



UNIVERSITI PUTRA MALAYSIA

***EFFECTIVENESS OF BREATHING EXERCISES, FOOT REFLEXOLOGY
AND MASSAGE ON MATERNAL AND NEW-BORN OUTCOMES AMONG
PRIM GRAVIDAE IN SAUDI ARABIA***

BALJON KAMILYA

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By

BALJON KAMILYA

**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia in
Fulfilment of the Requirements for the Degree of Doctor of Philosophy**

April 2021

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

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April 2021

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Introduction: Labour pain is an individual experience and one of the most severe pain that primigravidae may experience. Failure of a pregnant woman to address labour pain and anxiety may lead to abnormal labour. Despite the availability of many complementary non-pharmacological approaches, the quality of evidence is low, and the best approaches have yet to be established. Therefore, this study was aim to investigate the effects of a combination of breathing exercises, foot reflexology and back massage (BRM) on the labour experiences of primigravidae. This randomized controlled trial involved an intervention group receiving BRM and a control group receiving standard labour care. The two groups are stratified by intramuscular pethidine in labour to ensure each subgroup of the population is received suitable representation within the sample. This achieves a balance in the number of primigravidae with or without intramuscular pethidine given to intervention and control groups. Primigravidae at 24th week to 34th week of gestation without chronic diseases or pregnancy-related complications were recruited from antenatal clinics. The BRM intervention: Breathing exercises five minutes, foot reflexology 20 minutes, and leg and back massage 35 minutes was performed by a trained massage therapist who trained the research coordinators, the outcomes assessors, and the massage therapists. The primary outcomes included labour pain and anxiety. The labour pain was measured during and after uterine contractions at baseline (cervical dilation 6cm), during the intervention, immediately after the intervention, and every 60 minutes for two hours, while anxiety was measured at baseline (cervical dilation 6cm), immediately after the intervention, and every 60 minutes for two hours. The secondary outcomes that observed maternal outcomes included maternal stress hormone (adrenocorticotrophic hormone, cortisol, and oxytocin) levels, vital signs, duration of the labour, maternal satisfaction, and new-born outcomes including foetal heart rate and APGAR scores. Methods: The between- and within-group outcome measures were examined with the generalized linear mixed model, time series analyses, post hock test and Bonferroni test; non-parametric tests to compare between the groups. The sample size is estimated based on the between-group difference of 0.6 in

anxiety scores, which were lower different effect sizes, thus, it will produce a larger sample size estimation that can be used to measure both different pain and anxiety, 95% power and 5% α error, which yields a required sample size of 184 primigravidae (92 in each group) accounting for a 40% attrition rate. Ethical approval was obtained from the Ethical Committee for Research Involving Human Subjects of the Ministry of Health in Saudi Arabia (H-02-K-076-0319-109) on 14 April 2019 and from the Ethics Committee for Research Involving Human Subjects (JKEUPM) Universiti Putra Malaysia on 23 October 2019, reference number (JKEUPM-2019–169). Results: A total of 253 participants were eligible for the study; however, 225 of them (response rate of 88.9%) agreed to participate in the study. They were randomized into the intervention group (n=113), and the control group (n=112). Throughout the study, 19 participants from the intervention group and 22 participants from the control group dropped out of the study. Depending on the dropped out participants from the trial, that resulted in 94 participants in the intervention group and 90 in the control group. Baseline characteristics between the intervention group and control group were comparable except the serum cortisol level ($p<0.001$) and the scores for Motherhood Constellation-Anxiety ($p=0.032$). The results showed that BRM intervention reduced the Present Behavioural Intensity and Visual Analog Scale pain scores during and after contraction ($p<0.001$) compared to those in the control groups, and the pain scores gradually decreased in the intervention group, while the control group did not show significant changes in their pain scores. Additionally, the level of Birth Process-Anxiety was also significantly ($p<0.001$) reduced in the intervention group as compared to the control group. It was observed that the level of Motherhood Constellation- Anxiety gradually increased in both the intervention and the control groups. However, the intervention group exhibited lower maternal stress hormone levels, lower maternal pulse rate and blood pressure, shorter duration of labour, and higher maternal satisfaction and APGAR scores in their newborns compared to the control group. Conclusion: The findings of this study indicate substantial effectiveness of the combined BRM interventions in relieving labour pain and anxiety, and in improving maternal and new-born outcomes among the primigravidae. It is recommended that healthcare providers involved in the childbirth of primigravidae should consider implementing this combined non-pharmacological measure to improve labour experience, maternal, and new-born outcomes.

Keywords: Breathing exercises, Labour pain, Massage, Maternal stress hormones, Primigravidae, Reflexology.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

KEBERKESANAN LATIHAN PERNAFASAN, REFLEKSOLOGI KAKI DAN URUT KE ATAS NATIJAH MATERNAL DAN BAYI BAHARU LAHIR DALAM KALANGAN PRIMIGRAVIDA DI ARAB SAUDI

