

Effect of Therapeutic Touch on Maternal and Neonatal Outcomes in Primiparous Women: A Systematic Review and Meta-Analysis

SHAMPA SAHA¹, ATIMA BHARTI², ARPITA RAI³, AMIT KUMAR⁴, KUMARI SANDHYA⁵

ABSTRACT

Introduction: Childbirth is one of the most wonderful yet painful experiences in a woman's life. Non pharmacological interventions like Therapeutic Touch (TT) can improve labour experiences in women.

Aim: To assess the effect of TT on labour pain intensity, neonatal Appearance, Pulse, Grimace, Activity, Respiration (APGAR) score and admission to neonatal intensive care unit in primiparous women.

Materials and Methods: In this review, PubMed-MEDLINE, Google Scholar, Cochrane CENTRAL databases were searched till February 2022, for prospective studies fulfilling inclusion and exclusion criteria. Randomised controlled trials comparing TT and massage therapy with usual intranatal care in primiparous women with singleton foetus and without any risk factors for pregnancy were included in this review. Two independent reviewers extracted data and assessed the quality of the trials. The results were presented in form of forest plots.

Results: A total of 13 studies, including 1302 primiparous women, were included in the review for qualitative analysis. Amongst them ten studies involving 621 women included meta-analysis of labour pain intensity. Nine studies were included in the meta-analysis of the active phase of labour and four studies included in the transitional phase and one study in the fourth stage of labour. Eight studies used the Visual Analogue Scale (VAS) to assess pain intensity. Overall, there was a small reduction in pain intensity of primiparous women receiving massage/TT compared to routine care {SMD: -0.96 (95% CI: -1.33, -0.60)}. Significant reduction of pain intensity was found in active {SMD: -0.79 (95% CI: -1.26, -0.32)} and transitional phase of labour {SMD: -1.18 (95% CI: -1.67, -0.69)}. No significant reduction of neonatal admission to the intensive care unit and APGAR score <7 at 5 minutes {RR: 0.71 (95% CI: 0.31, 1.62)} was found.

Conclusion: TT has beneficial effect on reduction of labour pain intensity in primiparous women. But no detectable effect was found for neonatal outcomes.

Keywords: Appearance, pulse, grimace, activity, respiration score, Massage, Pain measurement, Parity

INTRODUCTION

Pregnancy and childbirth are one of the most amazing and unforgettable events in a woman's life, bringing physical and emotional changes to her body. In labour, women endure a wide range of pain and have a vast range of reactions to it. Women expressed labour pain through crying, screaming, and shouting. Fear of labour pain, especially in primigravida women, may affect their choice of type of delivery in subsequent labours, and increase mothers' tendency for caesarean section. Some women found that lying on their side, supporting their waist, squatting, and praying helped to reduce the pain [1]. Therefore, pain relief care for mothers during labour is very important. The use of Complementary and Alternative Medicine (CAM) for pain reduction among women during labour has grown in the past decade [2]. A wide range of cognitive, behavioural, and sensory therapies like relaxation, breathing techniques, movement and position change, music, touch, massage, acupressure, etc., have shown potential in reducing labour pain [3,4]. TT is one of the non pharmacological interventions that can improve labour experiences in women.

The TT is a sensory intervention that promotes relaxation and enhances positive thoughts and healing. TT is a technique for regulating, increasing, balancing, and preserving energy to alleviate disease or symptoms caused by vital energy field imbalances. Touching a patient relaxes them physically, emotionally, and spiritually. It enhances a person's physical health, helps them feel worthwhile, gives them confidence, peace, and boosts their self-esteem [5]. Massage or TT has been found to be an effective intervention to

decrease pain, anxiety, agitation, labour duration, hospital stay, and depressed mood in mothers [6-8].

TT for pain relief during labour stage can reduce need for analgesic drugs consumption. It can help in pain relief by assisting with relaxing, blocking sensory transmission in pain pathways, and boosting blood flow and oxygenation in tissues [9]. The quality of touch is crucial as the touch itself. For TT, a touch for roughly 15-20 minutes is sufficient for healing [10]. Previous studies have shown that massage, and reflexology was effective in reducing labour pain effectively [11-15]. A systematic review has shown that massage therapy, reflexology, and other manual methods have a positive effect on reduction of labour pain [16]. However, apart from massage and TT, the review by Smith CA et al., included several other methods for pain relief and found limited benefit of massage on pain intensity [16].

The present meta-analysis assess the effect of TT on labour pain intensity and APGAR score and admission to neonatal intensive care unit in the newborn in primiparous women.

MATERIALS AND METHODS

The protocol was prepared according to Preferred Reporting Items of Systematic reviews and Meta-Analysis (PRISMA) guidelines and registered at International Prospective Register of Systematic Reviews (PROSPERO) (Registration ID: CRD42022297713).

The review included randomised controlled trials reporting the effect of TT or massage therapy on the intensity of labour pain and APGAR score of neonates in primiparous women. The authors searched PubMed-MEDLINE, Google Scholar, Cochrane

Central Register of Controlled Trials (CENTRAL) and other clinical trial registry for this review. Preclinical studies, case report, case series, reviews, commentaries, observational studies including case control, cohorts, quasi-experimental studies, letters to editors, conference abstracts, editorials, methodological papers, dissertations and studies were excluded from this review. This review included studies published from 2002-2021. The last search for the studies was conducted on 10 February 2022. The key terms and MeSH terms for the Participants, Intervention, Control and Outcome (PICO) were used to search for the studies. The search strategy for different databases is depicted in the [Table/Fig-1].

