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## 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

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3 **Effectiveness of Breathing Exercises, Foot Reflexology and Back Massage (BRM) on**  
4 **Labour Pain, Anxiety, Duration, Satisfaction, Stress Hormones and New-born**  
5 **Outcomes among Primigravidae during the First Stage of Labour in Saudi Arabia:**  
6 **A Study Protocol for a Randomised Controlled Trial**  
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## ABSTRACT

**Introduction** Labour pain is among the severest pains primigravidae may experience during pregnancy. Failure to address labour pain and anxiety may lead to abnormal labour. Despite the many complementary non-pharmacological approaches, the quality of evidence is low, and best approaches are not established. This study protocol describes a proposed investigation of the effects of a combination of breathing exercises, foot reflexology and back massage (BRM) on the labour experiences of primigravidae.

**Methods and analysis** This randomised controlled trial will involve an intervention group receiving BRM and a control group receiving standard labour care. Primigravidae of 26–34 weeks of gestation without chronic diseases or pregnancy-related complications will be recruited from antenatal clinics. Eligible and consenting patients will be randomly allocated to the intervention or the control group stratified by intramuscular pethidine use. The BRM intervention will be delivered by trained masseuses. The primary outcomes of labour pain and anxiety will be measured during and after uterine contractions at baseline (cervical dilatation 6 cm) and post-BRM hourly for two hours. The secondary outcomes include maternal stress hormone (adrenocorticotrophic hormone, cortisol and oxytocin) levels, maternal vital signs, labour duration, maternal satisfaction, foetal heart rate and Apgar scores. The sample size is estimated based on the between-group difference of 0.6 in anxiety scores, 95% power and 5%  $\alpha$  error, which yields a required sample size of 154 (77 in each group) accounting for a 20% attrition rate. The between- and within-group outcome measures will be examined with mixed-effects regression models, time series analyses and paired t-test or equivalent non-parametric tests, respectively.

**Ethics and dissemination** Ethical approval was obtained from the Ethical Committee for Research Involving Human Subjects of the Ministry of Health in the Saudi Arabia (H-02-

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2  
3 K-076-0319-109) on 14 April 2019. Written informed consent will be obtained from all  
4  
5 the participants.  
6

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8 **Trial registration number and date** ISRCTN87414969, registered 3 May 2019  
9

10 **Keywords** Breathing exercises, Reflexology, Massage, Primigravidae, Labour pain, Stress  
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12 hormones.  
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## 14 15 **Article Summary**

### 16 17 18 **Strengths and Limitations of the Study**

- 19  
20 • This single-blinded parallel randomised controlled trial will explore the combined  
21  
22 effects of breathing exercises, feet reflexology and back massage (BRM) on pain  
23  
24 and anxiety relief during labour in healthy primigravidae with singleton foetus.  
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28 • The effects of BRM will be examined through the objective physiological outcomes  
29  
30 of stress hormone levels between groups before and after the intervention.  
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- 33  
34 • Trained masseuses will deliver BRM to pregnant women.  
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37 • The intervention will be applied for one hour and only once during the first stage  
38  
39 of labour after cervical dilatation of 6 centimetres.  
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- 41  
42 • Blinding of the primigravidae mothers is not possible, and there may be bias in the  
43  
44 self-assessed outcomes.  
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46 **Word count** 4,091 words  
47

## 48 49 **INTRODUCTION**

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52 Many primigravidae have reported experiencing various levels of pain and high levels of  
53  
54 anxiety about the labour process and outcomes. These feelings of pain and anxiety may  
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3 occur in the early stages of labour and during labour itself<sup>1-3</sup>. Anxiety extending to fear is  
4 a common issue related to labour, especially among primigravidae<sup>4,5</sup>. Other recorded  
5 negative perceptions and psychological effects influencing labour experiences include  
6 distress and feelings of powerlessness during labour for women and their families<sup>5-7</sup>.  
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14 When poorly managed, labour pain may lead to severe consequences for women such as  
15 prolonged labour<sup>5,8</sup>, which may increase the risk of foetal distress, head compressions,  
16 intrauterine foetal death, low Apgar scores and physical injuries to neonates<sup>5,9</sup>. Prolong  
17 labour results in increased risk of caesarean section, induced labour and assisted delivery  
18 using vacuum and forceps<sup>10,11</sup>. Studies have also reported negative mental impacts on  
19 women, sometimes to the extent of postnatal post-traumatic anxiety disorder<sup>12,13</sup> and  
20 subsequently reduced quality of life<sup>14</sup>. Feelings of anxiety often originate from possible  
21 birthing complications about which pregnant women have heard and read<sup>4,5,15,16</sup> and may  
22 even result in women refusing normal vaginal delivery and insisting on caesarean sections  
23 without medical indications<sup>17</sup>. It, therefore, is important for healthcare professionals to  
24 assist and educate all expectant mothers on labour pain management.  
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42 Appropriate labour pain management and interventions are important aspects of obstetric  
43 care to ensure optimum outcomes for mothers and babies<sup>18</sup>. Pharmacologic interventions  
44 used in management of labour pain include systemic sedatives, analgesics and regional  
45 anaesthesia<sup>19</sup>. Examples of these analgesics are aerosol and epidural opioids, intramuscular  
46 pethidine (IMP) and intravenous sedatives<sup>20,21</sup>. Some of these are expensive and may be  
47 associated with adverse effects on mothers, the labour process and neonates<sup>22</sup>.  
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3 In contrast, most non-pharmacological methods for labour pain management are simple  
4 and non-invasive and often are cheaper and safer than pharmacological interventions<sup>23–25</sup>.  
5  
6 Studies have found that non-pharmacological approaches, particularly breathing exercises,  
7  
8 have positive impacts on relief of labour pain<sup>26–28</sup> and anxiety in pregnant mothers<sup>29–31</sup>.  
9  
10 Non-pharmacological approaches are especially true for Lamaze breathing, deep breathing  
11  
12 exercises<sup>26–28,32,33</sup>, reflexology<sup>34,35</sup> and massage<sup>36</sup>. Non-pharmacology has been linked to a  
13  
14 shorter labour duration<sup>37</sup> and improved new-born outcomes<sup>38</sup>. Our systematic review found  
15  
16 that massage is beneficial for relieving labour pain<sup>39</sup> and is associated with greater  
17  
18 relaxation, higher alertness levels, improved mood and reduced stress hormone (cortisol)  
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20 levels and anxiety symptoms<sup>40</sup>.  
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## 26 **Rationale**

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28 It is hypothesised that non-pharmacological approach of labour pain management occurs  
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30 via the alteration of nociceptive stimuli and modification of the processing of nociceptive  
31  
32 input at the central level. With that, there is an overall improved sense of comfort and well-  
33  
34 being, ultimately leading to stronger coping capabilities by the mothers in labour <sup>41</sup>.  
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41 The physiological mechanism of breathing is a protective action as it is a fight-or-flight  
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43 reflex triggered by the central nervous system. Physiologically, deep abdominal breathing  
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45 stimulates the parasympathetic nervous system. As a result, the blood circulation in  
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47 pregnant women will undergo oxygenation, during which it will trigger the release of  
48  
49 endorphins which are associated with the decrease in heart rate and promoting the releasing  
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51 the feelings of calmness. At the same time, endorphins can also suppress the sympathetic  
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53 system, leading to a decrease in the release of stress hormones such as cortisol <sup>42,43</sup>.  
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3 As for reflexology, so far there has been no constructive explanation on the underlying  
4 mechanism in reducing labour pain<sup>35,37</sup>. However, there are several postulated theories for  
5 its mechanism of action. Firstly, the autonomic-somatic integration theory suggests that the  
6 pressure applied to the feet during reflexology compresses the receptors in the cells, thus  
7 opening up the ionic channels in the plasma membrane and triggering a local action  
8 potential to convey messages to the spinal cord and/or brain<sup>44</sup>. The application of  
9 alternating pressure to the feet may also produce predictable reflexive actions within the  
10 nervous system and activates the parasympathetic nervous system<sup>45</sup>.

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24 Another contemporary method explains that reflexology acts through a “sympathetic  
25 resonance” manner, in which energy wave between therapist and clients are inter-  
26 conducted to achieve homeostatic balance<sup>46</sup>. This may occur through local enzymatic  
27 reactions on receptive fields or through an improved blood supply as a result of local skin  
28 temperature changes following the skin-to-skin contact<sup>47</sup>. Reflexologists also believe that  
29 the application of deep pressure on certain reflex points of the sole and palm may break  
30 any calcium crystals and uric acid accumulated in nerve endings may cause blockages and  
31 induces pain<sup>48</sup>. Furthermore, reflexology also results in body relaxation and stimulation of  
32 any blocked nerve endings. These may propel any sluggish glands or organs to regain their  
33 normal functioning<sup>49</sup>. There is still ambiguity regarding the theories and mechanism of  
34 action of foot reflexology for labour pain, as compared to that for general pain.  
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60 Nonetheless, it is plausible to believe that reflexology techniques would have similar  
physiological effects for labour pain that bring about a sense of wellbeing, analgesia and  
subsequently the perception of pain relief through control gate<sup>38</sup>.

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3 Massage therapy is another type of the commonly used Complementary and Alternative  
4 Methods (CAM) for the promotion of health and wellbeing <sup>36</sup>. Massage produces a short-  
5 lived analgesic effect by activating the 'pain gate' mechanism <sup>50</sup>. Massage works as a potent  
6 mechanical stimulus and it is a particularly effective trigger for the pain gate process. A  
7 longer-lasting pain control appears to be mediated mainly by the descending pain  
8 suppression mechanism by activation of descending efferent pathways <sup>51</sup>. The inhibition of  
9 pain-transmission neurons is a combination of the physiological and neurological  
10 mechanisms and it is commonly activated by noxious stimulation <sup>52</sup>. Figure 1 summarized  
11 the possible mechanisms of massage <sup>53</sup>.  
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26 The three aforementioned therapies (i.e. BRM) for labour pain management have been  
27 shown to influence the secretion of certain stress hormones such as the cortisol,  
28 adrenocorticotrophic hormone (ACTH), and oxytocin <sup>40,54-56</sup>. Endorphins <sup>57</sup>. <sup>56-60</sup>.  
29 Endogenous oxytocin is a key component in the molecular pathways that buffer reaction  
30 to stress and decreases sensitivity to pain and inflammation<sup>61</sup> and Cortisol is an important  
31 hormone released during stressful conditions <sup>40</sup>.  
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### 41 **Significance of this clinical trial**

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44 Many studies have reported that not all pharmacologic and non-pharmacologic methods on  
45 their own would be able to eliminate labour pain satisfactorily. Despite the intervention,  
46 some mothers still endure some pain, anxiety, prolonged labour and suffer from negative  
47 maternal and perinatal consequences <sup>5,15,16</sup>. From the perspective of complementary  
48 management, BRM are the techniques with the highest potential in managing pain and  
49 anxiety for primigravidae. Other systematic reviews have also concluded that CAM  
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3 interventions to manage pain and anxiety during labour were often poorly executed and  
4 present with biases, thus resulting in low quality of evidence <sup>62-65</sup> with no strongly  
5 supported evidence <sup>66,67</sup>.  
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11 Therefore, there is a need for a rigorous and robust trial to examine the effect of the  
12 combined intervention of BRM on labour pain, anxiety, labour duration, satisfaction, stress  
13 hormones, and neonatal outcome among the primigravidae using multiple relevant  
14 outcome measures.  
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## 23 **METHODS AND DESIGN**

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25 This study aims to investigate the combined effect of breathing, reflexology and back  
26 massage on labor pain, duration of labor, anxiety, maternal satisfaction, stress hormones,  
27 and new-born outcome among primigravidae in Saudi Arabia. The specific objectives are  
28 1) to compare the effect of the combined breathing exercise, foot reflexology, and back  
29 massage (intervention) on labor pain intensity, anxiety level, duration of labor, maternal  
30 satisfaction, stress hormones, and neonatal outcome compared to the standard midwifery  
31 care (control), 2) to identify the predictors of pain, anxiety, duration of labor, the  
32 satisfaction of mother, and neonatal outcome from the baseline sociodemographic and  
33 obstetric characteristics.  
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### 47 **Study Design**

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49 The study design will be a single-blinded parallel randomised controlled trial (RCT), in  
50 which the participants are randomly assigned to receive either the BRM intervention or  
51 control care.  
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## Study Setting

This study will be conducted in the Makkah Maternity and Children Hospital, a governmental maternity hospital in Makkah, Saudi Arabia which provides only maternal and child health services. The hospital is a tertiary-level referral hospital with special services for paediatrics, gynaecology, and obstetrics services <sup>68</sup>. In Saudi Arabia, almost all tertiary hospitals, including our study site, offer systemic pharmacologic agents, either intravenous or intramuscular analgesics to manage pain during labour <sup>69</sup> however, non-invasive and non-pharmacological methods of pain relief during labour are not common practices <sup>69</sup>. To our best knowledge, the combined effect of BRM on primigravidae has not been investigated at any Saudi Arabia hospital prior to this trial.

## Participants

The study participants will include primigravidae, age 20- 35 years old, at 37 to 41 weeks of gestation, and in the first stage of labor. The inclusion criteria include singleton pregnancy, cephalic presentation, and regular contraction. In labor, the participants must achieve six centimeters of cervical dilatation, with a minimum of 3 contractions with at least moderate intensity every 10 minutes, in which the duration of the contraction must be between 30-60 seconds.

The exclusion criteria are diagnosed with underlying chronic diseases such as cardiovascular diseases, kidney disease, diabetes, asthma, mental health disorders, epilepsy, or seizure. Those with pregnancy-related diseases such as gestational diabetes, preeclampsia, cephalo-pelvic disproportion, polyhydramnios or oligohydramnios, and

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3 deep venous thrombosis will be excluded. Pregnancy with complications such as placenta  
4 praevia, antepartum hemorrhage, fetal distress or put on analgesics other than  
5 intramuscular Pethidine (IMP) will not be enrolled in the trial.  
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## 11 **Recruitment**

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15 Recruitment will be conducted at the antenatal clinic in the trial site. Only those who plan  
16 to deliver in the trial hospital's delivery room will be further briefed and assessed of their  
17 eligibility. In this hospital, antenatal mothers are given monthly follow-up appointments  
18 until 28 weeks' gestation. The frequency increases to 2-weekly until 32 weeks' gestation,  
19 before patients are seen weekly until delivery. For this study, we will approach  
20 primigravidae between 26 to 34 weeks of gestation in equal numbers based on the  
21 gestational weeks. In this way, the numbers of expected deliveries will be spread out in the  
22 subsequent 2-3 months.  
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35 At the antenatal clinic, the principal investigator will provide general health education  
36 about pain management during labor. The participant information sheet of this RCT will  
37 be provided for the eligible patients. If they are interested to participate, they will sign a  
38 written consent form and they will be identified through a unique stamp on their antenatal  
39 cards. When the consented participants arrive in the labour room for delivery, they will be  
40 re-evaluated for the eligibility.  
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## 49 **Randomisation**

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52 Since IMP is a commonly prescribed analgesic in labour and it may have substantial effects  
53 on the primigravidae and neonates, randomisation will be stratified according to the  
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3 administrative status of IMP. This will ensure the same numbers of primigravidae with and  
4 without IMP in the intervention and control groups. To achieve this, we use a block of size  
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6 4 with a 1:1 allocation ratio, leading to a possibility of 6 permutations. All possible block  
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8 sequences will be randomly generated with the help of free software from the internet  
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10 <https://www.sealedenvelope.com/simple-randomiser/v1/>. A random list will be created  
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12 after the sample size number, treatment groups, block sizes, list length, and stratification  
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14 factors are entered into the software. The order of the subjects will be used by the research  
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16 coordinator who is stationed in the delivery room to conduct the random group allocation  
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18 for primigravidae in labour who have achieved a cervical dilation of 6 cm. The principal  
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20 investigator, outcome assessors, and masseuses in this trial are not involved in the  
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22 allocation of interventional groups. Figure 2 outlines the CONSORT flow diagram.  
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### 28 **Data Collection**

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31 Every questionnaire will be coded with a unique number. Data collection in the delivery  
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33 room will be facilitated by the trained research coordinator and two outcome assessors.  
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35 The outcome assessors will be assigned to the same control or the intervention group on  
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37 the same day. Once the form is completed by the outcome assessors, it will be kept by the  
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39 research coordinator in a safe location in the delivery room.  
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45 Throughout all the outcome assessment time points, a masseuse will be present in the  
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47 delivery room of both the intervention and control groups. For the intervention group, the  
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49 primigravidae in labour will receive the BRM intervention by the masseuse. However, for  
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51 the control group, the practicing midwife will perform the routine labour care in the  
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53 presence of a masseuse such as touch therapy, ensuring the mother lying on the left side,  
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3 and providing encouragement and counselling. The outcome assessor will measure and  
4 assess at the same time points in both the intervention and control groups. Both the  
5 intervention and the control groups will be equipped with the similar extra equipment. This  
6 blinding effort is to further minimize biases during the outcome assessment. However,  
7 blinding of the participants will be impossible because the nature of the intervention does  
8 not allow to be applied.  
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### 10 11 12 **Interventions**

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The BRM intervention consists of 5 minutes of breathing exercise followed by 10 minutes  
of foot reflexology on each sole and 35 minutes of continuous massage over the lower  
limbs and back. And the masseuse will allow the primigravidae for moving and changing  
her position during intervention time and answer any question or inquiry. Table 1 provides  
a detailed procedure of the BRM intervention. As for the control group, the primigravidae  
in labour will receive routine practice.

### 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 **Training for the research team members**

A total of 13 research assistants will be recruited and trained for the intervention and data  
collection from June to December 2019 (Figure 4). They will be given the BRM training  
for one week by the principal investigator who has completed the professional massage  
training by a certified training center in Malaysia (Tim Body Care Training Centre  
1403695-D).

## Study Outcomes and Measures

There are nine outcomes comprising of two primary outcomes and seven secondary outcomes. The two primary outcomes are pain intensity and anxiety level (See Table 2).

In this study, the pain intensity will be measured multiple times during and after contraction (Figure 3a). It will first be measured at baseline before the intervention. 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) followed by another assessment halfway through the massage therapy (after 45 minutes) during and after contraction. Upon completion of the intervention, the measurement will be taken immediately followed by twice hourly thereafter during the first stage of labour. The pain will be measured for every participating primigravidae in both intervention and control groups. For the control group, the pain intensity will be measured, first at baseline before the intervention time at 6 cm. During the intervention time, the pain intensity will be measured after 25 minutes from the start of the intervention time, followed by another assessment after 45 minutes, during and after contraction. Upon completion of the intervention time, the measurement will be taken immediately followed by twice hourly thereafter during the first stage of labour (Figure 3b).