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Pengenalan: Sakit bersalin merupakan pengalaman individu dan salah satu kesakitan paling teruk yang dilalui oleh primigravida. Kegagalan seseorang wanita mengandung untuk menangani sakit bersalin dan kegelisahan mungkin membawa kepada bersalin abnormal. Walaupun terdapat banyak pendekatan bukan farmakologi komplementari, namun kualiti pembuktian adalah rendah, dan pendekatan terbaik masih tidak dapat ditentukan. Kajian ini bertujuan untuk meneliti kesan kombinasi latihan pernafasan, refleksologi kaki dan urutan belakang (BRM) ke atas pengalaman bersalin dirasakan primigravida. Percubaan terkawal terawak melibatkan kumpulan intervensi yang menerima BRM dan kumpulan kawalan yang menerima penjangakan bersalin standard, dipilih melalui suntikan petidina intramuskular yang digunakan ketika bersalin bagi memastikan setiap subkumpulan populasi mewakili representasi yang sesuai dalam sampel, yang mencapai keseimbangan dari segi bilangan primigravida dengan atau tanpa petidina intramuskular yang diberikan kepada kumpulan kawalan dan intervensi. Primigravida pada kehamilan minggu ke-24 hingga ke-34 tanpa penyakit kronik atau komplikasi berkaitan kehamilan telah dipilih dari klinik antenatal. Intervensi BRM: Bernafas lima minit, refleksologi 20 minit, dan urut 35 minit telah dilakukan oleh juruterapi urut terlatih yang melatih koordinator penyelidikan, penilai hasil, dan juruterapi urut. Dapatan utama kesakitan bersalin dan kegelisahan, sakit bersalin diukur semasa dan selepas kontraksi rahim berlaku pada aras dasar (dilatasi serviks 6sm) dan ketika intervensi, sejeurus selepas intervensi dan setiap 60 minit selama dua jam. Manakala, kegelisahan diukur pada aras dasar (dilatasi serviks 6sm), sejeurus selepas intervensi, dan setiap 60 minit selama dua jam. Dapatan sekunder merangkumi natijah maternal, termasuk tahap hormon stres maternal (hormon adrenokortikotropik, kortisol, dan oksitosin), tanda utama, tempoh bersalin, kepuasan maternal, dan natijah bayi baharu lahir termasuk kadar jantung janin dan skor APGAR. Kaedah: ukuran hasil antara dan dalam kumpulan telah diteliti melalui model campuran linear umum, analisis siri masa, ujian pascahock dan ujian Bonferroni; ujian bukan parametrik bagi membandingkan antara kumpulan. Saiz sampel dianggar berdasarkan perbezaan antara kumpulan 0.6

dalam skor kegelisahan, skor kegelisahan mana yang lebih rendah bagi saiz kesan berbeza, supaya ia dapat memberikan anggaran saiz sampel yang lebih besar yang dapat digunakan bagi mengukur kedua-dua kesakitan yang berbeza dan kegelisahan, 95% kekuatan dan 5%, α ralat yang menghasilkan saiz sampel yang perlu sebanyak 184 (92 dalam setiap kumpulan) yang menyumbang kepada kadar atrisi 40%. Kelulusan etika telah diperoleh daripada Jawatankuasa Etika Penyelidikan Melibatkan Subjek Manusia, Kementerian Kesihatan di Arab Saudi (H-02-K-076-0319-109) pada 14 April 2019 dan daripada Jawatankuasa Etika Penyelidikan Melibatkan Subjek Manusia (JKEUPM), Universiti Putra Malaysia pada 23 Oktober 2019, nombor rujukan (JKEUPM-2019-169). Sebanyak 253 peserta layak, hanya 225 (kadar respon, 88.9%) bersetuju untuk turut serta. Mereka dipilih secara rawak dalam kumpulan intervensi ($n = 113$) dan kumpulan kawalan ($n = 112$). Sepanjang kajian, 19 peserta keluar dari kumpulan intervensi manakala 22 peserta keluar dari kumpulan kawalan. Bergantung pada peserta yang dikeluarkan dari percubaan, itu menghasilkan 94 peserta dalam kumpulan intervensi dan 90 dalam kumpulan kawalan. Karakteristik aras dasar antara kumpulan intervensi dan kawalan telah dibandingkan kecuali tahap kortisol serum ($p < 0.001$) dan skor Kegelisahan Konstelasi Keibuan ($p = 0.032$). Dapatan menunjukkan intervensi BRM merendahkan Intensiti Tingkah Laku Semasa dan skor kesakitan Skala Analog Visual ketika dan selepas kontraksi ($p < 0.001$) berbanding dengan mereka dalam kumpulan kawalan, dan skor kesakitan secara beransur-ansur menurun dalam kumpulan intervensi, manakala kumpulan kawalan tidak menunjukkan perubahan yang signifikan dalam skor kesakitan mereka. Di samping itu, tahap Kegelisahan Proses Kelahiran juga secara signifikan ($p < 0.001$) berkurang dalam kumpulan intervensi berbanding dengan kumpulan kawalan. Kajian memperlihatkan bahawa tahap Kegelisahan Konstelasi Keibuan secara beransur-ansur meningkat dalam kedua-dua kumpulan intervensi dan kawalan. Walau bagaimanapun, kumpulan intervensi menunjukkan tahap hormon stres maternal yang lebih rendah, kadar denyutan nadi dan tekanan darah yang lebih rendah, skor APGAR yang lebih baik pada bayi mereka berbanding dengan kumpulan kawalan. Kesimpulan: Dapatan kajian menunjukkan keberkesanan intervensi BRM gabungan yang substansial dalam melegakan kesakitan bersalin dan kegelisahan, dan menambah baik natijah bayi baharu lahir dalam kalangan primigravida. Kajian mengesyorkan supaya pekerja jagaan kesihatan yang terlibat dalam proses kelahiran bayi harus mengambil kira untuk mengimplementasikan ukuran bukan farmakologikal gabungan ini bagi menambah baik pengalaman, natijah maternal dan bayi baharu lahir.