#1	"Parity" (Mesh) OR "Pregnant Women" (Mesh) OR "Gravidity" (Mesh) OR Primigravidi* (tw) OR Primiparity (tw)
#2	"Therapeutic Touch" (Mesh) OR "Mind-Body Therapies" (Mesh) OR massage (tw) OR "massage therapy*" (tw) OR "sacral pressure" (tw) OR "touch therapy*" (tw) OR "abdominal massage" (tw)
#3	"Labour Pain" (Mesh) OR "Obstetric Pain" (tw) OR "Labour Pains" (tw) OR "Pain Labour" (tw) OR "Pain Obstetric" (tw) OR "parturition pain" (tw) OR "childbirth pain*" (tw) OR "delivery pain" (tw) OR "birth pangs" (tw) OR "birth pain" (tw)
#4 (#1 AND #2 AND #3)	{("Parity" (Mesh) OR "Pregnant Women" (Mesh) OR "Gravidity" (Mesh) OR Primigravidi* (tw) OR Primiparity (tw)) AND ("Therapeutic Touch" (Mesh) OR "Mind-Body Therapies" (Mesh) OR massage (tw) OR "massage therapy*" (tw) OR "sacral pressure" (tw) OR "touch therapy*" (tw) OR "abdominal massage" (tw))} AND {"Labour Pain" (Mesh) OR "Obstetric Pain" (tw) OR "Labour Pains" (tw) OR "Pain Labour" (tw) OR "Pain Obstetric" (tw) OR "parturition pain" (tw) OR "childbirth pain*" (tw) OR "delivery pain" (tw) OR "birth pangs" (tw) OR "birth pain" (tw)}
#5	"Apgar Score" (Mesh) OR "Infant, Newborn" (Mesh)
#6 (#1 AND #2 AND #5)	{("Parity" (Mesh) OR "Pregnant Women" (Mesh) OR "Gravidity" (Mesh) OR Primigravidi* (tw) OR Primiparity (tw)) AND ("Therapeutic Touch" (Mesh) OR "Mind-Body Therapies" (Mesh) OR massage (tw) OR "massage therapy*" (tw) OR "sacral pressure" (tw) OR "touch therapy*" (tw) OR "abdominal massage" (tw))} AND {"Apgar Score" (Mesh)}
Google Scholar	
#1	Parity OR "Pregnant Women" OR Gravidity OR Primigravida OR Primiparity OR Primipara
#2	"Therapeutic Touch" OR "Mind-Body Therapies" OR massage OR "massage therapy*" OR "sacral pressure" OR "touch therapy*" OR "abdominal massage"
#3	"Labour Pain" OR "Obstetric Pain" OR "Labour Pains" OR "Pain Labour" OR "Pain Obstetric" OR "parturition pain" OR "childbirth pain" OR "childbirth pains" OR "delivery pain" OR "birth pangs" OR "birth pain" OR "pain intensity during labour"
#4 (#1 AND #2 AND #3)	Parity OR "Pregnant Women" OR Gravidity OR Primigravida OR Primiparity OR Primipara AND "Therapeutic Touch" OR "Mind-Body Therapies" OR massage OR "massage therapy*" OR "sacral pressure" OR "touch therapy*" OR "abdominal massage" AND "Labour Pain" OR "Obstetric Pain" OR "Labour Pains" OR "Pain Labour" OR "Pain Obstetric" OR "parturition pain" OR "childbirth pain" OR "childbirth pains" OR "delivery pain" OR "birth pangs" OR "birth pain" OR "pain intensity during labour"
#5	"Apgar Score"
#6 (#1 AND #2 AND #5)	{("Therapeutic Touch" OR "Mind-Body Therapies" OR massage OR "massage therapy*" OR "sacral pressure" OR "touch therapy*" OR "abdominal massage") AND "Apgar score AND (Parity OR Primigravida OR Primiparity OR primipara)}
Cochrane CENTRAL library search	
#1	Parity (Mesh)
#2	Pregnant women (Mesh)
#3	Gravidity (Mesh)
#4	Primigravidi* (tiab) OR Primiparity (tiab)
#5	#1 OR#2 OR #3 OR #4
#6	Therapeutic Touch (Mesh)
#7	Mind-Body therapies (Mesh)
#8	massage (tiab) OR "massage therapy*" (tiab) OR "sacral pressure" (tiab) OR "touch therapy*" (tiab) OR "abdominal massage" (tiab)
#9	#6 OR #7 OR #8
#10	"Labour Pain" (Mesh)

#11	"Obstetric Pain" OR "Labour Pains" OR "Pain Labour" OR "Pain Obstetric" OR "parturition pain" OR "childbirth pain*" OR "delivery pain" OR "birth pangs" OR "birth pain"
#12	#10 OR #11
#13	#5 AND #9 AND #12
#14	"Apgar Score" (Mesh)
#15	Infant, Newborn" (Mesh)
#16	#14 OR #15
#17	#5 AND #9 AND #16

[Table/Fig-1]: Search strategy. PubMed-MEDLINE.

