# The role of Shiatsu massage in labour: A study protocol

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**ABSTRACT**

Labour pain often cause anxiety among pregnant women. Despite the presence of various intrapartum analgesics methods, their side effects may affect the women's overall birth experience. Access to certain intrapartum analgesics is also limited in certain low-resource hospitals. Therefore, it is crucial to explore other alternatives for pain relief in labour. Shiatsu massage has a great potential as an intrapartum analgesia based on the evidence that has been published for other medical condition. This study aims to determine the safety and efficacy of Shiatsu massage in reducing pain and anxiety during labour. This is a concurrent mixed-method study design. The first phase is a quasi-experimental study (quantitative) and the second phase is the qualitative study. It involves four randomly selected low-risk maternity clinic in Samarinda, Indonesia. A total of 80 healthy nulliparous pregnant women at term with singleton pregnancy in latent phase of labour will be recruited. The participant will be randomized into either intervention (receiving Shiatsu massage) or control group using simple random sampling. This study had been registered in the Iranian Registry of Clinical Trials (Registry ID: IRCT20220317054316N1). The potential evidence on safety and efficacy of Shiatsu massage as intrapartum analgesia may support its use as an additional non-pharmacological intervention to safely reduce pain and anxiety during labour.
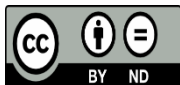
## 1. Introduction

Childbirth can be painful, exhausting, and frightening, and these emotions might increase as labour goes on [1]. The sympathetic nervous system will be stimulated by the stress to release more catecholamines [2]. It will further intensify the pain and potentially prolong the first and second stages of labour, thus resulting in an unpleasant childbirth experience [3]. Prolonged labour either in the first or second stage of labour is

associated with fetal and maternal complications [4]. According to a study done on 288 Swedish women, only 28% of them viewed labour pain as positive but 41% thought it was the worst thing that had ever happened to them [5].

There is various intrapartum analgesia available, which can be divided into two main groups i.e., pharmacological and non-pharmacological. Despite the availability of pharmacological analgesia, its side effects and other multidimensional phenomena indicate that pharmacological analgesia alone may not able to manage labour pain adequately [6]. The non-pharmacological methods satisfy the three requirements of simplicity, safety and preserving foetal homeostasis in the labouring mothers because they have no impact on delivery and no adverse consequences on either the mother or the foetus [2].

Shiatsu massage on of the well-known physical therapy in the provision of complementary medicine [7]. Shiatsu is derived from a Japanese word that means "finger pressure" [8]. Shiatsu massage is a type of intense and powerful massage that can calm people and relieve physical pain as well as anxiety and other symptoms. Shiatsu massage, according to the theory of Oriental Medicine, promotes a natural healing power to lessen symptoms by pressing Shiatsu points with the palms and thumbs all over the body [9]. Shiatsu massage is performed on 'tsubo' points. These points are connected to certain muscles, nerves and endocrine system glands, respectively. By performing Shiatsu massage, it stimulates the body to release endorphin hormones, which act as the body's natural pain relief [10].

The Shiatsu massage works by its effect on the pain pathway. During labour, the pain impulses are delivered by nociceptors-C nerve fibres to the sympathetic nerve, and Shiatsu massage can provide a direct pain reduction effect using the gate control theory. When the mechanoreceptor is activated by gentle pressure and stretching movements during the Shiatsu massage, the Aß- type thick, twisted nerve fibres receive direct non-nocuous stimuli. It will then go to lamina II and III Subtansia gelatinosa, the dorsal horn of the spinal cord via the neospinothalamic tract fast pathway. An increase in Aß stimulation will trigger the release of enkephalin interneurons found in the dorsal horn of the spinal cord. This neurotransmitter activates a voltage-dependent magnesium blockade to close the gate in the subtansia gelatinosa and causes less pain [11].

Many works of literature have demonstrated the benefits of Shiatsu massage in various medical indications, such as for stress and anxiety, pain, muscle/joint issues, migraine, ability to cope, mind-body awareness, mobility, energy and mental clarity, and sleep disturbances [10], [12- 14]. No major or significant adverse effects were reported from these studies. Mild symptoms such as temporary fatigue and difficulty coping with emotional reactions have been reported [14]. Shiatsu massage has been demonstrated to be a safe physical therapy if it is performed by a credentialed trained masseuse, and associated with various potential benefits [15]. However, the lack of scientific research on Shiatsu massage particularly as part of labour management has hindered its use as a non-pharmacological intrapartum analgesia method.

Therefore, it is essential to study the role of Shiatsu massage in labour to have more effective and safe alternative pain relief options for women in labour. This study aims to study the safety and efficacy of Shiatsu massage in reducing pain and anxiety during labour among nulliparous pregnant women as the primary outcome. The second outcome is to determine the impact of shiatsu massage on the foetal heart rate, frequency and duration of the uterine contractions, blood pressure pulse and temperature, vaginal tusses and postpartum bleeding.

