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EFFECTIVENESS OF BACK MASSAGE & LAMAZE BREATHING ON LABOR OUTCOMES AMONG PRIMIGRAVIDA IN TERTIARY CARE HOSPITALS, LAHORE PAKISTAN: A RANDOMIZED CONTROL TRIAL

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Abstract: *Labor pain is the most severe pain that first-time pregnant women experience during pregnancy and childbirth. If labor pain and anxiety are not addressed, they can lead to abnormal labor. Although there are many complementary non-pharmacological approaches to coping with labor pain, the quality of evidence is low and the best approaches are not established. This study protocol describes a proposed investigation of the effects of Lamaze breathing exercises and back massage on the labor experiences of first-time pregnant women.*

Keywords: Anxiety, Back Massage, Lamaze Breathing Exercises, Labor Pain, Non-Pharmacological Approaches

Introduction

Women view childbirth as a natural process in life. However, first-time delivery attendees may experience fear about the delivery outcome. Women who are naturally anxious and tense tend to cope less with stress than those who are relaxed and confident. Additionally, women already fatigued from several hours of labor may be less able to tolerate pain (1).

WHO recommends non-clinical measures to reduce the medically unnecessary use of cesarean sections, such as educating primigravida on childbirth relaxation techniques, including Lamaze breathing techniques, and providing psychosocial support. These measures can reduce pain intensity, labour duration, maternal blood pressure, maternal confidence and self-efficacy, and the APGAR score of newborns. Women in Pakistan must, therefore, receive adequate education to choose vaginal birth as their preferred delivery method, which can reduce the risk of maternal mortality (2).

Lamaze breathing techniques help mothers prepare psychologically and physically to give birth without using pain-relieving drugs (3). Lamaze classes encourage women to recognise their innate abilities to cope successfully with labour challenges and have a stress-free and safe delivery (4). Lamaze breathing education is an effective noninvasive, non-pharmacologic, supportive breathing education that improves the behavioral responses of women during labor (5).

According to UNICEF (2015), 178/100,000 mothers die during childbirth in Pakistan. Moreover, a survey by UNICEF (2019) indicated that the maternal mortality ratio in Pakistan is 186 deaths per 100,000 live births. Pakistan ranks 139th among countries worldwide, where maternal mortality is 186/per 100,000 live births (6) (UNFPA Pakistan. 2021-05-24).

Globally, 30% of all pregnant women develop severe pain during labor, prolonged labor duration, hypertension during pregnancy, and unhealthy pregnancy outcomes. According to the World Health Organization, C-section rates higher than 10% are not linked to a decrease in maternal or newborn death (7). Therefore, educating women in Pakistan about vaginal birth is critical in reducing maternal mortality (2).

According to Lynna Y. Littleton's book Maternity Nursing Care (2005, 2013), women have different health needs throughout their lives. Physiological differences between men and women persist before birth and continue throughout life. Pregnancy is a time of significant change and adaptation for women. Nurses can play a vital role in helping women achieve healthy, positive pregnancies by supporting, nurturing, educating, and caring for pregnant women and their families during labor.

Labor pain is a challenging issue for nurses and doctors and requires specific intervention protocols. Massage is an ancient technique that has been widely employed during labor and positively affects women in labor (8). Active labor management minimises the duration of labor, lowers surgical interventions, and improves maternal self-efficacy, and labor outcomes during all three stages of labor.

A. Parimala Priya (2011) stated that expectant mothers, especially primigravida, cannot constantly adjust during labor. They scream with pain and become exhausted much earlier, using their power of pushing the fetus before time, which may result in early rupture of membranes following prolonged and complicated labor, leading to cesarean section (9, 10).

Various breathing techniques and pain management strategies could improve the health status of mothers and newborns and lower the rate of cesarean deliveries for first-time mothers. Aerobic respiration practices also improve the fetal APGAR score in early neonates, and there is no

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evidence of trauma associated with various breathing techniques (11, 12). Therefore, Lamaze breathing can help primigravida mothers reduce pain perception during pregnancy by diverting their focus. It was determined that lower back massage has a significant impact on reducing labor pain and increasing satisfaction with birth. Health professionals working in the delivery unit can use massage intervention to decrease pain, reduce delivery time, and increase maternal satisfaction with birth.

The rationale of the Study

Birth preparation classes and education have been integral components of maternity care for many years, typically included in antenatal care during pregnancy. While these classes vary in structure and content, they commonly encompass three key elements:

Providing essential information about pregnancy, intrapartum care, childbirth, and postpartum care is crucial for primigravida mothers and trained birth attendants.

Teaching breathing and relaxation techniques to expectant mothers during antenatal helps prepare them for labor and birth. Trainers educate mothers on these techniques to ensure their understanding and compliance.

Another common practice is implementing back massage during labor, typically initiated when the mother reaches 6 cm dilation. Trained gynecologists or massage therapists instruct labor room staff on the proper technique, which serves as a complementary therapy during childbirth.

Lamaze breathing, a central component of birth preparation, triggers a protective response through the central nervous system. Deep abdominal breathing stimulates the parasympathetic nervous system, promoting blood oxygenation in pregnant women. This process triggers the release of endorphins, which lower heart rate and induce feelings of calmness. Additionally, endorphins suppress the sympathetic system, reducing the release of stress hormones like cortisol.

Back massage during labor targets reflex points in the back, effectively releasing oxytocin, a hormone that initiates and regulates uterine contractions while promoting relaxation during contractions. The mechanism behind this therapy is theorised to involve the autonomic-somatic integration theory, where pressure applied to the back stimulates receptors, opening ionic channels in cell membranes to convey messages to the spinal cord and brain.

Massage therapy, a commonly used complementary and alternative medicine (CAM), promotes health and well-being by activating pain suppression mechanisms. It triggers short-lived analgesic effects through the "pain gate" mechanism and longer-lasting pain control via descending pain suppression pathways.

Lamaze breathing exercises and back massage for labor pain management influence the secretion of stress hormones such as cortisol, adrenocorticotropic hormone (ACTH), oxytocin (OT), and possibly endorphins. Oxytocin is vital in stress buffering and pain sensitivity reduction, while cortisol is released during stressful conditions.