Inclusion criteria: This review included studies published from 2002-2021 on primiparous women without known risk factors, those who were in active labour with 4 cm of cervical dilatation and outcomes of study was labour pain and/or neonatal APGAR score.

Exclusion criteria: Those studies with women of high risk pregnancy, having multiple foetus, received infertility treatment or have chronic physical or psychiatric illness or presence of co-morbidity in primiparous women, presence of health problems in the foetus or those who have received pharmacological anaesthesia for pain previously were excluded from the review.

Interventions: An investigator's light or deep stroke with a flat surface of hand on the back, head, forehead, shoulder, abdomen, legs, and hands of a woman in the active stage of labour starting from cervical dilatation to full dilatation of cervix in every alternate hour is referred to as TT. Massage therapy using the hands of the performer/therapist were primarily included as intervention in this review. Use of oil during massage, aromatherapy and reflexology using materials other than hands were not included in this review. Routine care provided for the primiparous women was considered as the comparator intervention.

Primary and secondary outcomes: The primary maternal outcome was the intensity of labour pain. The secondary outcomes reported in this review were neonatal APGAR score at 1 minute and 5 minutes, APGAR score <7 at 5 minute and admission to neonatal intensive care unit.

Screening and reviewing of studies: Following initial searching of the databases, duplicates were removed using Zotero software 5.0. Then, two reviewers (SS, AB) independently screened the titles and abstracts of studies selected from the database search using the Rayyan-web app for systematic review [17]. The articles eligible for full text review were identified and extracted. The authors (SS, AB) independently reviewed the identified full text articles for their possible inclusion. Any disagreement arising in the process was resolved by discussion between the authors (SS, AB). The final list of the included studies that met the inclusion and exclusion criteria was prepared.

Data Collection, Extraction and Management

The Data Extraction Form (DEF) was prepared for the study and relevant information including participant details and study details including study design, country of research, sample size, age, gestational age, stage of delivery, instruments for measuring pain intensity, intensity of labour pain scores in active phase, transitional phase and second stage of labour, APGAR score at 1 minute and 5 minutes and admission to neonatal intensive care unit were recorded in the DEF. Data on the intensity of labour pain (mean), (standard deviation), and total participants were independently extracted from included studies by the reviewers (SS, AB).

Assessment of risk of bias in included studies: Two authors independently assessed the risk of bias for each trial using the criteria outlined in the Risk of Bias tool 2.0 of the Cochrane risk-of-bias tool for randomised trials (RoB 2) [18]. Studies were described as low risk, some concerns or high risk depending on the criteria given in the Cochrane handbook [19]. Any disagreement was resolved by discussion or by involving a third assessor.

STATISTICAL ANALYSIS

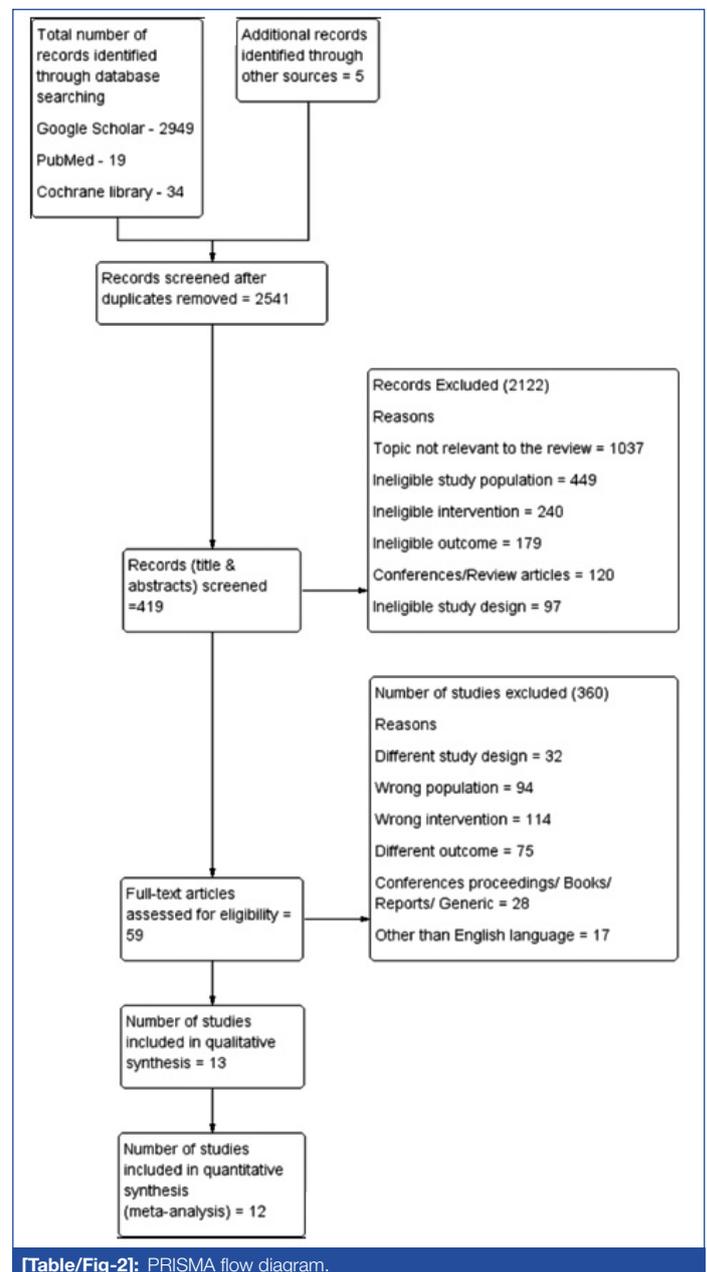
For continuous variables (pain intensity score), the authors calculated the pooled standardised mean difference between TT and the routine maternity care for the active and transitional phase of first stage of labour, and fourth stage of labour. For neonatal APGAR score at 1 minute and 5 minutes, mean difference between the two groups was pooled. The pooled Risk Ratio (RR) for neonatal Apgar score of less than 7 at 5 minutes and admission to neonatal intensive care unit was calculated between TT and usual intranatal care. The authors assessed the heterogeneity between the studies using visual inspection of forest plots, the Cochran-Q test and I^2 statistic. Heterogeneity was considered if I^2 value was greater than 25% or Cochran-Q >0.1. Heterogeneity was graded as low, moderate, and high for I^2 values of 25%, 50%, and 75%. In case of heterogeneity, random effect model was used. The authors explored the sources of the heterogeneity by sensitivity analysis according to the risk of bias of included studies. For the outcome intensity of labour pain, publication bias was investigated using funnel plots. Statistical analyses were performed, and forest plot were prepared by Rev Man 5.4 software. Two-sided p-value <0.05 was considered statistically significant, except for the subgroup analysis and heterogeneity test, in which p-value of 0.10 was considered significant.