The ASPWL will be used to assess anxiety during labour. The anxiety level will be measured at cervical dilatation of 6cm, after the completion of the interventions, and twice every 60 minutes during the first stage of labour. For the control group, the assessment will be performed when the cervix is 6 cm, after one hour (synchronized to the completion of



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3 the intervention in the intervention group), and twice every 60 minutes during the first stage  
4 of labour (Figure 3b).  
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10 The secondary outcomes measured in the RCT include maternal stress hormones level,  
11 maternal VS, duration of labour, maternal satisfaction, FHR, and neonatal Apgar score.  
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13 (See Table 3).  
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18 The stress hormones level will be measured again one and a half hour after the patient has  
19 reached 6 cm of cervical dilatation. Blood samples will again be taken by midwives on  
20 duty in the delivery room. This occurs after the BRM intervention in the intervention group,  
21 and the same will occur at the same timing in the control group. The blood sample will be  
22 sent to a laboratory in the hospital immediately by the research coordinator.  
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32 The maternal V/S and FHR will be collected twice at 6cm cervical dilatation and  
33 immediately post-BRM for intervention group, and the same data will be collected at the  
34 timing for the control groups.  
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41 The Apgar Scores (taken from the delivery room medical record) and maternal satisfaction  
42 will be measured only once at the end of the childbirth before the transfer of the mother  
43 from the delivery room to postnatal wards.  
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### 48 **Sample size**

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51 The sample size estimation was based on a review of similar literature on pain and anxiety  
52 as outcomes<sup>70</sup> and calculated using G\*power free software<sup>70</sup>. We estimated the effect size  
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3 of 0.6 on anxiety mean score reduction in the intervention group compared to the control  
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5 <sup>70</sup> as this gives a larger required sample size compared to that based on the primary outcome  
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7 of pain. Thus, with the power of 95% at  $\alpha$  error 0.05, the required sample size is 128 for  
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9 the two groups. It is further inflated to 154 with a 20% attrition rate. Therefore, a minimum  
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11 number of 77 primigravidae will be recruited for each group.  
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### 14 15 **Statistical analysis**

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18 Data will be entered by a blinded enumerator. The database will be checked for accuracy  
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20 before analysis. The principal investigator has the overall responsibility for compilation,  
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22 maintenance, and management of the study database. The analysis will be performed using  
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24 IBM Statistical Package for Social Science (SPSS) version 25.  
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29 Descriptive statistical analysis will be performed according to the distribution of the data,  
30  
31 using means and standard deviations for data with normal distribution, and median and  
32  
33 inter-quartile ranges for data that are not normally distributed. Normality testing will be  
34  
35 conducted for all continuous variables using different methods such as Histogram and p-p  
36  
37 plot. Categorical variables will be reported in frequencies and percentages.  
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43 The differences between the groups and times level will be analysed using a mixed model  
44  
45 or Generalised Linear Mixed Model (GLMM). GLMM is appropriate where repeated  
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47 measurements are made on the same statistical units. GLMM is also used to accommodate  
48  
49 non-normal distribution in outcome data. The variables of time in a categorical form,  
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51 intervention group, a group\*time interaction, and the baseline random part of the model  
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53 will include a random intercept and an unstructured correlation matrix for the correlation  
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3 of measurements within pregnant women. The fixed part of the model will include pain  
4 score whereby the difference in pain score at every time point will be tested using a linear  
5 contrast. We will take the pain intensity measured with PBI and VAS at one-hour post  
6 intervention as the main co-primary outcomes. This is because the effects of the massage  
7 and reflexology are still observable and fairly compared to the control group <sup>44,51</sup>.

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16 Any significant baseline imbalances will be adjusted for in the analysis. If necessary,  
17 multiple imputations will be conducted for the missing data. A calculated 95% confidence  
18 interval and two-sided  $\alpha$  of 0.05 will be used to test significance. In addition, we will  
19 analyze PBI and VAS at same time points and measure the agreement between PBI and  
20 VAS by using the Spearman correlation coefficient and interclass correlation. We will  
21 analyze other outcomes in the same statistical strategy as mentioned above. Additionally,  
22 we will conduct time series analyses to examine the patterns of change in the outcomes  
23 between the two groups and after BRM intervention.

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37 Independent effect of socio-demographic and obstetric characteristics on each primary and  
38 secondary outcome at one-hour post-intervention will be analysed using the multiple linear  
39 regression analyses.

## 40 41 42 43 44 45 **Discussion**

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48 There are different types of complementary therapies that have been shown to be beneficial  
49 to reduce or alleviate labour pain but the evidence is scarce on the effects of combined  
50 therapies <sup>71</sup>. Safe and efficient pain management is important for pregnant women and their  
51 families <sup>18</sup>. Therefore, we design this trial to study the effects of BRM on labour pain and  
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3 other psychological and physiological impacts among the primigravidae. The study  
4 protocol for an RCT is to determine the combined effect of BRM on the intensity of pain  
5 and level of anxiety in primigravidae during the first stage of labour. Additional outcomes  
6 that will be assessed include the maternal satisfaction, stress hormones, maternal VS, FHR,  
7 and neonatal Apgar score.  
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17 In this study, we will assess the outcomes using a mixture of subjective and objective tools.  
18 For example, pain intensity and anxiety levels are subjective measurements, they are  
19 subjective due to the personal feelings and judgment of the respondents. Duration of labour,  
20 neonatal Apgar score, and maternal stress hormones level of ACTH, cortisol, and oxytocin  
21 will be the objective measurements. This is one of the strengths of our study. These stress  
22 hormones are the objective outcomes that will indicate the stress response to the BRM  
23 intervention conducted on the primigravidae.  
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35 Some of the tools used in this study such as VAS might not be the gold or referent standard  
36 to measure labour pain outcome but this is one of the multiple outcomes and alternative  
37 ways of measuring the effectiveness of BRM. VAS is a commonly used graphic rating  
38 method <sup>72</sup>. However, VAS has its inconsistency of results and has ceiling effect <sup>73,74</sup>.  
39 Recognizing this inadequacy, we will ensure the participants understand the VAS scoring  
40 at admission to the delivery room before they are asked to indicate their pain level later,  
41 and the labour pain outcome will be measured by two different methods and multiple  
42 measurements will be taken during and after contraction, before and after the intervention.  
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3 As alluded to, we will complement VAS with pain intensity assessment using the PBI<sup>70</sup> to  
4 be rated by outcome assessors. There will also be other outcomes that are related to the  
5 maternal response to pain, which are the anxiety level and maternal stress hormones<sup>75</sup>.  
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12 There are several other limitations in this study. Firstly, the intervention will be performed  
13 for one hour during which it may be interrupted by routine medical care such as regular  
14 vaginal examinations, VS measurements, and fetal heart monitoring. However, we believe  
15 that this will not reduce the effect of BRM intervention, because we can start the BRM  
16 before or after labour care routine. Secondly, the process of labour and birthing is  
17 unpredictable even if the participants are low-risk pregnant women. In certain instances,  
18 the process of the intervention might not go well as planned and this may reduce the sample  
19 size. Some patients may end up needing a caesarean section due to various reasons and  
20 some may suffer from other obstetric complications during delivery. As a result, we have  
21 inflated the sample size accordingly. Apart from that, results from this study will not be  
22 generalisable to multigravidae as we include only primigravidae. Nevertheless, we believe  
23 primigravidae will benefit the most from the intervention as they are likely to experience a  
24 higher level of labour pain and a longer duration of the labour compared to multigravidae.  
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44 Also, the intervention will be applied only once and only during the first stage of labour  
45 even though the first stage of labour among primigravidae take approximately 8-12 hours.  
46 By timing the intervention after cervical dilation of 6 cm and above, the effect of the  
47 combined BRM could exert its most influences if there is any on the labour experience of  
48 the primigravidae and neonatal outcome because this period is believed to be with the  
49 highest levels of labour pain.  
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3 This study will assess the anxiety level of pregnant mothers. Unlike the labour pain, the  
4 level of anxiety can be affected by the individual characteristics, previous life experience,  
5 and other environmental causes <sup>76</sup>. However, we believe that these factors may not play a  
6 significant role after effective randomisation.  
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14 Apart from the actual labour experience, there are a few other external factors that may  
15 affect the maternal satisfaction, such as the delivery room services, the health of the baby,  
16 the gender of the child, family support, and other psychosocial factors. As satisfaction is a  
17 multi-dimensional and complex feeling, it is difficult to measure with a single tool and to  
18 narrow it down to only the first stage of labour.  
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28 It is understood that a birthing process is a natural event, especially for low-risk women.  
29 Thus, the management of labour should be in a supportive manner with minimal or no  
30 interferences. This study will provide good-quality evidence on the effects of the combined  
31 BRM for labor pain management. These findings will be important for primigravidae and  
32 their family members during the decision making about labour pain management.  
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#### 49 **Author Contributions**

50  
51 KB drafted, formulated, and submitted the manuscript. All authors MHR, AHI, LK & BHC  
52 contributed to the study designs, read, revised, and approved the research protocol critically  
53 for important intellectual content and helped to draft the final manuscript. All authors  
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3 approved the final manuscript for submission. Authorship eligibility is in accordance with  
4  
5 the International Committee of Medical Journal Editors (ICMJE) guidelines.  
6  
7

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17  
18 and interpretation of the data and writing of the manuscript.  
19  
20

### 21 **Competing Interest**

22  
23  
24 The authors declare that they have no competing interests.  
25  
26

### 27 **Patient Consent for Publication**

28  
29 Not applicable since this is a study protocol.  
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### 32 **Availability of Data and Materials**

33  
34 The datasets will be available from the corresponding author for reasonable purposes by  
35  
36 healthcare professionals, clinicians or scientists in the related fields. Deidentified and  
37  
38 anonymised participant data for all the outcomes will be shared once the results have been  
39  
40 published and will be made available for as long as possible. Data use will be advised to  
41  
42 refer to the published study protocol and trial register.  
43  
44

### 45 **Ethics Approval and Consent to Participate**

46  
47 Ethics approval has been obtained from the Ethical Committee for Research Involving  
48  
49 Human Subjects of the Ministry of Health in the Saudi Arabia (H-02-K-076-0319-109) on  
50  
51 14/April/2019. Additional administrative approvals will be requested from the medical  
52  
53 director of Makkah Maternity and Children Hospital.  
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**Figure Legend**

Figure 1 Mechanisms of Massage therapy

Figure 2 The CONSORT flow diagram

Figure 3 (a) shows the timeline of outcomes measurement in the intervention group; (b) shows the timeline of outcomes measurement in the control group

Figure 4 Research personnel training and responsibility matrix

For peer review only

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9 Table 2 Summary of Primary Outcomes and Measurement Tools  
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**Table 1 Steps of the Intervention**

<b>Steps</b>	<b>Process</b>
1.	Prepare the equipment.
2.	Explain the procedure to the primigravidae & advise her to lay on the left side with a pillow on the side of the stomach.
<b>Breathing Exercise Intervention for 5 minutes</b>	
3.	Ask the primigravidae to perform deep breathing slowly through the nose for two seconds and then consciously release the air during breathing out for another two seconds during contractions.
4.	Rest for 1-3 seconds then repeat the same technique for a total of 5 minutes.
<b>Reflexology Intervention Technique for 10 minutes on each foot</b>	
5.	Put a towel under the left foot and cover the right leg.
6.	Apply warm oil over the left foot and roll it left to right for 5 times.
7.	Press palms on the Achilles heel and knead the ankle for 5 times.
8.	Knead the thumb pads on the central and bottom parts of the heel for 5 times.
9.	Knead the foot following the *CIUW shape on the lateral and intermediate aspects of the foot followed by **MST shape for 5 times.
10.	Press the wooden stick of the reflexology on the toes, forefoot, mid-foot, and hind-foot for 5 times.
11.	Repeat Steps 6-11 on the right foot for 5 times.
<b>Lower Limbs Massage for 2 minutes 30 seconds on each leg</b>	
12.	Effleurage massage on the flexed leg by using two hands whole lower leg for 3 times.
13.	Half effleurage massage from the heel to the popliteal area for 3 times.
14.	Palm and thumb kneading on the gastrocnemius muscle over the lateral & medial sides, followed by the scooping on the gastrocnemius, each step for 3 times.
15.	Thumb kneading on the hamstring muscle over the medial, intermediate, and lateral sides for 3 times.
16.	Repeat Steps 12-17 on the right leg for 3 times.
<b>Lower Back Massage for 15 minutes</b>	
17.	Effleurage massage from the sacrum to the shoulders and deltoids for 3 times.
18.	Thumb kneading & pressure over the lateral sides of the lumbar area of the spine for 3 times.
19.	Apply fist knuckling motion and thumb kneading on the lower back, side by side, for 3 times.
<b>Upper Back Massage for 15 minutes</b>	
20.	Effleurage massage followed by palm kneading from the lumbar region to trapezius laterally for 3 times.

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21. Thumb kneading over both sides of erector spinae, then draining between the ribs towards the armpit areas for 3 times.
  22. Apply squeeze on the deltoid muscle with draining towards the armpit for 3 times.
  23. Apply finger kneading on trapezius muscle, followed by fist scooping for 3 times.
  24. Finally, press on the neck and shoulder area on both sides for 3 times.

\*CIUW-shape: C-shape; I-shape; U-shape, and W-shape, \*\*MST-shape: M-shape, S-shape, and T-shape.

**Table 2 Summary of Primary Outcomes and Measurement Tools**

<b>Primary Outcomes</b>	<b>measurement tools</b>	<b>Psychometric tests</b>	<b>Method of assessment</b>
<b>Pain</b>	PBI	-100% inter-rater reliability - <i>r</i> coefficient was 0.45, 0.50, and 0.44 between PBI and PPI. <sup>70,77</sup>	-assessor-rated <sup>70</sup> -five-category behavioural observation scale
	VAS	-moderate correlation ( <i>r</i> = 0.54) with the verbal rating and is considered valuable when mixed with other tools <sup>78,79</sup> - 0.97 intraclass correlation coefficient of 24 hours interval test-retest reliability <sup>80</sup>	- self-reported VAS <sup>72</sup> - contains six different coloured parts anchored by two extremes of 'no pain' and excruciating pain - to mark on the line- map by primigravidae <sup>81</sup> .
<b>Anxiety</b>	ASPWL	- > 0.8 concordance test content validity index -Kendall's W between the opinions of the experts ( <i>W</i> = 0.090; <i>P</i> = 0.080) with Cronbach's alpha level of 0.77 <sup>82</sup> . significantly correlated ( <i>r</i> = 0.369) Beck Anxiety Scale <sup>82</sup>	-questionnaire consists of nine items <sup>82</sup> - a 5-point scale and the higher the mean score the more anxiety

**Table 3 Summary of Secondary Outcomes and Measurement Tools**

<b>Secondary outcomes</b>	<b>Measurement tools</b>	<b>Method of assessment</b>
<b>Maternal stress hormones level,</b>	Blood sample for ACTH, cortisol, oxytocin	Blood sample will be drawn from the median cubital vein during the insertion of IV cannula (routine care)
<b>Duration of labour,</b>	Partograph	Partograph at two separate time intervals, a sum of labour duration from 3 to 6 cm of cervical dilatation and from 6 cm to delivery of the placenta
<b>Maternal satisfaction,</b>	SSQ <sup>83</sup>	Self-reported 7-point scale (1-7) from “strongly disagree to “strongly agree” with higher scores signifying the higher level of satisfaction
<b>Maternal VS</b>	Thermometer Sphygmomanometer	Recorded on the vital sign monitoring chart and cardiocotograph (CTG)
<b>FHR</b>		Recorded on the vital sign monitoring chart and cardiocotograph (CTG)
<b>Neonatal Apgar score</b>	Apgar score table	Taken from the delivery room medical record



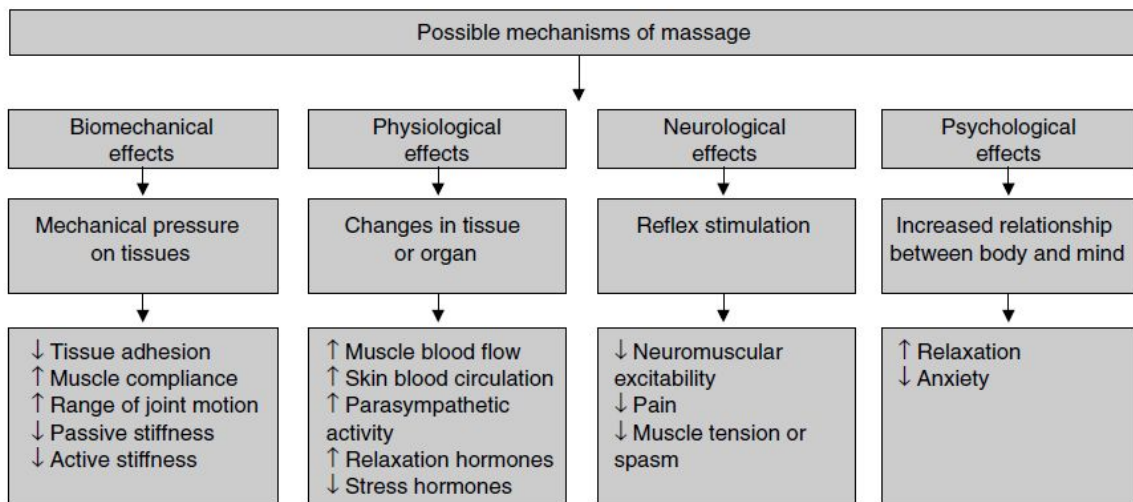
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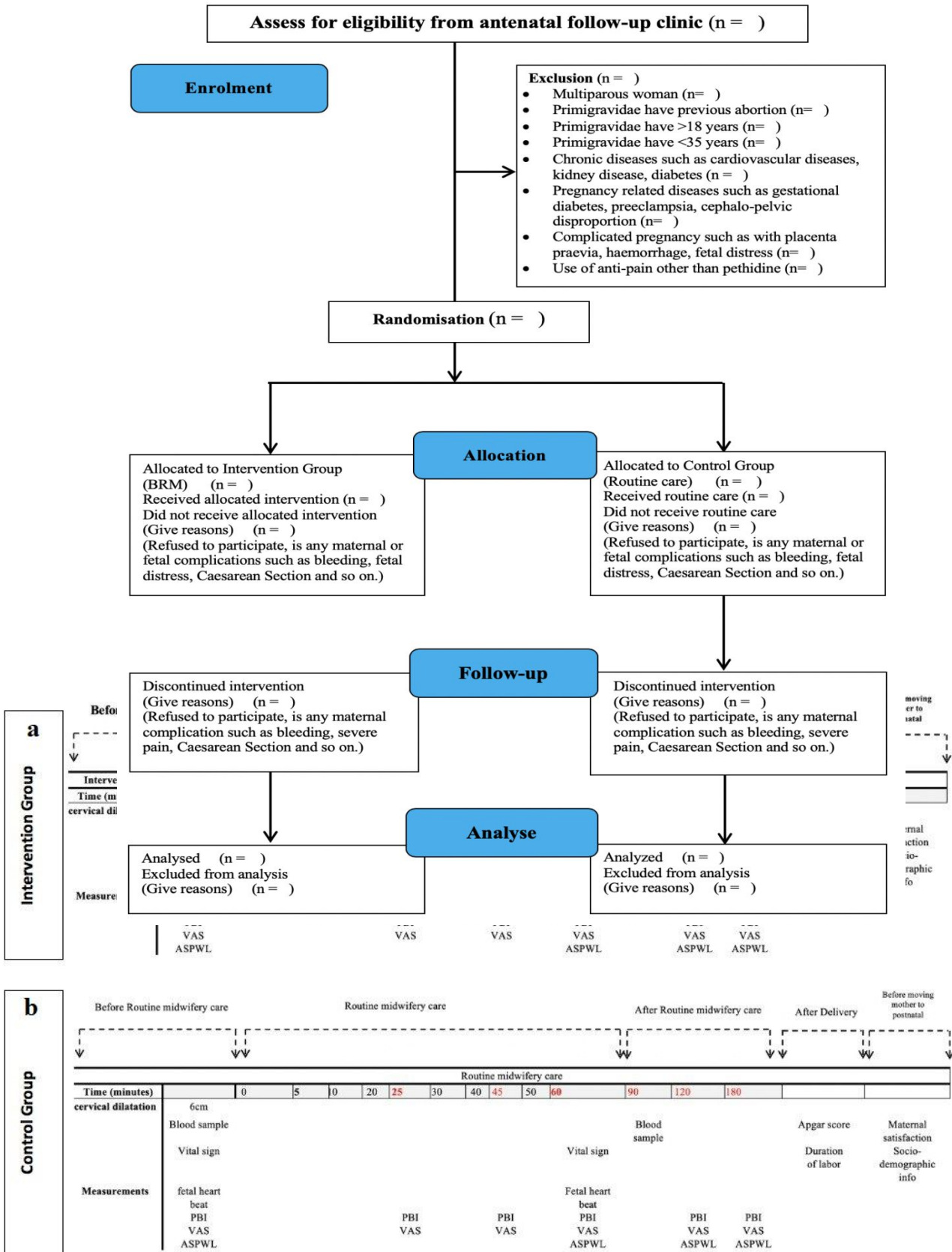
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18 Figure 4 Research personnel training and responsibility matrix  
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**Figure 1 Mechanisms of Massage therapy**



### 13 Research Assistants + 1 Principal Investigator

- Recruitment of nursing students who completed a 5-year nursing degree training and awaiting their job posting,
- Assigned to their preferred and suitable roles (coordinators, the outcome assessors, or masseuses),
- One week training as research assistants in their respective roles,
- A pilot study to ensure their competency,
- Written study manual as a reference guide to be provided to all research assistants.