Methods and Design

This study investigates the combined effect of back massage and Lamaze breathing techniques on labour pain, duration of labour, anxiety, maternal satisfaction and efficacy, stress hormones, and newborn outcome among primigravidae in Lahore, Pakistan.

The specific objectives are

(1) to compare the effect of the combined Lamaze breathing exercise and back massage (intervention) on labour pain intensity, anxiety level, duration of labour, maternal satisfaction and self-efficacy, stress hormones and neonatal outcome compared with the standard midwifery care (control);

(2) To identify the predictors of pain, anxiety, duration of labour, the satisfaction of the mother and neonatal outcome from the baseline socio-demographic and obstetric characteristics.

Study Design

The study design will be a single-masked parallel randomised controlled trial (RCT), in which participants are randomly assigned to receive either the Lamaze breathing techniques and massage therapy intervention or control care.

Study Setting

This study will be conducted in the Lady Willingdon Hospital Lahore for the interventional group & Lady Aitchison Hospital Lahore for the control group in Pakistan. The hospitals are tertiary-level, governmental referral hospitals with special paediatrics, gynaecology and obstetrics services. In Lahore, Pakistan, almost all tertiary hospitals, including our study site, offer systemic pharmacological agents, either intravenous or intramuscular analgesics, to manage pain during labour. However, providing non-invasive and non-pharmacological methods of pain relief during labour is not common practice in Pakistan. To our knowledge, the combined effect of back massage and Lamaze breathing technique on primigravidae has not been investigated at any Pakistani hospital before this trial.

Participants

The study participants will include primigravidae, aged 20–35 years old, at 37–41 weeks of gestation, and in the first stage of labour. The inclusion criteria include singleton pregnancy, cephalic presentation and regular contraction. In labour, the participants must achieve 6 cm of cervical dilatation, with a minimum of three contractions of at least moderate intensity every 10 min, in which the duration of the contraction must be between 30 s and 60 s.

The exclusion criteria include diagnosis of underlying chronic diseases such as cardiovascular disease, kidney disease, diabetes, asthma, mental health disorders, epilepsy or seizure; pregnancy-related diseases such as gestational diabetes, preeclampsia, cephalo-pelvic disproportion, polyhydramnios or oligohydramnios or deep venous thrombosis; and pregnancy complications such as placenta praevia, antepartum haemorrhage, fetal distress or being put on analgesics other than IMP.

Recruitment

Recruitment will be conducted at the antenatal department at the trial site. Only those planning to deliver in the trial hospital's delivery room will be further briefed and assessed for eligibility. At this hospital, antenatal mothers are given monthly follow-up appointments until 28 weeks gestation. The frequency increases biweekly until 32 weeks' gestation; patients are seen weekly until delivery.

For this study, we will approach primigravidae between 26 and 34 weeks of gestation in equal numbers based on the gestational weeks. This means that about an equal number of primigravidae at the weeks of gestation of 26, 28, 30, 32 and 34 will be recruited to spread the occurrence of labour

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in the subsequent 2–3 months to increase the feasibility of the back massage and Lamaze breathing techniques intervention. Because participant recruitment and the training of the research team members are estimated to last up to 2–3 months, women of 34+ weeks gestation cannot be recruited during this period because they will inevitably go into labour before the research preparations are complete.

At the antenatal department in the suggested hospital, the principal investigator will provide general health education as nonpharmacological measures for pain management during labour. The participant information sheet for this RCT will be provided to eligible patients. If they are interested in participating, they will sign a written consent form and be identified by a unique stamp on their antenatal cards. When the participants arrive in the labour room for delivery, they will be re-evaluated for eligibility.

Randomisation

In the labour room, commonly many analgesics are used to reduce the pain intensity during labour among primigravidae and have bad effects on the APGAR score of neonates. Randomisation will be stratified according to the administrative status of analgesics. This will ensure the same number of primigravidae with and without analgesia in the intervention and control groups. To achieve this, we use a block of size 4 with a 1:1 allocation ratio, leading to a possibility of 6 permutations. All possible block sequences will be randomly generated with the help of free software from the internet https://www.sealedenvelope.com/ simple-randomiser/v1/. A random list will be created after the sample size number, treatment groups, block sizes, list length and stratification factors are entered into the software. The order of the subjects will be used by the research coordinator or Assisstant who will be stationed in the OPD of Antenatal department to conduct the random group allocation for primi- gravidae.

The principal investigator, outcome assessors and massage therapist in this trial will not be involved in the allocation of the interventional groups.

Significance of this clinical trial

Millions of women give birth each year all over the world, there aren't many statistics that can be used to help and boost a pregnant woman's pregnancy outcomes by using Lamaze breathing techniques during the antenatal period among primigravida and back massage during labour in the labour department, especially in Lahore Pakistan, that pregnant mother may learn Lamaze breathing techniques during her pregnancy and might use them in her labouring process to produce better labor outcomes.

Mothers have inadequate knowledge regarding Lamaze breathing and relaxation techniques, which can be used during their pregnancy and labor and can improve the outcome of labour. Many researches are available regarding other relaxation techniques as massage, joint breathing exercises & foot reflexology but minimal researches have been done to document the effectiveness of the Lamaze breathing technique as a coping strategy during pregnancy & labor with the use of back massage. Literature showed that Lamaze breathing techniques, along with the back massage, are the most helpful during childbirth, diverting the attention of the mother from pain and improving outcomes (13, 14).

The non-pharmacological approach reduces pain and enhances the comfort and the women will remain active during the use of breathing techniques and reduces the perception of pain and improves the maternal blood pressure, satisfaction for labor and deliver a healthy new born (15).

The current study will infer that prenatal education was based on Lamaze breathing techniques to improve maternal self-efficacy and confidence, forbearance of labor pain, reduction in duration of labor stages, progress maternal blood pressure, and improvement of neonate APGAR score among Primigravida women.

Numerous studies were conducted at the international level earlier than this one. Still, only very few studies relevant to this research were conducted in the targeted region (Lahore) of Punjab, Pakistan. Moreover, objective for conducting this study is to reduce the perception of pain, improve the confidence during labor & child birth and improve the regular vaginal deliveries with Lamaze breathing techniques and back massage with healthy outcomes as healthy mother and healthy baby. These techniques will reduce the number of Caesarean section rates and other complications regarding mothers and newborns in Lahore, Pakistan.