RESULTS

A total of 3007 articles were searched from different databases and 59 articles were found eligible for full-text selection. Out of 59 articles, 13 studies met the inclusion and exclusion criteria and were included in qualitative synthesis and 12 studies in quantitative synthesis or meta-analysis [Table/Fig-2].

This review included 13 randomised trials with a total of 1302 primiparous women. The characteristics of the included studies were described in [Table/Fig-3]. Ten studies (Chang MY et al., 2002, Gallo RBS et al., 2013, Gallo RBS et al., 2017, Karami NK et al., 2007, Kamjoo A et al., 2018, Levett KK 2016, Pinar SE and Demirel G 2020, Sadat HZ et al., 2016 and Bolbol-Haghighi N et al., 2016, Janssen P et al., 2012) included two-arm trials, two studies (Kimber L et al., 2008 and Maghalian M et al., 2021) included three-arm trials and one study (Gönenç IM and Terzioğlu F 2020) included four-arm trials [13-15,20-29]. All studies included routine maternity care as the control intervention. Data could not be extracted from the study by Kamjoo A et al., 2018 [21]. Therefore, twelve studies were included for the outcome- labour pain intensity and three studies were included for the neonatal outcome in the meta-analysis.

The TT or massage therapy was the intervention in the review. Three studies applied massage for 30 minutes [15,28,29]. Massage was applied by therapist/physiotherapist in five studies [14,20,24,26,28]. The intervention in two studies were applied by therapist/midwife [25,27]. The intervention in six studies was performed by the researcher [13,15,22,23,28,29]. Massage comprising abdominal effleurage, sacral pressure, shoulder, and kneading for 30 minute was applied in four studies [14,15,25,29]. Three studies applied Swedish massage [13,20,26]. Gallo RBS et al., applied three non pharmacological interventions: exercises on a Swiss ball, lumbosacral massage, and a warm shower for about 40 minute each [20]. Massage was applied in the second phase using periodic ascending kneading hand actions, and a return with sliding, through the lateral region of the trunk in association with sacral pressure. Kimber L et al., applied massage using slow rhythmic long stroke massage movements, using the palm of the hands with relaxation techniques for a two and half hour between 35- and 37-weeks' gestation and Levett KK taught visualisation, breathing, massage and yoga to the participants prior to 36 weeks' gestation with a birth partner [22,27]. Pinar SE and Demirel G included TT for 15 minutes in the active phase of the first stage of labour and in the second stage of labour by using rhythmic and soft movements on the hand [23]. Kamjoo A et al., applied a 10-minutes mild massage on the entire



[Table/Fig-2]: PRISMA flow diagram.

surface of each foot, in the active labour phase [21]. Primiparous women over 37 weeks of gestation were the participants in eleven studies. Two studies (Kimber L 2008 and Levett KK 2016) recruited women less than 37 weeks of gestation [22,27].

The meta-analysis of labour pain intensity included ten studies involving 621 women [13-15,20,23,24,26-29]. Nine studies [13-15,20,23,24,26,27,29] were included in the meta-analysis of the active phase of labour and four studies [15,24,26,28] included in the transitional phase and one study [23] in the fourth stage of labour. Eight studies used the Visual Analogue Scale (VAS) to assess pain intensity [13,14,20,23,24,27-29]. The McGill Pain Questionnaire was used by Janssen P et al., 2012 [26], and one study used the self-reported pain intensity (PPI) scale [15].

