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The effectiveness of breathing exercise, foot reflexology, and back massage (BRM) during the first stage of labor on labor pain, duration, anxiety, satisfaction, stress hormones, and newborn outcomes in women in Saudi Arabia who are pregnant for the first time

Submission date
02/03/2019

Recruitment status
No longer recruiting

Registration date
01/05/2019

Overall study status
Completed

Last Edited
07/06/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
Labor pain is one of the most severe pains that women experience during their lives and can affect mothers' lives and decisions. Failure of the labor process can result in longer labor and having an assisted delivery or Caesarean. Longer labor duration can increase the risk for health problems for the baby. Fear and anxiety from intense labor pain can lead the mother to request Caesarean delivery for her next child. Reducing pain and discomfort during labor and birth is an important part of caring for laboring women. Sedatives (calming drugs), analgesics (painkillers) and regional anesthesia (blocking sensation below the waist) such as epidurals can be used. Alternatively, non-drug pain management techniques are less intrusive, low-cost, simple, effective, and have no side effects. This study aims to investigate the effect of a combination of breathing exercises, reflexology and massage therapy on labor pain, duration of labor, anxiety, maternal satisfaction, stress hormones and newborn health in women in Saudi Arabia having their first child.

Who can participate?
Women aged 20 to 35 years who are pregnant for the first time and have not had previous miscarriages.

What does the study involve?
Participants will be asked to join this study while they are at antenatal clinic. If interested and eligible to participate, participants will be asked for consent to participate. The participants are randomly allocated to one of two groups.
The intervention group will receive 5 minutes of breathing exercises followed by foot reflexology for 10 minutes in each sole and 35 minutes lower limb and back massage

continuously. The control group will receive the routine labor pain management in the ward such as changing position, exercises provided by midwives or using pethidine injections or inhaled pain treatments such as gas and air. The treatment for both groups will be started from when the cervix is open by 6 cm for the next 60 minutes.

What are the possible benefits and risks of participating?
The potential benefits are that there might be reduced pain and anxiety for the mother without her having to take more invasive treatments. The mother's satisfaction with the birth process might be increased following the relaxation therapy. Shorter labor might prevent health problems for the baby. There are no risks from the breathing exercises, reflexology or massage.

Where is the study run from?
Umm Al-Qura University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
November 2018 to June 2020 (updated 06/02/2020, previously: December 2019)

Who is funding the study?
Umm Al-Qura University (Saudi Arabia)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GS51719

Study information

Scientific Title
Effectiveness of breathing exercises, foot reflexology and back massage (BRM) on labour pain, anxiety, duration, satisfaction, stress hormones and new-born outcomes among primigravidae during the first stage of labour in Saudi Arabia: a study protocol for a randomised controlled trial

Acronym
BRM

Study hypothesis
There is a significant difference in mean of pain score, duration, anxiety, maternal satisfaction, stress hormones and newborn outcome between the intervention group and the control group.

Specific objectives:
1. To determine the association of intensity of pain, anxiety level, duration of labor, maternal satisfaction, stress hormones and newborn outcome between intervention groups (combination of breathing exercise, foot reflexology, and warm olive oil massage) and control group
2. To identify the predictors of pain, anxiety, duration of labor, and satisfaction of mother and newborn from the baseline sociodemographic and obstetric characteristics

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/04/2019, Kingdom of Saudi Arabia, Ministry of Health General Administration for Researches & Studies IRB-Makkah (Abdulaziz City for Science and Technology, P.O. Box 6086, Riyadh 11442; +966 114883555; research-makkah@moh.gov.sa), ref: H-02-K-076-0319-109
2. Approved 23/10/2019, Ethics Committee for Research Involving Human Subjects (JKEUPM) Universiti Putra Malaysia (Universiti Putra Malaysia, 43400 UPM Serdang, Selangor Darul Ehsan, Malaysia; +966 3-9769 1002; tncpi@upm.edu.my) ref: JKEUPM-2019-169

Study design
Open-label parallel-arm single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available.

Condition
Labor

Interventions
The intervention consists of three components in sequence: breathing exercises, foot reflexology and the back massage on top of standard nursing care in the delivery room. The intervention will last for 1 hour. The breathing exercises will take 5 min, reflexology 20 min and 35 min for lower limb and back massage.

The intervention group will receive 5 minutes breathing exercise followed by foot reflexology for 10 minutes in each sole and 35 minutes lower limbs and back massage continuously on top of the standard usual midwifery care.

The breathing exercises involve asking the woman to slowly and deeply breathe in through the nose during contractions for 2 s and consciously release air during breathing out for 2 s.

The foot reflexology involves pressure on a special area on the sole of the foot to stimulate the nerves, with each step repeated five times:
1. Pressing the palms on the Achilles tendon and kneading the ankle
2. Kneading the thumb pads on the centre of the sole and bottom of the heel
3. Following the CIUW-shape and MST-shape on the foot lateral, intermediate, & combined on the foot
4. Pressing with a stick on the toes, ball, central foot and heel

The back massage involves each step repeated three times:
1. Effleurage from the sacrum to the shoulder and deltoids
2. Applying thumb kneading and lateral pressure at the lumbar spine
3. Applying fist knuckling motion and thumb kneading on the lower back at one side then the other
4. Follow the upper back by applying the thumb kneading on the side of the erector spinae, then draining between the ribs towards the armpit area
5. Applying finger kneading on the trapezius muscle, following fist scooping
6. Pressing on the neck and shoulder area on each side.

