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Aromatherapy in childbirth: a pilot randomised controlled trial

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Objectives We aimed to determine the feasibility of conducting a randomised controlled trial (RCT) on the use of aromatherapy during labour as a care option that could improve maternal and neonatal outcomes.

Design RCT comparing aromatherapy with standard care during labour.

Setting District general maternity unit in Italy.

Sample Two hundred and fifty-one women randomised to aromatherapy and 262 controls.

Methods Participants randomly assigned to administration of selected essential oils during labour by midwives specifically trained in their use and modes of application.

Main outcome measures Intrapartum outcomes were the following: operative delivery, spontaneous delivery, first- and second-stage augmentation, pharmacological pain relief, artificial rupture of membranes, vaginal examinations, episiotomy, labour length, neonatal wellbeing (Apgar scores) and transfer to neonatal intensive care unit (NICU).

Results There were no significant differences for the following outcomes: caesarean section (relative risk [RR] 0.99, 95% CI: 0.70–1.41), ventouse (RR 1.5, 95% CI: 0.31–7.62), Kristeller manoeuvre (RR 0.97, 95% CI: 0.64–1.48), spontaneous vaginal delivery (RR 0.99, 95% CI: 0.75–1.3), first-stage augmentation (RR 1.01, 95% CI: 0.83–1.4) and second-stage augmentation (RR 1.18, 95% CI: 0.82–1.7). Significantly more babies born to control participants were transferred to NICU, 0 versus 6 (2%), $P = 0.017$. Pain perception was reduced in aromatherapy group for nulliparae. The study, however, was underpowered.

Conclusion This study demonstrated that it is possible to undertake an RCT using aromatherapy as an intervention to examine a range of intrapartum outcomes, and it provides useful information for future sample size calculations.

Keywords Aromatherapy, childbirth, complementary and alternative medicine, intrapartum, labour, midwifery.

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Introduction

Over the past decade, interest in complementary and alternative medicine (CAM) has escalated among healthcare professionals and the public worldwide.[1] The World Health Organization undertook a review of CAM use in developed and developing countries and noted that people in industrialised countries were using CAM as a means of disease prevention and health maintenance.[1]

Two national surveys in the USA reported the highest CAM uptake among women of reproductive age.[2,3] In nursing and midwifery, CAM is increasingly perceived as an integrated part of practice, rather than fringe.[4–7] Authors of a systematic review analysing a range of nonpharmacological labour pain relief methods, including CAM, discuss their appeal to women in childbirth as offering them a means of flexible comfort and control.[8] The attraction for midwives reflects a midwifery model in which they can employ CAM and other nonpharmacological methods to facilitate a woman to maximise her innate coping mechanisms in childbirth. Within this paradigm, pain in labour is viewed as a complex physiological phenomenon that encompasses psychological, emotional, spiritual and physical dimensions. This approach represents a shift from the medical model, which views labour pain simply as something to be eradicated.[9] Some nursing and midwifery education programmes incorporate CAM in their

curricula.[10–12] There is evidence that medical students also receive CAM education.[13] The Nursing and Midwifery Council includes the use of CAM in its *Guidelines for the Administration of Medicines*.[14]

A systematic review of the use of CAM for pain management in labour reported one aromatherapy randomised controlled trial (RCT).[15] This very small study of 22 women comparing one essential oil (EO) with another on maternal pain perception during labour failed to detect any significant difference for any outcome.[16]

The use of aromatherapy in labour was explored in an observational study undertaken in a district general maternity unit in the UK and involving a sample of 8053 participants.[17] All consenting women who presented in labour were eligible to participate, with the exception of those with multiple allergies or those in premature labour (<36/40 weeks of gestation). Irrespective of maternal parity or labour onset (spontaneous versus induced), women consistently reported aromatherapy as a helpful adjunct to their labour experience, and there was a lower epidural rate and opioid injection rate in the aromatherapy group.[18] Following completion of the study in 1998, aromatherapy became part of mainstream care in the unit, providing a care model that other hospitals have adopted. The large data set from this study provided the basis for the pilot RCT. This is the first RCT to examine the effects of aromatherapy on the incidence of intrapartum interventions and outcome. The purpose of this study was to compare the effect of aromatherapy on a range of intrapartum outcomes with standard care during labour.