**2. Materials and Methods**

This will be a concurrent design of a mix-method study. It contains two parts of study The first part of this study will be an intervention (quantitative) study and the second part will be a qualitative study. It involves a collection of qualitative and quantitative data in the same phase, independently. Then, the interpretation of the result was conducted at the same time to obtain a better conclusion at the end of the study [16].

**Phase 1**

*Study design*

This study is a quasi-experimental. Four low-risk maternity clinics will be randomly selected as the study sites. The intervention will receive a shiatsu massage and routine care during the antenatal check-up, while the comparison group will receive only routine care during the antenatal check-up. The comparison will be conducted between these two groups at the time interval of T0 (baseline), T1 (latent phase) and T2 (active and transition phase). The pre and post-intervention measurements for both groups will be obtained.

*Hypotheses*

Ha1: There is a significant difference in the labour pain and anxiety score between the intervention and comparison groups after applying Shiatsu massage. H02: There were no significant differences in the frequency of uterine contractions, foetal heart rate, blood pressure, body temperature, pulse rate, cervical dilatation, descent of the foetal head, amniotic membrane status and duration of labour between the intervention and comparison groups in each phase of labour. H03: There were no significant differences in the observed results two hours after delivery (fundal height, urine output, and postpartum bleeding) between the intervention and comparison groups.

*Study setting*

There are 17 maternity clinics in the city of Samarinda, East Kalimantan, Indonesia. All of these maternity clinics are practising a "Normal Delivery of Standard Application (APN)". However, there will only four maternity clinics were selected in this study. Two maternity clinics will be assigned to the intervention group (routine care in labour and Shiatsu massage) and the other two maternity clinics to the control group (routine care in labour).

*Study population and Recruitment*

The study population will be all pregnant women attending for normal vaginal delivery at the study sites. The inclusion criteria are (a) nulliparous pregnant women; (b) at 37 to 42 weeks of gestation ;(c) has a singleton fetus and cephalic presentation; (d); in the latent phase of labour; and (e) who agreed to participate in the study. The exclusion criteria are (a) severe pre-eclampsia; (b) psychiatric disorder; (c) had other comorbidities such as cardiovascular, nephrology, neurology, haematology, musculoskeletal disorder diagnosed by the doctor during pregnancy; (d) contraindicated for vaginal delivery; and (e) contraindicated for Shiatsu massages, such as varicose veins, presence of wounds, fractures, new scars, and areas of inflammation.

*Sample size calculation*

The sample size will be calculated based on the results of a study by [17] who found that the pain score during the latent phase of the delivery was $4.67 \pm 1.37$ points in the comparison group and $3.57 \pm 1.43$ points in the intervention group (received sacral massage). During the transient phase, the pain score in the comparison group was $9.70 \pm 0.53$ points and in the experimental group was $8.83 \pm 1.78$ points. From the result, it was found that the difference mean score in the comparison group was 5.03 units and in the experimental group was 5.26 points. Therefore, the difference in pain scores between these groups was 0.23 points.

By taking a significant level of 0.05, 80% power of the study and the difference in pain score between these two groups of at least 0.23 points with a standard deviation of 0.5, the sample size required for each group will be 74 using the formula $N = [2\sigma2 (z\alpha + z\beta)2]/ \Delta2$. After adjusting for the attrition rate by 10 percent, the minimum sample size required in this study was 80. Therefore, 40 pregnant mothers were selected for each group (20 each in the four clinics).

*Sampling method*
Systematic sampling will be applied in this study. The sampling interval will be calculated by dividing the population size by the desired sample size. All pregnant women who deliver in these four maternity clinics during the study period will be selected as the population size.

It is estimated that a total of 50 normal deliveries per month in the selected four maternity clinics. Therefore, within three months it is estimated that a total of 150 normal deliveries from the four maternity clinics. From the sample size calculation, this study needs a minimum of 20 deliveries from each maternity clinic. Therefore, the sequence of recruitment for pregnant women to each study site was:  3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42, 45, 48, 51, 54, 57, and 59, etc.

*Recruitment of pregnant women*
The recruitment process of the pregnant women will be conducted by the principal investigator at the selected clinic. The pregnant women will be screened based on the inclusion and exclusion criteria.

*Selection of the pregnant woman*
The selected pregnant women will receive information about the research and be offered to participate in this study. If they agreed, informed consent will be obtained from them as a legal, ethical requirement in human research.