Outcomes

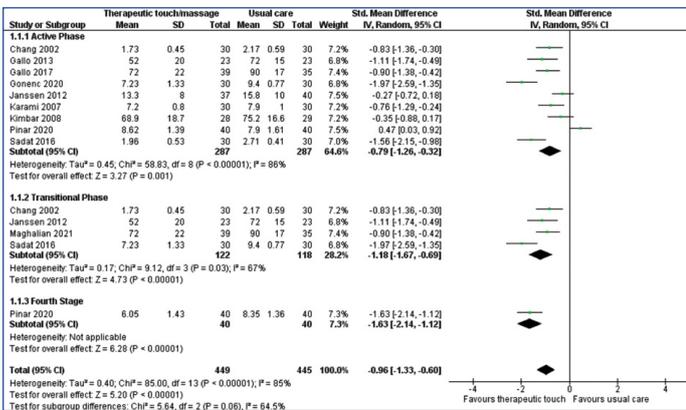
Pain intensity: Overall, there was a small reduction in pain intensity of primiparous women receiving massage/TT compared to routine care (SMD: -0.96 (95% CI: -1.33, -0.60), $I^2=85\%$). The difference of pain intensity in the active phase of labour was (SMD: -0.79 (95% CI: -1.26, -0.32, $I^2=86\%$) including 574 women and in the transitional phase, the difference was slightly greater than active phase {SMD: -1.18 (95% CI: -1.67, -0.69), $I^2=67\%$ }. In the fourth stage of labour, highest reduction of pain intensity was recorded {SMD: -1.63 (95% CI: -2.14, -1.12)} [Table/Fig-4].

Author/Year	Country/Setting	Study design (Period)	Sample size (Randomised/Analysed)	Participants age (years): Mean (EG/CG) Inclusion/Exclusion criteria	Interventions experimental group and control group	Outcome measured/Time point	Results/Outcomes
Bolbol-haGhiGhi-N et al., [25] 2016	Iran/ Hospital	RCT (October 2013 to June 2015)	Total: 100 Randomised EG: 50; CG: 50. Analysed EG: 50; CG: 50	Age- EG: 25.84 (5.22), CG: 23.42 (4.51) 100 women aged between 18-45 years with singleton live foetus were included.	EG: Intervention included massage plus partogram. Massage to 'under belly', upper thighs, sacral region, shoulders and legs for minimum of 30 minutes by midwifery students. CG: Usual care plus partogram	Appgar score recorded at 1 minute and at 5 minute Others: Duration of labour, type of delivery, oxytocin augmentation	Appgar score at 1 and 5 minutes
Chang MY [15] 2002	Taiwan/ Regional hospital	RCT (September 1999 to January 2000)	Total: 83 Randomised EG:42; CG: 41. Analysed EG: 30; CG:30	Age- EG: 28 (3.74), CG: 27.9 (3.85)	EG: 30 minutes massage in latent, active, transitional phase CG: Standard care	Labour pain intensity at latent (3-4 cm), active (5-7cm) and transitional phase (8-10 cm)	Pain intensity assessed by the present behavioural intensity scale on a scale of 0-5.
Gallo RBS 2013 [14]	Brazil/ Reference Center of Women's Health	RCT (September 2009 to May 2010)	Total: 46 Randomised EG: 23; CG: 23. Analysed EG: 23; CG:23	Age- EG: 19 (3), CG: 19 (4). primigravida, a single foetus in cephalic position, low-risk pregnancy, atleast 37 weeks of gestation, spontaneous onset of labour, cervical dilation of 4-5 cm were included.	EG: 30 minute rhythmic, ascending, kneading hand movements, sacral pressure between T10 and S4 CG: Routine maternity care	Pain severity in active phase of labour (4-5 cm) Appgar score recorded at 1 minute and at 5 minute	Pain intensity assessed by participant on a 0-100 mm VAS Appgar score (0 to 10) of newborn >7 at fifth minute
Gallo RBS 2017 [20]	São Paulo, Brazil/ Reference Center of Women's Health	RCT cross-over (October 2011 to July 2012)	Total: 80 Randomised EG: 40; CG: 40. Analysed EG: 39 CG: 35	Age- EG: 21 (4), CG: 22 (4) primigravida with a low-risk pregnancy; a gestational age > 37 weeks; a single foetus in the cephalic position; spontaneous onset of labour; cervical dilation of 4 to 5 cm were included.	EG: 3 interventions given. First, pelvic motion exercises while sitting on a Swiss exercise ball for 40 min Second, massage for 40 minutes, using rhythmic ascending kneading hand movements with sacral pressure between T10 and S4. Third, warm shower for 40 minutes CG: Routine maternity care	Labour pain intensity in active phase of labour Appgar score recorded at 1 minute and at 5 minute	Pain intensity assessed by the participant on a Visual Analogue Scale (VAS) of 0 to 100 mm Appgar score of newborn (0 to 10) at first minute and fifth minute
Gönenç IM and Terzioğlu F 2020 [29]	Turkey/ Women's health, education, and research hospital	22 (Four arm) factorial trial RCT (August 2012 to March 2013)	Total: 120 Randomised EG: 30; CG: 30. Analysed EG: 30; CG: 30	Age- EG: 23.4 (3.2), CG: 22.4 (3) primiparous, 20-30 years, less than 4-cm cervical dilatation, at 38-42 weeks gestation, single and healthy foetus were included.	EG: 30-minute massage session of head, neck, shoulder, back, arms, hands, legs, and feet during the latent, active and transition phases. CG: Standard care	Labour pain intensity in active phase of labour Appgar score recorded at 1 minute and at 5 minute	Pain intensity assessed by the participant on a Visual Analogue Scale (VAS) of 0 to 10 cm ruler scale
Janssen P et al., 2012 [26]	Canada/ Women's hospital	RCT	Total: 77 Randomised EG: 37; CG: 40. Analysed EG: 37; CG: 40	Nulliparity, singleton gestation, cephalic presentation, term gestation, maternal age 18-35 years were included.	EG: Swedish massage administered up to five hours CG: Standard care	Labour pain intensity	Pain intensity assessed by the Short Form McGill Pain Questionnaire which utilises 16 descriptors. The scale is ranked on an intensity scale of 0=none, 1=mild, 2=moderate, and 3=severe.
Karami NK 2007 [13]	Iran/ Hospital	RCT (2004)	Total: 60 Randomised EG: 30; CG: 30 Analysed EG: 30; CG: 30	Primiparous women aged 20-35 years, single alive foetus and gestational age of 38 to 42 weeks.	EG: Swedish massage using effleurage technique administered on sacrum, buttocks, shoulders, waist, foot and hand CG: Standard care	Labour pain intensity in first stage of labour at 8-10 cm	Pain intensity assessed by Visual Analogue Scale (VAS)
Kimber L et al., [27] 2008	UK/ Maternity Unit, Banbury	Three arm RCT (2004 to 2006)	Total: 90 Randomised Massage and relaxation group: 30; Placebo group: 30; CG: 30. Analysed Randomised Massage and relaxation: 29; placebo group: 28; CG: 27	Age- Massage and relaxation group: 30, range -18-4, CG: 30, range -19-41. women booked for care and birth at the unit during the trial period were included.	EG: 2.5-hour slow rhythmic long stroke massage movements using the flats of the hands on the lower back and upper and lower limbs atleast 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening. It was combined with slow rhythmic breathing. CG: Standard care Placebo group: Music with relaxation techniques	Labour pain intensity in first stage of labour Others: Admission to neonatal intensive care	Pain intensity assessed by Visual Analogue Scale (VAS)
Kamjoo A et al., 2018 [21]	Iran/ Hospital	RCT (2014)	Total: 240 Randomised EG: 120; CG: 120. Analysed EG: 120; CG: 120	Age- EG: 24.4 (4.6), CG: 25.2 (5.2) 18 to 35 years, Iranian nationality, 37 th to 42 nd week of pregnancy were included.	EG: Reflexology consisting mild massage was done on the whole surface of the foot. It was followed by a massage of the reflexive spot, duration- 20 minute CG: Standard care	Labour pain intensity and length of labour in the active phase of labour (5-7 cm and 8-10 cm)	Pain intensity assessed by VAS diagram, numbered from 0 to 10. Zero is indicative of no pain and 10 indicates the most intense pain.