Methods

This was a prospective RCT with two arms comparing aromatherapy administration in labour with standard care without aromatherapy. The study also included a preference arm. The rationale for this decision was two-fold: not to limit maternal choice and to enable the testing of preference effects.[19] Additional information was gathered in the form of a short questionnaire to elicit maternal and midwife feedbacks about receiving and administering aromatherapy. This paper reports on the results for the two randomised groups.

The study was conducted from 1 May to 31 December 2003 at San Gerardo Hospital, Milan, Italy (2800 births, 2003). Prior to the onset, researcher E.B. provided the midwives with oral and written information about the study's purpose and detailed instruction on completing the data form and the EOs under investigation—their chemical component outline, modes of application and safe storage. Additional preparation was provided to two midwives (V.Z. and D.P.) who volunteered to enter the information from the data forms onto a specially organised SPSS (SPSS Inc., Chicago, IL, USA) spreadsheet.

When they presented on delivery suite at San Gerardo Hospital, nulliparous and multiparous women entered the trial. An explanatory leaflet drafted by senior obstetrician, A.R. in collaboration with E.B., was distributed in advance to all antenatal clinic staff caring for women booked to deliver at San Gerardo Hospital. Woman gave informed consent to participate when in labour following discussion with their midwife, which was documented in their notes. Inclusion criteria comprised nulliparous and multiparous women with a gestation >36 completed weeks and singleton pregnancy with cephalic presentation. Exclusion criteria included <36 weeks of gestation, multiple pregnancy, breech presentation and women booked for elective caesarean section. Preterm gestation was excluded to reduce possible confounding factors (e.g. neonatal intensive care unit [NICU] admission). Multiple pregnancy and breech presentation were excluded because the incidence is low and delivery more likely to be by elective caesarean section.

On the labour ward, randomisation was accomplished by taking consecutively numbered, sealed, opaque envelopes that contained the allocation to either arm of the trial. Each envelope was identical in appearance and weight. The randomly generated computer sequence (1:1 ratio) was prepared before the trial started by statistician R.O. in Oxford and was only known to him. Thus, allocation concealment was assured to the point of opening the envelope. Blinding was obviously not possible.

For women randomised to receive aromatherapy, the decision as to which EO to use, why, together with mode(s) of application was reached through discussion between the midwife and woman. They could use one of the following five EOs: Roman chamomile (*Chamaemelum nobile*), clary sage (*Salvia sclarea*), frankincense (*Boswellia carteri*), lavender (*Lavandula augustifolium*) and mandarin (*Citrus reticulata*). Each EO used in the study had a certificate of analysis and gas chromatography prior to use to ensure that it was as free from contaminants as possible. Sweet almond (*Prunus amygdalus*) was provided as carrier oil for massage. All oils were purchased from a supplier in the UK. Aromatherapy was administered for one of the following reasons: to reduce fear, reduce anxiety, alleviate pain or to augment contractions. Our rationale was to evaluate the use of EOs as a means of facilitating the mechanism of labour, thereby reducing the potential rate of intrapartum interventions. Modes of application included acupressure points, taper, compress, footbath, massage or birthing pool. It was decided not to blend the EOs to reduce the possibility of allergic response, ease the administration process, as the midwives were not qualified aromatherapists, and facilitate unambiguous analyses. This resulted in each woman assigned aromatherapy receiving one EO.

To test the trial's hypothesis, data were collected on the following outcomes: spontaneous and induced labour onset, use of pharmacological and nonpharmacological (apart from aromatherapy) pain relief, spontaneous and artificial rupture

of membranes, number of vaginal examinations, labour augmentation commenced in either the first or second stage of labour using intravenous infusion of oxytocin, episiotomy and type of delivery. Additional information was collected for the subgroup of women who used aromatherapy to relieve pain. Women were asked to self-rate their level of pain immediately prior to receiving aromatherapy and 30 minutes afterwards using a 10-point Lickert scale. We could not collect comparable data for the control group due to the difficulty in assuring a matched control. Neonatal outcome data included Apgar scores at 1, 5 and 10 minutes and admission to the NICU. Data on associated adverse effects were also collected.

