged to practise a slow breathing rhythm and visualisation techniques were taken from readings in a well known book (Broncher, 1992). The woman and her birth partner chose their favourite music.

Women allocated to the control group were given the option and encouraged to attend the usual antenatal preparation classes currently available at the trial site. Women in the intervention and placebo groups were also able to attend the usual antenatal classes. For the duration of the trial there were three two and half hour classes, which included an antenatal and labour session incorporating information about labour, methods of pain relief and types of delivery.

2.2. Staff training

A self-selected group of 18 midwives were trained to care for women in the three arms of the trial. Training included successful completion of the accredited massage course designed to enable midwives and maternity care assistants to learn the fundamentals of massage and touch, develop a basic understanding of neuroendocrine responses to massage in late pregnancy, labour and birth, and the importance of a physical environment conducive to massage. They learnt the techniques of this structured massage programme designed to reduce maternal pain and anxiety during late pregnancy, labour and birth and were able to perform the intervention in a safe and effective manner.

Midwives were aware of the need to provide comparable care to women in all other respects and to adopt an open and positive approach to labour support in all three groups. Research awareness and information sessions on the needs and expectations of women in the placebo arm of the trial were given. Information was also given to midwives and care assistants about the various visualisation readings the couples had been given and were taught how to support the couples in this group. The key words and music used by couples at home to aid relaxation were also used in labour.

The trained midwives attended one pre-trial study day in September 2004. Time was taken to discuss the trial protocol and ensure that midwives felt equally competent to support couples in all arms of the trial. The rota for delivery suite was organised so that these midwives provided care for all women in the trial during labour. From December 2004, information about the trial was disseminated to all remaining staff working within the maternity unit, community clinics and GP surgeries through posters, display boards and written information sheets.

Throughout the trial, regular meetings were held to highlight issues and respond to ongoing queries from midwives and other members of staff. As new doctors arrived, meetings were held to familiarise them with the trial. The research midwife was available so that midwives could ask for updates when the unit was quiet. She also attended meetings for senior midwives, maternity care assistants and medical staff to provide updates. Regular sessions were undertaken to update techniques specific to the intervention and placebo arms.

2.3. Outcome measures

The primary outcome measure was self-reported labour pain, using the Visual Analogue Scale (VAS), a

horizontal, unmarked 100 mm scale widely validated for use within 48 h of birth, to assess overall labour pain (Capogna et al., 1996; Noble et al., 2005). During the feasibility study, many women made a sharp distinction between labour and birth pain. For the current study, therefore, participants were asked to use two separate VAS scales, to record labour and birth pain(s), around 90 min following birth, before transfer from labour care. During this time-frame all mothers and babies, regardless of mode of birth, remained in skin contact in a quiet, dimly lit room with minimal disturbance. The secondary outcomes were the use of pharmacological analgesia, obstetric interventions, birth outcomes and women's birth related worries based on the Cambridge Birth Worry Scale, maternal satisfaction and sense of control (Labour Agentry Scale). (Green et al., 1990; Hodnett and Simmons-Tropea, 1987).

A customized version of the Cambridge Birth Worry Scale was completed immediately prior to randomisation (baseline measure) and repeated with the antenatal questionnaire sent to women and their partners at 38 weeks gestation. This measure was included to assess whether the intervention had any antenatal effects on women's worry levels about birth. The short form of the Labour Agentry Scale was included in the postnatal questionnaire sent to women and their partners at 6 weeks following birth (Hodnett and Simmons-Tropea, 1987). A specifically designed data collection form recording secondary outcomes from labour records was completed by the midwife providing labour care. Additional information was provided by the midwife, indicating the degree to which participants complied with the allocated techniques during labour. Midwives collecting these data were not blinded to group allocation but those who elected to participate felt able to do this because they did not have strong positive or negative views about the intervention and wished to see good quality evidence for future care.

All forms were tested and found effective and acceptable, with good response rates in the feasibility study. Ante- and postnatal self-completion questionnaires were used to report compliance with and response to the allocated intervention, expectations of and satisfaction with birth.