It also aims to reduce needless medical/surgical intervention and use non-pharmacological interventions such as Lamaze breathing techniques and back massage to increase the rate of normal deliveries with maternal satisfaction and decrease the perception of labour pain and duration of labour, with the highest APGAR score in newborns. Lamaze breathing techniques and back massage can also minimise the client's hospital stay.

Theoretical Significance

From a theoretical point of view, recent studies have shown that the Lamaze breathing method helps to reduce pain perception by diverting attention from pain and focusing on healthy labour outcomes. It also increases maternal satisfaction with delivering a healthy baby and creating a safe delivery environment. The study also assisted prenatal, natal, and intranatal education regarding Lamaze breathing techniques to encompass the labor process.

Lamaze is based on focused breathing, mainly involving muscle relaxation, structured breathing, and focus shifting. The distracting technique (Lamaze breathing) can reduce pain perception, and maternal satisfaction can be increased to deliver a healthy baby (16).

Lamaze breathing is a technique based on the idea that controlled breathing can enhance relaxation, decrease pain perception, and increase maternal comfort (3).

The basic theory of massage therapy is the theory of gate control, which Melzack and Schaffelberg expressed. This theory explains two kinds of small-diameter nerve fibres and large-diameter fibres, which have different functions. Midwives have a substantial share in reducing non-pharmacological pain. Interventions included in the non-pharmacological approach are psychological analgesia that has been carried out since pregnancy, relaxation, massage, stimulation of the cutaneous, aromatherapy, hypnosis, acupuncture and yoga.

In the current high-intervention birth environment, most women need to use a wide variety of comfort strategies in labor, such as controlled breathing and conscious relaxation. Although Lamaze breathing is quite different from the breathing techniques introduced in 1960, conscious breathing and relaxation which are valuable, evidence-

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based strategies to manage pain, facilitate labor and improve vaginal delivery rates (17).

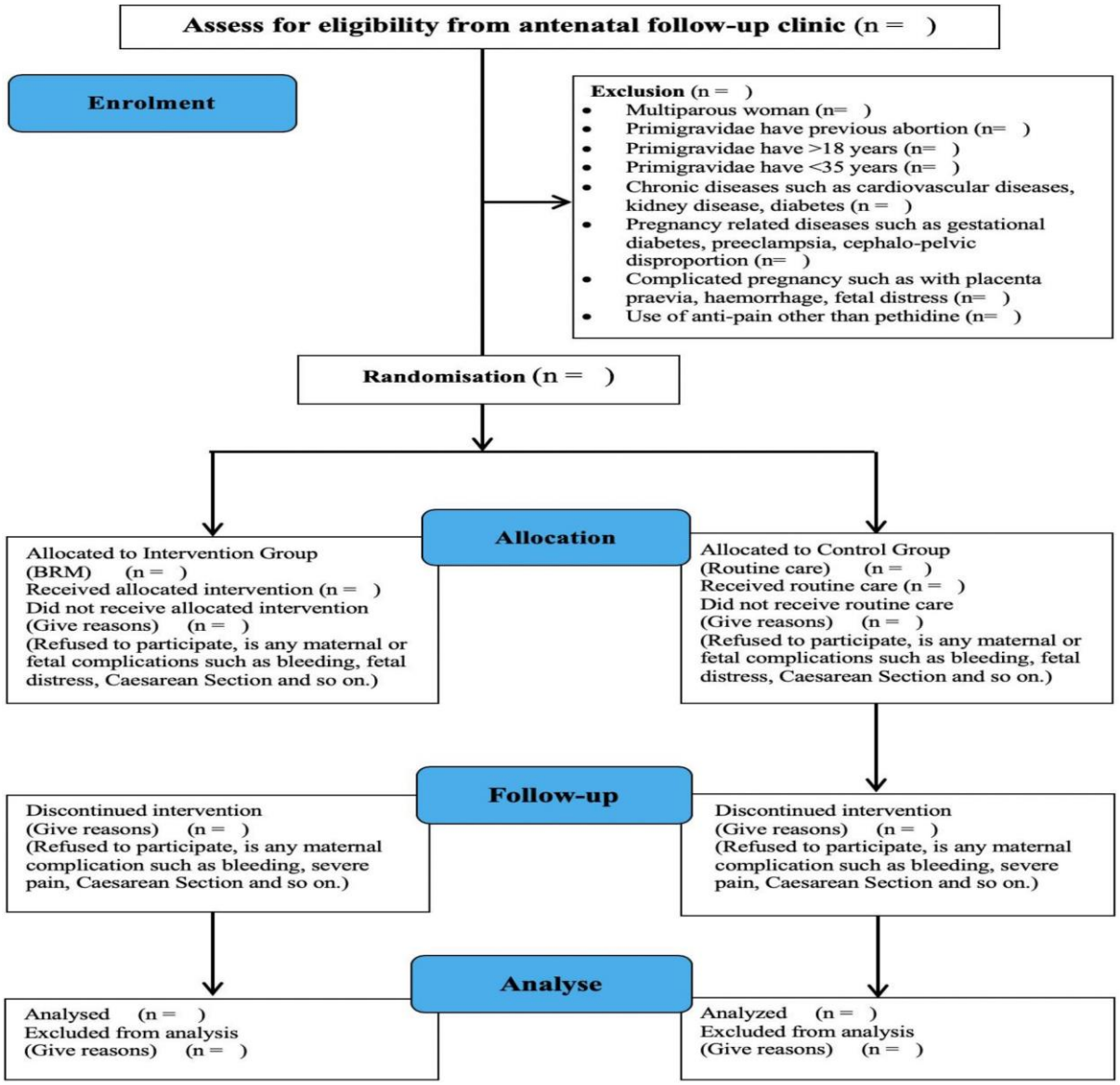

Fig.1 Consolidated Standards of Reporting Trials flow diagram.

Practical Significance

1: This study will help the primigravida to focus on breathing, mainly involving muscle relaxation with Lamaze structured breathing, and divert attention from pain to breathing pattern. It will help for muscle relaxation during labor & is guarded by a specific relaxation procedure that assists women to relax voluntary muscles to the greatest extent possible.

2: Muscle relaxation and structured breathing will help the woman in labor distract themselves from their negative emotions through breathing movements. This will help the mothers stay calm during labor and increase their confidence in their ability to give birth to a healthy baby.