Ethical considerations

The midwives completed the data form contemporaneously as they cared for the women, and the information was entered onto an SPSS spreadsheet. Each woman was assigned an ID code, ensuring data set anonymity. The Research Ethics Committee at San Gerardo Hospital, University of Milan, Italy, approved the trial. Care for women randomised not to receive aromatherapy was the same apart from the intervention under investigation. Women could withdraw from the study at any point.

Statistics

Data from all randomised women were analysed by intention to treat. Data analyst was not blind to the group allocation. Descriptive statistics for type of delivery (Table 2), labour onset, membrane rupture, first- or second-stage augmentation and episiotomy (Table 3) were undertaken using chi-square and relative risk (RR) tests as appropriate. If the chi-square test was not valid—for instance in 2×2 tables with expected frequencies less than 5—the Fisher's exact test was employed. For example, in the case of 'ventouse' delivery, a Fisher's exact test was performed. Two-tailed *t* test was used to analyse continuous data. For example, a paired *t* test was performed to assess the pain level before and after receiving aromatherapy. *t* test was also used to assess difference between nulliparous and multiparous mothers in pain reduction after receiving aromatherapy. Statistical significance was defined as $P < 0.05$, with 95% confidence intervals. Data were analysed using SPSS 13.0.1.

Results

Five hundred and thirteen women were randomised, 251 received aromatherapy and 262 were controls. Five hundred and eleven women completed the trial as randomised, 249 (99%) for aromatherapy group and 262 (100%) controls. Two women declined the aromatherapy (Figure 1). Both arrived in advanced labour, so it may be assumed that time did not enable aromatherapy administration. We obtained 100% follow up.

At trial entry, maternal characteristics were similar (Table 1), and ethnicity proportions reflected the local population.

There were no differences in the type of delivery between the aromatherapy and control group, and each had the same high spontaneous vaginal birth proportion (89%) (Table 2). Likewise, there were no differences in intrapartum events (Table 3), apart from a slight, nonsignificant reduction in artificial rupture of membranes for the aromatherapy group (43%) compared with the controls (50%), RR = 0.87, 95% CI 0.73–1.03 ($P = 0.11$). The mean length of first and second stage of labour was the same for each group (Table 3), 217 minutes + 112 SD versus 216 minutes + 130 SD first-stage labour for aromatherapy and control groups, respectively, and 35 minutes + 26 SD versus 33 minutes + 23 SD second-stage labour for aromatherapy and controls, respectively.

Mean Apgar scores were not different for either group (Table 4) at 1, 5 and 10 minutes. There was, however, a significant reduction in NICU admission for infants of the aromatherapy group, of whom there were none compared with six (2%) of the controls; '*' indicates significance at 5% level using Fisher's exact test.

The EO most frequently used was lavender (*L. augustifolium*), 112 (45%) women, followed by mandarin (*C. reticulata*), 65 (26%) women, and Roman chamomile (*C. nobile*), 18 (7%). Frankincense (*B. carteri*) was used by 26 (10%) women, and a further 28 (11%) women used clary sage (*S. sclarea*). Pain was cited as the most common reason for aromatherapy use, 95 (38%) women, followed by anxiety, 74 (30%) women. Forty-five (18%) women used aromatherapy to diminish fear. Labour augmentation was the reason for aromatherapy administration for the remaining 35 (14%) women. Taper (drop of EO on absorbent paper, attached to woman's clothing) was the preferred mode of aromatherapy application, 99 (37%) women, followed by massage, 85 (32%) women, and the birthing pool, 51 (20%) women. Fourteen (5%) women had acupressure and two (4%) used aromatherapy compresses (towels dipped in aromatherapy water). Footbath was the least used mode, 11 (4%) women. Two hundred and thirty-six (94%) women used one mode of aromatherapy application, 11 (4%) used two modes aromatherapy and 2 (0.8%) used three modes. There were no reports of associated adverse effects for women.