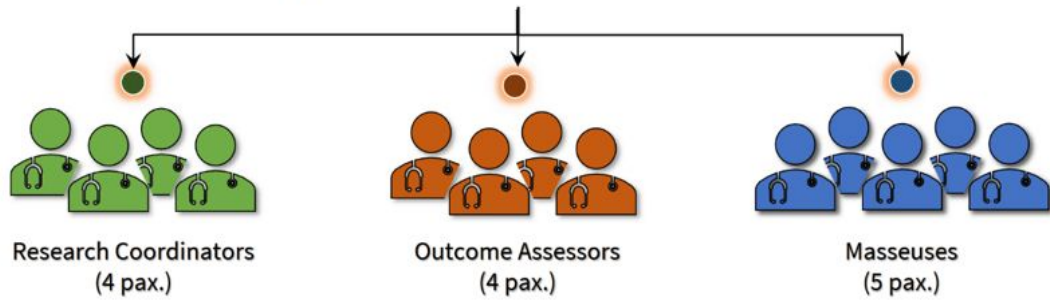


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<ul style="list-style-type: none"> <li>• Recruit eligible primigravidae at the antenatal clinic deliver brief health education on labour pain management at the antenatal clinic for 6 weeks,</li> <li>• Reassess the primigravidae women's consent and eligibility,</li> <li>• Allocate the women to either the intervention or control group,</li> <li>• Alert the masseuses and outcome assessors when the cervical dilatation of the trial participant reaches 6 cm,</li> <li>• Distribute outcomes assessment record form to the outcome assessors,</li> <li>• Encode the questionnaire package according to the participant's allocated group,</li> <li>• Organise the entry sequence for the outcome assessors and the masseuses to enter the delivery rooms according to the scheduled time.</li> </ul>	<ul style="list-style-type: none"> <li>• Assess and fill-up questionnaires:                             <ol style="list-style-type: none"> <li>1. Present behavioural Intensity (PBI),</li> <li>2. Visual Analog Scale (VAS),</li> <li>3. Anxiety Assessment Scale for primigravidae Women in labour (AASPWL),</li> <li>4. Six Simple Questions (SSQ) for maternal satisfaction.</li> </ol> </li> <li>• Retrieve the maternal vital signs, duration of labour, fetal heart rate, and neonatal Apgar score from the health records,</li> <li>• Record all the outcomes in the designated form.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform breathing exercise, foot reflexology and back massage during labour (BRM).                             <ol style="list-style-type: none"> <li>1. Breathing exercise (5min),</li> <li>2. Foot Reflexology (10 min in each foot),</li> <li>3. Back massage (35min).</li> </ol> </li> </ul>
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Sub-divided into two shifts per day to ensure all the eligible and consented primigravidae will be captured



Day Shift (9 am – 9 pm)

2 Coordinators, 3 Masseuses, and 2 Outcome Assessors



Night Shift (9 pm – 9 am)

2 Coordinators, 2 Masseuses, 2 Outcome Assessors, and Principal Investigator

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**Figure 4** Research personnel training and responsibility matrix

For peer review only

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
<b>Administrative information</b>		
Title	<u>#1</u> Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet	3
2			registered, name of intended registry	
3				
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6	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	4
7			Registration Data Set	
8	data set			
9				
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12	Protocol version	<a href="#">#3</a>	Date and version identifier	4
13				
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15	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	20
16			support	
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20	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol	20
21			contributors	
22	responsibilities:			
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28	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	1,20
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38	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	20
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
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52	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	N/A
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
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and other individuals or groups overseeing the trial,  
 if applicable (see Item 21a for data monitoring  
 committee)

## Introduction

Background and rationale	<a href="#">#6a</a>	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4,5
Background and rationale: choice of comparators	<a href="#">#6b</a>	Explanation for choice of comparators	5
Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	8
Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9,11

## Methods:

### Participants, interventions, and outcomes

Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic hospital) and list of countries where data	9
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1		will be collected. Reference to where list of study	
2		sites can be obtained	
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6	Eligibility criteria	<a href="#">#10</a> Inclusion and exclusion criteria for participants. If	9,10
7		applicable, eligibility criteria for study centres and	
8		individuals who will perform the interventions (eg,	
9		surgeons, psychotherapists)	
10			
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12			
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15			
16	Interventions:	<a href="#">#11a</a> Interventions for each group with sufficient detail to	12, Table 1
17	description	allow replication, including how and when they will	
18		be administered	
19			
20			
21			
22			
23	Interventions:	<a href="#">#11b</a> Criteria for discontinuing or modifying allocated	N/A
24	modifications	interventions for a given trial participant (eg, drug	
25		dose change in response to harms, participant	
26		request, or improving / worsening disease)	
27			
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32			
33	Interventions:	<a href="#">#11c</a> Strategies to improve adherence to intervention	N/A
34	adherence	protocols, and any procedures for monitoring	
35		adherence (eg, drug tablet return; laboratory tests)	
36			
37			
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40			
41	Interventions:	<a href="#">#11d</a> Relevant concomitant care and interventions that	9,10
42	concomitant care	are permitted or prohibited during the trial	
43			
44			
45			
46	Outcomes	<a href="#">#12</a> Primary, secondary, and other outcomes, including	13,14, table 2,
47		the specific measurement variable (eg, systolic	3
48		blood pressure), analysis metric (eg, change from	
49		baseline, final value, time to event), method of	
50		aggregation (eg, median, proportion), and time point	
51		for each outcome. Explanation of the clinical	
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1 relevance of chosen efficacy and harm outcomes is  
 2  
 3 strongly recommended  
 4

5  
 6 Participant timeline [#13](#) Time schedule of enrolment, interventions (including Figure 3a, 3b  
 7 any run-ins and washouts), assessments, and visits  
 8 for participants. A schematic diagram is highly  
 9 recommended (see Figure)  
 10  
 11  
 12  
 13

14  
 15 Sample size [#14](#) Estimated number of participants needed to achieve 15  
 16 study objectives and how it was determined,  
 17 including clinical and statistical assumptions  
 18 supporting any sample size calculations  
 19  
 20  
 21  
 22  
 23  
 24

25 Recruitment [#15](#) Strategies for achieving adequate participant 10,11  
 26 enrolment to reach target sample size  
 27  
 28  
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 30

### 31 Methods:

#### 32 Assignment of 33 interventions (for 34 controlled trials)

35 Allocation: [#16a](#) Method of generating the allocation sequence (eg, 11  
 36 sequence computer-generated random numbers), and list of  
 37 generation any factors for stratification. To reduce predictability  
 38 of a random sequence, details of any planned  
 39 restriction (eg, blocking) should be provided in a  
 40 separate document that is unavailable to those who  
 41 enrol participants or assign interventions  
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1	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence	11,12
2				
3	concealment		(eg, central telephone; sequentially numbered,	
4				
5	mechanism		opaque, sealed envelopes), describing any steps to	
6				
7				
8			conceal the sequence until interventions are	
9				
10			assigned	
11				
12				
13	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will	Figure 4
14				
15	implementation		enrol participants, and who will assign participants	
16				
17			to interventions	
18				
19				
20				
21	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to	12,17
22				
23			interventions (eg, trial participants, care providers,	
24				
25			outcome assessors, data analysts), and how	
26				
27				
28	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is	N/A
29				
30	emergency		permissible, and procedure for revealing a	
31				
32	unblinding		participant's allocated intervention during the trial	
33				
34				
35				
36	<b>Methods: Data</b>			
37				
38	<b>collection,</b>			
39				
40	<b>management, and</b>			
41				
42	<b>analysis</b>			
43				
44				
45				
46	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome,	12,Figure 4
47				
48			baseline, and other trial data, including any related	
49				
50			processes to promote data quality (eg, duplicate	
51				
52			measurements, training of assessors) and a	
53				
54			description of study instruments (eg, questionnaires,	
55				
56			laboratory tests) along with their reliability and	
57				
58				
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1		validity, if known. Reference to where data collection	
2		forms can be found, if not in the protocol	
3			
4			
5			
6	Data collection plan: <a href="#">#18b</a>	Plans to promote participant retention and complete	N/A
7			
8	retention	follow-up, including list of any outcome data to be	
9		collected for participants who discontinue or deviate	
10		from intervention protocols	
11			
12			
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14			
15			
16	Data management <a href="#">#19</a>	Plans for data entry, coding, security, and storage,	15
17		including any related processes to promote data	
18		quality (eg, double data entry; range checks for data	
19		values). Reference to where details of data	
20		management procedures can be found, if not in the	
21		protocol	
22			
23			
24			
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29			
30	Statistics: outcomes <a href="#">#20a</a>	Statistical methods for analysing primary and	15,16
31		secondary outcomes. Reference to where other	
32		details of the statistical analysis plan can be found, if	
33		not in the protocol	
34			
35			
36			
37			
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39			
40	Statistics: additional <a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup	16
41		and adjusted analyses)	
42	analyses		
43			
44			
45	Statistics: analysis <a href="#">#20c</a>	Definition of analysis population relating to protocol	Not mentioned
46			
47	population and	non-adherence (eg, as randomised analysis), and	
48		any statistical methods to handle missing data (eg,	
49	missing data	multiple imputation)	
50			
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55	<b>Methods: Monitoring</b>		
56			
57			
58			
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1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	22
2				
3	formal committee		summary of its role and reporting structure;	
4				
5			statement of whether it is independent from the	
6				
7			sponsor and competing interests; and reference to	
8				
9			where further details about its charter can be found,	
10				
11			if not in the protocol. Alternatively, an explanation of	
12				
13			why a DMC is not needed	
14				
15				
16				
17				
18	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	N/A
19				
20	interim analysis		guidelines, including who will have access to these	
21				
22			interim results and make the final decision to	
23				
24			terminate the trial	
25				
26				
27				
28	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and	N/A(no sever
29				
30			managing solicited and spontaneously reported	adverse
31				
32			adverse events and other unintended effects of trial	effects of BRM
33				
34			interventions or trial conduct	recorded)
35				
36				
37				
38	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct,	N/A
39				
40			if any, and whether the process will be independent	
41				
42			from investigators and the sponsor	
43				
44				
45	<b>Ethics and</b>			
46				
47	<b>dissemination</b>			
48				
49				
50				
51	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	2, 3, 21
52				
53	approval		institutional review board (REC / IRB) approval	
54				
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1	Protocol	<a href="#">#25</a>	Plans for communicating important protocol	2,21
2				
3	amendments		modifications (eg, changes to eligibility criteria,	
4			outcomes, analyses) to relevant parties (eg,	
5			investigators, REC / IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
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12				
13	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from	3,11
14			potential trial participants or authorised surrogates,	
15			and how (see Item 32)	
16				
17				
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21	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use	N/A
22	ancillary studies		of participant data and biological specimens in	
23			ancillary studies, if applicable	
24				
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28	Confidentiality	<a href="#">#27</a>	How personal information about potential and	3,11
29			enrolled participants will be collected, shared, and	
30			maintained in order to protect confidentiality before,	
31			during, and after the trial	
32				
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38	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal	20
39	interests		investigators for the overall trial and each study site	
40				
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43				
44	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial	20
45			dataset, and disclosure of contractual agreements	
46			that limit such access for investigators	
47				
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51	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care,	N/A
52	trial care		and for compensation to those who suffer harm from	
53			trial participation	
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1	Dissemination	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate	2
2				
3	policy: trial results		trial results to participants, healthcare professionals,	
4			the public, and other relevant groups (eg, via	
5			publication, reporting in results databases, or other	
6			data sharing arrangements), including any	
7			publication restrictions	
8				
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14				
15	Dissemination	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended	22
16	policy: authorship		use of professional writers	
17				
18				
19				
20				
21	Dissemination	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	Not mentioned
22	policy: reproducible		protocol, participant-level dataset, and statistical	
23	research		code	
24				
25				
26				
27				
28				
29	<b>Appendices</b>			
30				
31				
32	Informed consent	<a href="#">#32</a>	Model consent form and other related	22
33	materials		documentation given to participants and authorised	
34			surrogates	
35				
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38				
39	Biological	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and	N/A
40	specimens		storage of biological specimens for genetic or	
41			molecular analysis in the current trial and for future	
42			use in ancillary studies, if applicable	
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# BMJ Open

## 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

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<b>Primary Subject Heading</b>:	Complementary medicine
Secondary Subject Heading:	Complementary medicine, Nursing, Emergency medicine, General practice / Family practice, Public health
Keywords:	Breathing exercises, Reflexology, Massage, Primigravidae, Labour pain, Stress hormones

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1 **Effectiveness of Breathing Exercises, Foot Reflexology and Back Massage (BRM) on**  
2 **Labour Pain, Anxiety, Duration, Satisfaction, Stress Hormones and New-born**  
3 **Outcomes among Primigravidae during the First Stage of Labour in Saudi Arabia:**  
4 **A Study Protocol for a Randomised Controlled Trial**

5  
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1  
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3 **1 ABSTRACT**  
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6 **2 Introduction** Labour pain is among the severest pains primigravidae may experience  
7  
8 during pregnancy. Failure to address labour pain and anxiety may lead to abnormal labour.  
9  
10 Despite the many complementary non-pharmacological approaches to coping with labour  
11  
12 pain, the quality of evidence is low and best approaches are not established. This study  
13  
14 protocol describes a proposed investigation of the effects of a combination of breathing  
15  
16 exercises, foot reflexology and back massage (BRM) on the labour experiences of  
17  
18 primigravidae.  
19  
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21

22 **9 Methods and analysis** This randomised controlled trial will involve an intervention group  
23  
24 receiving BRM and standard labour care, and a control group receiving only standard  
25  
26 labour care. Primigravidae of 26–34 weeks of gestation without chronic diseases or  
27  
28 pregnancy-related complications will be recruited from antenatal clinics. Eligible and  
29  
30 consenting patients will be randomly allocated to the intervention or the control group  
31  
32 stratified by intramuscular pethidine (IMP) use. The BRM intervention will be delivered  
33  
34 by a trained massage therapist. The primary outcomes of labour pain and anxiety will be  
35  
36 measured during and after uterine contractions at baseline (cervical dilatation 6 cm) and  
37  
38 post-BRM hourly for two hours. The secondary outcomes include maternal stress hormone  
39  
40 (adrenocorticotrophic hormone, cortisol and oxytocin) levels, maternal vital signs (V/S),  
41  
42 foetal heart rate (FHR), labour duration, Apgar scores, and maternal satisfaction. The  
43  
44 sample size is estimated based on the between-group difference of 0.6 in anxiety scores,  
45  
46 95% power and 5%  $\alpha$  error, which yields a required sample size of 154 (77 in each group)  
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1 be examined with mixed-effects regression models, time series analyses and paired t-test  
2 or equivalent non-parametric tests, respectively.

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10 **Ethics and dissemination** Ethical approval was obtained from the Ethical Committee for  
11 Research Involving Human Subjects of the Ministry of Health in the Saudi Arabia (H-02-  
12 K-076-0319-109) on 14 April 2019, and from the Ethics Committee for Research Involving  
13 Human Subjects (JKEUPM) Universiti Putra Malaysia on 23 October 2019, reference  
14 number: JKEUPM-2019-169. Written informed consent will be obtained from all  
15 participants. Results from this trial will be presented at regional, national and international  
16 conferences and published in indexed journals.

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26 **Trial registration number and date** ISRCTN87414969, registered 3 May 2019

27  
28 **Keywords** Breathing exercises, Reflexology, Massage, Primigravidae, Labour pain, Stress  
29 hormones.  
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## 1 Article Summary

### 2 Strengths and Limitations of the Study

- 4 • This single-blind, parallel, randomised controlled trial will explore the combined  
5 effects of breathing exercises, foot reflexology and back massage (BRM) on pain  
6 and anxiety during labour in healthy primigravidae with a singleton foetus.
- 7 • The effects of BRM will also be examined through objective physiological  
8 measurement of stress hormone levels and comparison of these levels between  
9 groups before and after the intervention.
- 10 • The intervention will be applied for one hour and only once during the first stage  
11 of labour after cervical dilatation of 6 centimetres.
- 12 • Blinding of the primigravidae mothers is not possible, and there may be bias in the  
13 self-assessed subjective outcomes such as the Visual Analog Scale.
- 14 • The expertise and experience of the nursing graduates who are trained to be the  
15 massage therapists is considered an important factor in the quality of treatment  
16 provided and this may underestimate the effect of BRM.

17 **Word count 4,907 words**

## 1 INTRODUCTION

2 Many primigravidae have reported experiencing various levels of pain during labour and  
3 high levels of anxiety about the labour process and its outcomes [1-3]. Anxiety escalating  
4 to fear is a common issue related to labour, especially among primigravidae [4, 5]. Other  
5 recorded negative perceptions and psychological effects influencing labour experiences  
6 include distress and feelings of powerlessness during labour for women and their families  
7 [5-7].

8 When poorly managed, labour pain may lead to severe consequences for women, such as  
9 prolonged labour [5, 8], which may increase the risk of foetal distress, head compression,  
10 intrauterine foetal death, low Apgar scores and physical injuries to neonates [5, 9].  
11 Prolonged labour results in increased risk of caesarean section, induced labour and assisted  
12 delivery using vacuum and forceps [10, 11]. Studies have also reported negative mental  
13 impacts on women, sometimes even including postnatal post-traumatic stress disorder [12,  
14 13], and subsequently reduced quality of life [14]. Feelings of anxiety often originate from  
15 possible birthing complications about which pregnant women have heard and read [4, 5,  
16 15, 16], and may even result in women refusing normal vaginal delivery and insisting on  
17 caesarean sections without medical indications [17]. It is therefore important for healthcare  
18 professionals to assist and educate all expectant mothers on labour pain management.

19 Appropriate labour pain management and interventions are important aspects of obstetric  
20 care to ensure optimum outcomes for mothers and babies [18]. Pharmacologic  
21 interventions used in the management of labour pain include systemic sedatives, analgesics

1 and regional anaesthesia [19]. Examples of these analgesics are aerosol and epidural  
2 opioids, intramuscular pethidine (IMP) and intravenous sedatives [20, 21]. Some of these  
3 are expensive and may be associated with adverse effects on mothers, the labour process  
4 and neonates [22]. In contrast, most non-pharmacological methods for labour pain  
5 management are simple and non-invasive, and are often cheaper and safer than  
6 pharmacological interventions [23-25]. Studies have found that non-pharmacological  
7 approaches, particularly breathing exercises, have positive impacts on relief of labour pain  
8 [26-28], and anxiety in pregnant mothers [29-31]. This is especially true for Lamaze  
9 breathing, deep breathing exercises [26-28, 32, 33], reflexology [34, 35], and massage [36].  
10 Non-pharmacological approaches have been linked to shorter labour duration [37], and  
11 improved new-born outcomes [38]. Our systematic review found that massage is beneficial  
12 for relieving labour pain [39], and is associated with greater relaxation, higher alertness  
13 levels, improved mood and reduced stress hormone (cortisol) levels and anxiety symptoms  
14 [40].

## 15 **Rationale**

16 It is hypothesised that the non-pharmacological approach of labour pain management  
17 occurs via the alteration of nociceptive stimuli and modification of the processing of  
18 nociceptive input at the central level, resulting in an overall improved sense of comfort and  
19 well-being, ultimately leading to stronger coping capabilities by the mothers in labour [41].

20 The physiological mechanism of breathing is a protective action as it is a fight-or-flight  
21 reflex triggered by the central nervous system. Physiologically, deep abdominal breathing  
22 stimulates the parasympathetic nervous system. As a result, the blood circulation in

1 pregnant women will undergo oxygenation, which will trigger the release of endorphins  
2 associated with decrease in heart rate and increase in feelings of calmness. At the same  
3 time, endorphins can also suppress the sympathetic system, leading to a decrease in the  
4 release of stress hormones such as cortisol [42, 43].