3: Non-pharmacological methods include distraction, relaxation techniques, hypnosis, and reducing pain and pharmacological perception, namely the use of analgesic drugs. Non-pharmacological control is cheaper, more straightforward, effective and without adverse effects. This method can also increase satisfaction during childbirth because the mother can control her feelings and strength so that it helps the mother to be more relaxed and comfortable during labour (18).

4: The current study will infer that education based on Lamaze breathing techniques will improve maternal confidence and self-efficacy, forbearance of labor pain, and reduction in the duration of labor stages. It will also stabilise maternal blood pressure and improve neonate APGAR score among Primigravida women.

Methods and design

The purpose of the study will be to examine the effectiveness of Back Massage & Lamaze breathing techniques as antenatal education on the perception of pain intensity level, estimation of duration of labor stages with

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Partograph, maternal confidence & Self efficacy by using Bandura's self-efficacy inventory, blood pressure monitoring with BP apparatus and O2 saturation with pulse oximeter & APGAR score of neonates will be measured through defined rating scale within one minute. Approval of the research design, data collection tool, and data collection technique will be granted by MAHSA University's Review Board—additional informed consent information in selecting research setting and data collection

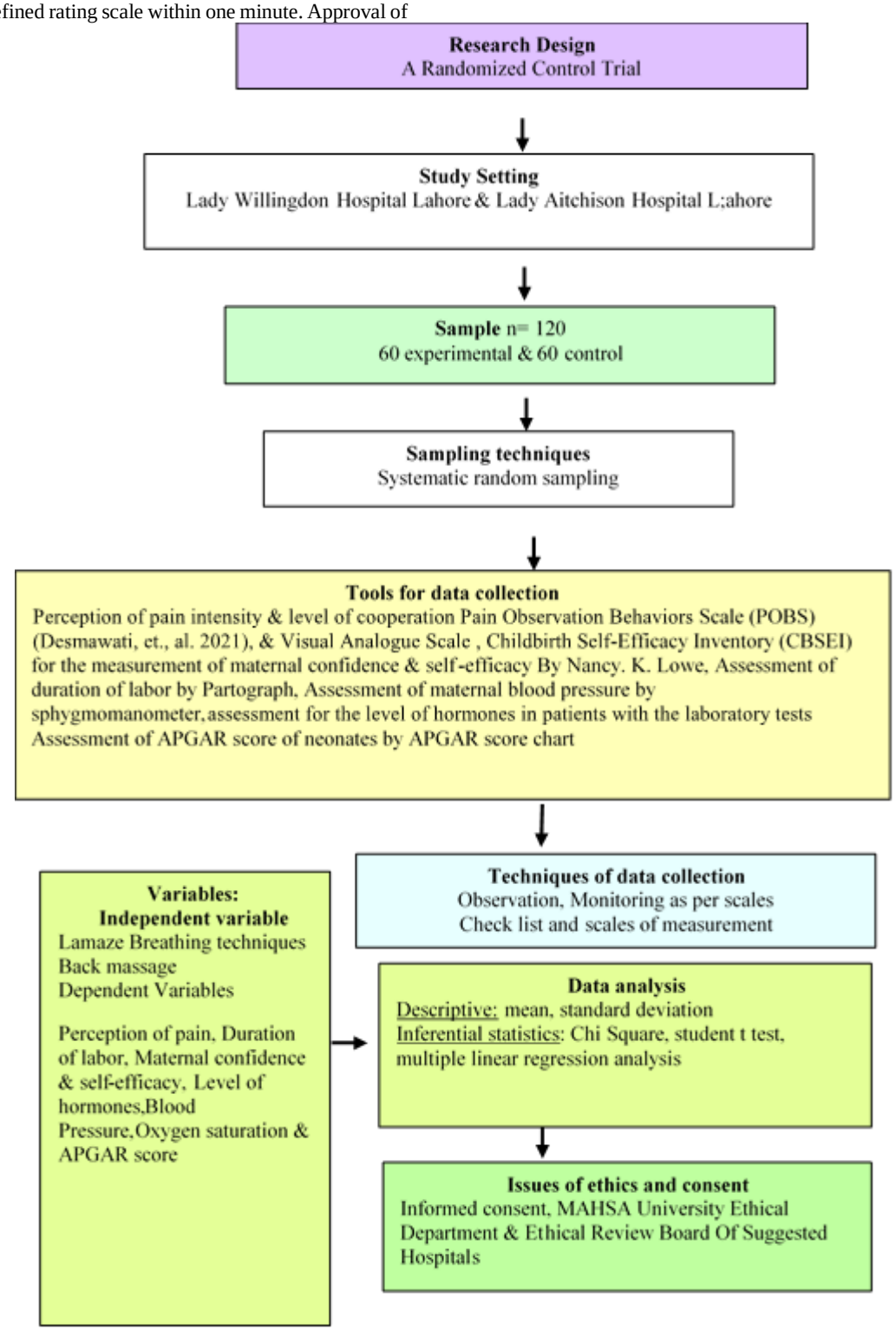

Fig 2.