Kata kunci: Senaman pernafasan, Sakit bersalin, Urut, Hormon stres maternal, Primigravida, Refleksologi.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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LIST OF ABBREVIATIONS

BRM	Breathing, Reflexology, And Massage
UPM	Universiti Putra Malaysia
JKEUPM	Ethics Committee For Research Involving Human Subjects University Of Putra Malaysia
WHO	World Health Organization
CAM	Complementary Alternative Medicine
CS	Caesarean Sections
MCH	Maternal Children Hospital
RCTs	Randomized Control Trials
PBI	Present Behavioural Intensity
VAS	Visual Analog Scale
AASPWL	Anxiety Assessment Scale for Pregnant Women in Labour
VS	Vital Signs
FHR	Foetal Heart Rate
APGAR scores	An acronym for A-pppearance, P-ulse, G-rimace, A-ctivity and R- espiration
CTG	Cardio-Toco-Graphy
SSQ	Simple Six Questions
MEDLINE	Medical Literature Analysis and Retrieval System Online
CINAHAL	Cumulative Index of Nursing and Allied Heath Literature
SCOPUS	Skills, Knowledge and Organizational Performance
CONSORT	Consolidation Standards of Reporting Trails
SVD	Spontaneous Vaginal Delivery
MOH	Ministry of Health
STAIS	State-Trait Anxiety Inventory Scale
ACTH	Adrenocorticotropic Hormone

BP-Anxiety	Birth Process Anxiety
MC- Anxiety	Motherhood Constellation
P1	Principal Investigator
C1	Outcome Assessors
RC	Research coordinator
MT	Massage Therapist
RAs	Research Assistants
T/ R/ HR	Temperature/ Respiration/ Heart Rate
BP	Blood Pressure
SBP/ DBP	Systolic Blood Pressure/ Diastolic Blood Pressure
SMD	Standardized Mean Difference
CI	Confidence Interval
SPSS	Statistical Package for Social Science
ANOVA	Analysis Of Variance
GLMM	Generalized Linear Mixed Model
ICC	Interclass Correlation
EM	Expectation-Maximization
MCR	Missing Completely at Random
ITT	Intent-To-Treat
PPA	Per-Protocol Analysis
χ^2	Chi-Square Test
VASA	Visual Analog Scale for Anxiety
BMI	Body Mass Index
Cm	Centimetre

CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter gives an overview of the research topic, which includes the background, problem statement and the study objectives, research questions, hypothesis, definition of the study variables, and comments on the significance of the study. The focus of this research was to assess the effectiveness of the combined breathing exercise, foot reflexology and massage BRM on maternal outcomes such as labour pain, anxiety, maternal stress hormones, duration of labour, maternal satisfaction, and new-born outcomes among primigravidae during the first stage of labour in Saudi Arabia

1.2 Background of the Study

Pregnancy is approximately a nine-month period which is one of the important phases for women; a time of great happiness and fulfilment for women and their families (World Health Organization, 2018) followed by the process of labour and birth (Hanley et al., 2016). The initial thought that comes into an expectant woman's mind is the pain associated with the process of labour. Labour is a highly individualized experience, and the associated pain is the central and universal part of a woman's experience of childbirth (Akköz Çevik & Karaduman, 2020). Labour is a normal physiological process, but it is one of the most severe types of pain a woman may experience. The intensity of the labour pain is variously reported as mild, moderate, severe, or very severe (Azizi et al., 2020).

Labour pain is due to either physical factors, such as uterine contractions, or psychological factors; fear and anxiety, previous experiences, and inadequate support and knowledge (Sethi & Barnabas, 2017). Severe forms of perinatal anxiety adversely affect both mother and foetus (Levy et al., 2020). For mothers, anxiety prolongs the duration of labour and increases the rate of caesarean sections (CS), and the new-born of such mothers are more prone to develop endocrine disorders due to the high hypothalamic-pituitary-adrenal axis activity in response to high maternal anxiety (Demsar et al., 2018; Shahhosseini et al., 2015).

Previous studies have highlighted that labour pain and anxiety are the chief problems of concern that increase the duration of labour and maternal stress hormones, and also affect maternal and new-born outcomes (Cicek & Basar, 2017; Demsar et al., 2018; Levy et al., 2020). A satisfactory labour process can be achieved by reducing the pain and anxiety during labour, which further helps in establishing a good relationship between a mother and her new-born, bringing positive maternal and new-born outcomes (Wilde-larsson, Hildingsson, & Angeby, 2018).

Management of labour pain and discomfort during labour is a challenge for obstetric care (Moghimi-Hanjani et al., 2015), though many pharmacological and non-pharmacological therapies for labour pain management are available (Ferguson et al., 2016).

Pharmacological labour pain management includes opioids, narcotics, epidural analgesia, Para cervical block, spinal block, pudendal block, and nitrous oxide (Simkin & Klein, 2015). Opioids are widely used for labour analgesia, pethidine is feasible easy to be given even by midwives or provides, significant pain relief (Smith et al., 2018a). The available non-pharmacological therapies to relieve labour pain are water birth and water immersion, transcutaneous electrical nerve stimulation, application of hot and cold pack, acupressure, reflexology, massage, guided imaginary, relaxation, breathing exercises, aromatherapy, music therapy, positioning, physiotherapy and hydrotherapy (Bhore, 2016; Ghiasi et al., 2019).

The majority of pharmacological labour pain management agents are expensive and have certain adverse effects on mothers and new-born (Smith et al., 2018a). However, most of the non-pharmacological labour pain management methods are cheap and have the potential to benefit the mother and new-born (Jones, 2015). Non-pharmaceutical methods of labour pain management are likely to be better than pharmacological options because they are cost-effective and non-invasive. They are also simple to implement and encourage women's participation in the labour process (Azizi et al., 2020). Non-pharmacological therapies are preferred methods by pregnant women because they trust these therapies as safer alternatives to pharmacological treatments, given the opportunity to be involved in their labour process, and increase their control over the childbearing experience (Close et al., 2016).

The World Health Organization (WHO) has also highlighted the importance of the use of Complementary Alternative Medicine (CAM) to treat, diagnose or prevent illness (WHO, 2004). Moreover, the literature revealed that 37% to 83.7% of women use CAM during labour in Australia and Iran respectively (Dehcheshmeh & Rafiei, 2015).

