

# Effectiveness of a childbirth massage programme for labour pain relief in nulliparous pregnant women at term: a randomised controlled trial

CY Lai \*, Margaret KW Wong, WH Tong, SY Chu, KY Lau, Agnes ML Tam, LL Hui, Terence TH Lao, TY Leung

## ABSTRACT

**Introduction:** The effect of massage for pain relief during labour has been controversial. This study investigated the efficacy of a programme combining intrapartum massage, controlled breathing, and visualisation for non-pharmacological pain relief during labour.

**Methods:** This randomised controlled trial was conducted in two public hospitals in Hong Kong. Participants were healthy low-risk nulliparous Chinese women  $\geq 18$  years old whose partners were available to learn massage technique. Recruitment was performed at 32 to 36 weeks of gestation; women were randomised to attend a 2-hour childbirth massage class at 36 weeks of gestation or to receive usual care. The primary outcome variable was the intrapartum use of epidural analgesia or intramuscular pethidine injection.

**Results:** In total, 233 and 246 women were randomised to the massage and control groups, respectively. The use of epidural analgesia or pethidine did not differ between the massage and control groups (12.0% vs 15.9%;  $P=0.226$ ). Linear-by-linear analysis demonstrated a trend whereby fewer women used strong pharmacological pain relief in the massage group, and a greater proportion of women had analgesic-free labour (29.2% vs 21.5%;  $P=0.041$ ). Cervical dilatation at the time of pethidine/epidural analgesia request was significantly greater

in the massage group ( $3.8 \pm 1.7$  cm vs  $2.3 \pm 1.0$  cm;  $P<0.001$ ).

**Conclusion:** The use of a massage programme appeared to modulate pain perception in labouring women, such that fewer women requested epidural analgesia and a shift was observed towards the use of weaker pain relief modalities; in particular, more women in the massage group were analgesic-free during labour.

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### New knowledge added by this study

- In this randomised controlled trial of healthy low-risk nulliparous Chinese women, fewer women used strong pharmacological pain relief in the childbirth massage group, and a greater proportion of women had analgesic-free labour, compared with the control group.
- Cervical dilatation at the time of pethidine/epidural analgesia request was significantly greater in the childbirth massage group than in the control group.

### Implications for clinical practice or policy

- A structured childbirth massage programme delivered by qualified midwife trainers can provide couples with both theoretical knowledge and practical skills, which help to modulate pain perception among labouring women.
- With appropriate training, massage can be an efficacious option for labour pain relief with no associated adverse effects on delivery.

## Introduction

Labour is regarded as a time of suffering in a woman's life, during which she may experience

intensive pain that lasts for many hours. Ineffective labour pain management could create a negative life experience for a woman, which may negatively

## 足月妊娠的初產婦女在分娩時以按摩作為緩解疼痛的成效的隨機研究

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**引言：**按摩對緩解分娩疼痛的效果目前仍有爭議。本研究旨在評估一項結合產時按摩、呼吸控制和可視化的非藥物性方案的鎮痛效果。

**方法：**在香港兩家公立醫院進行隨機對照研究。受試者為健康、低風險的初產婦，年齡18歲或以上，且其伴侶可學習按摩技術。受試者招募在妊娠32至36週進行；妊娠36週時，受試者被隨機分配參加2小時按摩課程或接受常規產檢。主要結局為受試者在分娩過程中硬膜外麻醉或哌替啶的使用情況。

**結果：**233名和246名孕婦被隨機分為按摩組和對照組。硬膜外麻醉 / 哌替啶的使用率在兩組孕婦中無顯著差異（12.0%比15.9%； $P=0.226$ ）。線性分析結果顯示在按摩組中，使用強效藥物止痛的產婦較少，未使用鎮痛藥物的產婦比例較高（29.2%比21.5%； $P=0.041$ ）。在要求哌替啶 / 硬膜外鎮痛時，按摩組的宮頸擴張程度更顯著（ $3.8 \pm 1.7$  cm比 $2.3 \pm 1.0$  cm； $P<0.001$ ）。