Maghalian M et al., 2021 [28]	Iran/ Labour ward of University of Medical Sciences	Three arm RCT (2019 to 2020)	Total: 90 Randomised EG: 30; CG: 30. Analysed EG: 30; CG: 30	Age - EG: 23.6 (5.9), CG: 22.6 (5.3) primiparous pregnant women, singleton pregnancies between 38 and 40 weeks, cervical dilatation 4 cm, cephalic fetal presentation, no rupture of membranes, lack of drug addiction and smoking, having low-risk pregnancy were included.	EG: Two massage techniques of effleurage and petrissage 30-45 min at the T10-S4 levels at the onset and end of the active phase. The intervention was started with effleurage technique and then petrissage technique was applied. The duration of two massage techniques was same. CG: Standard care Third group: Interferential electrical stimulation (IES)	Labour pain intensity at the end of active phase (8-10 cm cervical dilatation), childbirth experience, active phase duration, score of childbirth satisfaction, fetal heart rate abnormalities, and neonatal Apgar score in the 1 st and 5 th min	Pain intensity assessed by VAS scale, scaled line with a 10 cm length
Pinar SE and Demirel G 2020 [23]	Turkey/ Maternity unit of a public hospital	RCT (July to December 2019)	Total: 80 Randomised EG: 40; CG: 40. Analysed EG: 40; CG: 40	Age - EG: 26.6 (5.5), CG: 25.1 (5.2) first pregnancy, not a high-risk pregnancy, no health problems with the baby or herself, a single foetus were included.	EG: Therapeutic touch was applied twice (in the active phase of the first stage of labour, and the second was done in the second stage of labour) for 15 minutes using rhythmic and soft movements on the hand of the woman. CG: Usual routine care	Labour pain intensity in active phase of labour, anxiety and childbirth attitude	Pain intensity assessed by Visual Analogue Scale (VAS), anxiety by state Anxiety Inventory (SAI) and childbirth attitude by Childbirth Attitudes Questionnaire
Sadat HZ et al., 2016 [24]	Iran/ Labour ward	RCT (2007 to 2008)	Total: 60 Randomised EG: 30; CG: 30. Analysed EG: 30; CG: 30	Age - EG: 21.9 (3.2), CG: 22 (3.7) primigravida women aged between 18 to 35 years, gestational age between 38-42 weeks, primigravida, cephalic presentation were included.	EG: manual effleurage (superficial and deep) massage for 15 minutes CG: standard care	Labour pain intensity at 5 cm and 8 cm and duration of pain	Pain intensity assessed by VAS scale
Levett KK 2016 [22]	Australia/ Antenatal clinic	RCT (April 2012 to August 2013)	Total: 176 Randomised EG: 89; CG: 87. Analysed EG: 88; CG: 83	Age - EG: 30.41 (4.99), CG: 28.87 (5.24) Women who had a singleton pregnancy with a cephalic presentation were included.	EG: 2-day course involving visualisation, yoga, breathing techniques, massage, acupressure, and facilitated partner support. CG: Standard care	Apgar score recorded at 5 minute	Apgar scores <7 at 5 minutes