*The Intervention: Shiatsu massage*
The intervention of this study is a Shiatsu massage. It is a form of Japanese bodywork characterized by applying comfortable pressure using fingers to knead, press, and stretch at certain points on the body to the meridians. Before applying the Shiatsu massage, the specific sacral groove work needs to be identified or it is called an implementation step. After that, the shiatsu massage will be applied based on the phase of labour following the Shiatsu protocol i.e.:
i.      Latent phase (1 – 3 cm opening of os)
ii.     Active phase (4 – 7 cm opening of os)
iii.    Transition phase (8 – 9 cm opening of os)

*Implementation step*
The implementation step is to determine the specific sacral groove work where the Bladder 31 (BL31), Bladder 32 (BL32), Bladder 33 (BL33) and Bladder 34 (BL34) are identified.
i.      Bladder 31 (BL31) is identified at the sacral region, posterior to the first sacral foramen.
ii.     Bladder 32 (BL32) is identified at the sacral region, in the second posterior halfway between the posterior superior iliac spine and the spinous process of the second sacral vertebra.
iii.    Bladder 33 (BL33) is identified at the sacral region, in the third posterior sacral foramen.
iv.     Bladder 34 (BL34) is identified at the sacral region, in the fourth posterior sacral foramen.
The importance of the identification of the specific sacral groove is to balance the energy of the sacrum so that the woman feels comfortable and to help with pain relief in labour [18]. The illustration of the specific sacral groove is shown in Figure 1.
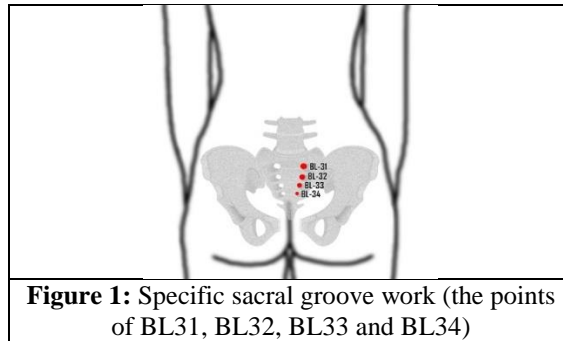
**Figure 1:** Specific sacral groove work (the points of BL31, BL32, BL33 and BL34)

a.      Latent phase (1-3 cm):

The Shiatsu massage will be started by gentle massage around the crease at the pressing point Bladder (BL) 31 to Bladder (BL) 34.

i.      Step 1: By using both thumbs, the sacral point will be determined above the iliac crest (pelvis). The rest of the fingers act as a primary hand to ensure that the thumb joint is straight, and the masseuse uses their body weight to lean and apply static pressure (Figure 2a).

ii.      Step 2: Then, one thumb will be placed on top of the other thumb. The pressing process will be applied for three seconds at each pressing point once (BL31, BL32, BL33 and BL34) (Figure 2b). The diagrammatic representation for the specific sacral groove work is shown in Figure 1 (the points of BL31, BL32, BL33 and BL34).

iii.      Step 3: Next, the primary hand will be wrapped around the working hand to provide support (Figure 2c).

iv.      Step 4: Lastly, the knuckles of both index fingers will be placed in the highest sacral point, the masseuse leaned in with body weight, and the knuckles will be rolled in a straight line down the sacrum as far as possible (Figure 2d). This will be repeated, starting with the index finger knuckle in the second point down, in three seconds with a rotary pressing motion. Then the process of pressing will be withheld for three seconds, and the rotating pressing will be applied again for three seconds.

b.      Active phase (4-7 cm):

i.      Step 5: The masseuse determines the buttock point that is parallel to the fourth lumbar segment (L4), which is about 3.5 thumbs from the midline. Subsequently, with both thumbs on each side, the masseuse's finger will cup the top of the iliac crest once (Figure 2e).

c.      Transition phase (8-10 cm):

i.      Step 6: The masseuse will determine the Kidney 1 (KI-1) point that is located at 1/3 on top of the sole on flexion of the foot (pulling the toes). Firm pressure will be applied inward and forward to the direction of the big toe (Figure 2f).

ii.      Step 7: The Heart Protector (HP) 8 point on the centre of the palm (Figure 2g), and the HP-6 point on the wrist crease between the tendons (Figure 2h) will be pressed for one minute at each point.