**結論：**使用按摩方案可調節孕產婦的疼痛感知，減少其對硬膜外麻醉鎮痛的需求，增加非藥物性鎮痛的選擇。值得注意的是，按摩組中更多孕產婦在分娩期間未使用止痛藥物。

impact postpartum sexual and marital satisfaction.<sup>1,2</sup> Labour pain involves both physical and psychological elements such as uterine contractions, tension, fear, anxiety, and the sensations of powerlessness and a loss of control.<sup>3</sup> Current remedies for labour pain include pharmacological and non-pharmacological interventions. The most common pharmacological interventions include nitrous oxide inhalation, the injection of narcotic analgesics (eg, pethidine), and epidural analgesia. However, these methods are associated with adverse effects such as nausea and vomiting, longer first and second stages of labour, hypotension, motor blockade, fever, and urinary retention; they can also lead to neonatal respiratory depression and newborn sleepiness that affects breastfeeding.<sup>4-9</sup> Hence, women prefer safer and simpler non-pharmacological pain relief methods.<sup>10,11</sup>

A notable non-pharmacological remedy is massage, which may provide pain relief to the site of application, along with overall psychological relaxation.<sup>12</sup> The pressure applied during massage is presumed to block the transmission of pain impulses to the brain, while stimulating local release of endorphins.<sup>13</sup> Randomised controlled trials concerning intrapartum massage have been conducted in various countries over the past two decades.<sup>12,14-23</sup> However, there have been conflicting findings concerning beneficial effects (ie, reductions in pain score or the use of pharmacological analgesia)<sup>12,14-17,21</sup> because of small sample sizes

which ranged from 28 women<sup>12</sup> to 176 women.<sup>21</sup> Furthermore, the duration of intrapartum massage was either unspecified<sup>15,21</sup> or lasted for only 30 to 40 minutes.<sup>12,14,18,19,22,23</sup> In addition, intrapartum massage was performed by various types of people: student midwives,<sup>22</sup> therapists<sup>17,19</sup> or partners who had received training by therapists immediately before labour.<sup>12,14</sup> These factors probably influenced the effectiveness, consistency, and duration of the application of massage. A recent Cochrane review concluded that the current quality of evidence regarding intrapartum massage is low to very low.<sup>24</sup> Therefore, this randomised controlled study investigated the efficacy of a comprehensive massage programme, combined with controlled breathing and visualisation—all initiated during the antenatal period—as a non-pharmacological pain relief method during labour, with the goal of reducing pethidine or epidural analgesia use.

## Methods

### Design and recruitment

This randomised controlled study was conducted in two public hospitals in Hong Kong, where the midwives were responsible for intrapartum management and natural vaginal delivery of low-risk pregnancies. The respective annual childbirth rates were approximately 5000 and 7000; the caesarean section rates were 21% and 23%.<sup>25</sup> Recruitment commenced in September 2016 and completed in December 2017. The recruitment of women was conducted at 32 to 36 weeks of gestation during their routine antenatal visit by a team of research midwives. The inclusion criteria were low-risk nulliparous Chinese women aged  $\geq 18$  years, who could communicate in Cantonese, and who carried a singleton pregnancy without known contraindications for vaginal delivery. Exclusion criteria were the use of massage among women in the control group, the absence of a partner to learn the massage technique, planned delivery in hospitals other than the study sites, and planned caesarean delivery. There was no exclusion of recruited women who attempted vaginal delivery or induction of labour but eventually required intrapartum caesarean delivery.

Randomisation was conducted via two-by-two blocking with a block size of 4; a computer-generated number indicating either the study or control group was sealed in an opaque envelope. After a woman had provided written informed consent to participate, the midwife revealed the group allocation by opening the envelope. Because there were multiple midwifery staff responsible for participant recruitment at different occasions, none of the staff were aware of the allocation of previous participants; hence, they were unable to guess the group allocation.

## Intervention

Couples (ie, participating women and their partners) randomised to the massage group were invited to attend a 2-hour childbirth massage programme class at 36 weeks of gestation. This programme was based on the United Kingdom's Royal College of Midwives accredited course 'Towards Natural Childbirth and Beyond'.<sup>26</sup> It included a 30-minute theoretical explanation of the evidence underpinning the childbirth massage programme, followed by a 90-minute practicum. During the 90-minute practicum, the couples received training by accredited midwifery trainers with respect to the massage technique, controlled breathing, and visualisation, in accordance with the methods used in previous studies.<sup>16,20</sup> The massage areas included the lower back and four limbs. Couples were taught how to synchronise the massage strokes with slow rhythmic breathing. Visualisation (ie, a mind mapping component) was also taught.<sup>26</sup> In this process, the woman was asked to imagine something comfortable, which could bring her to a relaxed state. Subsequently, the couples were encouraged to practise the massage technique regularly at home in the evening, in a dimly lit and quiet environment, with the aim of encouraging relaxation and improving the quality and duration of sleep.<sup>27</sup> The control group received standard antenatal education without instruction concerning massage, controlled breathing, or visualisation techniques.