5 As for reflexology, so far there has been no constructive explanation of the underlying  
6 mechanism in reducing labour pain [35, 37]. The reflexology therapist will apply pressure  
7 many times on specific points of the feet that are energetically connected to certain parts  
8 and organs of the body. These include reflex points on the tips of the fingers that reflect  
9 the head, brain, and pituitary gland, and are believed to facilitate the secretion of the  
10 endogenous endorphins that reduce labour pain, stress, fatigue and anxiety [44, 45].  
11 Pressure on the solar plexus at the border of the upper and middle one-third of the sole is  
12 believed to facilitate the functions of the body's nervous system [46]. Pressure on the lower  
13 part of the forefoot reflects the heart and lungs. While pressure on the bridge of the foot  
14 reflects the liver and kidney and the heel will reflect the lower back, legs, pelvic region  
15 uterus, and intestines. The uterine point is believed to be located in the indented region  
16 between the inner ankles and the sole [47]. Therefore, it is believed to be helpful during  
17 labour. The pressure on toe and heel stimulate the reflex points in the pelvis. The pressure  
18 on the middle toe facilitate the cervical dilation and ease uterine contractions [48, 49].

19 However, there are several postulated theories for its mechanism of action. Firstly, the  
20 autonomic-somatic integration theory suggests that the pressure applied to the feet during  
21 reflexology compresses the receptors in the cells, thus opening up the ionic channels in the  
22 plasma membrane and triggering a local action with the potential to convey messages to



1 the spinal cord and/or brain [50]. The application of alternating pressure to the feet may  
2 also produce predictable reflexive actions within the nervous system and activate the  
3 parasympathetic nervous system [51].

4 Another contemporary method explains that reflexology acts through “sympathetic  
5 resonance,” in which an energy wave flows between therapist and client, promoting  
6 homeostatic balance [52]. This may occur through local enzymatic reactions on receptive  
7 fields or through an improved blood supply as a result of local skin temperature changes  
8 following the skin-to-skin contact [53]. Reflexologists also believe that the application of  
9 deep pressure on certain reflex points of the sole and palm may break any calcium crystals  
10 and uric acid accumulated in nerve endings that may cause blockages and induce pain [54].

11 Reflexology also results in body relaxation and stimulation of any blocked nerve endings,  
12 which may propel any sluggish glands or organs to regain their normal functioning [55].

13 Ambiguity remains regarding the theories and mechanism of action of foot reflexology for  
14 labour pain, as compared to that for general pain [35-37]. Nonetheless, it is plausible to  
15 believe that reflexology techniques would have similar physiological effects for labour pain  
16 that bring about a sense of wellbeing, analgesia and subsequently the perception of pain  
17 relief [38]. Figure 1 summarizes the possible mechanisms of Reflexology therapy.

18 Massage therapy is another type of commonly used Complementary and Alternative  
19 Method (CAM) for the promotion of health and wellbeing [36]. Massage is a potent  
20 mechanical stimulus that produces a short-lived analgesic effect by activating the ‘pain  
21 gate’ mechanism [56]. Longer-lasting pain control appears to be mediated mainly by the

1 descending pain suppression mechanism by activation of descending efferent pathways  
2 [57]. The inhibition of pain-transmission neurons involves a combination of physiological  
3 and neurological mechanisms and it is commonly activated by noxious stimulation [58].  
4 Figure 2 summarizes the possible mechanisms action of massage therapy [59].

5 The three aforementioned therapies (i.e. BRM) for labour pain management have been  
6 shown to influence the secretion of certain stress hormones such as cortisol,  
7 adrenocorticotrophic hormone (ACTH), and oxytocin (OT) [40, 49, 60, 61], endorphins [61-  
8 65]. Endogenous oxytocin is a key component in the molecular pathways that buffer  
9 reaction to stress and decrease sensitivity to pain and inflammation [66]; cortisol is an  
10 important hormone released during stressful conditions [40].

### 11 **Significance of this clinical trial**

12 Many studies have reported that not all pharmacologic and non-pharmacologic methods on  
13 their own are able to reduce labour pain satisfactorily. Despite the intervention, some  
14 mothers still endure some pain, anxiety and prolonged labour, and suffer from negative  
15 maternal and perinatal consequences [5, 15, 16]. From the perspective of complementary  
16 management, BRM are the techniques with the highest potential for managing pain and  
17 anxiety for primigravidae. Systematic reviews have concluded that CAM interventions to  
18 manage pain and anxiety during labour have often been biased and/or poorly executed, thus  
19 resulting in low quality of evidence [67-70], or no strongly supported evidence [71, 72].  
20 Therefore, there is a need for a rigorous and robust trial to examine the effect of the  
21 combined intervention of BRM on labour pain, anxiety, stress hormones, V/S, FHR,

1 duration of labour, Apgar Scores and maternal satisfaction among the primigravidae using  
2 multiple relevant outcome measures.

### 3 **METHODS AND DESIGN**

4 This study aims to investigate the combined effect of BRM on labour pain, duration of  
5 labour, anxiety, maternal satisfaction, stress hormones, and new-born outcome among  
6 primigravidae in Saudi Arabia. The specific objectives are 1) to compare the effect of the  
7 combined breathing exercise, foot reflexology, and back massage (intervention) on labour  
8 pain intensity, anxiety level, duration of labour, maternal satisfaction, stress hormones, and  
9 neonatal outcome compared to the standard midwifery care (control); 2) to identify the  
10 predictors of pain, anxiety, duration of labour, the satisfaction of mother, and neonatal  
11 outcome from the baseline sociodemographic and obstetric characteristics.

#### 12 **Study Design**

13 The study design will be a single-blind parallel randomised controlled trial (RCT), in which  
14 participants are randomly assigned to receive either the BRM intervention or control care.

#### 15 **Study Setting**

16 This study will be conducted in the Makkah Maternity and Children Hospital (MCH) in  
17 Makkah, Saudi Arabia. The hospital is a tertiary-level, governmental referral hospital with  
18 special services for paediatrics, gynaecology, and obstetrics [73]. In Saudi Arabia, almost  
19 all tertiary hospitals, including our study site, offer systemic pharmacologic agents, either  
20 intravenous or intramuscular analgesics to manage pain during labour [74]; however,

1 providing non-invasive and non-pharmacological methods of pain relief during labour are  
2 not common practices [74]. To our best knowledge, the combined effect of BRM on  
3 primigravidae has not been investigated at any Saudi Arabia hospital prior to this trial.

#### 4 **Participants**

5 The study participants will include primigravidae, age 20–35 years old, at 37 to 41 weeks  
6 of gestation, and in the first stage of labour. The inclusion criteria include singleton  
7 pregnancy, cephalic presentation, and regular contraction. In labour, the participants must  
8 achieve six centimetres of cervical dilatation, with a minimum of 3 contractions of at least  
9 moderate intensity every 10 minutes, in which the duration of the contraction must be  
10 between 30–60 seconds.

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

#### 17 **Patient and Public Involvement**

18 Patients are involved in the questionnaire's face and content validity testing. Based on  
19 feedback from the patients in a pilot study, improvement to the questionnaires' approaches  
20 and trial processes will be implemented. Patient preferences were not directly obtained

1 with regard to choosing the BRM intervention; this was based on the principal  
2 investigator's practice experience and encounters with pregnant women.

### 3 **Recruitment**

4 Recruitment will be conducted at the antenatal clinic at the trial site. Only those who plan  
5 to deliver in the trial hospital's delivery room will be further briefed and assessed for their  
6 eligibility. At this hospital, antenatal mothers are given monthly follow-up appointments  
7 until 28 weeks' gestation. The frequency increases to bi-weekly until 32 weeks' gestation;  
8 then patients are seen weekly until delivery.

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

17 At the antenatal clinic, the principal investigator will provide general health education  
18 about pain management during labour. The participant information sheet of this RCT will  
19 be provided for the eligible patients. If they are interested in participating, they will sign a  
20 written consent form and will be identified by a unique stamp on their antenatal cards.

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2  
3 1 When the participants arrive in the labour room for delivery, they will be re-evaluated for  
4  
5 2 the eligibility.  
6  
7

### 8 9 3 **Randomisation**

10  
11 4 Since IMP is a commonly prescribed analgesic in labour, and may have substantial effects  
12  
13 5 on the primigravidae and neonates, randomisation will be stratified according to the  
14  
15 6 administrative status of IMP. This will ensure the same numbers of primigravidae with and  
16  
17 7 without IMP in the intervention and control groups. To achieve this, we use a block of size  
18  
19 8 4 with a 1:1 allocation ratio, leading to a possibility of 6 permutations. All possible block  
20  
21 9 sequences will be randomly generated with the help of free software from the internet  
22  
23 10 <https://www.sealedenvelope.com/simple-randomiser/v1/>. A random list will be created  
24  
25 11 after the sample size number, treatment groups, block sizes, list length, and stratification  
26  
27 12 factors are entered into the software. The order of the subjects will be used by the research  
28  
29 13 coordinator who will be stationed in the delivery room to conduct the random group  
30  
31 14 allocation for primigravidae in labour who have achieved a cervical dilation of 6 cm. The  
32  
33 15 principal investigator, outcome assessors, and massage therapist in this trial will not be  
34  
35 16 involved in the allocation of the interventional groups. Figure 3 outlines the CONSORT  
36  
37 17 flow diagram.  
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### 45 18 **Data Collection**

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48 19 Every questionnaire will be coded with a unique number. Data collection in the delivery  
49  
50 20 room will be facilitated by the trained research coordinator and two outcome assessors.  
51  
52 21 The outcome assessors will be assigned to the control or the intervention group on the same  
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1 day. Once the form is completed by the outcome assessors, it will be kept by the research coordinator in a safe location in the delivery room.

Throughout all of the outcome assessment time points, a massage therapist will be present in the delivery room of both the intervention and control groups. For the intervention group, the primigravidae in labour will receive the BRM intervention from the massage therapist. For the control group, the practicing midwife will perform routine labour care such as touch therapy, ensuring that the mother lies on her left side, and providing encouragement and counselling. The outcome assessor will measure and assess both the intervention and control groups at the same time points. Both groups will be equipped with similar extra equipment. This blinding effort is intended to minimize biases during the outcome assessment. However, blinding of the participants will be impossible due to the nature of the intervention.

### 13 **Interventions**

14 The BRM intervention consists of 5 minutes of breathing exercise followed by 10 minutes  
15 of foot reflexology on each sole and 35 minutes of continuous massage over the lower  
16 limbs and back. The massage therapist will allow the primigravidae to lie on the left side  
17 [75], to move and change her position during the intervention, and answer any question or  
18 inquiry. Table 1 provides a detailed explanation of the BRM intervention procedure. As  
19 for the control group, the primigravidae in labour will receive routine labour room care.

20

21

## 1 **Training for the research team members**

2 A total of 13 research assistants will be recruited and trained for the intervention and data  
3 collection from June to December 2019, (Figure 4). They will be given the BRM training  
4 for one week by the principal investigator who has completed the professional massage  
5 and reflexology training at a certified training centre in Malaysia (Tim Body Care Training  
6 Centre 1403695-D) for six months including training and working.

## 7 **Study Outcomes and Measures**

8 There are eight outcomes: two primary outcomes and six secondary outcomes. The two  
9 primary outcomes are pain intensity and anxiety level (See Table 2). Pain intensity is  
10 measured with the Present Behavioural Intensity (PBI) [76,77] and the self-report Visual  
11 Analog Scale (VAS) [78-82], while anxiety is measure with Anxiety Assessment Scale for  
12 Pregnant Women in Labour (AASPWL) [83].

13 The outcome assessor will ask the pregnant women to pick a colour on an A-4 sized paper  
14 that contains six different coloured parts, from no pain (score 1) to most severe pain (score  
15 6) based on her level of pain [81, 84]. The researcher selected the VAS questionnaire  
16 because it is an acceptable tool and relatively easy to administer to women in labour. Pain  
17 intensity will be measured at baseline before the intervention, and multiple times during  
18 and after contractions (Figure 5a). During the intervention, pain intensity will be measured  
19 after the breathing exercise and foot reflexology therapy (after 25 minutes from the start of  
20 the intervention), followed by another assessment halfway through the massage therapy  
21 (after 45 minutes) during and after contraction. Pain intensity will be measured for every



1 participating primigravidae in both the intervention and control group. For the control  
2 group, pain intensity will be measured first at baseline before the intervention at 6 cm.  
3 During the intervention, pain intensity will be measured after 25 minutes from the start of  
4 the intervention time, followed by another assessment after 45 minutes, during and after  
5 contraction. Upon completion of the intervention, the measurement will be taken  
6 immediately, and twice hourly thereafter during the first stage of labour (Figure 5b).

7 The AASPWL will be used to assess anxiety during labour. The anxiety level will be  
8 measured at cervical dilatation of 6cm, after the completion of the interventions, and twice  
9 every 60 minutes during the first stage of labour. For the control group, the assessment will  
10 be performed when the cervix is at 6 cm, after one hour (synchronized to the completion  
11 of the intervention in the intervention group), and twice every 60 minutes during the first  
12 stage of labour (Figure 3b).

13 The secondary outcomes measured in the RCT include maternal stress hormones level,  
14 maternal V/S, FHR, duration of labour, neonatal Apgar score, and maternal satisfaction  
15 [85] (See Table 3).

16 The stress hormones level will be measured at baseline, and again one and a half hour after  
17 the patient has reached 6 cm of cervical dilatation (Figure 5). Blood samples will again be  
18 taken by midwives on duty in the delivery room. This will occur after the BRM intervention  
19 in the intervention group (Figure 5a), and at the same time in the control group (Figure 5b).

20 The research assessors will collect an 8 ml blood sample in a plain tube, of which 3 mls is  
21 for ACTH, 3 mls for cortisol, and 2 mls for OT hormones; it will be sent immediately to

1 the MCH laboratory to carefully avoid any haemolysis of the samples. Hormones will be  
2 analysed by the sandwich ELISA technique using commercial kits by Cobas e411 Analyzer  
3 (HITACHI, USA) for ACTH hormone, and Abbot Architect I200 Analyzer (Abbott, USA)  
4 for Cortisol and OT hormones.

5 Since cortisol levels follow a diurnal variation or circadian rhythm where the hormone  
6 levels peak in the morning and fall at night, and vary in accordance with a number of factors  
7 including age, time of day, stress level, sample type, laboratory location and the method  
8 used for testing [86, 87], we will use a chart from the laboratory to verify the normal  
9 cortisol range in the morning, noon, afternoon, evening, or night, and compare these ranges  
10 to the blood samples taken to determine whether the blood test results of the participants  
11 before and after the intervention are high, normal or low.

12 ACTH and cortisol levels are interrelated. When the cortisol levels are at their peak, ACTH  
13 levels generally fall and vice versa [88]. Hence, it may be understood that ACTH and  
14 cortisol have corresponding levels at any given point of time. This provides a relative value  
15 for both stress hormones. With regard to OT, the blood sample test for the pregnant  
16 woman will be higher if she receives an infusion of OT during intervention [89, 90]. If the  
17 events are equal in both groups, we will proceed to the analysis as planned. If the events  
18 are many and unequal in both groups, we will either conduct a separate statistical analysis  
19 stratified according to the event of OT infusion. If the number of event occurrences is low,  
20 we may exclude these participants and analyse the outcome as planned. However, the  
21 author will investigate the oxytocin level before and after applying the BRM in addition to  
22 childbirth. Oxytocin increases with contraction and hypothetically with and after BRM.

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3 1 The oxytocin will increase in the second stage, inhibit the Stress hormones, and will  
4  
5 2 increase after apply the BRM.  
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10 3 Maternal V/S and FHR will be collected twice at 6cm cervical dilatation and immediately  
11  
12 4 post-BRM for the intervention group, and the same data will be collected at the same timing  
13  
14 5 for the control groups. The Apgar Scores (taken from the delivery room medical record)  
15  
16 6 and maternal satisfaction will be measured only once at the completion of the childbirth,  
17  
18 7 before the transfer of the mother from the delivery room to the postnatal ward.  
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### 23 8 **Sample size**

24  
25 9 The sample size estimation was based on a review of similar literature on pain and anxiety  
26  
27 10 as outcomes [76], and calculated using G\*power free software [76]. We estimated an effect  
28  
29 11 size of 0.6 on anxiety mean score reduction in the intervention group compared to the  
30  
31 12 control [76], as this gives a larger required sample size compared to that based on the  
32  
33 13 primary outcome of pain. Thus, with the power of 95% at  $\alpha$  error 0.05, the required sample  
34  
35 14 size is 128 for the two groups. It is further inflated to 154 to account for a predicted 20%  
36  
37 15 attrition rate. Therefore, a minimum number of 77 primigravidae will be recruited for each  
38  
39 16 group.  
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### 46 17 **Statistical analysis**

47  
48 18 Data will be entered by a blinded enumerator. The database will be checked for accuracy  
49  
50 19 before analysis. The principal investigator has the overall responsibility for the  
51  
52 20 compilation, maintenance, and management of the study database. The analysis will be  
53  
54 21 performed using IBM Statistical Package for Social Science (SPSS) version 25.  
55  
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1 Descriptive statistical analysis will be performed according to the distribution of the data,  
2 using means and standard deviations for data with normal distribution, and median and  
3 inter-quartile ranges for data that are not normally distributed. Normality testing will be  
4 conducted for all continuous variables using different methods such as Histogram and p-p  
5 plot. Categorical variables will be reported in frequencies and percentages.

6 The differences between the groups and times level will be analysed using a Generalised  
7 Linear Mixed Model (GLMM). GLMM is appropriate where repeated measurements are  
8 made on the same statistical units. GLMM will also be used to accommodate non-normal  
9 distribution in outcome data. The variables of time in a categorical form, intervention  
10 group, group\*time interaction, and the baseline random part of the model will include a  
11 random intercept and an unstructured correlation matrix for the correlation of  
12 measurements within pregnant women. The fixed part of the model will include pain score,  
13 whereby the difference in pain score at every time point will be tested using a linear  
14 contrast. We will take the pain intensity measured with PBI and VAS at one-hour post  
15 intervention as the main co-primary outcomes. This is because the effects of the massage  
16 and reflexology will still be observable, and thus the intervention group can be fairly  
17 compared to the control group [50-57].

18 Any significant baseline imbalances will be adjusted for in the analysis. If necessary,  
19 multiple imputations will be conducted for the missing data. A calculated 95% confidence  
20 interval and two-sided  $\alpha$  of 0.05 will be used to test significance. In addition, we will  
21 analyse PBI and VAS at the same time points and measure the agreement between PBI and  
22 VAS by using the Spearman correlation coefficient and interclass correlation. We will

1 analyse other outcomes using the same statistical strategy mentioned above. Additionally,  
2 we will conduct time series analyses to examine the patterns of change in the outcomes  
3 between the two groups and after BRM intervention.

4 The independent effect(s) of socio-demographic and obstetric characteristics on each  
5 primary and secondary outcome at one-hour post-intervention will be analysed using  
6 multiple linear regression analyses.

## 7 **Discussion**

8 Safe and efficient pain management is important for pregnant women and their families  
9 [18], and different types of CAM have been shown to be beneficial to reduce or alleviate  
10 labour pain. However, evidence is scarce regarding the effects of combined therapies [91].  
11 Therefore, we designed this trial to study the effects of BRM on labour pain and other  
12 psychological and physiological impacts among primigravidae. The study protocol for the  
13 RCT is to determine the combined effect of BRM on the intensity of pain and level of  
14 anxiety in primigravidae during the first stage of labour. Additional outcomes that will be  
15 assessed include stress hormones, maternal VS, FHR, duration labour, neonatal Apgar  
16 score, and maternal satisfaction.

17  
18 In this study, the intervention will be applied only once and only during the first stage of  
19 labour even though the first stage of labour among primigravidae takes approximately 8–  
20 12 hours. By timing the intervention after cervical dilation of 6 cm, the effect of the  
21 combined BRM could exert its greatest influences (if any) on the labour experience of the

1 primigravidae and neonatal outcome, because this period is believed to accompany the  
2 highest levels of labour pain [92, 93].