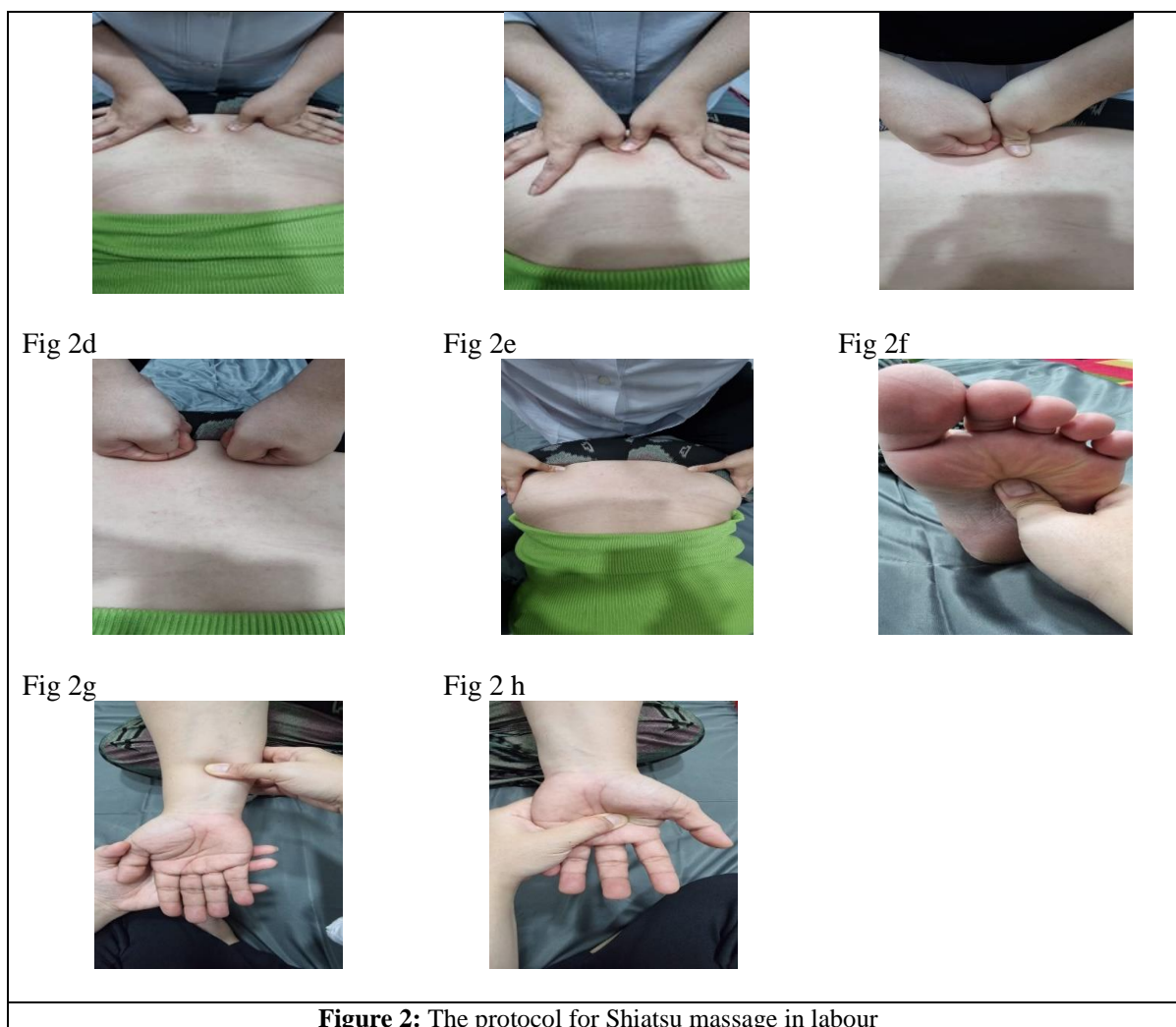| Fig 2a | Fig 2b | Fig 2c |
| --- | --- | --- |
|  |  |  |

**Figure 2:** The protocol for Shiatsu massage in labour

All the participants in the intervention group will receive a Shiatsu massage three times in each phase.

*Comparison group*
The comparison group received only routine care throughout the antenatal period from the researcher for 20 minutes beginning at the latent phase to the transition phase. The care will be based on the standard 60 steps of normal delivery care.

*Assessment of the pain score, anxiety score and other measurements*
The assessment of pain and anxiety scores in the intervention and comparison groups will be conducted at baseline (T0), 30 minutes after the latent phase (T1) and 30 minutes after the active phase (T2). The other measurements taken include fetal heart rate, frequency and duration of uterine contractions, blood pressure mother, pulse mother, temperature mother, vaginal tusses (cervical dilatation and amnion fluid), Postpartum uterine height, and the amount of postpartum bleeding. The summary of assessment taken is summarized in Table 1.

**Table 1.** Measurement taken during the study period

| Measurement for intervention and comparison groups | Intervals taken |
|---|---|
| i.   Self-perceived pain | Baseline, 30 minutes after shiatsu massage given at latent phase (T1) and 30 minutes after shiatsu massage |

| | | given in active phase and transition phases (T2). |
|---|---|---|
| ii. | Self-perceived anxiety | Baseline, 30 minutes after shiatsu massage given at latent phase (T1) and 30 minutes after shiatsu massage given in active phase and transition phases (T2). |
| iii. | Foetal heart rate | Measurement taken every 30 minutes. |
| iv. | Frequency and Duration of the Uterine Contractions | Measurement taken every 30 minutes. |
| v. | Blood pressure | Measurement taken every four hours. |
| vi. | Pulse mother | Measurement taken every 30 minutes. |
| vii. | Temperature mother | Measurement taken every two hours. |
| viii. | vaginal tusses (cervical dilatation and amnion fluid) | Measurement taken every four hours. |
| ix. | Postpartum uterine height | Measurement were carried out every 15 minutes for the first hour, and 30 minutes for the second hour. |
| x. | Postpartum bleeding | Measurement were carried out every 15 minutes for the first hour, and 30 minutes for the second hour. |

*Methods of Data Collection*

Data will be collected using various methods:

a.          Face-to-Face Interview

This method will be conducted to obtain information about socio-demographic (i.e., age, education, occupation, and ethnicity).

b.          Review of Medical Record

This method will be conducted to obtain the history of medical or antenatal history of the pregnant woman.

c.          Labour medical record.