When a woman in the massage group was admitted to the study hospital at onset of labour or for planned labour induction, her partner was first asked to demonstrate massage technique to the research team midwives to ensure that the partner could perform the procedure properly. If labour was not yet established, each woman was encouraged to relax through self-massage on her abdomen and legs. When labour commenced, the partner stayed to provide arm and shoulder massage for relaxation or lateral sacral massage for pain relief, according to the woman's preference. There was no time limit for massage as long as the couple was happy and felt comfortable to continue the procedure throughout the labour. The partner could take a break in times of fatigue, or when the woman fell asleep. The partners of women in the control group were also encouraged to accompany the women during labour and delivery. Women in both groups otherwise received the same intrapartum care. They received explanations concerning the effectiveness of various analgesic methods according to the ranking of reported efficacy<sup>4,7</sup>: epidural was ranked highest, followed by pethidine, then nitrous oxide and other non-pharmacological analgesia methods (including transcutaneous nerve stimulation, birthing ball, and warm pads). Women could choose various methods or a combination of methods according to their pain

tolerance and acceptance, using a step-up approach or direct implementation of the most effective methods. The degree of labour pain was assessed using the visual analogue scale for pain (ranging from 0 [no pain] to 10 [most painful]) at different stages of labour: latent phase (cervical dilatation of 1-3 cm), active phase (cervical dilatation of 4-7 cm), late active phase (cervical dilatation of 8-9 cm), and second stage (cervical dilatation of 10 cm); it was also assessed when the women first requested pethidine or epidural analgesia.

## Outcome measures

The primary outcome of this study was the use of the two most effective pharmacological methods (as described above): intramuscular pethidine injection or epidural analgesia. Women were also categorised according to the type of analgesia that they eventually received: none of the analgesic methods; non-pharmacological methods only; nitrous oxide  $\pm$  non-pharmacological methods; pethidine  $\pm$  other pain relief except epidural; or epidural  $\pm$  above methods. The proportions of women that received each type of analgesia were also compared as one of the secondary outcomes. Other secondary outcomes included intrapartum caesarean rate, duration of labour, the pain score at the point when the women first requested pethidine or epidural analgesia, the interval between the onset of labour to the time of making such a request, and the cervical dilatation at which such a request was made.

## Sample size calculation

A previous study reported a reduction of 60% in the epidural rate with the use of intrapartum massage when compared with the control group.<sup>2</sup> Therefore, our study sample size was calculated based on the assumption that the requirement for pethidine injection or epidural analgesia could be reduced by 60% (ie, from the current 15% according to Hospital Authority data to 6%) in the study group. Using an 80% power (beta) threshold and a two-tailed alpha value of 5%, we calculated that 181 participants were required in each arm. The method of calculation was obtained from the website of Department of Obstetrics and Gynaecology, the Chinese University of Hong Kong (<http://www.obg.cuhk.edu.hk/ResearchSupport/StatTools/index.php>). Because we anticipated that 40% of the recruited participants would be excluded (eg, because of a shift to a private hospital for delivery, change to elective caesarean section, or withdrawal from the study), we planned to recruit 300 participants for each arm.

## Statistical analysis

The Chi squared test and *t* test were used to assess differences in baseline characteristics, obstetric

outcomes, neonatal outcomes, and the proportions of women using specific pharmacological pain relief methods between the massage and control groups. Linear-by-linear association was used to assess trends regarding the use of different types of analgesia. The *t* test was used to compare between-group differences in the stage of labour, cervical dilatation, and pain score among participants who used pethidine/epidural, as well as the mean pain scores in different phases of labour among participants who did not use any pain relief modalities. A P value of <0.05 was considered statistically significant. All analyses used a per-protocol approach. Intention-to-treat analysis (including all participants recruited at baseline) could not be conducted because information collected during labour (eg, the use of pain relief modalities) was not available for participants who delivered in other hospitals, required caesarean section before pain labour commenced, or withdrew from the study. Statistical analyses were performed using SPSS software (Windows version 22.0; IBM Corp, Armonk [NY], United States).