Data for self-rated maternal pain perception using a 10-point Lickert scale (0–100 score) were collected just before and 30–40 minutes after receiving aromatherapy. Nulliparae reported a reduction in pain perception following aromatherapy, mean 75 (19 SD) before versus mean 72 (18 SD) after the administration. Multiparae registered no difference, mean 69 (SD 19) before versus mean 68 (SD 19) after the administration.

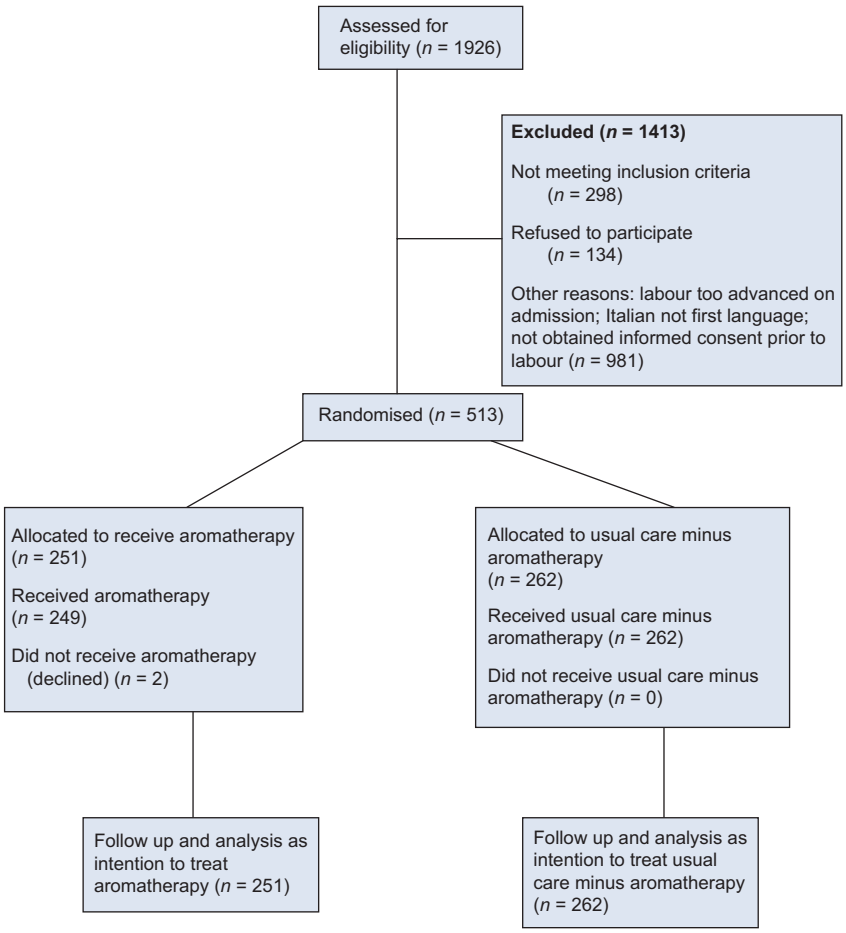

Figure 1. Recruitment and participation

Discussion

This is the first RCT to examine the use of aromatherapy on a wide range of intrapartum outcomes. Randomisation was successful, and the baseline characteristics were similar between the two groups. No maternal adverse effects associated with aromatherapy application were reported, and there were no related neonatal ill effects. The difference found in NICU transfer for the controls (six, 2%) versus none in the aromatherapy group may have occurred due to chance. Our study was not powered to detect a difference in this outcome. Four of the six infants were born by spontaneous vaginal birth, one with Kristeller manoeuvre and one by emergency caesarean section.