3 We will assess the outcomes using a mixture of subjective and objective tools. For  
4 example, pain intensity and anxiety levels are subjective measurements, based on the  
5 personal feelings and judgments of the respondents. Duration of labour, neonatal Apgar  
6 score, and maternal stress hormones level of ACTH, cortisol, and oxytocin are objective  
7 measurements that will indicate the stress response to the BRM intervention conducted on  
8 the primigravidae. This is one of the strengths of our study.

9 VAS is one of several ways of measuring the effectiveness of BRM, and is a commonly  
10 used graphic rating method [76, 84]. However, VAS might not be the gold standard to  
11 measure labour pain, given the inconsistency of its results and its ceiling effect [84, 94].  
12 Recognizing this inadequacy, we will ensure that the participants understand the VAS  
13 scoring at admission to the delivery room before they are asked to indicate their pain level  
14 later. Labour pain outcome will also be measured via pain intensity assessment using the  
15 PBI [76], which will be rated by outcome assessors. Multiple measurements will be taken  
16 during and after contraction, and before and after the intervention. There will also be other  
17 outcomes, related to maternal response to pain, namely anxiety level and maternal stress  
18 hormones [95].

19 This study has several other limitations. First, the intervention will be performed for one  
20 hour, during which it may be interrupted by routine medical care such as regular vaginal  
21 examinations, V/S measurements, and FHR monitoring. However, we believe that this will

1 not reduce the effect of the BRM intervention, because we can start the BRM before or  
2 after the labour care routine. Second, the process of labour and birthing is unpredictable  
3 even if the participants are low-risk. In certain instances, the process of the intervention  
4 might not go well as planned and this may reduce the sample size. Some patients may end  
5 up needing a caesarean section, and some may suffer from other obstetric complications  
6 during delivery. As a result, we have inflated the sample size accordingly. Third, the results  
7 from this study will not be generalisable to multigravidae as we include only primigravidae.  
8 Nevertheless, we believe that primigravidae will benefit the most from the intervention as  
9 they are likely to experience a higher level of labour pain and a longer duration of labour  
10 compared to multigravidae. Fourth, placebo effects can influence patient outcomes after  
11 (CAM), resulting in high rates of good outcomes, which may be wrongly attributed to  
12 specific treatment effects [96].

13  
14 We recognise that the expertise and experience level of the reflexologist is an important  
15 factor in the quality of treatment provided and this may affect the outcomes of the BRM.  
16 The massage therapists and the outcome assessors will be given the appropriate training  
17 on the BRM for one week by the principal investigator who attended a professional training  
18 and was certified. After the training, they will be tested in a pilot study to ensure their  
19 competency in performing the BRM. Additional quality control measures for the outcome  
20 assessors are planned, as they will be assigned to the control delivery room or the  
21 intervention delivery room on the same day. All of the completed assessment forms will  
22 be reviewed and kept by the research coordinator in a safe location in the delivery room.

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2  
3 1 Any issues on the form such as blank spaces and extreme values will be immediately  
4  
5 2 clarified and resolved.  
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9

10 3 In addition to labour pain, this study will assess the anxiety level of pregnant mothers.  
11  
12 4 Unlike labour pain, anxiety level can be affected by individual characteristics, previous life  
13  
14 5 experiences, and other environmental causes [97]. However, we believe that these factors  
15  
16 6 will not play a significant role after effective randomisation.  
17  
18  
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21 7 Apart from the actual labour experience, there are a few other external factors that may  
22  
23 8 affect maternal satisfaction, such as the delivery room services, the health of the baby, the  
24  
25 9 gender of the child, family support, and other psychosocial factors. As satisfaction is a  
26  
27 10 multi-dimensional and complex feeling, it is difficult to measure with a single tool and to  
28  
29 11 narrow it down to only the first stage of labour.  
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34 12 It is understood that a birthing process is a natural event, especially for low-risk women.  
35  
36 13 Thus, the management of labour should be conducted in a supportive manner with minimal  
37  
38 14 or no interferences. This study will provide high-quality evidence about the effects of the  
39  
40 15 combined BRM for labour pain management. These findings will be important for hospitals  
41  
42 16 offerings for expectant mothers in providing a rationale for their decisions about which  
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44 17 alternative treatments to offer, to primigravidae and their family members during decision  
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46 18 making about labour pain management.  
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4 and Saudi Arabia Culture Mission in Saudi Arabia.

## 5 **Author Contributions**

6 KB drafted, formulated, and submitted the manuscript. All authors MHR, AHI, LK & BHC  
7 contributed to the study designs, read, revised, and approved the research protocol critically  
8 for important intellectual content and helped to draft the final manuscript. All authors  
9 approved the final manuscript for submission. Authorship eligibility is in accordance with  
10 the International Committee of Medical Journal Editors (ICMJE) guidelines.

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14 covers the study and research process. The Financial Guarantee will cover all the research's  
15 payments. The funders will not be involved in the study design, data collection, analysis  
16 and interpretation of the data and writing of the manuscript.

## 17 **Competing Interest**

18 The authors declare that they have no competing interests.

## 19 **Patient Consent for Publication**

20 Not applicable since this is a study protocol.

## 1 **Availability of Data and Materials**

2 The datasets will be available from the corresponding author on reasonable request. The  
3 data will be kept for a maximum period of two years from the end of data analysis and will  
4 be placed in a sealed envelope that will remain with the primary author. Subsequently, the  
5 forms will be destroyed via a shredding machine located at UPM in the presence of my  
6 supervisor and some academic staff. The soft copy and record data, as well as the  
7 questionnaires and database of hard copy will be deleted, and we will re-setup windows in  
8 the computer to destroy the database after a maximum period of two years.

## 9 **Ethics Approval and Consent to Participate**

10 Ethics approval was obtained from the Ethical Committee for Research Involving Human  
11 Subjects of the Ministry of Health in the Saudi Arabia (H-02-K-076-0319-109) on 14 April  
12 2019, and from the Ethics Committee for Research Involving Human Subjects (JKEUPM)  
13 Universiti Putra Malaysia on 23 October 2019, reference number (JKEUPM-2019-169).  
14 Additional administrative approval will be requested from the medical director of the  
15 Makkah Maternity and Children Hospital. The participant information sheet for the  
16 pregnant women will be also provided. If they are interested and eligible to participate,  
17 pregnant women will sign consent forms. Consent form contains purpose of this study,  
18 procedures involved in the research pre and post intervention. They will inform the  
19 potential benefits and risk of the intervention research. Participants will be given an  
20 affirmation of confidentiality and protection the data collection. The results won't be  
21 disseminated to the study participants, except If one of the participants would like to know  
22 her results, her mobile number will be taken and a message will be sent.

## 1 **Patient and Public Involvement**

2 Patients are involved in the questionnaire's face and content validity testing. Based on  
3 feedback from the patients in a pilot study, improvement to the questionnaires' approaches  
4 and trial processes will be implemented. Patient preferences were not directly obtained  
5 with regard to choosing the BRM intervention; this was based on the principal  
6 investigator's practice experience and encounters with pregnant women. However, the  
7 patients will be involved in the recruitment to and conduct of the study. They will attend  
8 antenatal class and agreement by consent to share in this study. Also, they will answer all  
9 questionnaires pre and post the intervention. In addition, they will need to agree to BRM  
10 as the intervention.

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## Figure Legend

Figure 1 Mechanisms of action Reflexology therapy.

Figure 2 Mechanisms of action Massage therapy.

Figure 3 CONSORT flow diagram.

Figure 4 Research personnel training and responsibility matrix.

Figure 5 (a) shows the timeline of outcomes measurement in the intervention group; (b) shows the timeline of outcomes measurement in the control group.

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3 **Table Legend**  
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5 Table 1 Steps of the Intervention.  
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8 Table 2 Summary of Primary Outcomes and Measurement Tools.  
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10 Table 3 Summary of Secondary Outcomes and Measurement Tools.  
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**Table 1: Steps of the Intervention**

<b>Steps</b>	<b>Process</b>
1.	Prepare the equipment.
2.	Explain the procedure to the primigravida & advise her to lay on her left side* with a pillow on the side of her stomach.
<b>Breathing Exercise Intervention for 5 minutes</b>	
3.	Ask the primigravida to perform deep breathing by inhaling slowly through the nose for two seconds and then consciously release the air by breathing out for another two seconds during contractions.
4.	Rest for 1–3 seconds, then repeat the same technique for a total of 5 minutes. Then proceed to the reflexology as described below.
<b>Reflexology Intervention Technique for 10 minutes on each foot</b>	
5.	Put a towel under the right foot and cover the left leg.
6.	Apply warm oil over the right foot and roll it left to right 5 times.
7.	Press palms on the Achilles heel and knead the ankle 5 times.
8.	Knead the thumb pads on the central and bottom parts of the heel 5 times.
9.	Knead the foot following the CIUW** shape on the lateral and intermediate aspects of the foot followed by the MST*** shape 5 times.
10.	Press the wooden reflexology stick on the toes, forefoot, mid-foot, and hind-foot 5 times.
11.	Repeat Steps 5–11 on the opposite side. Then proceed to the next lower limbs massage.
<b>Lower Limbs Massage for 2 minutes 30 seconds on each leg</b>	
12.	Effleurage massage on the whole, lower flexed leg by using two hands 3 times.
13.	Half effleurage massage from the heel to the popliteal area 3 times.
14.	Palm and thumb kneading on the gastrocnemius muscle over the lateral & medial sides, followed by scooping on the gastrocnemius, each step 3 times.
15.	Thumb kneading on the hamstring muscle over the medial, intermediate, and lateral sides 3 times.
16.	Repeat Steps 12–17 on the right leg. Then proceed to lower back massage.
<b>Lower Back Massage for 15 minutes</b>	
17.	Effleurage massage from the sacrum to the shoulders and deltoids 3 times.
18.	Thumb kneading & pressure over the lateral sides of the lumbar area of the spine 3 times.
19.	Apply fist knuckling motion and thumb kneading on the lower back, side by side, 3 times. Then proceed to upper back massage.

---

**Upper Back Massage for 15 minutes**

20. Effleurage massage followed by palm kneading from the lumbar region to trapezius laterally 3 times.
  21. Thumb kneading over both sides of erector spinae, then draining between the ribs towards the armpit areas 3 times.
  22. Apply squeeze on the deltoid muscle with draining towards the armpit 3 times.
  23. Apply finger kneading on trapezius muscle, followed by fist scooping 3 times.
  24. Finally, press on the neck and shoulder area on both sides 3 times.
- 

\* The left side position allows maximum blood flow to the placenta, because it applies less pressure from the foetus on the vena cava [75].

\*\*CIUW shape: C-shape; I-shape; U-shape, and W-shape. These shapes indicate the orientation and placement of the palms and knuckles of the therapist.

\*\*\*MST shape: M-shape, S-shape, and T-shape. These shapes indicate the orientation and placement of the palms and knuckles of the therapist.

**Table 2: Summary of Primary Outcomes and Measurement Tools**

Primary Outcomes	Tools	Psychometric tests	Method of assessment
<b>Pain</b>	PBI	100% inter-rater reliability <i>r</i> coefficient was 0.45, 0.50, and 0.44 between PBI and PPI [76, 77].	Assessor-rated [76]: five-category behavioural observation scale
	VAS	Moderate correlation ( <i>r</i> = 0.54) with the verbal rating and is considered valuable when mixed with other tools [78, 79]; 0.97 intraclass correlation coefficient of 24 hours interval test-retest reliability [80].	Self-reported VAS [81], contains six different coloured parts anchored by two extremes of 'no pain' and excruciating pain to mark on the line-map by primigravidae [82].
<b>Anxiety</b>	AASPWL	> 0.8 concordance test content validity index Kendall's <i>W</i> between the opinions of the experts ( <i>W</i> = 0.090; <i>P</i> = 0.080) with Cronbach's alpha level of 0.77 [83]; significantly correlated ( <i>r</i> = 0.369) with the Beck Anxiety Scale [83].	Questionnaire consists of nine items [83], on a 5-point scale: the higher the mean score the higher the anxiety

PBI= Present Behavioural Intensity; VAS= Visual Analog Scale; AASPWL= Anxiety Assessment Scale for Pregnant Women in Labour.



**Table 3 Summary of Secondary Outcomes and Measurement Tools**

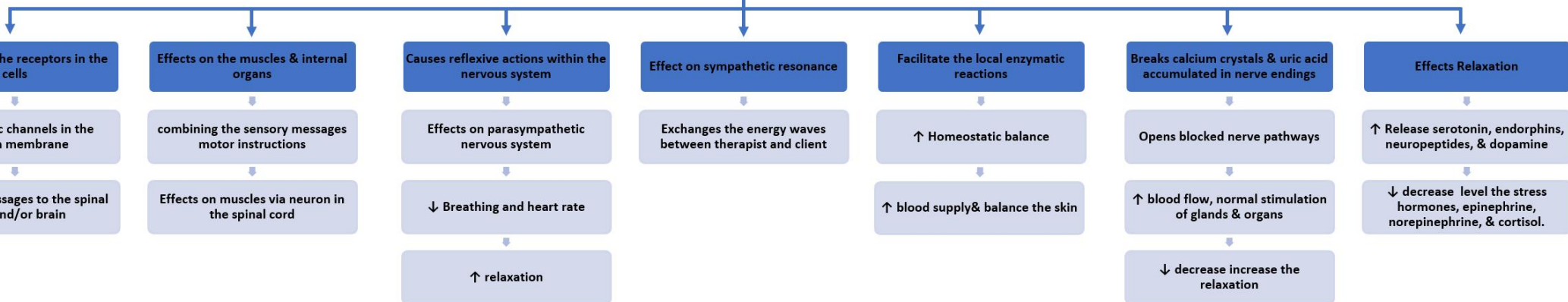
<b>Secondary outcomes</b>	<b>Measurement tools</b>	<b>Method of assessment</b>
<b>Maternal stress hormones level</b>	Blood sample for ACTH, cortisol, oxytocin	Blood sample will be drawn from the median cubital vein during the insertion of IV cannula (routine care)
<b>Maternal vital sign</b>	Thermometer Sphygmomanometer	Recorded on the vital sign monitoring chart and cardiocograph.
<b>FHR</b>	Cardiocograph	Recorded on the vital sign monitoring chart, cardiocograph chart, and partograph.
<b>Duration of labour</b>	Partograph	Partograph at two separate time intervals, a sum of labour duration from 3 to 6 cm of cervical dilatation and from 6 cm to delivery of the placenta
<b>Neonatal Apgar score</b>	Apgar score table	Taken from the delivery room medical record
<b>Maternal satisfaction</b>	Six Simple Questions [85].	Self-reported 7-point scale (1-7) from “strongly disagree to “strongly agree” with higher scores signifying the higher level of satisfaction

ACTH= adrenocorticotropic hormone

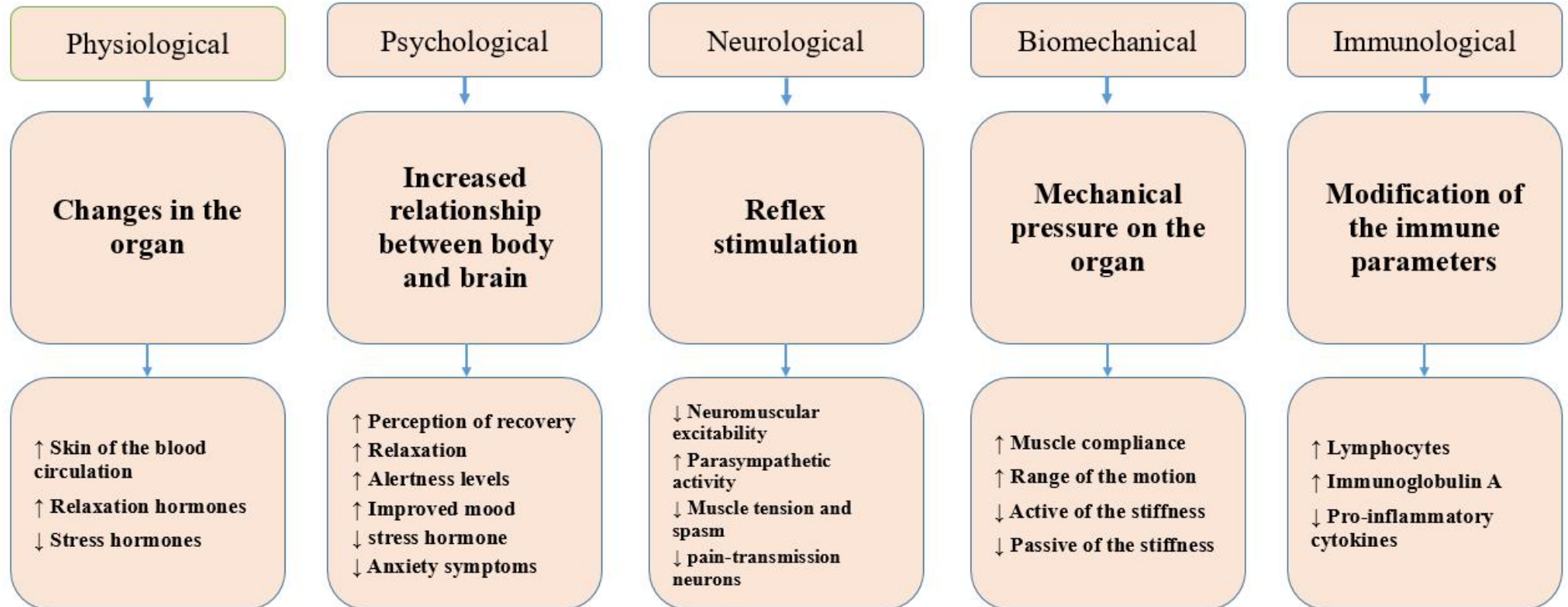
# Mechanisms of the Reflexology

pressure on certain reflex points

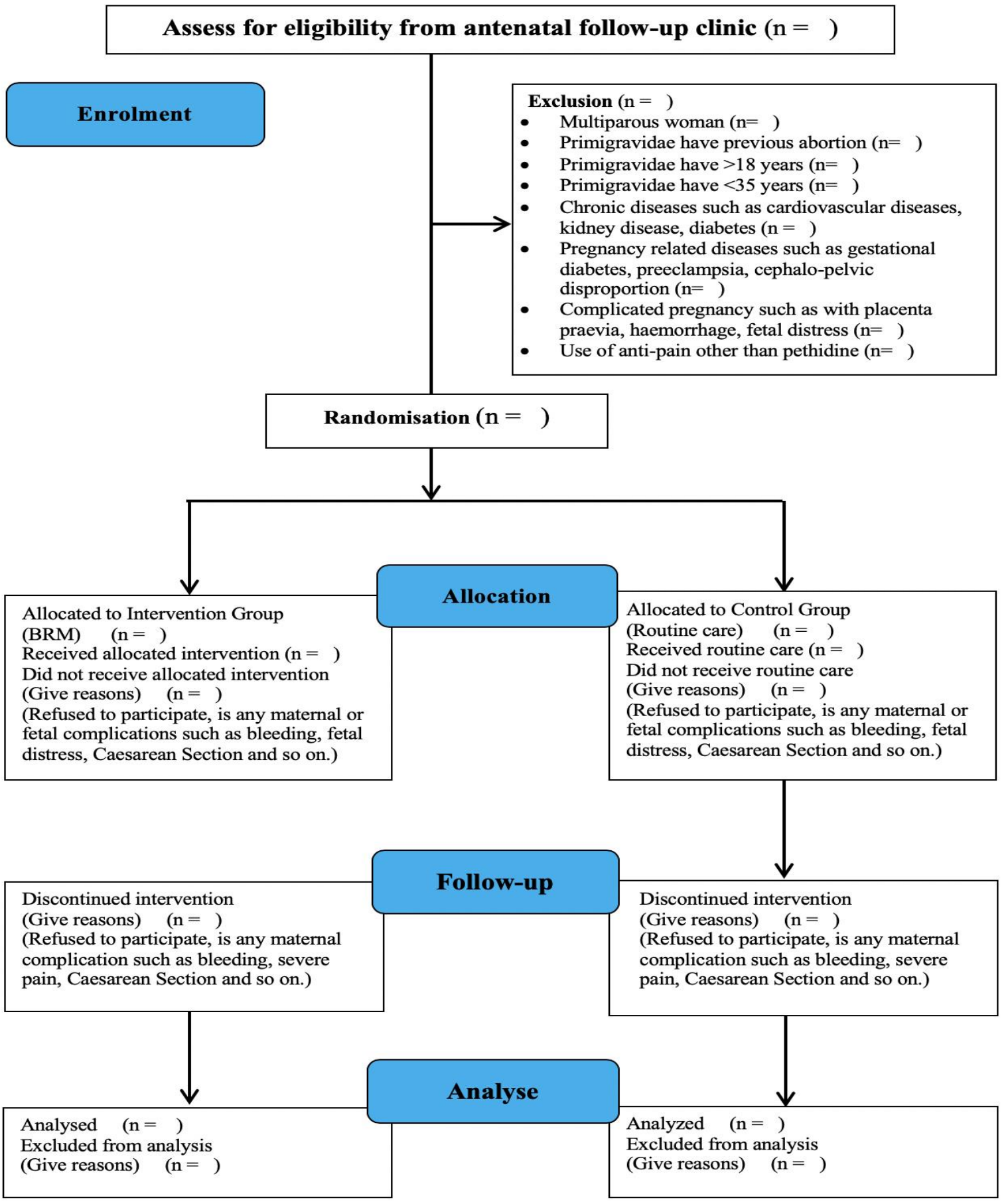
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# Mechanisms of Massage



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### 13 Research Assistants + 1 Principal Investigator

- Recruitment of nursing students who completed a 5-year nursing degree training and awaiting their job posting.
- Assigned to their preferred and suitable roles (coordinators, the outcome assessors, or massage therapists).
- One week training as research assistants in their respective roles.
- A pilot study to ensure their competency.
- Written study manual as a reference guide to be provided to all research assistants.