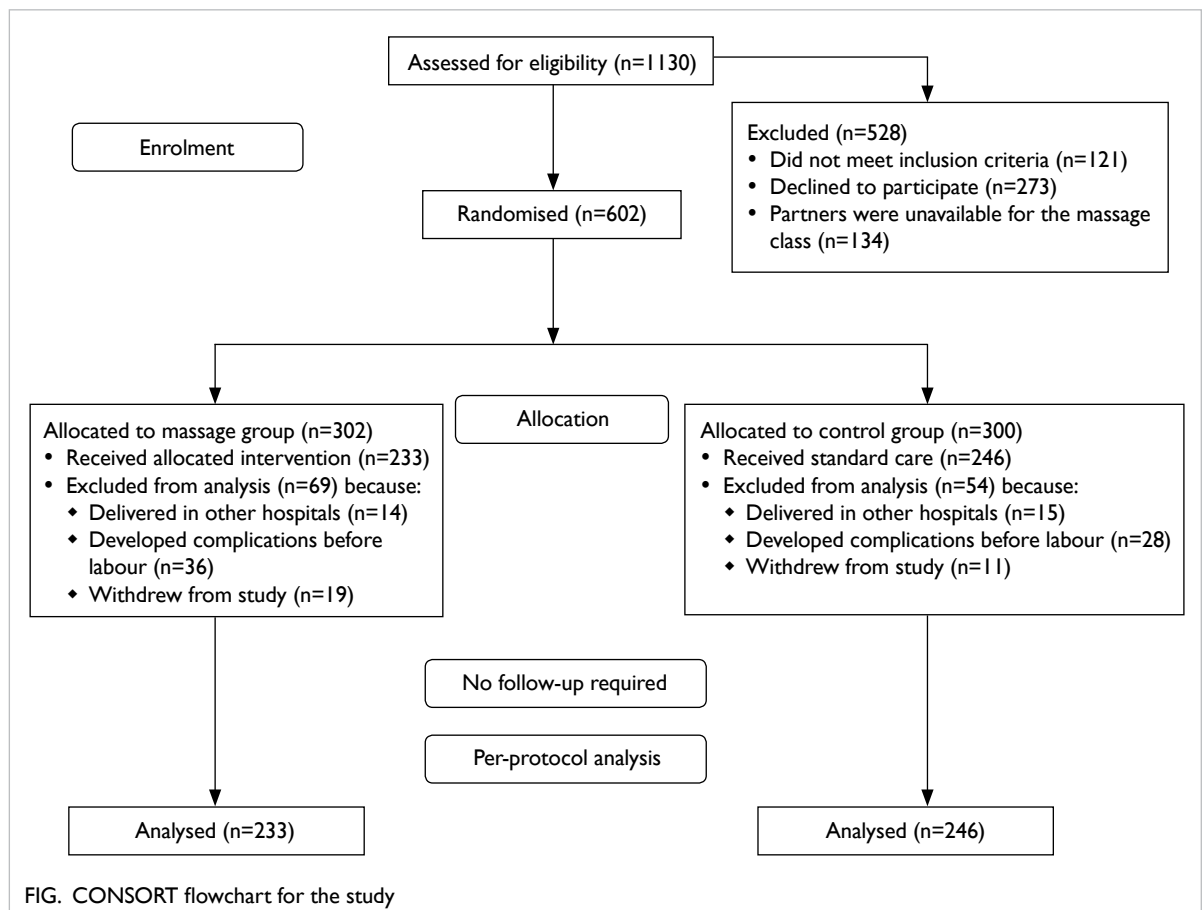
## Results

Of the 1130 women eligible for this study, 528 were excluded for reasons shown in the Figure; thus,

602 women were randomised to the massage group (n=302) and control group (n=300). Furthermore, 69 (22.8%) and 54 (18.0%) women were subsequently excluded from the massage and control groups, respectively, for reasons such as delivery in private hospitals, planned caesarean section, development of complications before labour, or withdrawal from the study. Finally, 479 pregnant women (233 in the massage group and 246 in the control group) were included in the per-protocol analysis.