This method will be conducted to record the progress of labour, and the condition of the mother and fetus during the labour process based on the partograph sheet.

d.          Self-administered questionnaire

This method will be conducted to assess pain and anxiety scores. The outcome measure of pain will be assessed using a pain intensity scale and the outcome measure for anxiety was assessed using The Hamilton Rating Scale (HARS).

i.          The Pain Intensity Scale.

The pain intensity scale is a numerical rating scale that will be used to assess pain intensity. The pain level is expressed in figures that range from 0 to 10. A score of zero indicates there is no pain at all, and a score of 10 indicates the worst possible pain. The pain intensity score will be determined by measuring the distance between the end of the painless line to the point indicated by the pregnant woman. It is illustrated in Figure 3.



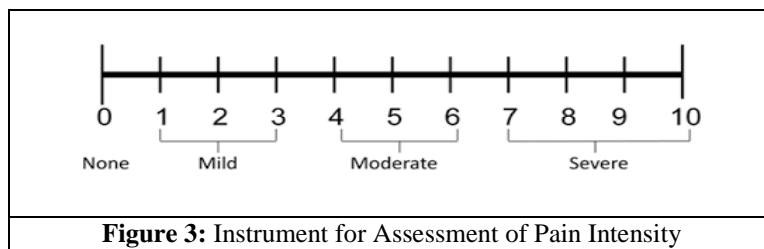**Figure 3:** Instrument for Assessment of Pain Intensity

ii.          The Hamilton Rating Scale (HAM-A)

Hamilton Anxiety Rating Scale (HAM-A) will be used to assess the self-perceived anxiety symptoms' severity. It was developed by Hamilton et al. (1956). It consisted of 14 items with three domains: a series of symptoms measure psychic anxiety (mental agitation (items 1 to 3) and psychological distress (items 4 to 6)

and somatic anxiety physical complaints related to anxiety (items 7 to 14).

In this study, the Indonesian language of HARS will be used. The instrument has been validated in the Indonesian language which has been validated by Ramdan (2018). It has a high level of internal consistency, as measured by Cronbach's alpha. 0.756 and Pearson correlation ranged from 0.529 to 0.727.

Each item was assessed using an ordinal scale range from 0 =not present: 1 = mild: 2 = moderate: 3 = severe and 4 = very severe. The minimum score will be 0, and the maximum score will be 56. A score of less than 14 indicates no worries; a score of 14 – 20 indicates mild anxiety; a score of 21 – 27 indicates moderate anxiety; a score of 28 – 41 indicates severe anxiety; and a score of 42 – 56 very severe anxiety.

*Flowchart of phase 1*
The flowchart of phase 1 study is shown in Figure 4.