The control group will receive only the standard usual midwifery care which includes changing position and intramuscular pethidine. If women in labor are anxious, the midwives may also provide consultation and support comprising touch therapy, encouragement and counseling.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Assessor-rated pain intensity measured using a present behavioral intensity (PBI) scale during a contraction and when there is absence of contraction at baseline, during intervention and post-intervention immediately after the intervention and twice-hourly thereafter during the first stage of labor. During the intervention, the pain intensity will be measured after breathing exercise and foot reflexology therapy (after 25 minutes from the start of the intervention). Similarly, the third pain intensity will be assessed halfway through the massage therapy (after 45 minutes) during and after contraction. The pain measurements for the control group will be taken in a similar manner before and after contraction beginning when the cervix is 6 cm dilated, during the intervention, and two times after intervention in the first stage.
2. Patient-reported pain intensity recorded using a visual analog scale (VAS) during a contraction and when there is absence of contraction at baseline, during intervention and post-intervention immediately after the intervention and twice-hourly thereafter during the first stage of labor. During the intervention, the pain intensity will be measured after breathing exercise and foot reflexology therapy (after 25 minutes from the start of the intervention). Similarly, the third pain intensity will be assessed halfway through the massage therapy (after 45 minutes) during and after contraction. The pain measurements for the control group will be taken in a similar manner before and after contraction beginning when the cervix is 6 cm dilated, during the intervention, and two times after intervention in the first stage.
3. Anxiety during labor assessed using the Anxiety Assessment Scale for Pregnant Women in Labor (AASPWL) . There are nine questions with two sub-dimensions: six questions on the birth process and three questions on motherhood constellation (grouping). The anxiety level will be measured at 6 cm dilation, after the completion of the interventions, and twice every hour during the first stage of labor.

Secondary outcome measures

Current secondary outcome measures as of 06/02/2020:
1. Levels of maternal adrenocorticotrophic hormone (ACTH), Cortisol, and Oxytocin in the blood. Samples were taken on before starting the intervention and will be measured again one and a half hour after the pregnant woman has reached 6 cm of cervical dilatation
2. Maternal vital signs measured by usual monitoring pre- and post-intervention
3. Fetal heart rate measured by cardiotocography pre- and post-intervention
4. Duration of labour measured from 3 to 6 cm cervical dilation and from 6 cm to the end of the first stage of labour using a partograph
5. Assessed the new-born health by using Apgar Scores during 1st and 5th min after delivery (taken from the delivery room medical record)
6. Maternal satisfaction assessed using Six Simple Questions (SSQ), a short questionnaire to assess maternal satisfaction during labour and delivery, measured once after delivery of the baby before the transfer of the mother to postnatal wards

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Previous secondary outcome measures:
1. Duration of labor measured from 3 cm cervical dilation and 6 cm dilation to the end of the first stage of labor using a partograph
2. Maternal satisfaction assessed using Six Simple Questions (SSQ), a short questionnaire to assess maternal satisfaction during labor and delivery, measured once after delivery of the baby before the transfer of the mother to postnatal wards
3. Levels of maternal adrenocorticotrophic hormone (ACTH) and cortisol in the blood. Samples were taken on admission and 90 min after 6 cm dilatation.
4. Levels of maternal oxytocin in the blood. Samples were taken on admission and 90 min after 6 cm dilatation.
5. Maternal vital signs measured by usual monitoring pre- and post-intervention

6. Fetal heart rate measured by cardiotocography pre- and post-intervention
7. Post-delivery health of the newborn assessed using Apgar scores taken at 1 and 5 min after birth

Overall study start date
15/02/2019

Overall study end date
30/05/2020

Eligibility

Participant inclusion criteria
1. Primigravida women without any previous pregnancies such as miscarriages
2. Aged 20 to 35 years
3. At 37 to 41 weeks gestation when in labor
4. Having regular contractions with cervical dilatation of at least 6 cm
5. Regularly attended antenatal clinic from 26 to 34 weeks
6. Singleton pregnancy
7. Cephalic presentation in labor

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
145 Primigravida women

Total final enrolment
225

Participant exclusion criteria
1. Diagnosed with chronic diseases before or during the pregnancy, such as cardiovascular diseases, kidney disease, diabetes, asthma, mental health or psychological disorders, epilepsy or seizures
2. Pregnancy-related diseases, such as gestational diabetes, preeclampsia, cephalopelvic disproportion (CPD), polyhydramnios or oligohydramnios, and deep venous thrombosis (DVT)
3. Complicated pregnancy, such as placenta-previa, haemorrhage, fetal distress
4. Use of analgesics other than intramuscular pethidine

Recruitment start date
01/05/2019

Recruitment end date
31/03/2020

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Maternity and Children Hospital
Makkah
Saudi Arabia
21955

Sponsor information

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Funder(s)

Funder type
University/education

Funder Name
Umm Al-Qura University

Alternative Name(s)
UQU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in 2019. Additional documents such as the study protocol, systematic review, and a research thesis, and others will be available upon request. The study protocol is not yet published.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan
The datasets will be available from the corresponding author for reasonable purposes by healthcare professionals, clinicians or scientists in the related fields. Deidentified and anonymised participant data for all the outcomes will be shared once the results have been published and will be made available for as long as possible. Data used will be advised to refer to the published study protocol and trial register.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/06/2020	17/06/2020	Yes	No
Results article		25/02/2022	07/06/2022	Yes	No