There were no significant differences between groups in terms of maternal age, height, or demographic characteristics nor in the proportions of women who underwent induction of labour, augmentation of labour, or delivered by caesarean section (Table 1). The mean duration of labour did not differ between the massage and control groups. No significant differences were found in gestational age at delivery, birthweight, or the proportion of babies with Apgar score  $\geq 8$  at 5 minutes (Table 1). All women in the massage group practised massage during labour (n=233). The duration of massage ranged from 35 minutes to 195 minutes (median, 100 minutes).

The proportion of women who used pethidine or epidural did not significantly differ between the massage and control groups (12.0% vs 15.9%;



P=0.226). However, linear-by-linear association analysis showed a significant shift in the massage group, from using stronger analgesics (eg, epidural analgesia: 2.1% in the massage group vs 5.7% in the control group) to weaker analgesics. Thus, more women in the massage group required none of the analgesics, compared with women in the control group (29.2% vs 21.5%; P=0.041) [Table 2].

Among women who needed pethidine or epidural for pain control, there was no difference between the two groups in terms of the pain score at the point when they requested these pain relief modalities, or the interval between the onset of labour to the time of requesting these modalities (Table 3). However, the cervical dilatation at which pethidine or epidural was first requested was significantly greater in the massage group (3.8 ± 1.7 cm) than in the control group (2.3 ± 1.0 cm; P<0.001) [Table 3].

Among women who needed none of the pain relief modalities, the pain scores progressively increased with cervical dilatation, although there were no differences between the two groups (Table 4).

## Discussion

Although our study did not show a statistically significant reduction in the number of women who used either pethidine or epidural analgesia with the practice of massage (12.0% vs 15.9%), linear-by-linear analysis revealed that there was a statistically significant overall shift in the pattern of analgesics use in the massage group: a smaller proportion of women requested epidural analgesia (2.1% vs 5.7%) and a larger proportion of women requested none of the pain relief methods (29.2% vs 21.5%). Our results suggest that the pain perceptions of labouring women were improved by the training and practice of massage, controlled breathing, and visualisation. Thus, some women who initially requested the stronger methods (eg, epidural analgesia) might have achieved satisfactory pain control with weaker analgesic methods (eg, pethidine or nitrous oxide). Similarly, women who initially requested pethidine or nitrous oxide might have shifted to non-pharmacological methods only; this led to a greater proportion of women in the massage group who requested no analgesia.

## Interpretation

Although pain scores are commonly used to compare analgesic effectiveness, such comparisons are often difficult on the basis of a single pain score during labour. This is because the labour process is generally long and its characteristics are variable; labouring women might use more than one method of pain relief at different stages of labour. Nonetheless, if

TABLE 1. Maternal background and birth outcomes between pregnant women who attended a 2-hour childbirth massage class at 36 weeks of gestation (massage group) and those who received usual care (control group)\*

	Massage group (n=233)	Control group (n=246)	P value†
Age, y	31.3 ± 3.7	30.7 ± 3.8	0.05
Height, cm	158.6 ± 5.5	158.0 ± 5.6	0.21
Education			0.08
Secondary	67 (28.8%)	93 (37.8%)	
Tertiary	166 (71.2%)	153 (62.2%)	
Occupation			0.79
Professional	40 (17.2%)	42 (17.1%)	
Clerical	105 (45.1%)	102 (41.5%)	
Service/technical type	42 (18.0%)	52 (21.1%)	
Housewives/unemployed	46 (19.7%)	50 (20.3%)	
Induction of labour	106 (45.5%)	117 (47.6%)	0.65
Augmentation of labour	27 (11.6%)	36 (14.6%)	0.32
Mode of delivery			0.42
Spontaneous vaginal delivery	177 (76.0%)	189 (76.8%)	
Ventouse extraction	26 (11.2%)	20 (8.1%)	
Forceps delivery	4 (1.7%)	2 (0.8%)	
Caesarean section	26 (11.2%)	35 (14.2%)	
Duration of labour, h	7.8 ± 4.5	8.0 ± 4.9	0.62
Gestations at delivery, wk	39.6 ± 1.0	39.5 ± 1.0	0.37
Birth weight, g	3153 ± 354	3093 ± 348	0.06
Apgar score ≥8 at 5 minutes	233 (100%)	246 (100%)	-