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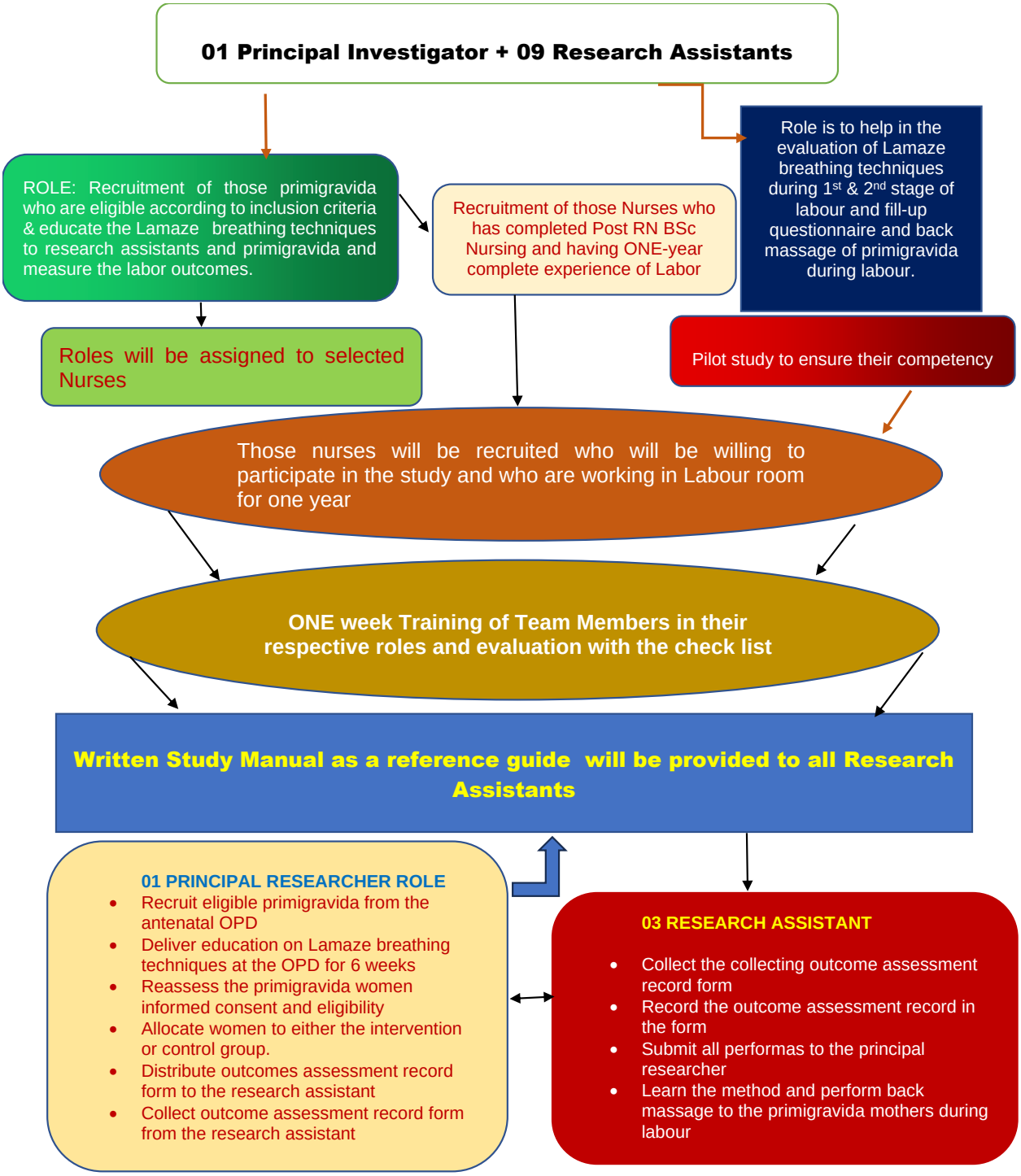

Fig 3

Research design:
This study will use a single-blind randomised Control Trial in which participants are randomly assigned to receive either a Lamaze breathing intervention and back massage or control care.
This study aims to investigate the combined effect of BRM on labour pain, duration of labour, anxiety, maternal satisfaction, and newborn outcome among primigravidae in Pakistan.

The study will attempt to:
i) Assess and evaluate the level of pain and anxiety during 1st stage of labour among primigravida before and after administration of back massage.
ii) Find out the relationship between the level of labour pain & anxiety among primigravida after administration of back massage and Lamaze breathing techniques.
The specific objectives are:

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To compare the effect of the combined Lamaze breathing exercise and back massage (intervention) on labour pain intensity, anxiety level, duration of labour, maternal satisfaction, and neonatal outcome compared with the standard midwifery care (control); to identify the predictors of pain, anxiety, duration of labour, the satisfaction of the mother and neonatal outcome from the baseline socio-demographic and obstetric care.