[Table/Fig-3]: Characteristics of the included studies [13-15,20-29].

PBI: Present behavioural intensity, EG: Experimental group, CG: Control group

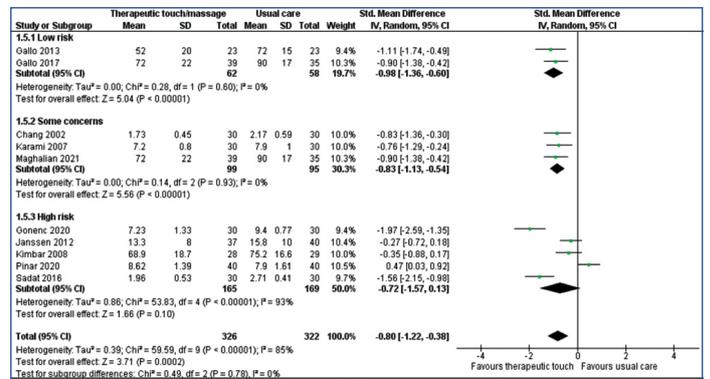


[Table/Fig-4]: Forest plot showing effect of Therapeutic Touch (TT) on labour pain intensity in primiparous women.

On sensitivity analysis, it was found that studies with low risk of bias (SMD: -0.98 (95% CI: -1.36, -0.60), I²=0%) and some concerns (SMD: -0.83 (95% CI: -1.13, -0.54), I²=0%) had significant reduction of pain intensity without any presence of heterogeneity. However, the studies with high risk of bias showed no significant reduction of pain intensity (SMD: -0.72 (95% CI: -1.57, 0.13), I²=93%) with substantial heterogeneity [Table/Fig-5].

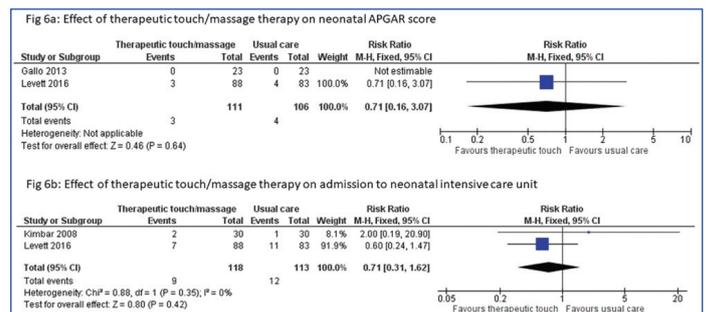
Apgar score less than seven at five minutes: Two studies reported APGAR score at 1 minute and 5 minutes [20,25], and two studies reported the number of neonates with APGAR score <7 at 5 minutes [20,22]. No significant effect was found for the outcome APGAR score < 7 at 5 minutes between the two groups {RR: 0.71 (95% CI: 0.16, 3.07)} [Table/Fig-6a].

Overall, significant reduction in APGAR score {MD: 0.55 (95% CI: 0.37, 0.73)} was found in the intervention group compared to the control group. However, there was no significant reduction in APGAR score at one minute {MD: 0.78 (95% CI: 0.47, 1.09)} between the two groups.



[Table/Fig-5]: Sensitivity analysis of the effect of Therapeutic Touch (TT) on pain intensity according to the risk of bias of the included studies.

Admission to neonatal intensive care unit: Two studies including 231 women, reported this outcome [22,27]. The studies found no significant reduction of admission to neonatal intensive care unit {RR: 0.71 (95% CI: 0.31, 1.62), I²=0%} in group receiving TT/ massage therapy compared to the women receiving the usual care [Table/Fig-6b].



[Table/Fig-6]: Forest plot showing effect of Therapeutic Touch (TT) on neonatal outcomes in primiparous women.

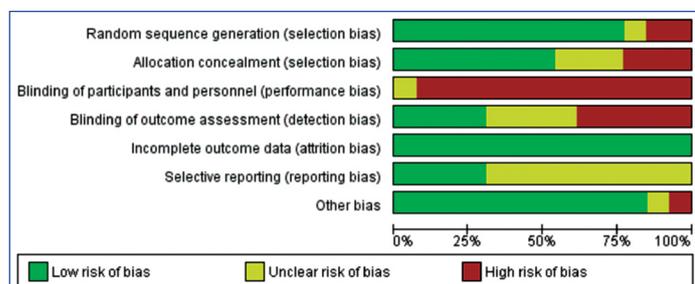
Risk of bias in included studies: Three studies were found of low risk of bias [14,20,22], three studies of some concerns [13,15,28] while seven studies were at high risk of bias [21,23-27,29]. None of the studies have shown missing outcome data. For randomisation domain, seven studies were found of low risk of bias [14,15,20,22,26,28,29], five had some concerns [13,23-25,27] and one study had high risk of bias [21]. Seven studies had high risk of bias for the assessment of the outcome [21,23,24,25-27,29] and one study had some concerns [13]. Eight studies had some concerns about the selection of the reported result [Table/Fig-7,8] [13,21,24-29]. The funnel plot showed asymmetry indicating probable publication bias.