\* Data are shown as No. (%) or mean ± standard deviation, unless otherwise specified

† P values assessed by Chi squared tests for categorical parameters and t test for continuous parameters

TABLE 2. Analgesic method selected by 479 pregnant women\*

Pain relief method selected	Massage group (n=233)	Control group (n=246)
No analgesia	68 (29.2%)	53 (21.5%)
Non-pharmacological methods only	58 (24.9%)	67 (27.2%)
Entonox with/without non-pharmacological methods	79 (33.9%)	87 (35.4%)
Pethidine with/without other pain relief except epidural	23 (9.9%)	25 (10.2%)
Epidural with/without other pain relief	5 (2.1%)	14 (5.7%)
P value for linear-by-linear association		0.041

\* Data are shown as No. (%), unless otherwise specified

the pain is intolerable, labouring women require a stronger analgesic method.<sup>28</sup> Hence, we used a pattern of analgesic utility (rather than a single pain score) as an indicator for the effectiveness of the massage programme; our linear-by-linear association findings indicated that the massage programme may reduce pain perception among

TABLE 3. Stage of labour, cervical dilatation, and pain score when pethidine/epidural was first used among 67 women who requested pethidine and/or epidural pain relief\*

	Massage group (n=28)	Control group (n=39)	P value†
Interval between the onset of labour and the first use of pethidine/epidural, h	7.1 ± 4.1	7.2 ± 4.8	0.81
Cervical dilatation, cm	3.8 ± 1.7	2.3 ± 1.0	<0.001
Pain score	7.6 ± 2.2	7.6 ± 2.8	0.932

\* Data are shown as mean ± standard deviation, unless otherwise specified

† P value assessed by *t* test

TABLE 4. Pain scores at different stages of cervical dilatation among 121 women who requested none of the pain relief modalities\*

	Massage group (n=68)	Control group (n=53)	P value
Pain score at cervical dilatation of ≤3 cm	4.5 ± 3.2	4.4 ± 2.8	0.931
Pain score at cervical dilatation of 4-7 cm	8.0 ± 2.1	8.2 ± 1.8	0.148
Pain score at cervical dilatation of 8-9 cm	9.3 ± 1.0	8.8 ± 1.5	0.804

\* Data are shown as mean ± standard deviation, unless otherwise specified

labouring women. Furthermore, the mean cervical dilatation at the time of pethidine or epidural analgesia request was higher in the massage group than in the control group (3.8 ± 1.7 cm vs 2.3 ± 1.0 cm). Notably, among women who requested pethidine or epidural analgesia, the pain score at the point of first pethidine or epidural analgesia request was very similar between the massage and control groups (7.6 ± 2.2 vs 7.6 ± 2.8). Although the midwives were not blinded to the allocation in this study, women in both groups received the same intrapartum care and could choose pain relief methods according to their pain tolerance and acceptance. These results further support the notion that the practice of massage might have modulated the pain perception among labouring women, such that they only requested stronger pharmacological pain relief during later phases of labour; additional studies are required to confirm the underlying biological mechanism.

Janssen et al<sup>17</sup> also reported a delay in epidural insertion by 1 cm of cervical dilatation (5.9 cm in the massage group vs 4.9 cm in the control group) in their randomised controlled trial. However, they failed to show a significant reduction in the rate of epidural analgesia use (81.1% in the massage group vs 65.0% in the control group). Importantly, their participants only learned and practised massage at the time of labour, while our participants began learning the massage programme during the antenatal period.