2.4. Statistical analysis

All quantitative data were entered onto a specifically designed access database, with independent double entry. Any discrepancies found in data entry were checked against the original records and reviewed by a research midwife who was independent of the study. The corrected data were then transferred to SPSS for analysis. For continuous measures, means and standard deviations were produced and compared using *t*-tests. For categorical measures, frequencies were produced and compared using chi squared. Data are presented as relative risks (RR) with 95% confidence interval (CI) for discrete data and mean difference with 95%CI for continuous data. Responses to open questions on the ante- and postnatal questionnaires were analysed using content analysis. These are not reported here, unless specifically referring to feasibility of the study, compliance with allocated interventions or appropriateness of the measures.

3. Results

A total of 90 women were randomised, 30 into each group (Fig. 1). The reasons women were not recruited are described in Fig. 1. Two women withdrew from the trial. Both were in the placebo group. One withdrew following randomisation and did not attend the class; one withdrew in early labour.

Table 1 shows that women randomised to the three arms of the trial were balanced in terms of age, parity, ethnicity, education and housing.

The response rate to the antenatal questionnaires was 90% in the control group; 93% in the placebo group and 96% in the intervention group. (VASa) was completed for 96% in the control group; 93% in the placebo and intervention groups. The postnatal questionnaire was completed by 93% of women in the control group; 86.6% in the placebo group and 93% in the intervention group (Fig. 1).

Compliance with the allocated strategies during pregnancy and labour is summarised in Table 2. In the intervention group, one woman had an elective caesarean section and one woman gave birth prior to the class. The remaining 28 practised as requested. In the placebo group 28 women practised as requested, one woman withdrew from the study and one woman gave birth prior to the class. In the control group, 13 women reported using some form of alternative coping/relaxation technique antenatally and during labour, and seven practised this with their birth partner. This finding suggests that a certain proportion of women were already planning to use alternative techniques such as massage, music or visualisation, or that recruitment to the trial may have raised their awareness and use of such techniques.

Table 3 gives the results for the primary outcomes. There were no significant differences between either the intervention or placebo group compared with the control group. The variability of scores to describe pain while giving birth (VASb) was very wide, since some women reported no pain or very little pain at this point, thus reducing the confidence with which any differences could be observed.

Table 4 shows the frequencies for all methods of pain relief used, apart from the allocated techniques and the