**Figure 4:** Flowchart of Phase 1 study
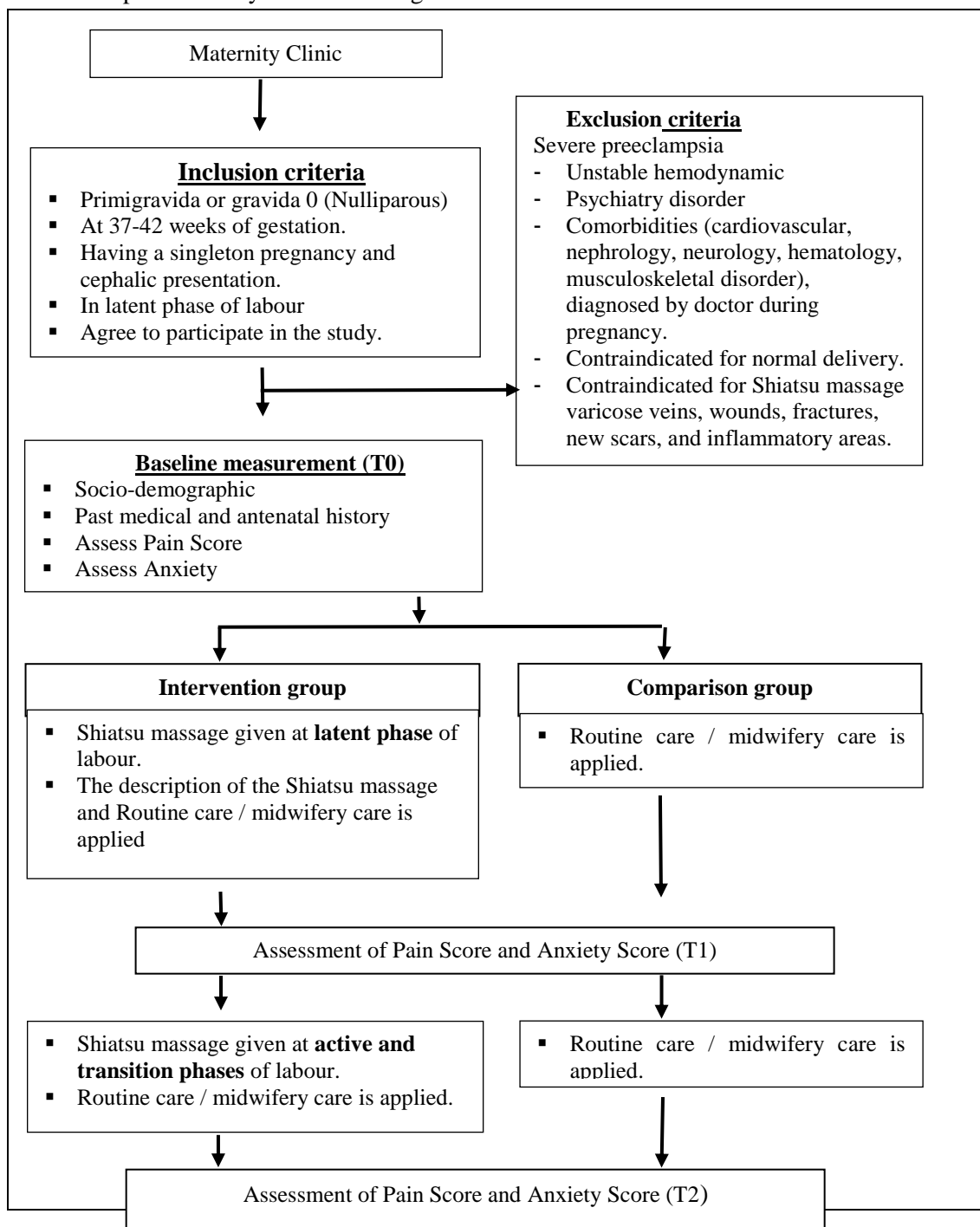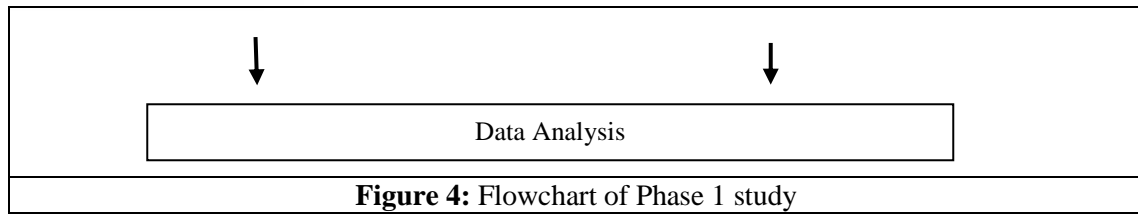
*Data Management*

Labour pain measurement sheets for each stage will be collected, and a questionnaire for anxiety will be checked at the end of each interview session before being assessed to ensure the completeness of the questionnaire. For each lost data record found, the women will be identified and contacted again via phone calls or home visits. The data will be entered and coded into the personal computer using a Statistical Package for Social Sciences (SPSS) Version 26.0. The data entry will be double-checked against the raw data to exclude typing errors. The outlier and extreme values will also check.

*Data Analysis*

In this study, an intention-to-treat (ITT) analysis will be applied. Any missing value will be handled by numerical imputation of the last observation carried forward (LOCF) to replace the missing value. The mixed design repeated measure analysis of variance (RM-ANOVA) will be carried out to compare the mean response over time for the intervention and comparison groups. Data will be entered into IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, N.Y., USA).

**Phase 2**

*Study design*

This is a phenomenological-based qualitative design study. This study is chosen to describe a woman's life experience as a particular phenomenon of the appearance of something [16] during labour after introducing the Shiatsu massage to reduce labour pain and anxiety during delivery.

*Study Population and Participant's Recruitment*

Phase 2 will be conducted at the study sites where the intervention is given in Phase 1 one day before the women are discharged from the clinic. Participants will be recruited through a purposive sampling method. The inclusive criteria are (a) women who received Shiatsu massage during labour (in the Phase 1 study), and (b) women who can communicate well in the Indonesian language.

*Sample size determination*

The sample size will be determined from the saturation data. The estimated sample size, in this case, will be 10 women. Theoretical saturation is estimated to be reached after all sample codes have been observed at least once. Collections are stopped when all themes reach their subthemes.