In another randomised controlled trial, Levett et al<sup>21</sup> showed that the incidence of epidural analgesia was significantly reduced (from 68.2%

to 23.9%) in a cohort of 176 Australian patients. However, their control group had a baseline epidural analgesia rate of 68.2%, which was much higher than the rate in our control group (ie, 5.7%, which is similar to the 6.6% reported previously in Hong Kong<sup>29</sup>). Possible reasons for the large difference in epidural rates between Australia and Hong Kong include variations in midwifery practices, pain tolerance among labouring women, and limited resources in Hong Kong public hospitals. Other obstetric practice differences include an overall (massage and control groups combined) higher normal vaginal delivery rate in our cohort than in the cohort reported by Levett et al<sup>21</sup> (76.4% vs 57.9%); our overall cohort also exhibited a lower instrumental delivery rate (10.9% vs 17.0%) and a lower caesarean section rate (12.7% vs 25.1%). Regardless of our low baseline epidural rate, we found a 60% reduction in epidural use in the massage group (2.1%), compared with the control group (5.7%). Finally, Levett et al<sup>21</sup> only reported the incidence of simultaneous use of pethidine and nitrous oxide, whereas we stratified analgesic methods according to the strength of pain relief; this allowed us to detect an overall shift towards weaker analgesics among women in the massage group.

Importantly, neither study (this study or the study by Levett et al<sup>21</sup>) demonstrated any reduction in the overall duration of labour in nulliparous women, although the cohort reported by Levett et al<sup>21</sup> exhibited a marked reduction in the rate of epidural use. In contrast, Bolbol-Haghighi et al<sup>22</sup> showed that massage practice was associated with significantly shorter durations in both the first stage (9.0 hours vs 11.5 hours) and the second stage of labour (49 minutes vs 64 minutes) among a cohort of Iranian women. However, their study included multiparous women with an overall vaginal delivery rate over 95%; they did not describe the availability of epidural analgesia for their participants. In summary, it remains unclear whether the practice of massage has consistent effects on labour progression; the underlying mechanisms of such effects are unknown.

### Strengths and limitations

This study had several strengths. First, it involved a large number of nulliparous labouring women. To our knowledge, this is the largest number of such women among similar published studies; it allowed us to identify any changes in the utilisation of different levels of analgesic methods, without any confounding effects related to multiparity.<sup>20,22</sup> Second, this study involved a team of accredited and dedicated midwife trainers, which enabled us to ensure that a consistent high-quality massage technique was applied to women in the study. Third, training at 36 weeks of gestation allowed each couple (ie, a participating woman and her partner)

to have sufficient time to practise massage at home and refine their technique before the woman began labour. Fourth, on admission prior to delivery, an accredited midwife trainer was available to verify each couple's massage technique and ensure quality. Finally, there was no limit to the duration of intrapartum massage; women could receive their preferred amount of massage to achieve optimal results.

There were some notable limitations in this study. First, because of the pain relief methods used, we were unable to incorporate blinding in the trial design. However, the midwives providing intrapartum care were not involved in data collection. Second, approximately one-fifth of the participants in each group had changes to their childbirth plan, including shift to a private hospital or to planned caesarean delivery; thus, they were excluded from the final analysis. Third, we could only assess the intrapartum massage provided by the participating women's partners; we could not assess the breathing and visualisation practice at home, which are also essential components of the overall massage programme. Finally, because continuous foetal heart monitoring was the standard method of intrapartum foetal surveillance in Hong Kong during the study period, women were unable to move freely during labour; this restriction might have limited the ability to perform certain massage techniques. Nevertheless, the shifts towards less epidural analgesia use and higher rates of analgesic-free labour, in the absence of adverse labour outcomes, support the efficacy of our massage programme.

## Conclusion

This study demonstrated an overall shift towards using weaker pain relief modalities among women participating in an intrapartum massage programme. The findings imply that massage, in combination with controlled breathing and visualisation, may modulate pain perception among labouring women, leading to higher rates of analgesic-free labour.

## Author contributions

Concept or design: CY Lai.

Acquisition of data: MKW Wong, WH Tong, SY Chu, KY Lau, AML Tam.

Analysis or interpretation of data: CY Lai, LL Hui.

Drafting of the manuscript: CY Lai, TTH Lao, TY Leung.

Critical revision of the manuscript for important intellectual content: All authors.

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

## Conflicts of interest

All authors have disclosed no conflicts of interest.

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## Ethics approval

The study was approved by The Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee (CREC Ref: 2016.332). The study has been registered at the Centre for Clinical Research and Biostatistics, The Chinese University of Hong Kong, (Unique Trial Number: CUHK\_CCRB00525; <https://www2.ccrb.cuhk.edu.hk/registry/public/393>). All participants were informed about the nature of the study and provided written consent to participate before randomisation into study groups.

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