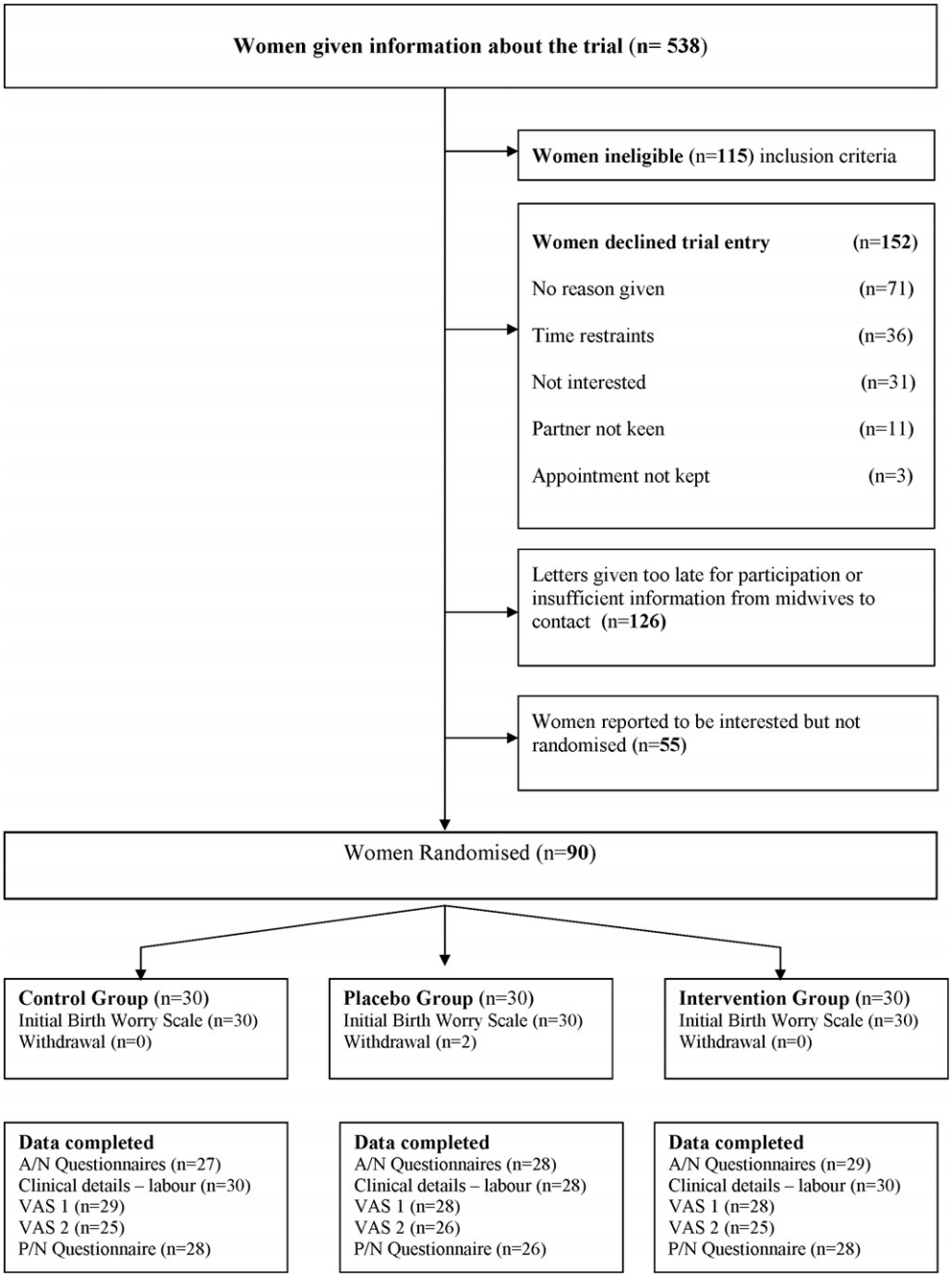

Fig. 1. Flow diagram of progress through phases of the randomised trial.

frequency of use of 'any pharmacological method of pain relief 'versus none in each group. There were no significant differences in the use of any form of pharmacological pain relief, apart from a higher use of meptid in the control group compared with the placebo group, although this is based on very small numbers.

Table 5 shows the frequencies for all interventions during labour and birth and the secondary outcome measures. None of these differed significantly. The intervention and placebo groups had longer labours but these comparisons are based on small numbers, since emergency and elective caesarean sections were excluded.

Table 6 shows women's general levels of worry, satisfaction and sense of control (Labour Agentry) as reported on the six-week postnatal questionnaire. There was a trend towards more positive views of labour, preparedness and sense of control in the intervention and placebo groups when compared with the control group with a significant increase in sense of control in the intervention group compared with control group (Labour Agentry Scale: music versus usual care mean difference

Table 1
Characteristics of women at trial entry

Characteristics	Control	Placebo	Intervention
Mean maternal age (years), range	30, 19-41	28.8, 18–38	30, 18–4
Nulliparous	21	21	21
Ethnicity			
White	22	27	28
Asian	1	0	1
African–Caribbean	4	0	0
Housing and education			
Home owners	19	21	22
Rented	6	5	4
Other	2	2	3
Degree level or above	13	12	13
A levels	8	6	9
GCSEs	5	10	7
Mean gestation at trial entry, SD (weeks)	33.0 (1.3)	33.1 (1.5)	32.9 (1.2)

−6.1 (95%CI −11.9 to −0.3) and massage versus usual care −6.1 (95%CI −11.6 to −0.6)). Worry levels at baseline were the same with a slight upward shift in worry levels at 38 weeks gestation in all groups. This suggests that changes in worry levels following randomisation or antenatal preparation did not distinguish the three groups and are unlikely to have influenced labour outcomes.