BRM is a combination of breathing exercises, foot reflexology and massage therapies. Breathing exercises relax the human body, reduce the perception of pain and increase one's sense of control over oneself (El-Refaye et al., 2016; Vakilian et al., 2018). Many studies reported that breathing exercises and massage decrease pain and anxiety during labour (Bhore, 2016). Furthermore, body relaxation techniques with consistent breathing patterns reduce labour pain, shorten the duration of labour, and improve women's sense of self-control (El-Refaye et al., 2016; Yuksel et al., 2017).

Reflexology is a therapeutic method of CAM, based on the belief that certain reflexes in the human body end in the surfaces of the feet and hands, and that applying therapeutic pressure on those specific points alleviates stress and brings relaxation (Jijimole et al., 2018).

Reflexology is the application of gentle pressure on specific points on a woman's hands and feet that encourage the pituitary glands to release the required hormones to relieve the pain and to speed up the process of labour (Jijimole et al., 2018). Reflexology influences the central and peripheral nervous system, autonomic nervous system, and secretion of hormones such as epinephrine and norepinephrine (Embong et al., 2017; Moghimi-Hanjani, 2015). In addition, the literature reveals that foot reflexology decreases labour pain intensity and duration of the labour stages. It also decreases complications and improves maternal and new-born outcomes (Moghimi-Hanjani et al., 2015; McCullough et al., 2018). Likewise, a study discovered the effectiveness of foot reflexology as a short-term anxiolytic effect during labour (Levy et al., 2020).

Massage is a very old method that has been used for thousands of years to relieve pain in the human body. Massage is a therapeutic pressing and rubbing of the skin, tendons, ligaments, and muscles (Ranjbaran et al., 2017). In addition, many studies revealed that massage decreases labour pain intensity (Akköz Çevik et al., 2020; Azizi et al., 2020; Gönenç et al., 2020; Lamadah & Nomani, 2016; Sadat et al., 2016), decreases anxiety levels during labour (Akköz Çevik et al. 2020; Lamadah & Nomani, 2016), and duration of the labour stages (Gönenç et al., 2020; Lamadah & Nomani, 2016; Sadat et al., 2016).

Several studies have reported the effectiveness of non-pharmacological therapies such as massage, acupressure, water immersion, breathing exercise, reflexology, transcutaneous electrical nerve stimulation for labour pain management, shortening the duration of labour, increasing maternal satisfaction with the labour process, and keeping the APGAR scores within the normal range (Afefy, 2015; Czech et al., 2018; Erdogan et al., 2017; ELFatah et al., 2015; Nehbandani et al., 2019; Yuksel et al., 2017). However, there is a lack of application of these non-pharmacological therapies in modern labour rooms to reduce labour pain and anxiety. Additionally, no accurate evaluation has been conducted regarding the effectiveness of a combination of breathing exercise, reflexology and massage therapy in reducing labour pain, anxiety, maternal stress hormones, duration of labour, and increasing maternal satisfaction and new-born outcomes among primigravidae during the first stage of labour in Saudi Arabia.

1.3 Management of Labour Pain and Anxiety

Labour pain and anxiety are serious problems of concern and have adverse consequences for both maternal and new-born outcomes (Demsar et al., 2018; Levy et al., 2020). Management of labour pain is a major part of obstetric care and a midwife can utilise simple and safe methods to maintain the health of the pregnant woman and her foetus (Simkin & Klein, 2015; Czech et al., 2018; Boateng et al., 2019). Pharmacological and non-pharmacological methods are available to reduce labour pain and anxiety (Ferguson et al., 2016).

1.3.1 Pharmacologic Methods

Pharmacological labour pain management includes opioids, narcotics, epidural analgesia, para cervical block, spinal block, pudendal block, and nitrous oxide (Simkin & Klein, 2015; Alleemudder et al., 2015). Opioids are widely used for labour analgesia and pethidine is the most commonly used opioid worldwide (Smith et al., 2018a). Pharmacological methods include anaesthesia and analgesia. Anaesthesia causes a partial or complete loss of sensation, while analgesia, decreases awareness of pain. It plays an important part in the pregnant woman's satisfaction during one of the most painful periods of her life. It may cause maternal side effects, such as dizziness, nausea, vomiting, hypotension, prolonged second-stage labour, and an increased risk of assisted delivery.

It also slows the progress of labour and reflex disorder in the second stage of delivery when is given too early before labour is well established. Besides, it decreases blood flow to the placenta, resulting in acidosis and foetal hypoxia. It causes impairment in the respiratory system of the foetus, foetal distress, stillbirth, and difficulty in lactation (Ahmadi et al., 2017; Mathew & Francis, 2016; Smith et al., 2018a). Meperidine (Pethidine) is a widely used analgesic that helps a pregnant woman to relax and cope with labour pain. However, it has some side effects, including nausea, sedation, late breastfeeding, and accumulation of metabolites (e.g. nor meperidine) (Burchell et al., 2016; Thomson et al., 2019).

A study conducted by Lalooha (2017) evaluated the effects of meperidine injection on 120 nulliparous women during the first and second stages of labour. The participants received 50 mg of meperidine intravenously at four cm cervical dilation. The results did not show any significant relationship between meperidine injection and the progression of labour. The mean interval time between pethidine injections given at the end of the first stage of labour was 120 ± 06 minutes in the intervention group and 133 ± 05 minutes in the control group, but the difference was not statistically significant ($p=0.6$).

Moreover, the average duration from the end of the second stage of labour till delivery was 45 ± 20 minutes in the intervention group and 41 ± 10 minutes in the control group, which was not statistically significant ($p=0.6$). In addition, Alleemudder et al. (2015) conducted a double-blind RCT on 506 women in the United Kingdom and compared intramuscular pethidine and intramuscular diamorphine for their efficacy and side effects. The results showed intramuscular diamorphine significantly increased maternal satisfaction with the analgesia but prolonged the duration of labour. Moreover, no significant differences were reported in new-born outcomes in either group. The study recommended that diamorphine should not be used as it increases labour duration and cost.