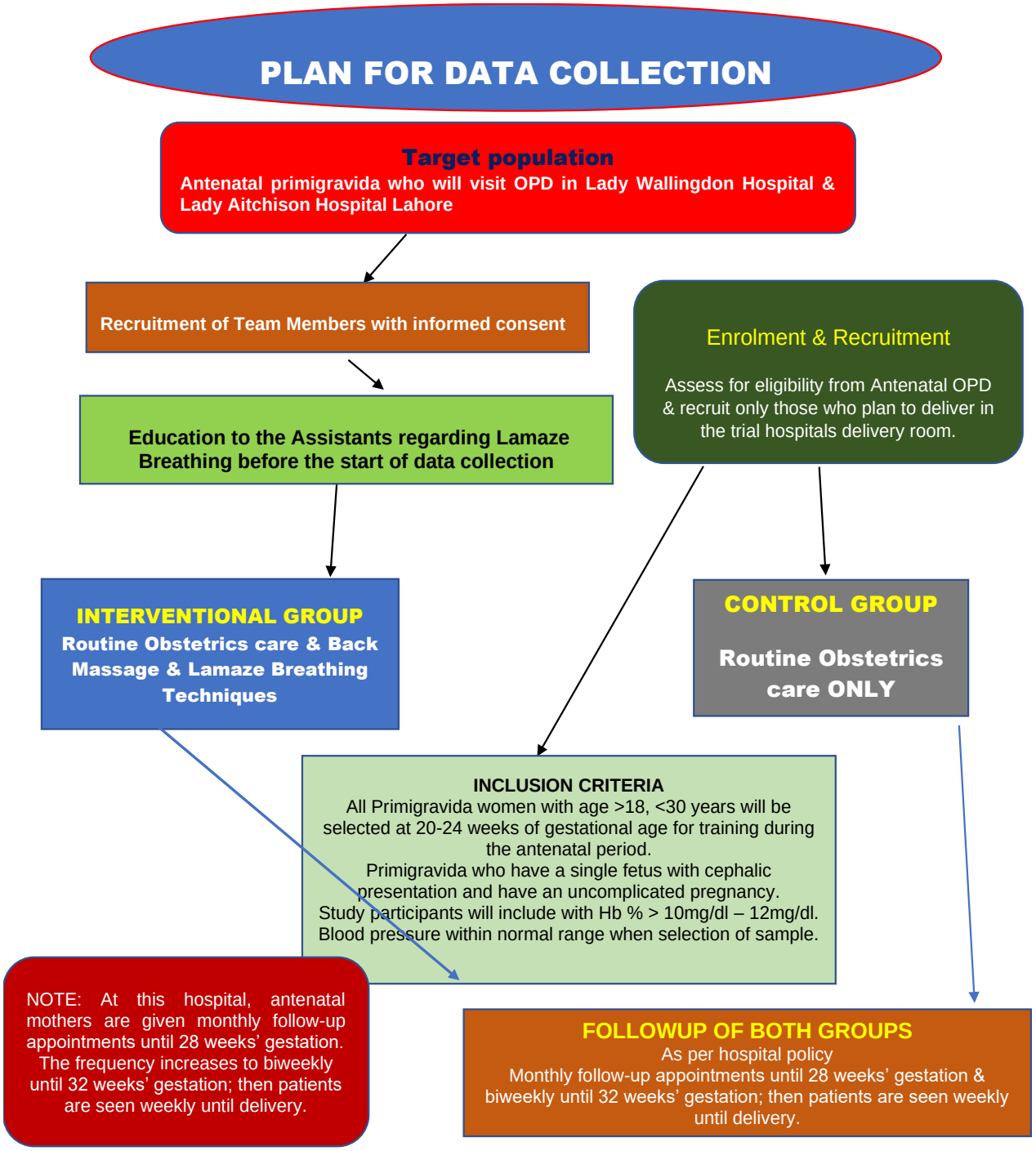

Fig 4

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Fig 5

Participants

Women attending the antenatal clinic will be eligible to participate in the study from 20-24 weeks of gestation. They will provide a subject information sheet. Women who are willing, interested, and eligible to participate signed individual consent forms.

Women will be eligible to enter the trial if they have a singleton pregnancy with a cephalic presentation, will have low risk (no pre-existing medical complications or existing obstetric complications), and will be first-time childbearing women (primigravida). Women will be excluded from entering the trial if they have pre-identified risk factors like eclampsia, preterm labour, placenta previa, multiple gestation, malpresentation and malposition.

Recruitment will be undertaken at two tertiary health care hospitals (Lady Willingdon Hospital for cases and Lady Aitchison Hospital for the control group) in Lahore.

All eligible antenatal women will be approached in the antenatal clinic individually and will be randomised to the study.

Randomisation

We used block randomisation to randomise participants into the groups. Randomisation was done in a 1:1 allocation ratio to ensure equal numbers in each group. An outpatient nurse did further allocation of participants to the intervention and standard care groups with the help of a sequentially numbered opaque sealed envelope (SNOSE). The randomisation of the study is illustrated in the reporting guidelines

[ref https://doi.org/10.6084/m9.figshare.19076597.v1].

Intervention

Five breathing patterns were introduced: cleansing breathing for relaxation, slow-paced breathing, modified-paced breathing, and patterned-paced breathing. These patterns were used during and following contractions. Gentle pushing and breath-hold during pushing were instructed during the second stage of labour, which encouraged the baby's descent.

Recruitment

Recruitment will be conducted at the OPD who will come for antenatal at the trial site. Only those planning to deliver in the trial hospital's delivery room will be further briefed and assessed for eligibility. At this hospital, antenatal mothers will be given monthly follow-up appointments until 28 weeks' gestation. The frequency increases biweekly until 32 weeks' gestation; then, patients are seen weekly until delivery.

For this study, we will approach primigravidae between 26 and 34 weeks of gestation in equal numbers based on the gestational weeks. This means that about an equal number of primigravidae at week of gestation of 26, 28, 30, 32 and 34 will be recruited to spread the occurrence of labour in the subsequent 2–3 months to increase the feasibility of the intervention. Because participant recruitment and the training of the research team members are estimated to last up to 2–3 months, women of 34+ weeks gestation cannot be recruited during this period because they will inevitably go into labour before the research preparations are complete.

At the OPD antenatal area, the principal investigator will provide all recruited mothers with general health education about pain management during labour.

The participant information sheet for this RCT will be provided to eligible patients. If they are interested in participating, they will sign a written consent form and be identified by a unique stamp on their antenatal cards. When the participants arrive in the labour room for delivery, they will be re-evaluated for eligibility.

Statistical Analysis

A blinded enumerator will enter data. The database will be checked for accuracy before analysis. The principal investigator is responsible for compiling, maintaining and managing the study database. The analysis will be performed using IBM Statistical Package for Social Science V.25.

Descriptive statistical analysis will be performed according to the data distribution, using means and SD for data with normal distribution and median and IQR for data that are not normally distributed. Normality testing will use Histograms and p–p plots for all continuous variables.

Categorical variables will be reported in frequencies and percentages. The differences between the groups and time levels will be analysed using a generalised linear mixed model (GLMM). GLMM is appropriate where repeated measurements are made on the same statistical units. GLMM will also be used to accommodate non-normal distribution in outcome data. The variables of time in a definite form, intervention group, group*time interaction and the model's baseline random part will include a random intercept and an unstructured correlation matrix for the correlation of measurements within pregnant women. The fixed part of the model will include the pain score, whereby the difference in pain score at every time point will be tested using a linear contrast. We will take the pain intensity measured with PBI and VAS at 1 hour post-intervention as the primary outcome. This is because the effects of the massage and Lamaze breathing techniques will still be observable, and thus, the intervention group can be fairly compared with the control group.

Any significant baseline imbalances will be adjusted for in the analysis. If necessary, multiple imputations will be conducted for the missing data. A calculated 95% CI and two-sided of 0.05 will be used to test significance. In addition, we will analyse PBI and VAS at the same time points and measure the agreement between PBI and VAS by using the Spearman correlation coefficient and inter-class correlation. We will analyse other outcomes using the same

statistical strategy mentioned above. Additionally, we will conduct time series analyses to examine the patterns of change in the outcomes between the two groups after the Back massage and Lamaze breathing intervention.
The independent effect(s) of socio-demographic and obstetric characteristics on each outcome at 1-hour post-intervention will be analysed using multiple linear regression analyses

Methodology

This randomised controlled trial (ClinicalTrials.gov ID: NCT06304311) will involve an intervention group that receives back massage therapy and Lamaze breathing techniques, standard labor care, and a control group that receives only standard labor care. First-time pregnant women between 26 and 34 weeks of gestation, without chronic diseases or pregnancy-related complications, will be recruited from antenatal departments at Lady Willingdon Hospital Lahore for the intervention group and Lady Aitchison Hospital Lahore for the control group. To reduce bias, eligible and consenting patients will be randomly assigned to the intervention or control group, hospital-wise. A trained massage therapist will deliver the massage therapy intervention.
The outcomes of labor pain and anxiety will be measured during and after uterine contractions at baseline (cervical dilation of 6 cm) and after the massage. Other outcomes include maternal stress hormone levels (adrenocorticotropic hormone, cortisol, and oxytocin), maternal vital signs, fetal heart rate, labor duration, APGAR scores, and maternal satisfaction and self-efficacy. The sample size is estimated based on a between-group difference of 0.6 in anxiety scores, 95% power, and 5% error, which yields a required sample size of 154 (77 in each group), accounting for a 20% attrition rate.
The between-group and within-group outcome measures will be examined with mixed-effect regression models, time series analyses, and paired t-tests or equivalent non-parametric tests.