Research coordinators  
(4 pax.)



Outcome Assessors  
(4 pax.)



Massage therapists  
(5 pax.)

- Recruit eligible primigravidae at the antenatal clinic deliver brief health education on labour pain management at the antenatal clinic for 6 weeks.
- Reassess the primigravidae women's consent and eligibility,
- Allocate the women to either the intervention or control group.
- Alert the massage therapists and outcome assessors when the cervical dilatation of the trial participant reaches 6 cm.
- Distribute outcomes assessment record form to the outcome assessors.
- Encode the questionnaire package according to the participant's allocated group.
- Organise the entry sequence for the outcome assessors and the massage therapists to enter the delivery rooms according to the scheduled time.

- Assess and fill-up questionnaires:
  - Present behavioural Intensity (PBI).
  - Visual Analog Scale (VAS).
  - Anxiety Assessment Scale for primigravidae Women in labour (AASPWL),
  - Six Simple Questions (SSQ) for maternal satisfaction.
- Retrieve the maternal vital signs, fetal heart rate, duration of labour, and neonatal Apgar score from the health records.
- Record all the outcomes in the designated form.

- Perform breathing exercise, foot reflexology and back massage during labour (BRM).
  - Breathing exercise (5min).
  - Foot Reflexology (10 min on each foot),
  - Back massage (35min).

Sub-divided into two shifts per day to ensure all the eligible and consented primigravidae will be captured



Day Shift (9 am - 9pm)

2 Coordinators, 3 Massage therapists, and 2 Outcome Assessors

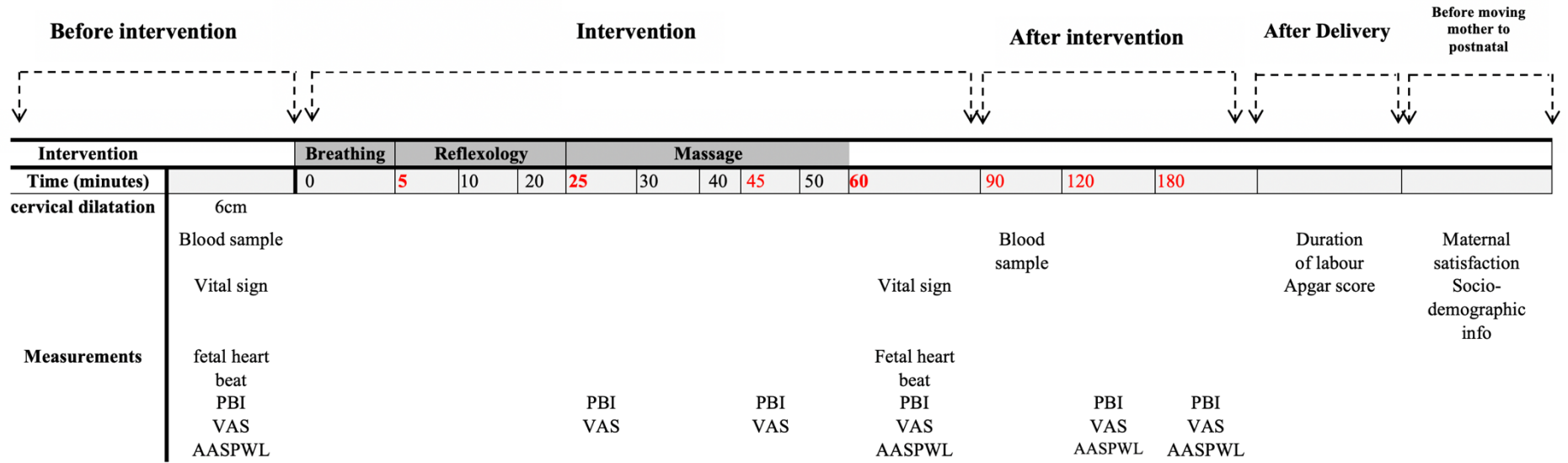


Night Shift (9 pm - 9 am)

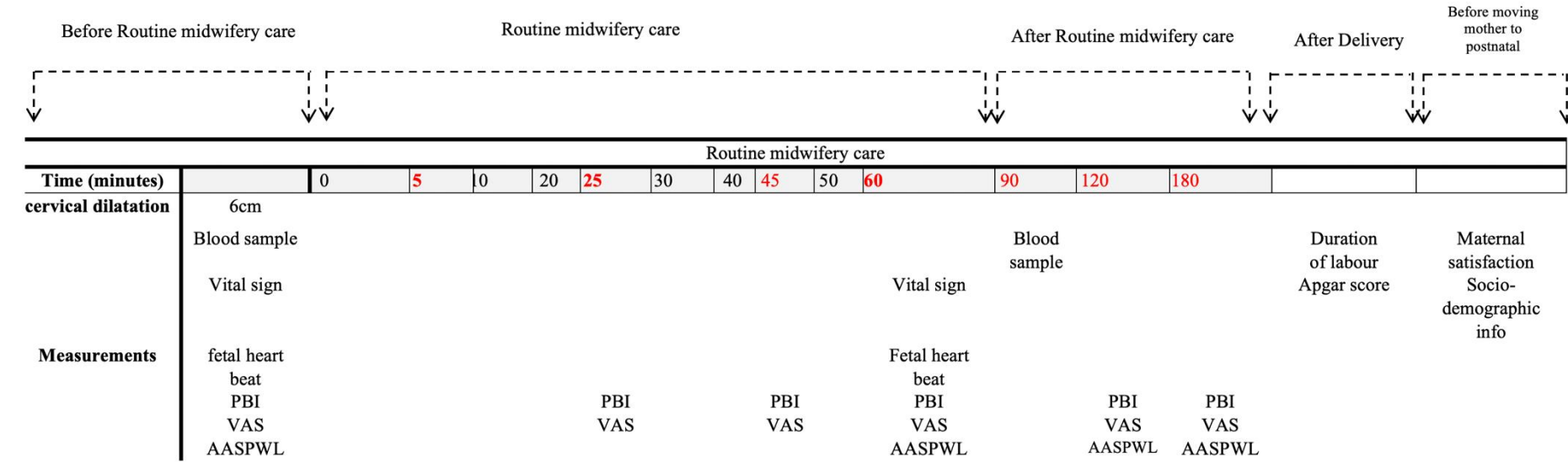
2 Coordinators, 2 Massage therapists, 2 Outcome Assessors, and Principal Investigator

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Intervention Group **a**



Control Group **b**



# BMJ Open

## 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

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<b>Primary Subject Heading</b>:	Complementary medicine
Secondary Subject Heading:	Complementary medicine, Nursing, Emergency medicine, General practice / Family practice, Public health
Keywords:	Breathing exercises, Reflexology, Massage, Primigravidae, Labour pain, Stress hormones

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1 **Effectiveness of Breathing Exercises, Foot Reflexology and Back Massage (BRM) on**  
2 **Labour Pain, Anxiety, Duration, Satisfaction, Stress Hormones and New-born**  
3 **Outcomes among Primigravidae during the First Stage of Labour in Saudi Arabia:**  
4 **A Study Protocol for a Randomised Controlled Trial**

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## 1 ABSTRACT

2 **Introduction** Labour pain is among the severest pains primigravidae may experience  
3 during pregnancy. Failure to address labour pain and anxiety may lead to abnormal labour.  
4 Despite the many complementary non-pharmacological approaches to coping with labour  
5 pain, the quality of evidence is low and best approaches are not established. This study  
6 protocol describes a proposed investigation of the effects of a combination of breathing  
7 exercises, foot reflexology and back massage (BRM) on the labour experiences of  
8 primigravidae.

9 **Methods and analysis** This randomised controlled trial will involve an intervention group  
10 receiving BRM and standard labour care, and a control group receiving only standard  
11 labour care. Primigravidae of 26–34 weeks of gestation without chronic diseases or  
12 pregnancy-related complications will be recruited from antenatal clinics. Eligible and  
13 consenting patients will be randomly allocated to the intervention or the control group  
14 stratified by intramuscular pethidine (IMP) use. The BRM intervention will be delivered  
15 by a trained massage therapist. The primary outcomes of labour pain and anxiety will be  
16 measured during and after uterine contractions at baseline (cervical dilatation 6 cm) and  
17 post-BRM hourly for two hours. The secondary outcomes include maternal stress hormone  
18 (adrenocorticotrophic hormone, cortisol and oxytocin) levels, maternal vital signs (V/S),  
19 foetal heart rate (FHR), labour duration, Apgar scores, and maternal satisfaction. The  
20 sample size is estimated based on the between-group difference of 0.6 in anxiety scores,  
21 95% power and 5%  $\alpha$  error, which yields a required sample size of 154 (77 in each group)  
22 accounting for a 20% attrition rate. The between- and within-group outcome measures will

1 be examined with mixed-effects regression models, time series analyses and paired t-test  
2 or equivalent non-parametric tests, respectively.

3 **Ethics and dissemination** Ethical approval was obtained from the Ethical Committee for  
4 Research Involving Human Subjects of the Ministry of Health in the Saudi Arabia (H-02-  
5 K-076-0319-109) on 14 April 2019, and from the Ethics Committee for Research Involving  
6 Human Subjects (JKEUPM) Universiti Putra Malaysia on 23 October 2019, reference  
7 number: JKEUPM-2019-169. Written informed consent will be obtained from all  
8 participants. Results from this trial will be presented at regional, national and international  
9 conferences and published in indexed journals.

10 **Trial registration number and date** ISRCTN87414969, registered 3 May 2019

11 **Keywords** Breathing exercises, Reflexology, Massage, Primigravidae, Labour pain, Stress  
12 hormones.

## 1 Article Summary

### 2 Strengths and Limitations of the Study

- 3 • This single-blind, parallel, randomised controlled trial will explore the combined  
4 effects of breathing exercises, foot reflexology and back massage (BRM) on pain  
5 and anxiety during labour in healthy primigravidae with a singleton foetus.
- 6 • The effects of BRM will also be examined through objective physiological  
7 measurement of stress hormone levels and comparison of these levels between  
8 groups before and after the intervention.
- 9 • The intervention will be applied for one hour and only once during the first stage  
10 of labour after cervical dilatation of 6 centimetres.
- 11 • Blinding of the primigravidae mothers is not possible, and there may be bias in the  
12 self-assessed subjective outcomes such as the Visual Analog Scale.
- 13 • The expertise and experience of the nursing graduates who are trained to be the  
14 massage therapists is considered an important factor in the quality of treatment  
15 provided and this may underestimate the effect of BRM.

16 **Word count 4,917 words**

## 1 INTRODUCTION

2 Many primigravidae have reported experiencing various levels of pain during labour and  
3 high levels of anxiety about the labour process and its outcomes.<sup>1-3</sup> Anxiety escalating to  
4 fear is a common issue related to labour, especially among primigravidae.<sup>4,5</sup> Other recorded  
5 negative perceptions and psychological effects influencing labour experiences include  
6 distress and feelings of powerlessness during labour for women and their families.<sup>5-7</sup>

7 When poorly managed, labour pain may lead to severe consequences for women, such as  
8 prolonged labour,<sup>5,8</sup> which may increase the risk of foetal distress, head compression,  
9 intrauterine foetal death, low Apgar scores and physical injuries to neonates.<sup>5,9</sup> Prolonged  
10 labour results in increased risk of caesarean section, induced labour and assisted delivery  
11 using vacuum and forceps.<sup>10,11</sup> Studies have also reported negative mental impacts on  
12 women, sometimes even including postnatal post-traumatic stress disorder,<sup>12,13</sup> and  
13 subsequently reduced quality of life.<sup>14</sup> Feelings of anxiety often originate from possible  
14 birthing complications about which pregnant women have heard and read,<sup>4,5,15,16</sup> and may  
15 even result in women refusing normal vaginal delivery and insisting on caesarean sections  
16 without medical indications.<sup>17</sup> It is therefore important for healthcare professionals to assist  
17 and educate all expectant mothers on labour pain management.

18 Appropriate labour pain management and interventions are important aspects of obstetric  
19 care to ensure optimum outcomes for mothers and babies.<sup>18</sup> Pharmacologic interventions  
20 used in the management of labour pain include systemic sedatives, analgesics and regional  
21 anaesthesia.<sup>19</sup> Examples of these analgesics are aerosol and epidural opioids, intramuscular

1 pethidine (IMP) and intravenous sedatives.<sup>20,21</sup> Some of these are expensive and may be  
2 associated with adverse effects on mothers, the labour process and neonates.<sup>22</sup> In contrast,  
3 most non-pharmacological methods for labour pain management are simple and non-  
4 invasive, and are often cheaper and safer than pharmacological interventions.<sup>23–25</sup> Studies  
5 have found that non-pharmacological approaches, particularly breathing exercises, have  
6 positive impacts on relief of labour pain,<sup>26–28</sup> and anxiety in pregnant mothers.<sup>29–31</sup> This is  
7 especially true for Lamaze breathing, deep breathing exercises,<sup>26–28,32,33</sup> reflexology,<sup>6,34</sup>  
8 and massage.<sup>35</sup> Non-pharmacological approaches have been linked to shorter labour  
9 duration,<sup>36</sup> and improved new-born outcomes.<sup>37</sup> Our systematic review found that massage  
10 is beneficial for relieving labour pain,<sup>38</sup> and is associated with greater relaxation, higher  
11 alertness levels, improved mood and reduced stress hormone (cortisol) levels and anxiety  
12 symptoms.<sup>39</sup>

### 13 **Rationale**

14 It is hypothesised that the non-pharmacological approach of labour pain management  
15 occurs via the alteration of nociceptive stimuli and modification of the processing of  
16 nociceptive input at the central level, resulting in an overall improved sense of comfort and  
17 well-being, ultimately leading to stronger coping capabilities by the mothers in labour.<sup>40</sup>

18 The physiological mechanism of breathing is a protective action as it is a fight-or-flight  
19 reflex triggered by the central nervous system. Physiologically, deep abdominal breathing  
20 stimulates the parasympathetic nervous system. As a result, the blood circulation in  
21 pregnant women will undergo oxygenation, which will trigger the release of endorphins  
22 associated with decrease in heart rate and increase in feelings of calmness. At the same

1 time, endorphins can also suppress the sympathetic system, leading to a decrease in the  
2 release of stress hormones such as cortisol.<sup>41, 42</sup>

3 As for reflexology, so far there has been no constructive explanation of the underlying  
4 mechanism in reducing labour pain.<sup>6,36</sup> The reflexology therapist will apply pressure three  
5 times on specific points of the feet that are energetically connected to certain parts and  
6 organs of the body. As with skin-to-skin contact during massage, reflexology point  
7 pressure could trigger the release of endogenous endorphins and encephalins that help to  
8 reduce labour pain, stress, fatigue and anxiety.<sup>43-46</sup> Pressure on the solar plexus at the  
9 border of the upper and middle one-third of the sole is believed to facilitate the functions  
10 of the body's nervous system.<sup>47</sup> Pressure on the lower part of the forefoot reflects the heart  
11 and lungs. While pressure on the bridge of the foot reflects the liver and kidney and the  
12 heel will reflect the lower back, legs, pelvic region uterus, and intestines. The uterine point  
13 is believed to be located in the indented region between the inner ankles and the sole.<sup>48</sup>  
14 Therefore, it is believed to be helpful during labour. The pressure on toe and heel stimulate  
15 the reflex points in the pelvis. It is effective by releasing the oxytocin hormone which start  
16 and regulate the uterine contractions and relax during contractions.<sup>49</sup>

17 However, there are several postulated theories for its mechanism of action. Firstly, the  
18 autonomic-somatic integration theory suggests that the pressure applied to the feet during  
19 reflexology compresses the receptors in the cells, thus opening up the ionic channels in the  
20 plasma membrane and triggering a local action with the potential to convey messages to  
21 the spinal cord and/or brain.<sup>46</sup> The application of alternating pressure to the feet may also  
22 produce predictable reflexive actions within the nervous system and activate the

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2  
3 1 parasympathetic nervous system.<sup>50</sup> Based on the energy theory that moves toward the head  
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5 2 from reflex points that stimulate the energy, neural paths, improve blood flow, release the  
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7 3 endorphins and relief pain.<sup>51</sup> Another contemporary method explains that reflexology acts  
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9 4 through “sympathetic resonance,” in which an energy wave flows between therapist and  
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11 5 client, promoting homeostatic balance.<sup>52</sup> This may occur through local enzymatic reactions  
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13 6 on receptive fields or through an improved blood supply as a result of local skin  
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15 7 temperature changes following the skin-to-skin contact.<sup>47</sup> Reflexologists also believe that  
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17 8 the application of deep pressure on certain reflex points of the sole and palm may break  
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19 9 any calcium crystals and uric acid accumulated in nerve endings that may cause blockages  
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21 10 and induce pain.<sup>53</sup>

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28 11 Reflexology also results in body relaxation and stimulation of any blocked nerve endings,  
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30 12 which may propel any sluggish glands or organs to regain their normal functioning.<sup>54</sup>  
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32 13 Ambiguity remains regarding the theories and mechanism of action of foot reflexology for  
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34 14 labour pain, as compared to that for general pain.<sup>6,35,36</sup> Nonetheless, it is plausible to believe  
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36 15 that reflexology techniques would have similar physiological effects for labour pain that  
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38 16 bring about a sense of wellbeing, analgesia and subsequently the perception of pain relief.<sup>37</sup>  
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40 17 Figure 1 summarizes the possible mechanisms of Reflexology therapy.