4. Discussion

Considerable effort was required to train staff and create a labour ward environment that was conducive to putting this simple intervention into practice consistently (Goldstone, 2000; Haines and Kimber, 2005a,b). Once this work had been done, it was possible to recruit women to this trial and deliver the intervention effectively.

The inclusion of the placebo group was felt to be important in this pilot trial, as the additional social support offered by the specific trial class, in late pregnancy and active involvement of a birthing partner in the intervention may have resulted in better outcomes. If differences had been observed, it could have been argued that these elements of the intervention, rather than the massage programme were responsible. However, very similar labour and birth pain scores were found between the control group and the placebo group.

Music was selected for the placebo group because it provided an auditory intervention that had been taught to couples by midwives within the unit. This ensured that both treatments were equally credible and acceptable to participants. However, the appropriateness of music as a placebo is open to criticism. Some studies have found that sedative music reduces the sensation and distress of labour pain and sedative music has also been found to reduce pain and anxiety in postoperative patients (Geden et al., 1989; Phumdoung and Good, 2003; Voss et al., 2004). In addition to its possible analgesic effects, music does not blind participants in any way to their group assignment (Ezzo, 2007). Nonetheless, for this particular massage intervention, it was necessary to control for the additional social support involved in the intervention, because social support during labour has been shown to reduce the need for pharmacological analgesia (Hodnett et al., 2003). Therefore,

Table 2
Use of antenatal and intrapartum relaxation techniques *n* (%)

Techniques	Frequency	Control	Placebo	Intervention
Number of practice sessions antenatally at home	Less than once a week	n/a	1 (03.3)	0
	1–2 times a week		12 (40.0)	14 (46.7)
	3 + times a week		14 (46.7)	14 (46.7)
	No response		3 (10.0)	2 (6.7)
Length of allocated antenatal session	Less than 10 min	n/a	4 (13.3)	0
	10–30 min		19 (63.3)	22 (43.3)
	Greater than 30 min		4 (13.3)	6 (20.0)
	No response		3 (10.0)	2 (6.7)
Control group use of alternative techniques?	Yes	13 (43.3)	n/a	n/a
	No	17 (56.7)		
Control group practised with birth partner?	Yes	7 (23.3)	n/a	n/a
	No	23 (76.7)		
Plan to use them in labour?	Yes	n/a	28 (93.3)	27 (90.0)
	No		0	0
	No response		2 (6.7)	3 (10.0)
Able to use them in labour?	Yes	n/a	15 (50.0)	20 (66.7)
	Only partly		7 (23.3)	5 (16.7)
	No		2 (6.7)	1 (3.3)
	No response		6 (20.0)	4 (13.3)
Which techniques did you use in labour? (tick all that apply)	Controlled breathing	18 (60.0)	22 (73.3)	21 (70.0)
	Visualisation	2 (6.7)	17 (56.7)	10 (33.3)
	Music	5 (16.7)	19 (63.3)	2 (6.7)
	Massage	6 (20.0)	4 (13.3)	25 (83.3)
	Other	3 (10.0)	3 (10.0)	0
	None	6 (20.0)	1 (3.3)	1 (3.3)
Duration of use of relaxation techniques in labour	Only early at home	n/a	1 (3.3)	2 (6.7)
	Only early at home and hospital		6 (20.0)	5 (16.7)
	For much of 1st stage		8 (26.7)	6 (20.0)
	Right through to 2nd stage		5 (16.7)	7 (23.3)
	Through some of 2nd stage		3 (10.0)	5 (16.7)
	No response		7 (23.3)	5 (16.7)

n/a = not applicable.