1.3.2 Non-pharmacologic Methods

Non-pharmacological methods are intended to promote the emotional experience during labour and the ability to cope with pain dependability and to teach pregnant women how to comfort themselves. Some pregnant women prefer to use non-pharmacological methods because they know that labour pain is a natural process and want to avoid the side effects and risks for themselves and their babies. Most childbirth-care professionals encourage pregnant women to use minimally invasive methods of pain management first, and then shift to other methods, if needed (Alleemudder et al., 2015). The available non-pharmacological therapies to relieve labour pain and anxiety are water birth and water immersion, application of hot and cold packs, acupressure, reflexology, massage, guided imagination, relaxation, breathing exercises, aromatherapy, music therapy, positioning, physiotherapy, and transcutaneous electrical nerve stimulation (Alleemudder et al., 2015; Bhore, 2016; Ghiasi et al., 2019).

Literature has illustrated the significant effectiveness of non-pharmacological therapies such as massage, acupressure, water immersion, heat therapy, breathing exercises, reflexology, transcutaneous electrical nerve stimulation, changing position, religions, music. These therapies can manage labour pain, anxiety, shorten the duration of labour, and improve the maternal and new-born outcomes, which are similar to the management's outcomes in this study (Afeby, 2015; Chuang et al., 2019; Czech et al., 2018; Erdogan et al., 2017; Istikomaha and Sulistianingsih, 2020; Kaur et al., 2020a; Nehbandani et al., 2019; Yuksel et al., 2017).

Istikomaha and Sulistianingsih (2020), reported results of a systematic review of 10 studies in which primigravidae women read the Holy Qur'an for 11- 60 minutes to decrease the labour pain in the first stage of labour. The majority of the participants read the Surat Al Rahman to provide a relaxation effect. The findings revealed that the reading of the Holy Qur'an significantly reduced labour pain during the first stage of labour.

Moreover, Chuang et al. (2019) reviewed five studies of music therapy on 392 primigravidae. 197 participants listened to music during labour and 195 received routine care. The findings revealed significantly lower pain scores and improved anxiety levels in the intervention group as compared to the routine care group.

Heat therapy is a non-pharmacological method that is applied to the sacral-perineal area during labour pain. The heat expands the blood vessels, improves the body's circulation, influences the transmission of pain impulses, and improves maternal satisfaction (Akbarzadeh et al., 2016).

A study was conducted to assess the effect of warm compress on labour pain during the first stage of labour. The results revealed a significant difference ($p=0.0001$) in labour pain between the experimental groups and control group at 45, 90, and 135 minutes after the intervention. (Bahuguna et al., 2018). Similarly, Kaur et al. (2020a) reported that the

moist heat (hydro-chollator pack) applied on the lumbosacral region had positive effects on labour pain, duration of labour, and foetal outcomes in nulliparous women. The results showed the pain scores were lower in the experimental group than the control group after the first, second, and third applications of warm compression ($p < 0.001$), ($p < 0.001$), and ($p < 0.001$) respectively.

Another method used in labour pain is acupressure. Yildirim et al. (2018) reported that acupressure on the Lumber4 region for 80 minutes helped to reduce the labour duration for approximately one hour on average ($p < 0.05$), and improved pulse and respiration rates ($p < 0.05$), Fetal Heart Rate (FHR) and APGAR scores in the experimental group. Similar findings were reported by a study that acupressure on the Lumber 4 region reduced the perception of labour pain, shortened the duration of labour, and increased maternal satisfaction ($p < 0.05$) (Hamlac & Yazici, 2017).

Using a birth ball is another method used in labour pain management. A study was conducted on 120 pregnant women who sat on the ball during labour. Participants applied the birth exercises for 10 to 20 minutes every hour from the active phase to 10 cm of cervical dilation. The results showed that 70% of the women in the intervention group reported less pain and anxiety scores shorter duration of labour, high satisfaction, and higher mean scores of the descent of the foetal head ($p < 0.0001$) as compared to the control group (Farrag & Omar, 2018).

Similar findings were reported by Emam & Al-Zahrani (2018), who conducted a study on 100 pregnant women using the upright position during the first stage of labour. The study found that the upright position during the first stage of labour had a positive effect on the progress of labour by decreasing the time interval of the uterine contraction and increasing the duration and frequency of uterine contractions. Moreover, the study reported lower pain scores, shorter duration of the three stages of labour, and high APGAR scores and maternal satisfaction in the upright position group, as compared to the recumbent position group. Another systematic review reported that the upright position during labour shortened the second stage of labour reduced the rate of instrumental delivery and episiotomy. However, it increased the risk of blood loss greater than 500 ml (Gupta et al., 2017).

A systematic review was conducted to assess the effects of water immersion during labour (first, second and third stage of labour) on women and their infants. It compared the studies that used water immersion with those using no immersion or other non-pharmacological forms of pain management during labour. The findings revealed that water immersion during the first stage of labour may have little effect on the mode of birth or perineal trauma; however, it may reduce the use of regional analgesia.

The result did not show any differences in maternal or neonatal outcomes (Cluett et al., 2018). Similarly, another systematic review was conducted and reviewed seven RCT studies on hydrotherapy or water immersion during labour. Six out of seven studies found that water immersion decreased labour pain, while one study reported a reduction in

anxiety and foetal mal-presentation, and an increase in maternal satisfaction during labour (Shaw-Battista, 2017).

1.4 Maternal Health Services

The development of health care services of the Saudi Arabia government is done for all levels: primary, secondary and tertiary. The health services are provided through primary health care centres and government and private institutions. The largest healthcare services in Saudi Arabia are the Ministry of Health (MOH) which provides 62% of patient care (Health statistic book, 2005) which was retrieved January 2007. It described the health care system in Saudi Arabia for mother health is before, and during pregnancy, childbirth, and postpartum. MOH has innovated the Mother and Child Health Passport System, which included the health of mother and child, medical history, monitoring a health condition, investigations, follows up of the maternal health status, record all in the system, and used as a reference for mother and child healthcare.