The study achieved its main objective in demonstrating that it is possible to undertake an RCT on the aromatherapy intervention. As it was a pilot study, the absence of significant results, particularly for instrumental or operative delivery, is not surprising because the sample size was underpowered. The emergency caesarean section rate for women >36 weeks of gestation in San Gerardo for 2003 was 7.8% (195/2504) of women; the RCT sample rate at 6% was similar. The unit's elective operative delivery rate for women >36 weeks of

Table 1. Participant characteristics at baseline

	Aromatherapy, *n* = 251	Control, *n* = 262
Ethnicity, *n* (%)		
White	212 (84)	224 (86)
Black	12 (5)	13 (5)
Hispanic	12 (5)	14 (5)
Asian	15 (6)	11 (4)
Mean maternal age (SD), years	31.6 (4.3)	31.6 (4.5)
Nulliparae, *n* = 290; *n* (%)	140 (48.2)	150 (51.7)
Multiparae, *n* = 223; *n* (%)	111 (49.7)	112 (50.2)
Mean gestation at delivery (SD), weeks	39.6 (2.4)	39.3 (1.2)

Table 2. Delivery outcome

Type of delivery	Aromatherapy, *n* = 251; *n* (%)	Control, *n* = 262; *n* (%)	RR (95% CI)	*P* value
Spontaneous vaginal birth	224 (89)	234 (89)	0.99 (0.75–1.3)	1.00
Kristeller	10 (4)	11 (4)	0.97 (0.64–1.48)	1.00
Ventouse	2 (1)	1 (<1)	1.5 (0.31–7.62)	0.97
Emergency caesarean section	15 (6)	16 (6)	0.99 (0.70–1.41)	1.00

gestation the same year was 5.6% (141/2504). A total caesarean section rate of 16.2% is modest for Italy, where the national average has climbed like other European countries in later years. In the year 2000, the national rate was 33.2%.[20] As can be seen from the results of this study, at almost 90%, San Gerardo has a high spontaneous vaginal birth rate.

No differences were found in the incidence of intrapartum interventions (Table 3). As in almost all Italian maternity units, midwives based at San Gerardo do not work as autonomous practitioners but under the direction of obstetricians, and the unit operates an active management approach to labour care. This includes at least 2-hourly vaginal examinations, frequent artificial rupture of membranes and a low threshold for labour augmentation with intravenous oxytocin infusion. At over 40%, the episiotomy rate is high. This adherence to protocols could account for the low uptake of aromatherapy to assist contractions. In contrast, midwives in the UK, for example, care for women in a more flexible way, aware that individuals differ in terms of cervical dilatation speed and so on, and only refer a labouring woman for medical opinion when they encounter a problem. Given the contextual issues and underpowered sample size, it is reasonable to suggest that it was unlikely to find differences in intrapartum interventions in this study.

San Gerardo is atypical of many maternity units in the UK in respect of its low use of pharmacological pain relief. In Italy overall, there is a traditional minimal uptake of pharmacological pain relief in childbirth. A law has been passed to specifically promote epidural use. In San Gerardo, in 2003, only 1.5% (40) of women had an epidural in labour, the main criteria being extreme maternal distress and severe pre-eclampsia. The unit does not offer opioid injection as an option because of the known adverse effects for both mother and baby and its limitation as an analgesic. As in other Italian

Table 3. Intrapartum events

Intrapartum events	Aromatherapy, *n* = 251	Control, *n* = 262	RR (95% CI)	*P* value
Labour onset				
Spontaneous	182 (73%)	192 (73%)	1.02 (0.84–1.24)	0.922
Induced	69 (27%)	70 (27%)		
Membrane rupture				
Spontaneous	143 (57%)	130 (50%)	0.87 (0.73–1.03)	0.11
Artificial	108 (43%)	132 (50%)		
Number of vaginal examinations per woman				
0	1	1	Not applicable	0.42
1	20 (8%)	37 (14%)		
2	76 (30%)	86 (33%)		
3	70 (28%)	62 (24%)		
4	46 (18%)	41 (16%)		
5	24 (10%)	19 (7%)		
6	11 (4%)	13 (5%)		
7	2 (<1%)	3 (1%)		
8	1	0		
Labour augmentation (intravenous infusion oxytocin)				
Commenced in first stage of labour	68 (28%)	66 (27%)	1.01 (0.83–1.24)	0.92
Commenced in second stage of labour	24 (10%)	18 (8%)	1.18 (0.82–1.7)	0.44
Episiotomy	113 (48%)	101 (41%)	1.15 (0.96–1.38)	0.146
Mean length of first stage of labour (SD), minutes	217 (111.5)	216 (130.0)		0.90
Mean length second stage of labour (SD), minutes	34.7 (25.5)	33.2 (22.7)		0.51