Table 3
Primary outcome measure: visual analogue scores for labour and birth pain

	Control	Placebo	Mean difference (95%CI)	Intervention	Mean difference (95%CI)
VASa, pain in labour, mean score (SD)	75.2 (16.6) $n = 29$	74.6 (16.9) $n = 28$	−0.6 (−9.5 to 8.3)	68.9 (18.7) $n = 28$	−6.3 (−5.7 to 3.1)
VASb, pain at birth, mean score (SD)	65.0 (33.7) $n = 25$	63.3 (31.1) $n = 26$	−1.7 (−19.9 to 16.5)	50.6 (32.3) $n = 25$	−14.4 (−33.2. to 4.4)

Table 4
Use of pharmacological analgesia in first stage of labour *n* (%)

	Control $n = 30$	Placebo $n = 29$	Risk difference (95%CI)	Intervention $n = 30$	Risk difference (95%CI)
Entonox (%)	19 (63)	14 (48)	−15 (−38 to 10)	14 (43)	−17 (−39 to 8)
Meptid (%)[a]	8 (27)	1 (3)	−23 (−41 to −5)	4 (13)	−13 (−33 to 7)
Epidural (inc spinal) (%)[b]	8 (27)	10 (34)	8 (−15 to 30)	10 (33)	7 (−16 to 28)
Any pharmacological agent (%)	21 (70)	18 (62)	−8 (−30 to 16)	18 (60)	−10 (−32 to 14)

[a] Meptid 100–150 mg .
[b] Bupivicane 0.1% and fentanol 2 μg/ml.

Table 5
Labour and birth interventions and outcomes

	Control $n = 30$	Placebo $n = 29$	Risk or mean difference (95%CI)	Intervention $n = 30$	Risk or mean difference (95%CI)
Spontaneous labour onset (%)	22 (73)	22 (76)	3 (−19 to 24)	24 (80)	7 (−15 to 27)
Cervical dilation on admission mean (SD)	4.0 (3.0)	4.0 (2.8)	0 (−1.5 to 1.5)	3.7 (3.0)	−0.3 (−1.9 to 1.3)
Augmentation (%)	7 (23)	9 (31)	8 (−15 to 29)	8 (27)	3 (−18 to 25)
ARM (%)	5 (17)	2 (7)	−10 (−27 to 8)	2 (7)	−10 (−28 to 7)
Planned CS (%)	0	1 (3)	–	1 (3)	–
CS during labour (%)	7 (23)	3 (10)	−13 (−32 to 7)	5 (17)	−7 (−27 to 14)
Instrumental delivery (%)	6 (20)	7 (24)	4 (−17 to 25)	4 (13)	−7 (−26 to 13)
SVD (%)	17 (57)	18 (62)	5 (−19 to 29)	20 (67)	10 (−14 to 32)
Duration of labour (min)[a]	$N = 23$	$N = 25$		$N = 24$	
1st stage	332.0 (200.6)	396.2 (217.3)		404.9 (222.8)	
2nd stage	47.0 (46.7)	53.2 (55.0)		75.1 (55.5)	
3rd stage	9.7 (12.8)	10.4 (9.1)		14.2 (18.8)	
Total mean (SD)	388.7 (233.5)	459.8 (233.4)	71 (−64.7 to 206.9)	494.2 (255.3)	105.4 (−38.5 to 249.4)
Resuscitation (%)	3 (10)	0	–	0	–
Admission to neonatal unit (%)	1 (3)	1 (3)	0 (−14 to 14)	2 (7)	3 (−11 to 18)

[a] Numbers exclude women undergoing elective or emergency caesarean section.

we selected a technique that included all elements of the programme except massage.

The experience of trial participation may have beneficial effects, through enhancing levels of support and confidence. As a consequence, it is possible that outcomes for women in all three arms of the trial were improved, compared with women not in the trial. Comparisons with routine statistics for this unit suggest the outcomes for the women participating in the trial were not atypical except a slightly lower use of pharmacological pain relief. Work undertaken in preparation for the study, including a protocol for labour ward care for all women, which minimized external distractions and stimulation, and selective use of electronic fetal monitoring and other birth technologies formed the model of care for the trial. These environmental strategies may have reduced the potential for observing differences, as well as ensuring that the use of the massage programme was feasible.