Discussion

Safe and efficient pain management is essential for pregnant women and their families, and different types of non-pharmacological measures are beneficial to reduce or alleviate labour pain. However, evidence regarding the effects of combined therapies is scarce. Therefore, we designed this trial to study the effects of back massage and Lamaze breathing techniques on labour pain and other psychological and physiological impacts among primigravidae. The study protocol for the RCT is to determine the combined effect of back massage and Lamaze breathing techniques on the intensity of pain and level of anxiety in primigravidae during the first stage of labour. Additional outcomes that will be assessed include stress hormones, maternal satisfaction and self-efficacy, duration of labour, and neonatal APGAR score. In this study, the intervention will be applied only once and only during the first stage of labour, even though the first stage of labour among primigravidae takes approximately 8–12 hours. By timing the intervention after cervical dilation of 6 cm, the effect of the combined back massage and Lamaze breathing techniques could exert its most significant influences (if any) on the labour experience of the primigravidae and neonatal outcome because this period is believed to accompany the highest levels of labour pain.
We will assess the outcomes using a mixture of subjective and objective tools. For example, pain intensity and anxiety levels are subjective measurements based on the respondents' personal feelings and judgments. Duration of labour, neonatal APGAR score, and maternal stress hormone levels of ACTH, cortisol, and oxytocin are objective measurements that will indicate the stress response to the back massage and Lamaze breathing intervention conducted on the primigravidae. This is one of the strengths of our study.
The Visual Analogue Scale (VAS) is a commonly used graphic rating method that measures the effectiveness of Lamaze breathing and back massage. However, given its inconsistency of results and ceiling effect, VAS might not be the gold standard for measuring labour pain.
Recognising this inadequacy, we will ensure that the participants understand the VAS scoring at admission to the delivery room before they are asked to indicate their pain level later. Labour pain outcome will also be measured via pain intensity assessment using the PBI,74, which outcome assessors will rate. Multiple measurements will be taken during, after contraction, and before and after the intervention. There will also be other outcomes related to maternal response to pain, namely anxiety level and maternal stress hormones.
This study has several other limitations. First, the intervention will be performed for 1 hour, during which it may be interrupted by routine medical care such as regular vaginal examinations, V/S measurements and FHR monitoring. However, we believe this will not reduce the effect of the Lamaze breathing and back massage intervention because we can start the back massage and Lamaze breathing before or after the labour care routine.
Second, the labour and birthing process is unpredictable, even if the participants are at low risk. In certain instances, the intervention process might not go as planned, and this may reduce the sample size. Some patients may end up needing a caesarean section, and some may suffer from other obstetric complications during delivery. As a result, we have inflated the sample size accordingly. Third, the results from this study will not be generalisable to multigravidae as we include only primigravidae. Nevertheless, primigravidae will benefit the most from the intervention as they are likely to experience a higher level of labour pain and a longer duration of labour than multigravidae. Fourth, placebo effects can influence patient outcomes after (CAM), resulting in high rates of good outcomes, which may be wrongly attributed to specific treatment effects.
We recognise that the expertise and experience level of the massager is an essential factor in the quality of treatment provided, which may affect the outcomes of the back massage and Lamaze breathing. The massage therapists and the outcome assessors will be given the appropriate training on Back massage and Lamaze breathing for one week by the principal investigator, who attended professional training and was certified. After the training, they will be tested in a

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pilot study to ensure their competency in performing the interventions. Additional quality control measures for the outcome assessors are planned, as they will be assigned to the control or intervention delivery room on the same day. All of the completed assessment forms will be reviewed and kept by the research coordinator in a safe location in the delivery room. Any issues on the form, such as blank spaces and extreme values, will be immediately clarified and resolved. In addition to labour pain, this study will assess the anxiety level of pregnant mothers. Unlike labour pain, anxiety levels can be affected by individual characteristics, previous life experiences and other environmental causes. However, we believe these factors will not play a significant role after adequate randomisation.

Apart from the actual labour experience, there are a few other external factors that may affect maternal satisfaction, such as the delivery room services, the health of the baby, the gender of the child, family support and other psycho-social factors. As satisfaction is a multidimensional and complex feeling, it isn't easy to measure with a single tool and to narrow it down to only the first stage of labour.

It is understood that the birthing process is a natural event, especially for low-risk women. Thus, the management of labour should be conducted in a supportive manner with minimal or no interference. This study will provide high-quality evidence about the effects of the combined intervention for labour pain management. These findings will be important for hospital offerings for expectant mothers in providing a rationale for their decisions about which alternative treatments to offer to primigravidae and their family members during decision-making about labour pain management.

Ethics approval and consent to participate

Ethics approval was obtained from the Ethical Committee for Research from the MAHSA University Malaysia **(MAHSA/PHD/SON/2024/01**). The participant information sheet for pregnant women will also be provided. Pregnant women will sign consent forms if they are interested and eligible to participate. The consent form contains the purpose of this study and procedures involved in the research pre-intervention and post-intervention. They will inform the potential benefits and risks of the intervention research. Participants will be given an affirmation of confidentiality and protection of the data collection. The results will not be disseminated to the study participants, except if one participant wants to know her results, her mobile number will be taken, and a message will be sent.

Patient and public involvement

Patients are involved in the questionnaire's face and content validity testing. Based on patient feedback in a pilot study, improvements to the questionnaires' approaches and trial processes will be implemented. Patient preferences were not directly obtained about choosing both interventions; this was based on the principal investigator's practice experience and encounters with pregnant women. However, the patients will be involved in the study's recruitment and conduct. They will attend antenatal classes and agree by consent to share in this study. Also, they will answer all questionnaires pre- and post-intervention. In addition, they will need to agree on back massage and Lamaze breathing as the intervention.