Accordingly, the health care pre-pregnancy provides information such as periodic maternal screening (breast, cervix, and colon), breastfeeding and new-born care programme. It offers a variety of health services, including premarital screening to check for hereditary blood diseases, infectious diseases, and immunization programmes such as German measles (rubella) and Chickenpox (varicella) to prevent dangerous effects on the fetuses, and chronic diseases (gestation diabetes, hypertension). A pregnant woman selects a government or private hospital to deliver her baby. Hospital Obstetric Practices in Saudi Arabia demonstrate the routine general practices concerning normal childbirth. A study in Saudi Arabia among nine government hospitals found that out of the total hospitals taken into account, eight hospitals reported that they routinely gave women as much information and explanation as they desired (Altaweli et al., 2014).

First Stage Labour: Routine physical examination, screening blood test for complete blood count and blood group, measuring vital signs (VS), checking urine test for ketones, protein, and sugar. Moreover, changing the pregnant woman's clothes to a hospital gown, pubic shaving, administering an intravenous infusion, monitoring FHR, taking oral fluids during labour and birth, using pain relief such as an intramuscular analgesic. Epidurals are never used in the delivery rooms in government hospitals. Regarding mobility the pregnant women, not all hospitals allow them to move or select the position of labour (Altaweli et al., 2014). Most governmental hospitals in Saudi Arabia do not allow any kind of supportive companion during childbirth such as (family members or friends) (Al-mandeel et al., 2013).

Second Stage Labour: Routine practices during the second stage of labour are as follows. One out of nine hospitals reported moving the pregnant women to a different room during the second stage. Most of the hospitals placed the pregnant woman in the lithotomy position; four out of nine hospitals reported routinely encouraging pregnant women to push at full dilatation and using episiotomy to all primigravidae women. Five out of nine hospitals ask the pregnant woman to bear down efforts (Valsalva Manoeuvre). Routinely seven the hospitals performed bladder catheterization.

Third Stage Labour: Routinely, all hospitals give prophylactic oxytocin, three out of nine hospitals used parenteral Ergometrine. All hospitals cut off the cord and examine the placenta and the membranes.

Fourth Stage Labour: Routinely all hospitals observe the women two hours after normal childbirth, permitting early skin-to-skin contact between the mother and her baby, checking uterine contraction, performing suction and warming the new-born.

Neonatal Care: Routinely, all hospitals check the APGAR scores and dextrose stick for new-born who has diabetic mother, urine output, meconium passage, and give Vitamin K and hepatitis vaccine intermuscular. (Altaweli et al., 2014).

1.5 Practising of Non-Pharmacological Methods in Saudi Arabia

Among Arab countries, Saudi Arabia is the leader in practising non-pharmacological methods or CAM. In Saudi Arabia, 25% of births are practised non-pharmacological therapies, followed by Egypt with 16.8% and Morocco with 16.2% (Zyoud et al., 2015). Non-pharmacological methods practised in Saudi Arabia are usually related to religious beliefs and the common practices are prayers and reciting or listening to the Quran alone or in water. Other types include herbs (8–76%), honey (14–73%) and dietary products (6–82%), black seed, and myrrh. There is Al-Hijama (the practice of cupping), which is a part of the prophetic medicine (up to 4–45%) and acupressure, which is mostly practised in a private clinic (Alrowais & Alyousefi, 2017; Alsharif & Mazanec, 2019). MOH in Saudi Arabia provides health care free for all citizens and residents, while non-pharmacological or CAM services are not free. MOH has established a centre for CAM services, which receives and coordinates with all the patients who need CAM services (Al-Rowais et al., 2012).

1.6 Problem Statement

Obstetric practices in maternal hospitals include physical violence and abusive practices such as tying the pregnant woman onto the bed, ignoring the pregnant woman's needs (i.e. ignoring her desires to choose a position for birth or a specific type of pain management), Using unnecessary medical management (i.e. cutting the perineum, conducting CS) and avoiding the use of non-pharmacology methods. All of those

practices could increase labour pain and anxiety, which are the greatest problems that a pregnant woman faces during labour (Saudi society of obstetrics & gynaecology, 2019).

Labour pain is one of the most severe pains that women experience during their lives, which could be affected by different physiological, psychological, and environmental factors (Boryri et al., 2016). Labour pain is associated with the same physiological process still not all pregnant women experience this pain in the same way. It is different from one pregnant woman to another. Failure in the progression of normal labour causes maternal fatigue and may lead to assisted delivery in primigravidae women and increase the risk of foetal distress, head compression, and foetal death (Ahmadi et al., 2017; AlSheeha, 2018).

Studies have shown that intense pain, anxiety, and prolonged labour increase the cases of assisted delivery and the maternal willingness to undergo CS without medical indication (Stoll et al., 2017). Unrelieved labour pain can cause negative outcomes for the mother, her baby and family, and maternal health care providers. As a component of maternal outcomes, it increases fear, stress, anxiety, depression, fatigue, hyperglycaemia, and hypertension (Havelka et al., 2015). Fear and anxiety are negative consequences of labour pain and propel women to refuse normal vaginal delivery (Aksoy et al., 2019), which eventually increases undesirable CS (Abd El-Aziz et al., 2017; Levy et al., 2020; Moghimi-Hanjani et al., 2015). Moreover, a severe form of perinatal anxiety increases the rate of CS delivery and has adverse consequences for maternal and neonatal outcomes (Levy et al., 2020).

According to the WHO, the ideal CS rate is accepted as 10-15%, Saleh et al., et al. (2017) and Prediger et al., (2020) reported that, in recent decades, the rates of CS in developed countries have increased to 30% of all births. A community-based study in Turkey revealed that 45% of babies were born by CS delivery (Yuksel et al., 2017). Previous studies have also reported an increase in the trend in CS delivery in Saudi Arabia (Al-Sheeha, 2018).