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46 18 Massage therapy is another type of commonly used Complementary and Alternative  
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48 19 Medicine (CAM) for the promotion of health and wellbeing.<sup>35</sup> Massage is a potent  
49  
50 20 mechanical stimulus that produces a short-lived analgesic effect by activating the ‘pain  
51  
52 21 gate’ mechanism.<sup>55</sup> Longer-lasting pain control appears to be mediated mainly by the  
53  
54 22 descending pain suppression mechanism by activation of descending efferent pathways.<sup>56</sup>  
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1 The inhibition of pain-transmission neurons involves a combination of physiological and  
2 neurological mechanisms and it is commonly activated by noxious stimulation.<sup>57</sup> Figure 2  
3 summarizes the possible mechanisms action of massage therapy.<sup>58</sup>

4 The three aforementioned therapies (i.e. BRM) for labour pain management have been  
5 shown to influence the secretion of certain stress hormones such as cortisol,  
6 adrenocorticotrophic hormone (ACTH),<sup>39,59</sup> oxytocin (OT),<sup>59</sup> and possibly also the  
7 endorphins.<sup>44,45</sup> Endogenous oxytocin is a key component in the molecular pathways that  
8 buffer reaction to stress and decrease sensitivity to pain and inflammation,<sup>60</sup> cortisol is an  
9 important hormone released during stressful conditions.<sup>39</sup>

#### 10 **Significance of this clinical trial**

11 Many studies have reported that not all pharmacologic and non-pharmacologic methods on  
12 their own are able to reduce labour pain satisfactorily. Despite the intervention, some  
13 mothers still endure some pain, anxiety and prolonged labour, and suffer from negative  
14 maternal and perinatal consequences.<sup>5,15,16</sup> From the perspective of complementary  
15 management, BRM are the techniques with the highest potential for managing pain and  
16 anxiety for primigravidae. Systematic reviews have concluded that CAM interventions to  
17 manage pain and anxiety during labour have often been biased and/or poorly executed, thus  
18 resulting in low quality of evidence,<sup>61-64</sup> or no strongly supported evidence.<sup>65-67</sup> Therefore,  
19 there is a need for a rigorous and robust trial to examine the effect of the combined  
20 intervention of BRM on labour pain, anxiety, stress hormones, V/S, FHR, duration of

1 labour, Apgar Scores and maternal satisfaction among the primigravidae using multiple  
2 relevant outcome measures.

### 3 **METHODS AND DESIGN**

4 This study aims to investigate the combined effect of BRM on labour pain, duration of  
5 labour, anxiety, maternal satisfaction, stress hormones, and new-born outcome among  
6 primigravidae in Saudi Arabia. The specific objectives are 1) to compare the effect of the  
7 combined breathing exercise, foot reflexology, and back massage (intervention) on labour  
8 pain intensity, anxiety level, duration of labour, maternal satisfaction, stress hormones, and  
9 neonatal outcome compared to the standard midwifery care (control); 2) to identify the  
10 predictors of pain, anxiety, duration of labour, the satisfaction of mother, and neonatal  
11 outcome from the baseline sociodemographic and obstetric characteristics.

#### 12 **Study Design**

13 The study design will be a single-blind parallel randomised controlled trial (RCT), in which  
14 participants are randomly assigned to receive either the BRM intervention or control care.

#### 15 **Study Setting**

16 This study will be conducted in the Makkah Maternity and Children Hospital (MCH) in  
17 Makkah, Saudi Arabia. The hospital is a tertiary-level, governmental referral hospital with  
18 special services for paediatrics, gynaecology, and obstetrics.<sup>68</sup> In Saudi Arabia, almost all  
19 tertiary hospitals, including our study site, offer systemic pharmacologic agents, either  
20 intravenous or intramuscular analgesics to manage pain during labour;<sup>69</sup> however,  
21 providing non-invasive and non-pharmacological methods of pain relief during labour are

1 not common practices.<sup>69</sup> To our best knowledge, the combined effect of BRM on  
2 primigravidae has not been investigated at any Saudi Arabia hospital prior to this trial.

### 3 **Participants**

4 The study participants will include primigravidae, age 20–35 years old, at 37 to 41 weeks  
5 of gestation, and in the first stage of labour. The inclusion criteria include singleton  
6 pregnancy, cephalic presentation, and regular contraction. In labour, the participants must  
7 achieve six centimetres of cervical dilatation, with a minimum of three contractions of at  
8 least moderate intensity every 10 minutes, in which the duration of the contraction must be  
9 between 30–60 seconds.

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

### 16 **Recruitment**

17 Recruitment will be conducted at the antenatal clinic at the trial site. Only those who plan  
18 to deliver in the trial hospital's delivery room will be further briefed and assessed for their  
19 eligibility. At this hospital, antenatal mothers are given monthly follow-up appointments

1 until 28 weeks' gestation. The frequency increases to bi-weekly until 32 weeks' gestation;  
2 then patients are seen weekly until delivery.

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

11 At the antenatal clinic, the principal investigator will provide general health education  
12 about pain management during labour. The participant information sheet of this RCT will  
13 be provided for the eligible patients. If they are interested in participating, they will sign a  
14 written consent form and will be identified by a unique stamp on their antenatal cards.  
15 When the participants arrive in the labour room for delivery, they will be re-evaluated for  
16 the eligibility.

## 17 **Randomisation**

18 Since IMP is a commonly prescribed analgesic in labour and may have substantial effects  
19 on the primigravidae and neonates, randomisation will be stratified according to the  
20 administrative status of IMP. This will ensure the same numbers of primigravidae with and

1 without IMP in the intervention and control groups. To achieve this, we use a block of size  
2 4 with a 1:1 allocation ratio, leading to a possibility of 6 permutations. All possible block  
3 sequences will be randomly generated with the help of free software from the internet  
4 <https://www.sealedenvelope.com/simple-randomiser/v1/>. A random list will be created  
5 after the sample size number, treatment groups, block sizes, list length, and stratification  
6 factors are entered into the software. The order of the subjects will be used by the research  
7 coordinator who will be stationed in the delivery room to conduct the random group  
8 allocation for primigravidae in labour who have achieved a cervical dilation of 6 cm. The  
9 principal investigator, outcome assessors, and massage therapist in this trial will not be  
10 involved in the allocation of the interventional groups. Figure 3 outlines the CONSORT  
11 flow diagram.

## 12 **Data Collection**

13 Every questionnaire will be coded with a unique number. Data collection in the delivery  
14 room will be facilitated by the trained research coordinator and two outcome assessors.  
15 The outcome assessors will be assigned to the control or the intervention group on the same  
16 day. Once the form is completed by the outcome assessors, it will be kept by the research  
17 coordinator in a safe location in the delivery room.

18 Throughout all of the outcome assessment time points, a massage therapist will be present  
19 in the delivery room of both the intervention and control groups. For the intervention group,  
20 the primigravidae in labour will receive the BRM intervention from the massage therapist.  
21 For the control group, the practicing midwife will perform routine labour care such as touch  
22 therapy, ensuring that the mother lies on her left side, and providing encouragement and

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3 1 counselling. The outcome assessor will measure and assess both the intervention and  
4  
5 2 control groups at the same time points. Both groups will be equipped with similar extra  
6  
7 3 equipment. This blinding effort is intended to minimize biases during the outcome  
8  
9 4 assessment. However, blinding of the participants will be impossible due to the nature of  
10  
11 5 the intervention.  
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## 14 15 16 6 **Interventions**

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19 7 The BRM intervention consists of 5 minutes of breathing exercise followed by 10 minutes  
20  
21 8 of foot reflexology on each sole and 35 minutes of continuous massage over the lower  
22  
23 9 limbs and back. The massage therapist will allow the primigravidae to lie on the left side,<sup>70</sup>  
24  
25 10 to move and change her position during the intervention and answer any question or  
26  
27 11 inquiry. Table 1 provides a detailed explanation of the BRM intervention procedure. As  
28  
29 12 for the control group, the primigravidae in labour will receive routine labour room care.  
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## 35 13 **Training for the research team members**

36  
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39 14 A total of 13 research assistants will be recruited and trained for the intervention and data  
40  
41 15 collection from June to December 2019, (Figure 4). They will be given the BRM training  
42  
43 16 for one week by the principal investigator who has completed the professional massage  
44  
45 17 and reflexology training at a certified training centre in Malaysia (Tim Body Care Training  
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47 18 Centre 1403695-D) for six months including training and working.  
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## 1 Study Outcomes and Measures

2 There are eight outcomes: two primary outcomes and six secondary outcomes. The two  
3 primary outcomes are pain intensity and anxiety level (See Table 2). Pain intensity is  
4 measured with the Present Behavioural Intensity (PBI)<sup>71,72</sup> and the self-report Visual  
5 Analog Scale (VAS),<sup>73-77</sup> while anxiety is measure with Anxiety Assessment Scale for  
6 Pregnant Women in Labour (AASPWL).<sup>78</sup>

7 The outcome assessor will ask the pregnant women to pick a colour on an A-4 sized paper  
8 that contains six different coloured parts, from no pain (score 1) to most severe pain (score  
9 6) based on her level of pain.<sup>76,79</sup> The researcher selected the VAS questionnaire because  
10 it is an acceptable tool and relatively easy to administer to women in labour. Pain intensity  
11 will be measured at baseline before the intervention, and multiple times during and after  
12 contractions (Figure 5a). During the intervention, pain intensity will be measured after the  
13 breathing exercise and foot reflexology therapy (after 25 minutes from the start of the  
14 intervention), followed by another assessment halfway through the massage therapy (after  
15 45 minutes) during and after contraction. Pain intensity will be measured for every  
16 participating primigravidae in both the intervention and control group. For the control  
17 group, pain intensity will be measured first at baseline before the intervention at 6 cm.  
18 During the intervention, pain intensity will be measured after 25 minutes from the start of  
19 the intervention time, followed by another assessment after 45 minutes, during and after  
20 contraction. Upon completion of the intervention, the measurement will be taken  
21 immediately, and twice hourly thereafter during the first stage of labour (Figure 5b).

1 The AASPWL will be used to assess anxiety during labour. The anxiety level will be  
2 measured at cervical dilatation of 6cm, after the completion of the interventions, and twice  
3 every 60 minutes during the first stage of labour. For the control group, the assessment will  
4 be performed when the cervix is at 6 cm, after one hour (synchronized to the completion  
5 of the intervention in the intervention group), and twice every 60 minutes during the first  
6 stage of labour (Figure 5b).

7 The secondary outcomes measured in the RCT include maternal stress hormones level,  
8 maternal V/S, FHR, duration of labour, neonatal Apgar score, and maternal satisfaction<sup>80</sup>  
9 (See Table 3).

10 The stress hormones level will be measured at baseline, and again one and a half hour after  
11 the patient has reached 6 cm of cervical dilatation (Figure 5). Blood samples will again be  
12 taken by midwives on duty in the delivery room. This will occur after the BRM intervention  
13 in the intervention group (Figure 5a), and at the same time in the control group (Figure 5b).

14 The research assessors will collect an 8 ml blood sample in a plain tube, of which 3mls is  
15 for ACTH, 3mls for cortisol, and 2mls for OT hormones; it will be sent immediately to the  
16 MCH laboratory to carefully avoid any haemolysis of the samples. Hormones will be  
17 analysed by the sandwich ELISA technique using commercial kits by Cobas e411 Analyzer  
18 (HITACHI, USA) for ACTH hormone, and Abbot Architect I200 Analyzer (Abbott, USA)  
19 for Cortisol and OT hormones.

20 Since cortisol levels follow a diurnal variation or circadian rhythm where the hormone  
21 levels peak in the morning and fall at night, and vary in accordance with a number of factors



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1 including age, time of day, stress level, sample type, laboratory location and the method  
2 used for testing,<sup>81,82</sup> we will use a chart from the laboratory to verify the normal cortisol  
3 range in the morning, noon, afternoon, evening, or night, and compare these ranges to the  
4 blood samples taken to determine whether the blood test results of the participants before  
5 and after the intervention are high, normal or low.

6 ACTH and cortisol levels are interrelated. When the cortisol levels are at their peak, ACTH  
7 levels generally fall and vice versa.<sup>83</sup> Hence, it may be understood that ACTH and cortisol  
8 have corresponding levels at any given point of time. This provides a relative value for  
9 both stress hormones. With regard to OT, the blood sample test for the pregnant woman  
10 will be higher if she receives an infusion of OT during intervention.<sup>84,85</sup> If the events are  
11 equal in both groups, we will proceed to the analysis as planned. If the events are many  
12 and unequal in both groups, we will either conduct a separate statistical analysis stratified  
13 according to the event of OT infusion. If the number of event occurrences is low, we may  
14 exclude these participants and analyse the outcome as planned. However, the author will  
15 investigate the oxytocin level before and after applying the BRM in addition to childbirth.  
16 Oxytocin increases with contraction and hypothetically with and after BRM. The oxytocin  
17 will increase in the second stage, inhibit the Stress hormones, and will increase after apply  
18 the BRM.

19 Maternal V/S and FHR will be collected twice at 6cm cervical dilatation and immediately  
20 post-BRM for the intervention group, and the same data will be collected at the same timing  
21 for the control groups. The Apgar Scores (taken from the delivery room medical record)

1 and maternal satisfaction will be measured only once at the completion of the childbirth,  
2 before the transfer of the mother from the delivery room to the postnatal ward.

### 3 **Sample size**

4 The sample size estimation was based on a review of similar literature on pain and anxiety  
5 as outcomes, and calculated using G\*power free software.<sup>86</sup> We estimated an effect size of  
6 0.6 on anxiety mean score reduction in the intervention group compared to the control,<sup>86</sup>  
7 as this gives a larger required sample size compared to that based on the primary outcome  
8 of pain. Thus, with the power of 95% at  $\alpha$  error 0.05, the required sample size is 128 for  
9 the two groups. It is further inflated to 154 to account for a predicted 20% attrition rate.  
10 Therefore, a minimum number of 77 primigravidae will be recruited for each group.

### 11 **Statistical analysis**

12 Data will be entered by a blinded enumerator. The database will be checked for accuracy  
13 before analysis. The principal investigator has the overall responsibility for the  
14 compilation, maintenance, and management of the study database. The analysis will be  
15 performed using IBM Statistical Package for Social Science (SPSS) version 25.

16 Descriptive statistical analysis will be performed according to the distribution of the data,  
17 using means and standard deviations for data with normal distribution, and median and  
18 inter-quartile ranges for data that are not normally distributed. Normality testing will be  
19 conducted for all continuous variables using different methods such as Histogram and p-p  
20 plot. Categorical variables will be reported in frequencies and percentages.

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3 1 The differences between the groups and times level will be analysed using a Generalised  
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5 2 Linear Mixed Model (GLMM). GLMM is appropriate where repeated measurements are  
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7 3 made on the same statistical units. GLMM will also be used to accommodate non-normal  
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9 4 distribution in outcome data. The variables of time in a categorical form, intervention  
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11 5 group, group\*time interaction, and the baseline random part of the model will include a  
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13 6 random intercept and an unstructured correlation matrix for the correlation of  
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15 7 measurements within pregnant women. The fixed part of the model will include pain score,  
16  
17 8 whereby the difference in pain score at every time point will be tested using a linear  
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19 9 contrast. We will take the pain intensity measured with PBI and VAS at one-hour post  
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21 10 intervention as the main co-primary outcomes. This is because the effects of the massage  
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23 11 and reflexology will still be observable, and thus the intervention group can be fairly  
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25 12 compared to the control group.<sup>46,50-53</sup>

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33 13 Any significant baseline imbalances will be adjusted for in the analysis. If necessary,  
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35 14 multiple imputations will be conducted for the missing data. A calculated 95% confidence  
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37 15 interval and two-sided  $\alpha$  of 0.05 will be used to test significance. In addition, we will  
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39 16 analyse PBI and VAS at the same time points and measure the agreement between PBI and  
40  
41 17 VAS by using the Spearman correlation coefficient and interclass correlation. We will  
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43 18 analyse other outcomes using the same statistical strategy mentioned above. Additionally,  
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45 19 we will conduct time series analyses to examine the patterns of change in the outcomes  
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47 20 between the two groups and after BRM intervention.  
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3 1 The independent effect(s) of socio-demographic and obstetric characteristics on each  
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5 2 primary and secondary outcome at one-hour post-intervention will be analysed using  
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7 3 multiple linear regression analyses.  
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#### 10 11 12 4 **DISCUSSION** 13 14

15 5 Safe and efficient pain management is important for pregnant women and their families,<sup>18</sup>  
16  
17 6 and different types of CAM have been shown to be beneficial to reduce or alleviate labour  
18  
19 7 pain. However, evidence is scarce regarding the effects of combined therapies.<sup>87</sup> Therefore,  
20  
21 8 we designed this trial to study the effects of BRM on labour pain and other psychological  
22  
23 9 and physiological impacts among primigravidae. The study protocol for the RCT is to  
24  
25 10 determine the combined effect of BRM on the intensity of pain and level of anxiety in  
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27 11 primigravidae during the first stage of labour. Additional outcomes that will be assessed  
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29 12 include stress hormones, maternal VS, FHR, duration labour, neonatal Apgar score, and  
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31 13 maternal satisfaction.  
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38 14 In this study, the intervention will be applied only once and only during the first stage of  
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40 15 labour even though the first stage of labour among primigravidae takes approximately 8–  
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42 16 12 hours. By timing the intervention after cervical dilation of 6 cm, the effect of the  
43  
44 17 combined BRM could exert its greatest influences (if any) on the labour experience of the  
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46 18 primigravidae and neonatal outcome, because this period is believed to accompany the  
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48 19 highest levels of labour pain.<sup>88,89</sup>  
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1 We will assess the outcomes using a mixture of subjective and objective tools. For  
2 example, pain intensity and anxiety levels are subjective measurements, based on the  
3 personal feelings and judgments of the respondents. Duration of labour, neonatal Apgar  
4 score, and maternal stress hormones level of ACTH, cortisol, and oxytocin are objective  
5 measurements that will indicate the stress response to the BRM intervention conducted on  
6 the primigravidae. This is one of the strengths of our study.

7 VAS is one of several ways of measuring the effectiveness of BRM, and is a commonly  
8 used graphic rating method.<sup>70,78</sup> However, VAS might not be the gold standard to measure  
9 labour pain, given the inconsistency of its results and its ceiling effect.<sup>78,90</sup> Recognizing  
10 this inadequacy, we will ensure that the participants understand the VAS scoring at  
11 admission to the delivery room before they are asked to indicate their pain level later.  
12 Labour pain outcome will also be measured via pain intensity assessment using the PBI,<sup>74</sup>  
13 which will be rated by outcome assessors. Multiple measurements will be taken during and  
14 after contraction, and before and after the intervention. There will also be other outcomes,  
15 related to maternal response to pain, namely anxiety level and maternal stress hormones.<sup>91</sup>

16 This study has several other limitations. First, the intervention will be performed for one  
17 hour, during which it may be interrupted by routine medical care such as regular vaginal  
18 examinations, V/S measurements, and FHR monitoring. However, we believe that this will  
19 not reduce the effect of the BRM intervention, because we can start the BRM before or  
20 after the labour care routine. Second, the process of labour and birthing is unpredictable  
21 even if the participants are low-risk. In certain instances, the process of the intervention  
22 might not go well as planned and this may reduce the sample size. Some patients may end

1 up needing a caesarean section, and some may suffer from other obstetric complications  
2 during delivery. As a result, we have inflated the sample size accordingly. Third, the results  
3 from this study will not be generalisable to multigravidae as we include only primigravidae.  
4 Nevertheless, we believe that primigravidae will benefit the most from the intervention as  
5 they are likely to experience a higher level of labour pain and a longer duration of labour  
6 compared to multigravidae. Fourth, placebo effects can influence patient outcomes after  
7 (CAM), resulting in high rates of good outcomes, which may be wrongly attributed to  
8 specific treatment effects.<sup>92</sup>

9 We recognise that the expertise and experience level of the reflexologist is an important  
10 factor in the quality of treatment provided and this may affect the outcomes of the BRM.

11 The massage therapists and the outcome assessors will be given the appropriate training  
12 on the BRM for one week by the principal investigator who attended a professional training  
13 and was certified. After the training, they will be tested in a pilot study to ensure their  
14 competency in performing the BRM. Additional quality control measures for the outcome  
15 assessors are planned, as they will be assigned to the control delivery room or the  
16 intervention delivery room on the same day. All of the completed assessment forms will  
17 be reviewed and kept by the research coordinator in a safe location in the delivery room.