While it is not possible to blind participants, whether professionals or 'patients', in studies of this type, considerable efforts were made to minimize possible biases. Only midwives and couples who expressed open views about the possible effects of different forms of pain relief in labour and about participating in research 'to see what helps' were included. While outcome measures were obtained by midwives providing care who could not be blinded to group allocation, the possibility of introducing bias was felt to be outweighed by the need to prevent women being disturbed by the presence of unknown researchers during and after labour. Midwives' reports indicated that the pilot study period was valuable for them to gain confidence with supporting the research process and the allocated techniques.

Table 6
Satisfaction, worry and labour agentry scores

Satisfaction (from postnatal questionnaire)		Control	Placebo	Intervention
Was labour/birth	Hard work but wonderful?	10	18	19
	OK in the end?	9	4	5
	Awful?	3	1	1
	Other?	6	3	3
	No response	2	4	2
How satisfied with care?	Very	18	22	22
	Some ways not others	10	4	6
	Not very	0	0	0
	No response	2	4	2
Looking back, how well prepared did you feel?	Well prepared	7	10	18
	Quite	16	12	8
	Not very	5	1	1
	Other	0	3	1
	No response	2	4	2
How do you feel you managed?	Very well	8	11	13
	Quite well	11	11	9
	Alright	3	0	4
	Not very well	5	2	1
	Not at all well	1	2	0
	No response	2	3	4
Worry scores[a]	Pre-randomisation	2 (1–2.8)	2 (1.5–2)	2 (1–3)
Median (IQR)	On ANQ (38 weeks)	2 (2–3)	2 (1–2.5)	2 (2–3)
Labour agentry scores[a] mean (SD)	Across all 10 items	33.6 (10.2)	27.5 (12)	27.5 (11.1)

Labour agentry scale: music versus usual care mean difference −6.1 (95%CI −11.9 to −0.3) and massage versus usual care −6.1 (95%CI −11.6 to −0.6).

[a] Lowest scores are most positive. Scoring conducted as per instructions of the originators of each scale.

This pilot trial was primarily designed to test feasibility and was not powered to test for differences in substantive outcome measures. As anticipated, no statistically significant differences were found in the primary or secondary measures. No significant differences were found on either VAS but the trend towards slightly lower mean scores in the intervention group suggests that an adequately powered study is justified to determine whether it is possible to reduce reported labour pain and use of pharmacological analgesia in women using this massage programme, compared to usual care. The data also suggest that alternative coping techniques may improve women's sense of control and satisfaction with childbirth. Sense of control in particular has been associated with positive psychological outcomes of birth. Both these areas have the potential to make a positive difference to supporting childbirth in the UK at a time of increasing worries about birth, and rising rates of obstetric intervention.

This pilot trial suggests that appropriate measures were used, given that the reliability and validity of the VAS for reporting labour pain have been shown in earlier research. The study also demonstrates the feasibility of conducting a larger trial. The analysis suggests that a two-arm pragmatic trial, comparing the massage programme with usual care would be justified. On the basis of VAS scores for labour pain, approximately 150 women in each arm of the trial would be sufficient to detect a reduction in VAS scores from 75 to 68 (with a standard deviation of 20) with 85% power and 5% significance. Such a trial could have considerable benefit for maternity care, in robustly testing a non-pharmacological intervention, which has demonstrated the potential to support women, birthing partners and midwives in coping with childbirth.

A two-arm pragmatic trial is not designed to determine the analgesic effects of the massage component of the programme. This would require a comparison between massage with relaxation techniques and relaxation techniques alone, practised by women and their birthing partners from 36 weeks gestation until birth. Current evidence on endogenous pain modulatory pathways that are activated by repeated massage for painful stimuli suggests that the analgesic effects of massage need to be studied using animal models (Uvnas-Moberg et al., 1993; Lund, 2000; Lund et al., 2002). The majority of recent trials on massage for labour and other forms of pain have been designed to test the effects of structured programmes of massage used in combination with other techniques (Field et al., 1997; Chang et al., 2002; Yildirim and Sahin, 2004; Ezzo, 2007). To improve the quality of evidence on massage interventions combined with relaxation techniques for labour and birth pain, our key task is to follow recent recommendations, to correct design flaws and methodological weakness in existing trials (Smith et al., 2006; Ezzo, 2007).

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