*Data collection*

The face-to-face interview will be conducted before the participants discharged from the study sites. All the eligible women will be offered to join this Phase 2 study. Another informed consent form will be obtained once any of them agree to participate.

The face-to-face interview will be conducted in Indonesian language by an interviewer. The whole interview will be recorded in an audio recorder. The participants will be briefed prior to the interview that they are free to express their opinions and beliefs during the interview. The probing questions are formulated based on three primary questions and each primary question is having three probing questions
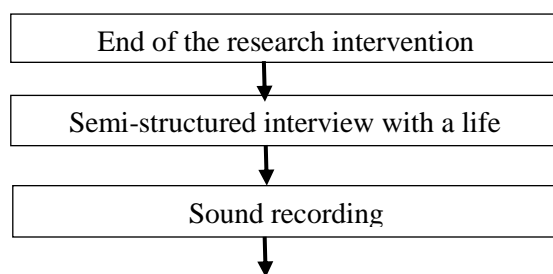
(Table 2).

**Table 2:** List of primary questions and probing questions during the interview

| Primary Questions | Probing Questions |
|---|---|
| i. How did you feel during delivery process? *(Bagaimana perasaan kamu selama proses pengiriman?)* | a. Do you feel comfortable during labour? *(Apakah kamu merasa nyaman selama persalinan?)* <br><br> b. Could you describe the labour pain? *(Bisakah kamu menggambarkan nyeri persalinan?)* <br><br> c. What did you do during the labour pain? *(Apa yang kamu lakukan selama nyeri persalinan?)* |
| ii. How is your experience with Shiatsu massage during labour? *(Bagaimana pengalaman kamu tentang pijat Shiatsu selama persalinan?)* | a. Do you get any effect from Shiatsu massage on labour pain? *(Apakah kamu mendapatkan efek pijat Shiatsu pada nyeri persalinan?)* <br><br> b. Is the shiatsu massage difficult for you? *(Apakah pijat Shiatsu sulit bagi Kamu?)* <br><br> c. How do you feel after Shiatsu massage? *(Bagaimana perasaan kamu setelah pijat Shiatsu?)* |
| iii. How is your opinion about the labour process and labour pain? Is it as your imagination? *(Bagaimana pendapat Kamu tentang proses persalinan, nyeri persalinan? Apakah sesuai dengan imajinasi kamu?)* | a. Is the labour process as scary as it seems? *(Apakah proses persalinan menakutkan seperti yang terlihat?)* <br><br> b. Does the giving birth traumatize you from having another pregnancy and delivery in future? *(Apakah melahirkan menyebabkan trauma menghadapi proses persalinan selanjutnya?)* <br><br> c. Do you want to do a shiatsu massage again in the future? *(Apakah Kamu ingin melakukan pijat Shiatsu lagi di masa mendatang?)* |

*The flowchart of the qualitative study*

This study phase will complete the sequential procedures of the intervention study. The sequential procedure is used to seek elaboration on the quantitative finding [16]. This method will be carried out to answer the research objectives by exploring the subjective effect of Shiatsu massage in reducing pain and anxiety in labour.

The intensity of withdrawal varies for each woman. The qualitative exploration will be used to explore the perceptions and feelings of each individual towards the experience of childbirth and shiatsu massage. Figure 5 shows the flowchart of qualitative research.
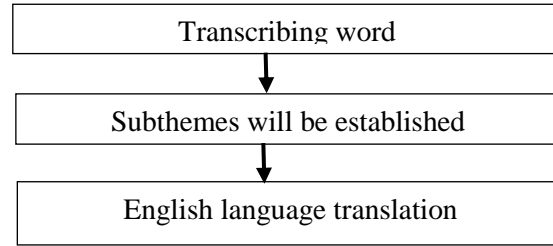
End of the research intervention

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Semi-structured interview with a life

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**Figure 5:** Flowchart of the qualitative study

*Data Analysis*

Data will be analyzed using NVivo Software. The stages in conducting qualitative data analysis will be started with managing the data obtained from audio recordings and transcribing them word for word. Then managing ideas will be done to understand the conceptual and theoretical problem, followed by solving the querying the data. Each translated quote from the women will be re-examined and verified by the researcher to match the context and true meaning of the interview session. The transcripts will be used as the data source for the theme analysis. Thematic analysis is a technique for categorizing data patterns, and then making reports by utilizing the data that has been obtained and the results of the transcripts of research reports that have been carried out [19].