Particularly in Makkah, as it was reported that about 32-40% CS delivery in 2018 in the Maternal Children Hospital (MCH). The findings revealed that fear and anxiety related to labour pain, and lack of pain and anxiety management were the main reasons for increases in the rate of CS delivery in the Makkah region (Statistic Centre Ministry of Health in Saudi Arabia, 2019).

It is important to manage labour pain and anxiety to reduce the CS rates and its associated complication on mothers and new-born. Opioids are widely used and they are significantly effective for labour pain management, but they have some negative effects on women and new-born (Abd El-Aziz, et al., 2017). Pharmacological methods are associated with poorer outcomes for new-born, including a higher rate of instrumental births, admission to special care, and the late initiation of breastfeeding beyond six weeks (Adams et al., 2015).

Even though various non-pharmacological methods for labour pain and anxiety management are available and many women opt for non-pharmacological methods for pain management (Thomson et al., 2019); however, evidence on the effectiveness of non-pharmacological labour pain management therapies are still debated (Levett et al., 2016). This is the main reason for preventing the application of non-pharmacological methods for labour pain management.

A number of studies have shown the effectiveness of different non-pharmacological labour pain management therapies. The effectiveness of breathing exercises, reflexology, and massage for different medical conditions has been examined separately in many studies conditions (Eman,2015; Moghimi-Hanjani et al., 2015; Mohamed & Bigawy, 2017).

However, there is a lack of evidence in studies using the combination of multiple non-pharmacological therapies like BRM, especially for pregnant women in labour pain (Mohamed & Bigawy, 2017). To our best of the researcher's knowledge, no study has been conducted previously used the combination of non-pharmacological therapies such as BRM to relieve labour pain during the first stage of labour for relieving labour pain and anxiety, and improving maternal and new-born outcomes in Saudi Arabia (Mohamed & Bigawy, 2017; Alrowais, et al., 2017).

The combination of three interventions with RCT design has been used for this study to generate evidence regarding the effectiveness of BRM to be used in the labour room. It will increase the acceptability and the use of this therapy by health care providers in their clinical practices.

Moreover, the combination of three interventions (breathing, reflexology, and massage) is used because it is a standard technique to enhance the physiological and psychological factors which affect labour pain and anxiety. From the physiological point of view, breathing, massage, and reflexology mechanisms demonstrated effects on labour pain and anxiety (Embong et al., 2017; Taheri, 2019). From the psychological point of view, touch and support during massage and reflexology are very appreciated by many Arabic pregnant women. Moreover, breathing exercises assist the pregnant woman to focus and concentrate on breathing techniques instead of uterine contractions and thus keep calm (Mathew & Francis, 2016; Embong et al., 2017).

1.7 Objectives of the Study

To achieve the main goal of the study, the following objectives are constructed.

1.7.1 General Objective

This study aimed to measure the effectiveness of BRM on labour pain, anxiety, maternal stress hormones, duration of labour, maternal satisfaction, and new-born outcomes among the primigravidae during the first stage of labour in Saudi Arabia.

1.7.2 Specific Objectives

Maternal outcomes

Objective 1: To determine the socio-demographic and obstetric characteristics of the primigravidae women.

Objective 2: To measure the baseline difference in research variables: maternal stress hormones, vital signs, foetal heart rate, pain intensity, and anxiety, between the intervention and control groups.

Objective 3: To measure the effectiveness of BRM on pain intensity during and after contractions pre and post-intervention.

Objective 4: To measure the effectiveness of BRM on anxiety pre and post-intervention.

Objective 5: To measure the effectiveness of BRM on maternal stress hormones, and vital signs pre and post-intervention.

Objective 6: To measure the effectiveness of BRM on the duration of labour, and maternal satisfaction post-intervention.

New-born Outcomes

Objective 7: To measure the effectiveness of BRM on foetal heart rate pre and post-intervention, and APGAR scores post-intervention.

1.8 Research Questions

To achieve the objectives of this study the following research questions are formulated.

Question 1: What is the difference of socio-demographic and obstetric characteristics between the study primigravidae women in the intervention and control groups?

Question 2: What are the baseline differences in maternal stress hormones, vital signs, fetal heart rate, pain intensity, and anxiety between intervention and control groups?

Question 3: What is the effectiveness of BRM on pain intensity, during and after contractions in pre and post-intervention?

Question 4: What is the effectiveness of BRM on anxiety scores in pre and post-intervention?

Question 5: What is the effectiveness of BRM on maternal stress hormones, and vital signs pre and post-intervention?

Question 6: What is the effectiveness of BRM on the duration of labour, and maternal satisfaction post-intervention?

Question 8: What is the effectiveness of BRM on foetal heart rate pre and post-intervention, and APGAR scores post-intervention?

1.9 Research Hypotheses

Research Hypotheses: The following are hypotheses of the study:

H0:1 There is no statistically significant effectiveness of BRM on pain intensity, during and after contractions in the pre and post-intervention.

H0:2 There is no statistically significant effectiveness of BRM on anxiety scores in the pre and post-intervention.

H0:3 There is no statistically significant effectiveness of BRM on maternal stress hormones, and vital signs, pre and post-intervention.

H0:4 There is no statistically significant effectiveness of BRM on the duration of labour, and maternal satisfaction post-intervention.

H0:5 There is no statistically significant effectiveness of BRM on fetal heart rate pre and post-intervention, and APGAR scores post-intervention.

1.10 Conceptual Definition of the Variables Study

1.10.1 Conceptual Definition of Independent Variables

The following are the independent variables of the study.

Breathing Exercises: Stimulate the parasympathetic nervous system, which increases the oxygen in the blood circulation. It is a process of respiration in which the oxygen is inhaled to the lungs through the nose or mouth, and carbon dioxide is exhaled. It triggers to release of endorphins, which increases feelings of calmness (Bordoni et al., 2018).