Study ID	D1	D2	D3	D4	D5	Overall
Gallo 2013	+	+	+	+	+	+
Chang 2002	+	!	+	+	+	!
Gallo 2017	+	+	+	+	+	+
Gonenc 2020	+	+	+	-	!	-
Janssen 2012	+	+	+	-	!	-
Kamjoo 2018	-	+	+	-	!	-
Karami 2007	!	+	+	!	!	!
Kimbar 2008	!	!	+	-	!	-
Levett 2016	+	+	+	+	+	+
Maghalian 2021	+	+	+	+	!	!
Pinar 2020	!	+	+	-	+	-
Sadat 2016	!	+	+	-	!	-
Bolbol-Haghighi 2016	!	+	+	-	!	-

+ Low risk
 ! Some concerns
 - High risk

D1 Randomisation process
 D2 Deviations from the intended interventions
 D3 Missing outcome data
 D4 Measurement of the outcome
 D5 Selection of the reported result

[Table/Fig-7]: Summary of risk of bias of individual studies.



[Table/Fig-8]: Risk of bias graph.

DISCUSSION

The review found small but significant pain reduction in the active phase and transitional phase of first stage of labour in primiparous women when compared with women received usual care in labour. This finding is comparable to a systematic review [16]. However, the study found no significant benefit in the second and third stage of labour. Another systematic review reporting the trials from Iran has shown significant evidence of the effect of massage therapy on primiparous women. The study showed a significant effect of massage therapy in latent, active and transitional phase of the labour [30]. The study by Ranjbaran M et al., included studies from Iran only, whereas the present review included studies all over the world [30]. Similar to this review, the systematic review conducted by Ganji J and Keramat A found evidence for massage in decreasing the intensity of labour pain [31]. Most of the studies included in that review were moderate to high bias. Alike that review, majority of the studies in this review had a high risk of bias. However, on sensitivity analysis of studies with low risk of bias, the authors found a significant reduction of intensity of pain than studies with some concerns and a high risk of bias.

The present review found no detectable effect of TT on neonatal outcomes (APGAR score and admission to neonatal intensive care unit). Though the APGAR score reported in the studies had shown better score in intervention groups than the group receiving the usual care. This is similar to the review by Smith CA et al., which also found no clear differences between experimental and control groups in terms of neonatal outcomes [16]. A review by Simkin P revealed that during labour, a nurse's reassuring touch and massage may help to relieve pain, reduce anxiety, and speed up the process with no known hazards [32]. The study by Simkin P reviewed the literature qualitatively with no statistical analysis [32].

Choudhary S et al., in a systematic review has shown that non pharmacological interventions for reducing labour pain have been effective in 10 studies included in the analysis [33]. He has shown back massages to be useful in relieving discomfort during labour. The review included only quasi-experimental study. Whereas the authors included only randomised trials in this review and found a positive effect of the intervention on pain intensity. Another quasi-experimental study by Kamal Abd Elkhalek N et al., shown similar positive effect of massage on intensity of pain in primigravida women [34].

A network meta-analysis by Hu Y et al., found that non pharmacological therapies, including massage therapy for labour pain management in low-risk pregnant women, are effective and safe [35]. The study emphasised the need for quality study to validate the effect of massage therapy on decrease in pain intensity, as most of the studies in the network analysis were low-to-moderate risk of biases. Sananpanichkul P et al., conducted a randomised controlled trial which included 59 nulliparous and multiparous pregnant women showed that there was no difference of pain score between the experimental group and routine intranatal care group [36]. Most of the studies in the review had some concerns to high risk of bias. Therefore, quality randomised trials are needed for further evaluation of TT on maternal pain intensity and neonatal outcomes.

Limitation(s)

First, this review includes TT as the intervention. However, there are other non pharmacological interventions that could be effective in reducing labour pain in primiparous women. This review could not explore those interventions. Secondly, most of the studies included in this review have risk of biases. The researchers must consider the quality of the studies while interpreting the results. None of the studies in this review could blind the participants, and very few studies could blind for intervention giver and outcome assessors. This might introduce the chances of outcome assessment being influenced by the outcome assessors. Moreover, the self-reported outcome like the intensity of pain may be affected because of the lack of blinding of the participants.

CONCLUSION(S)

This review found significant slight reduction in pain intensity in active, transitional and fourth stage of labour and no significant improvement of neonatal outcomes. The studies included in the review were mostly have biases regarding blinding of outcome assessors and reporting of the result. Therefore, the findings need to be interpreted cautiously. Future good quality randomised controlled trials are needed to evaluate the effect of TT on intensity of labour pain and neonatal outcomes.

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