18 Any issues on the form such as blank spaces and extreme values will be immediately  
19 clarified and resolved.

20 In addition to labour pain, this study will assess the anxiety level of pregnant mothers.

21 Unlike labour pain, anxiety level can be affected by individual characteristics, previous life

1 experiences, and other environmental causes.<sup>93</sup> However, we believe that these factors will  
2 not play a significant role after effective randomisation.

3 Apart from the actual labour experience, there are a few other external factors that may  
4 affect maternal satisfaction, such as the delivery room services, the health of the baby, the  
5 gender of the child, family support, and other psychosocial factors. As satisfaction is a  
6 multi-dimensional and complex feeling, it is difficult to measure with a single tool and to  
7 narrow it down to only the first stage of labour.

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

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18 and Saudi Arabia Culture Mission in Saudi Arabia. Also, we would like to acknowledge  
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## 1 **Author Contributions**

2 KB drafted, formulated, and submitted the manuscript. All authors MHR, AHI, LK & BHC  
3 contributed to the study designs, read, revised, and approved the research protocol critically  
4 for important intellectual content and helped to draft the final manuscript. All authors  
5 approved the final manuscript for submission. Authorship eligibility is in accordance with  
6 the International Committee of Medical Journal Editors (ICMJE) guidelines.

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11 payments. The funders will not be involved in the study design, data collection, analysis  
12 and interpretation of the data and writing of the manuscript.

## 13 **Competing Interest**

14 None declared.

## 15 **Patient Consent for Publication**

16 Not applicable since this is a study protocol.

## 17 **Availability of Data and Materials**

18 The datasets will be available from the corresponding author on reasonable request. The  
19 data will be kept for a maximum period of two years from the end of data analysis and will  
20 be placed in a sealed envelope that will remain with the primary author. Subsequently, the



1 forms will be destroyed via a shredding machine located at UPM in the presence of my  
2 supervisor and some academic staff. The soft copy and record data, as well as the  
3 questionnaires and database of hard copy will be deleted, and we will re-setup windows in  
4 the computer to destroy the database after a maximum period of two years.

### 5 **Ethics Approval and Consent to Participate**

6 Ethics approval was obtained from the Ethical Committee for Research Involving Human  
7 Subjects of the Ministry of Health in the Saudi Arabia (H-02-K-076-0319-109) on 14 April  
8 2019, and from the Ethics Committee for Research Involving Human Subjects (JKEUPM)  
9 Universiti Putra Malaysia on 23 October 2019, reference number (JKEUPM-2019-169).  
10 Additional administrative approval will be requested from the medical director of the  
11 Makkah Maternity and Children Hospital. The participant information sheet for the  
12 pregnant women will be also provided. If they are interested and eligible to participate,  
13 pregnant women will sign consent forms. Consent form contains purpose of this study,  
14 procedures involved in the research pre and post intervention. They will inform the  
15 potential benefits and risk of the intervention research. Participants will be given an  
16 affirmation of confidentiality and protection the data collection. The results won't be  
17 disseminated to the study participants, except If one of the participants would like to know  
18 her results, her mobile number will be taken and a message will be sent.

### 19 **Patient and Public Involvement**

20 Patients are involved in the questionnaire's face and content validity testing. Based on  
21 feedback from the patients in a pilot study, improvement to the questionnaires' approaches  
22 and trial processes will be implemented. Patient preferences were not directly obtained

1 with regard to choosing the BRM intervention; this was based on the principal  
2 investigator's practice experience and encounters with pregnant women. However, the  
3 patients will be involved in the recruitment to and conduct of the study. They will attend  
4 antenatal class and agreement by consent to share in this study. Also, they will answer all  
5 questionnaires pre and post the intervention. In addition, they will need to agree to BRM  
6 as the intervention.

For peer review only

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### Figure Legend

Figure 1 Mechanisms of action Reflexology therapy.

Figure 2 Mechanisms of action Massage therapy.

Figure 3 CONSORT flow diagram.

Figure 4 Research personnel training and responsibility matrix.

Figure 5 (a) shows the timeline of outcomes measurement in the intervention group; (b) shows the timeline of outcomes measurement in the control group.

**Table Legend**

Table 1 Steps of the Intervention.

Table 2 Summary of Primary Outcomes and Measurement Tools.

Table 3 Summary of Secondary Outcomes and Measurement Tools.

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**Table 1: Steps of the Intervention**

<b>Steps</b>	<b>Process</b>
1.	Prepare the equipment.
2.	Explain the procedure to the primigravida & advise her to lay on her left side* with a pillow on the side of her stomach.
<b>Breathing Exercise Intervention for 5 minutes</b>	
3.	Ask the primigravida to perform deep breathing by inhaling slowly through the nose for two seconds and then consciously release the air by breathing out for another two seconds during contractions.
4.	Rest for 1–3 seconds, then repeat the same technique for a total of 5 minutes. Then proceed to the reflexology as described below.
<b>Reflexology Intervention Technique for 10 minutes on each foot</b>	
5.	Put a towel under the right foot and cover the left leg.
6.	Apply warm oil over the right foot and roll it left to right 5 times.
7.	Press palms on the Achilles heel and knead the ankle 5 times.
8.	Knead the thumb pads on the central and bottom parts of the heel 5 times.
9.	Knead the foot following the CIUW** shape on the lateral and intermediate aspects of the foot followed by the MST*** shape 5 times.
10.	Press the wooden reflexology stick on the toes, forefoot, mid-foot, and hind-foot 5 times.
11.	Repeat Steps 5–11 on the opposite side. Then proceed to the next lower limbs massage.
<b>Lower Limbs Massage for 2 minutes 30 seconds on each leg</b>	
12.	Effleurage massage on the whole, lower flexed leg by using two hands 3 times.
13.	Half effleurage massage from the heel to the popliteal area 3 times.
14.	Palm and thumb kneading on the gastrocnemius muscle over the lateral & medial sides, followed by scooping on the gastrocnemius, each step 3 times.
15.	Thumb kneading on the hamstring muscle over the medial, intermediate, and lateral sides 3 times.
16.	Repeat Steps 12–17 on the right leg. Then proceed to lower back massage.
<b>Lower Back Massage for 15 minutes</b>	
17.	Effleurage massage from the sacrum to the shoulders and deltoids 3 times.
18.	Thumb kneading & pressure over the lateral sides of the lumbar area of the spine 3 times.
19.	Apply fist knuckling motion and thumb kneading on the lower back, side by side, 3 times. Then proceed to upper back massage.

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**Upper Back Massage for 15 minutes**

20. Effleurage massage followed by palm kneading from the lumbar region to trapezius laterally 3 times.
  21. Thumb kneading over both sides of erector spinae, then draining between the ribs towards the armpit areas 3 times.
  22. Apply squeeze on the deltoid muscle with draining towards the armpit 3 times.
  23. Apply finger kneading on trapezius muscle, followed by fist scooping 3 times.
  24. Finally, press on the neck and shoulder area on both sides 3 times.
- 

\* The left side position allows maximum blood flow to the placenta, because it applies less pressure from the foetus on the vena cava.<sup>70</sup>

\*\*CIUW shape: C-shape; I-shape; U-shape, and W-shape. These shapes indicate the orientation and placement of the palms and knuckles of the therapist.

\*\*\*MST shape: M-shape, S-shape, and T-shape. These shapes indicate the orientation and placement of the palms and knuckles of the therapist.

**Table 2: Summary of Primary Outcomes and Measurement Tools**

Primary Outcomes	Tools	Psychometric tests	Method of assessment
<b>Pain</b>	PBI	100% inter-rater reliability <i>r</i> coefficient was 0.45, 0.50, and 0.44 between PBI and PPI. <sup>71,72</sup>	Assessor-rated, <sup>71</sup> five-category behavioural observation scale
	VAS	Moderate correlation ( <i>r</i> = 0.54) with the verbal rating and is considered valuable when mixed with other tools; <sup>73,74</sup> 0.97 intraclass correlation coefficient of 24 hours interval test-retest reliability. <sup>75</sup>	Self-reported VAS, <sup>76</sup> contains six different coloured parts anchored by two extremes of 'no pain' and excruciating pain to mark on the line-map by primigravidae. <sup>77</sup>
<b>Anxiety</b>	AASPWL	> 0.8 concordance test content validity index Kendall's <i>W</i> between the opinions of the experts ( <i>W</i> = 0.090; <i>P</i> = 0.080) with Cronbach's alpha level of 0.77; <sup>78</sup> significantly correlated ( <i>r</i> = 0.369) with the Beck Anxiety Scale. <sup>78</sup>	Questionnaire consists of nine items, <sup>78</sup> on a 5-point scale: the higher the mean score the higher the anxiety

PBI= Present Behavioural Intensity; VAS= Visual Analog Scale; AASPWL= Anxiety Assessment Scale for Pregnant Women in Labour.

**Table 3 Summary of Secondary Outcomes and Measurement Tools**

<b>Secondary outcomes</b>	<b>Measurement tools</b>	<b>Method of assessment</b>
<b>Maternal stress hormones level</b>	Blood sample for ACTH, cortisol, oxytocin	Blood sample will be drawn from the median cubital vein during the insertion of IV cannula (routine care)
<b>Maternal vital sign</b>	Thermometer Sphygmomanometer	Recorded on the vital sign monitoring chart and cardiocograph.
<b>FHR</b>	Cardiocograph	Recorded on the vital sign monitoring chart, cardiocograph chart, and partograph.
<b>Duration of labour</b>	Partograph	Partograph at two separate time intervals, a sum of labour duration from 3 to 6 cm of cervical dilatation and from 6 cm to delivery of the placenta
<b>Neonatal Apgar score</b>	Apgar score table	Taken from the delivery room medical record
<b>Maternal satisfaction</b>	Six Simple Questions. <sup>80</sup>	Self-reported 7-point scale (1-7) from “strongly disagree to “strongly agree” with higher scores signifying the higher level of satisfaction

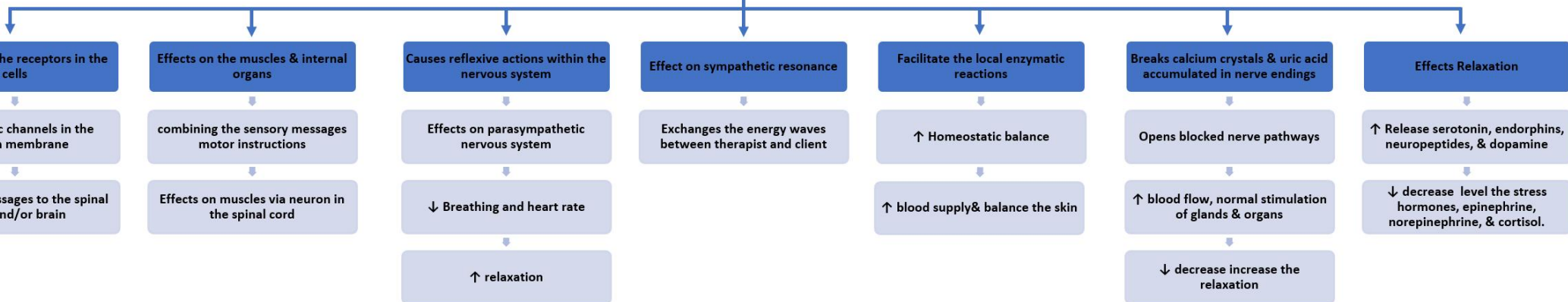
ACTH= adrenocorticotropic hormone



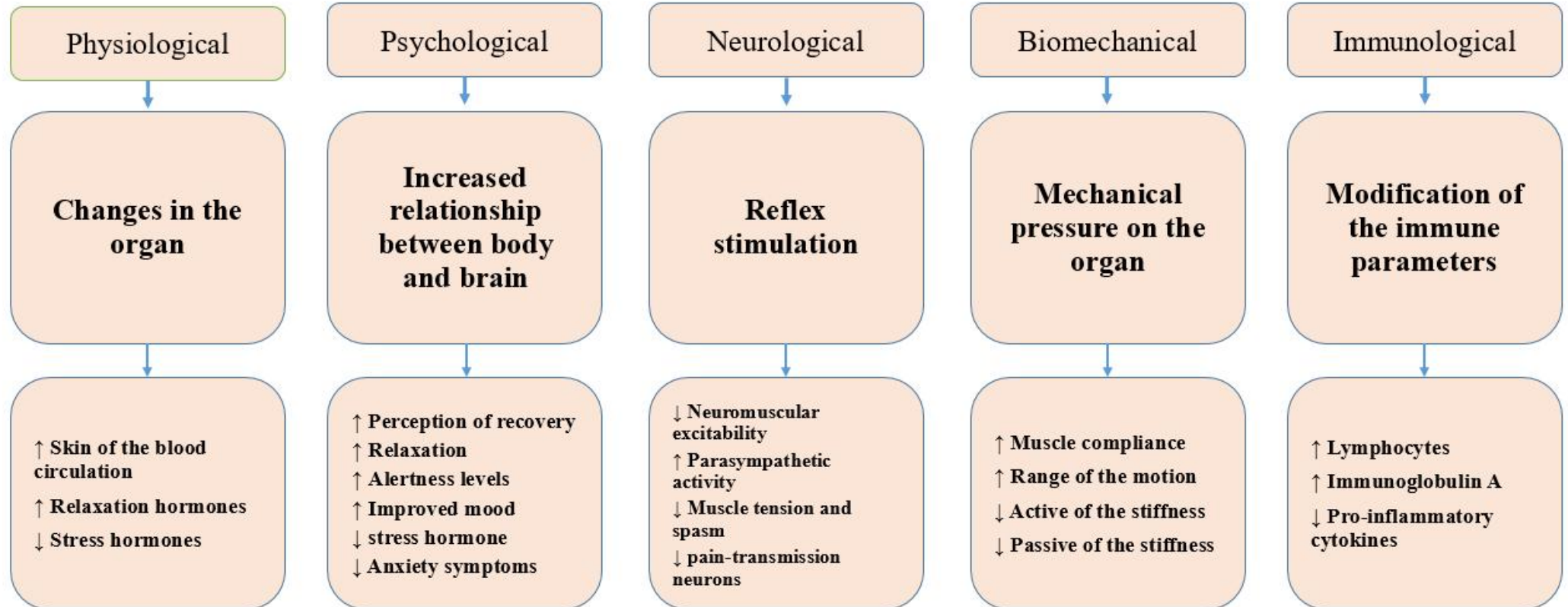
# Mechanisms of the Reflexology

pressure on certain reflex points

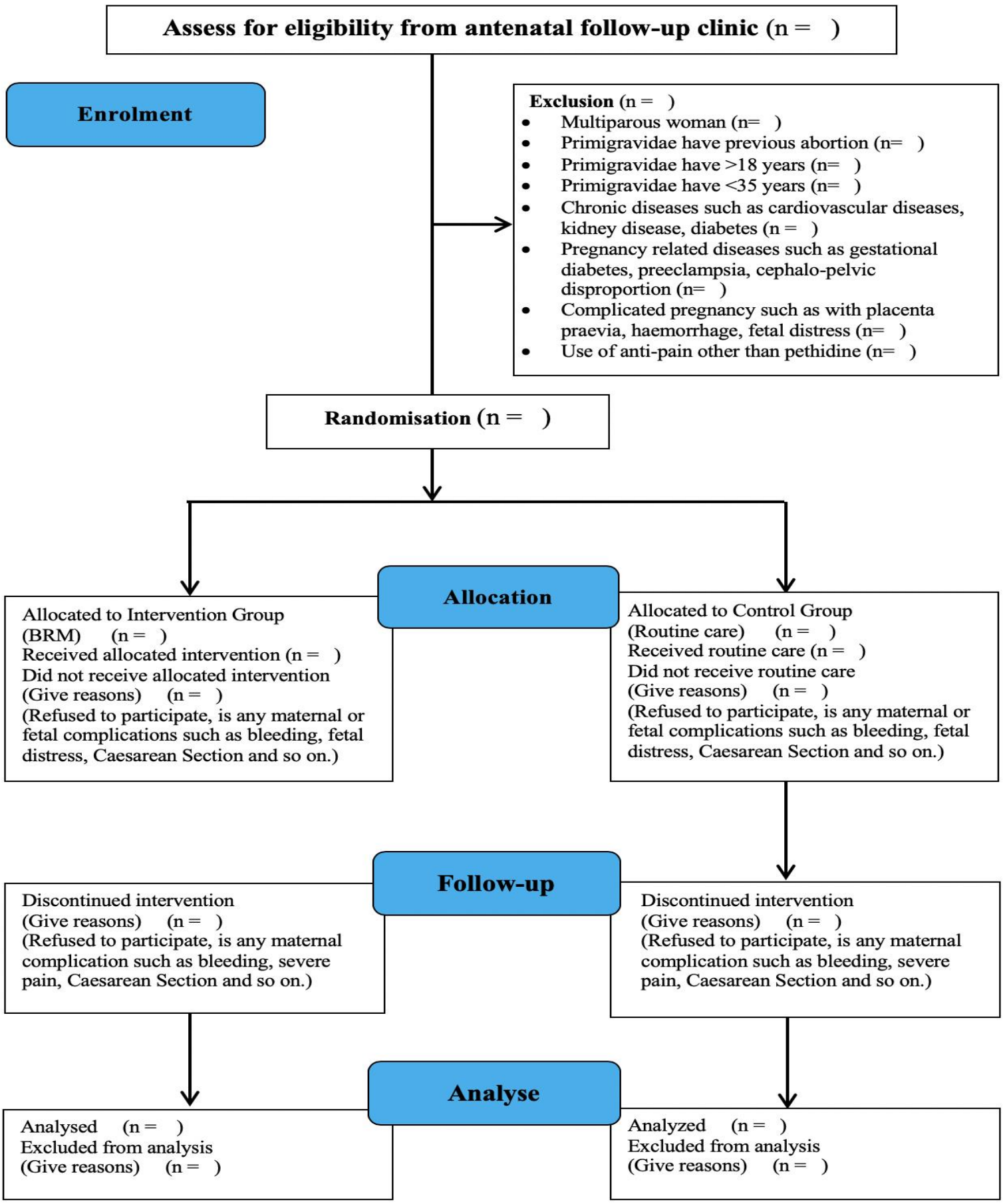
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# Mechanisms of Massage



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### 13 Research Assistants + 1 Principal Investigator

- Recruitment of nursing students who completed a 5-year nursing degree training and awaiting their job posting.
- Assigned to their preferred and suitable roles (coordinators, the outcome assessors, or massage therapists).
- One week training as research assistants in their respective roles.
- A pilot study to ensure their competency.
- Written study manual as a reference guide to be provided to all research assistants.



Research coordinators  
(4 pax.)



Outcome Assessors  
(4 pax.)



Massage therapists  
(5 pax.)

- Recruit eligible primigravidae at the antenatal clinic deliver brief health education on labour pain management at the antenatal clinic for 6 weeks.
- Reassess the primigravidae women's consent and eligibility,
- Allocate the women to either the intervention or control group.
- Alert the massage therapists and outcome assessors when the cervical dilatation of the trial participant reaches 6 cm.
- Distribute outcomes assessment record form to the outcome assessors.
- Encode the questionnaire package according to the participant's allocated group.
- Organise the entry sequence for the outcome assessors and the massage therapists to enter the delivery rooms according to the scheduled time.

- Assess and fill-up questionnaires:
  - Present behavioural Intensity (PBI).
  - Visual Analog Scale (VAS).
  - Anxiety Assessment Scale for primigravidae Women in labour (AASPWL),
  - Six Simple Questions (SSQ) for maternal satisfaction.
- Retrieve the maternal vital signs, fetal heart rate, duration of labour, and neonatal Apgar score from the health records.
- Record all the outcomes in the designated form.

- Perform breathing exercise, foot reflexology and back massage during labour (BRM).
  - Breathing exercise (5min).
  - Foot Reflexology (10 min on each foot),
  - Back massage (35min).

Sub-divided into two shifts per day to ensure all the eligible and consented primigravidae will be captured



Day Shift (9 am - 9pm)

2 Coordinators, 3 Massage therapists, and 2 Outcome Assessors



Night Shift (9 pm - 9 am)

2 Coordinators, 2 Massage therapists, 2 Outcome Assessors, and Principal Investigator