Teaching plan for Lamaze breathing technique

Facilitator: Ms. Tahira Shaheen
Topic: Lamaze Breathing Techniques
Date/Time:----------
Venue: Counselling room
No of participants: 15 primigravida
Duration: 60 minutes

Goal: To improve the knowledge & practices of Lamaze breathing techniques during pregnancy & labor.

Learning objectives	Time	Resources	Teaching methods	Evaluation
At the end of this lecture, the participants will be able to:				
Introduce the concept of Breathing techniques and Lamaze breathig techniques	02 minutes		Brainstorming	
Identify the patterns of Lamaze breathing.	05 minutes	Multimedia	Video player	Questions & Answers
Discuss the benefits of Lamaze breathing techniques	03 minutes	Whiteboard & marker	Interactive Lecture	Questions & Answers
Describe the role of Lamaze breathing in Labor	05 minutes	Multimedia	Interactive Lecture	Quiz Session
Practicing the Lamaze breathing techniques	15 minutes	Demonstration	Roleplay	Return Demonstration
Learn the skill of Lamaze breathing.	15 minutes	Return Demonstration	Video player	Return Demonstration
Clarify the queries of participants	15 minutes	Q & A session	Discussion	Summarised by the participants

Teaching plan for Back Massage

Facilitator: Ms. Tahira Shaheen
Topic: Back Massage
Date/Time:----------
Venue: Counselling room
No of participants: Assistants
Duration: 60 minutes

[Citation: Shaheen, T. (2024). Effectiveness of back massage & lamaze breathing on labor outcomes among primigravida in tertiary care hospitals, Lahore Pakistan: a randomized control trial. *Biol. Clin. Sci. Res. J.*, **2024***: 879*. doi: https://doi.org/10.54112/bcsrj.v2024i1.879]

Goal: To improve the knowledge & practices of Back Massage during pregnancy & labour.

Learning objectives	Time	Resources	Teaching methods	Evaluation
At the end of this lecture, the participants will be able to:				
Introduce the concept of Back Massage.	02 minutes		Brainstorming	Questions & Answers
Identify the patterns of Back Massage	05 minutes	Multimedia	Video player	Questions & Answers
Discuss the benefits of Back Massage	03 minutes	Multimedia	Interactive Lecture	Quiz Session
Describe the role of Back Massage in Labor process.	05 minutes	Whiteboard & marker	Interactive Lecture	Return Demonstration
Practicing the Back Massage	15 minutes	Video Player	Roleplay	Return Demonstration
Learn the skill of Back Massage	15 minutes	Video Player	Video player	Summarised by the participants
Clarify the queries of participants	15 minutes		Discussion	Questions & Answers

Evaluation and compliance

Women in the intervention group will be continued practicing breathing exercises and compliance will be monitored with help of a cue card for Lamaze breathing techniques along with the daily fetal movement count (Sadovsky method, as advised by the obstetrician) till labor will start.

This cue card will be followed-up by the research investigator during biweekly antenatal visits. They will be asked to demonstrate the breathing technique she has been practising at home. Occasionally, the investigator checked for compliance through phone calls and enquired if they had any difficulties.

Instruments

- Informed consent will be taken by the primigravida mothers by Annexure I
- Perception of pain intensity & level of cooperation during Labor Pain by Pain Observation Behaviors Scale (POBS) (Desmawati et. al. 2021), (15 is average and five is low) & Visual Analogue Scale (consists of 0 – 10 points. Zero score means No pain, 10 for "Severe pain".) by Annexure IV & VI.
- Childbirth Self-Efficacy Inventory (CBSEI) for measuring maternal confidence & self-efficacy By Nancy. K. Lowe (Annexure V) for the experimental and control group. (Tool indicates one which indicates not all helpful, and ten very helpful)
- Assessment of duration of labour by Partograph.
- Assessment of maternal blood pressure by sphygmomanometer /monitor as systolic and diastolic
- Assessment of APGAR score of neonates by APGAR score chart

Validity and reliability

Validity: The validity of the tools will be established in consultation with four nursing experts (MSN) and one obstetrician.

I will get permission to use the selected tools from the researcher who developed and used this tool before.

No changes will be made to the standardised tools.

Reliability: The reliability of the visual analogue scale will be established using the inter-rater reliability method.

Pilot study

The pilot study will be conducted at Lady Willingdon Hospital in Lahore, Pakistan.

The investigator will obtain written permission from the medical superintendent and each participant before the study.

The study will be conducted on six mothers who met inclusion criteria and will be selected using a simple random sampling method. 1-2 samples will be selected per day in the Outpatient Department as the experimental group; 3 teaching sessions will be given using videos, demonstrations & return demonstrations for 60 minutes per session. At the same time, primigravida will be selected as the control group, and labour outcomes will be evaluated.

Strength and limitation of the study

This single-masked, parallel, randomised, controlled trial will explore the effects of back massage and Lamaze breathing on pain and anxiety during labour in healthy primigravidae with a singleton fetus.

► The effects of back massage and Lamaze breathing will also be examined by objectively measuring stress hormone levels and comparing these levels between groups before and after the intervention.

►The massage therapy intervention will be applied for 1 hour and only once during the first stage of labour after cervical dilatation of 6 cm.

- The Lamaze breathing intervention will be applied throughout the first stage of labour till the delivery of the baby.

► Blinding the primigravidae mothers is impossible, and the self-assessed subjective outcomes, such as the Visual Analogue Scale, may be biased.

► The expertise and experience of the nursing graduates who are trained to be massage therapists are considered important factors in the quality of treatment provided.

► The expertise and experience of the nursing graduates who are trained to be Lamaze breathing experts are considered important factors in the quality of the intervention provided during labour.

Declarations

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Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department concerned. (MAHSA/PHD/SON/2024/01)
Consent for publication.
Approved
Funding
Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

TAHIRA SHAHEEN (PhD student)
Study Design, Review of Literature.
Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, drafting article.
LIM GEK MUI (HOD)
Final Approval of the study and critical analysis
RUSLI NORDIN (Professor, Dean)
Final Approval of the study and critical analysis

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