Table 4. Neonatal outcomes

Neonatal outcomes	Aromatherapy, *n* = 251	Control, *n* = 262	*P* value
Apgar score at 1 minute, mean (SD)	9.1 (0.79)	9.1 (0.81)	0.38
Apgar score at 5 minutes, mean (SD)	10 (0.34)	10 (0.46)	0.92
Apgar score at 10 minutes, mean (SD)	10 (0.17)	10 (0.63)	0.68
Admission to NICU	0	6 (2%)	0.017*

*Significant at 5% level using Fisher's exact test.

units, San Gerardo does not use inhalational analgesia. Nonpharmacological options include water (the unit has two birthing pools and a 5% water birth rate) and adoption of positions that promote maternal comfort while also facilitating the mechanism of labour by women upon encouragement of midwives. A few of the midwives provide reflexology and homeopathy. Alternatively, a woman may choose to use her own homeopathic remedies. San Gerardo provides one-to-one midwifery support for labouring women, which is known to be a key benefit both for mother and baby.[21] Aromatherapy offered women an additional nonpharmacological pain relief option. The low uptake of pharmacological pain relief at San Gerardo limited the potential to investigate the effect of aromatherapy for this outcome.

In this study, 86% (217 women) had aromatherapy to reduce anxiety, fear or pain. It is interesting to note that aromatherapy appeared to slightly diminish pain perception for nulliparae and to stabilise it for multiparae, when on a continuum, pain and anxiety tend to intensify as labour progresses. A limitation of this study is lack of comparative data. The problem is identifying an appropriate (similar) subgroup of women in the control group. In the UK observational study, the highest proportion, 67% (5390 women), availed of aromatherapy for anxiety, fear or pain.[17] In later years, the gate theory of pain has been developed into the neuromatrix theory.[22] This acknowledges the multifaceted nature and subjectivity of pain sensation by incorporating the mind, body and spirit elements.

Women and midwives commented favourably on using aromatherapy as a means of easing maternal anxiety, fear, pain and enhancing wellbeing. Both women and midwives also mentioned how aromatherapy administration facilitated the development of a supportive, empathetic rapport, which extended for some to the birth partner, who felt more actively involved as he/she could assist in the massage for example.

Massage was a popular mode of aromatherapy application, administered to 85 (32%) women. An RCT examining the effects of nonaromatherapy (base oil alone) massage on pain and anxiety in labour reported less pain in the experimental group.[23]

Recruitment rate of the eligible women (513/1628) at 37% was modest. A logistic factor could have accounted for some women not being willing to participate. In Italy, there is a disjointed care system, wherein many women receive antenatal care from obstetricians who may not be linked to the hospital where they deliver. There is no national community midwifery service. This fragmentation resulted in some women presenting at San Gerardo not having heard about the study in sufficient advance to consent. In addition, some women presented too advanced in labour to consent.

The primary objective of this study was to investigate if aromatherapy administration affected the rate of intrapartum interventions. For future studies to have sufficient power to detect a difference in the incidence of artificial rupture of membranes, labour augmentation commenced in the first stage, labour augmentation commenced in the second stage or episiotomy, we have calculated the sample size that would be required to detect a 5 or 10% reduction. With 80% power and significance of 0.05, a study would need a sample of 1000 (5% reduction) or 400 (10% reduction) women randomised to each arm. This assumes an underlying 75% prevalence of one of the listed interventions.

Conclusion

This study shows that it is feasible to undertake an RCT on aromatherapy in labour. There were no associated adverse effects of using the EOs on maternal or neonatal outcomes. The results of this study form a good basis for undertaking an RCT on a sample large enough to identify statistical significance on outcomes important to women and midwives. Given the increasing popularity of aromatherapy in maternity care and the lack of sufficient evidence of efficacy, this should assume priority.

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