Reflexology: An application of gentle pressure on the specific points on a woman's hands and feet that encourages the pituitary glands to release the required hormones to relieve pain and to speed up the process of labour (Jijimole et al., 2018).

Massage: A therapeutic pressing and rubbing of the skin, tendons, ligaments and muscles (Ranjbaran et al., 2017).

1.10.2 Conceptual Definition of Dependent variables

Labour pain and anxiety are the primary dependent variables of the study, and the maternal stress hormones, duration of labour, maternal satisfaction, and APGAR scores are also measured as secondary outcomes.

Labour Pain: A painful, regular uterine contraction that happens more than once every 10 minutes, with gradual cervical dilation and effacement that descends the present part and expels the foetus and placenta (Lee et al., 2016).

Anxiety: An abnormal apprehension and fear that is marked by physical signs such as tension, sweating and increased pulse rate, uncertainty about the reality and nature of the threat, and self-doubt about one's capacity to cope with it (Videbeck, 2010).

1.11 Operation Definition of the Variables Study

Further details of the variables including their psychometric properties are described in Section 3.23 in this thesis.

Labour Pain Intensity was measured using the assessor-rated Present Behavioural Intensity (PBI) scale, through the assessor's observation of the five-category behavioural observation (Appendix-A: Domain: C), and a self-report Visual Analog Scale (VAS). The participants are asked to pick the appropriate colour on an A-4 sized paper depending on the level of pain (Appendix-A: Domain: D).

Present Behavioural Intensity (PBI) Scale is behavioural observation used to assess the current pain behavioural manifestations, which includes respiratory alterations, motor response for instance breathless or gasping, and nervousness and agitation. PBI is measured using the assessor-rated scale through the assessor's observation of the five-category behavioural observation.

Visual Analog Scale (VAS) is an instrument used to measure pain intensity during experimental studies. It is a vertical or horizontal line attached by words at both ends of the line such as no pain and the most pain.

Anxiety Assessment Scale for Pregnant Women in Labour (AASPWL) was utilized to assess anxiety during labour. The anxiety assessment scale for pregnant women in labour has two sub-dimensions: the first sub-dimension included anxiety related to the "birth process" and the second sub-dimension included anxiety related to motherhood, which is called "motherhood constellation".

Anxiety was measured by asking the participants nine questions regarding the anxiety assessment scale for pregnant women in labour and it consists of two subscales: Birth Process-Anxiety (BP- Anxiety) and Mother Constellation-Anxiety (MC- Anxiety) (Appendix-A: Domain: E).

Stress Hormones: Adrenocorticotrophic (ACTH), cortisol, and oxytocin hormones were measured through a laboratory blood test (Appendix-A: Domain: A).

Adrenocorticotrophic Hormone is a polypeptide tropic hormone. ACTH is secreted by the anterior pituitary gland, a component of the hypothalamic-pituitary-adrenal axis, and produces reactions during stress.

Cortisol Hormone is a steroid hormone known as the stress hormone, which is produced and controlled by the hypothalamus gland.

Oxytocin Hormone is a peptide and neuropeptide hormone that is released by the posterior pituitary. It helps reproduction, labour, birth, after delivery, and social bonding.

Vital Signs are body temperature, pulse, respiration, and blood pressure monitored by maternal VS monitor machine (Appendix-A: Domain: B).

Foetal Heart Rate was monitored by a Cardiotocography (CTG) machine (Appendix-A: Domain: B).

Duration of Labour starts on regular uterine contractions with gradual cervical dilation and effacement. It was calculated and recorded from 3-6 cm and from 6cm to the delivery of the placenta by using the partograph (Appendix-A: Domain: F).

Maternal Satisfaction was measured using the Simple Six Questions (SSQ) tool. (Appendix-A: Domain: G).

APGAR scores are an abbreviation for A-ppearance, P-ulse, G-rimace, A-ctivity and R-espiration and were assessed the new-born using a new-born assessment sheet (a routine part of new-born assessment at Maternal Children Hospital, Makkah) (Appendix-A: Domain: H).

1.12 Significance of the Study

The main contribution of this study is to improve the quality of the labour process by reducing pain, anxiety and the duration of labour, and to use cost-effective, non-pharmacological therapies to deliver positive maternal and new-born outcomes. This is apparently the first study, to the best of the researcher's knowledge that examines the effectiveness of BRM on maternal outcomes such as labour pain, anxiety, maternal stress hormones, duration of labour, maternal satisfaction and new-born outcomes such as FHR and APGAR scores among primigravidae during the first stage of labour in Saudi Arabia.

The findings of this study determine the use of BRM as a cost-effective, non-pharmacological and safe measure to reduce labour pain and anxiety. Moreover, this study is likely to contribute to the existing literature that is useful for obstetricians, midwives and nurses by providing a better understanding of the effectiveness of BRM in labour pain among primigravidae women. Also, it encourages healthcare professionals to use BRM in their clinical practices.

Furthermore, the findings of the study are also expected to be helpful for pregnant women to understand BRM therapy and to identify its potential effects and safety during labour. The study highly recommends nursing faculties introduce BRM therapy to midwifery students by including it into the midwifery curriculum. In addition, the study uncovered areas for future studies. The findings are helpful to the MOH to scale up training programs in BRM for midwives and to implement BRM in maternity hospitals to achieve good maternal and new-born outcomes.

1.13 Summary

This chapter provided a background of labour, labour pain, anxiety, the consequences of labour pain and anxiety, and labour pain management options including the CAM. It shed light on some evidence of why labour pain and anxiety management are important, and thus commented on the significance of this study. This chapter also provides the objectives of the study, research questions, research hypothesis, conceptual and operational definitions of dependent and independent variables.



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