Then, visual modelling will be done to show the relationship between conceptual and theoretical data. The researcher analyzed specific and then made codes and classifications for each statement from the participants. Then researcher will distil or filter data, arrange themes, and interpretation data and translate it into English. The flow of the analysis using NVivo software is shown in Figure 6.
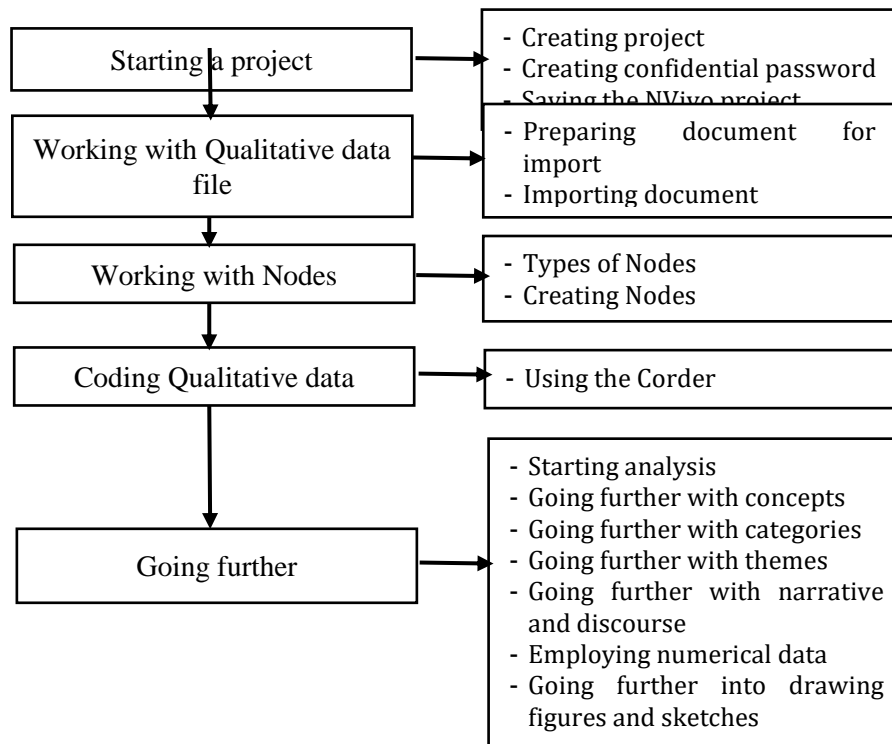
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             ▼                      │ - Saving the NVivo project     │
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**Figure 6:** Procedure Followed in Applying NVivo Software

*Mix Methods Analyst*

There are several ways to link data from the two research designs for the analyst [20] i.e.: (a) connecting one database link to the other sampling, (b) building one database informs the data collection approach of the other; (c) merging two databases for analyst; and (4) Embedding data collection and analyst link still describe multiple points.

The quantitative data will be collected with an instrument using a series of scales and the qualitative data will be collected using parallel or similar questions [21]. Merging data typically occurs after the statistical analysis of the numerical data and qualitative analysis of the textual data.

## 3. Results and Discussions

*Result*

For phase 1, the outcome measures include the Numerical Rating Scale (NRS) and Hamilton Anxiety Rating Scale (HAM -A). For the intervention group, the findings will be assessments at T0 (upon recruitment in the latent phase), T1 (30 minutes after the Shiatsu massage performed) in the latent phase and T2 (the final assessment taken 30 minutes after Shiatsu massage during active or transition phase, 30 minutes after Shiatsu massage).

For control group, the assessment findings will be at recruitment (T0), about 50-60 minutes after the first assessment, in latent phase (T1) and at the final assessment taken in active and transition phase, before delivery (T2).

Intrapartum details including vital sign reading as well as delivery details will be obtained. Presence of any complications intrapartum and postpartum will be recorded as well.

For phase 2, the themes and subthemes identified during the interview on the participants who receive Shiatsu massage intrapartum on how they feel during labour, their perception on use of Shiatsu massage in labour and participants' opinion on the labour process and labour pain.

*Discussion*

This study compares the efficacy of Shiatsu massage as a physical therapy during labour in reducing the women's pain and anxiety as the primary outcome and determines the impact of shiatsu massage on the foetal heart rate, frequency and duration of the uterine contractions, blood pressure pulse and temperature, vaginal tusses and postpartum bleeding as the secondary outcome. It is to scrutinise whether Shiatsu massage is an effective and safe complementary treatment to be offered to women who are going for vaginal delivery.

The Shiatsu massage during childbirth is considered to have minimal side effects, and it is easy to administer to women who are about to give birth. Shiatsu massage will decrease the catecholamine release while increasing the endorphin release. This will relax the muscles and reduce the mothers' anxiety [22], [23]. Although Shiatsu has not been widely used among pregnant and childbirth women, few studies have been conducted to evaluate the effect of Shiatsu massage on labour progress. To date, there is still an absence of evidence to evaluate the effectiveness of Shiatsu massage in reducing labour pain and anxiety. Therefore, it is crucial to have well-designed research that allows scientific evaluation of the efficacy and

safety of Shiatsu massage in reducing pain and anxiety in labour. It is also essential to determine whether Shiatsu massage can improve women's birth experience.

## 4. Conclusion

The potential evidence on safety and efficacy of Shiatsu massage as intrapartum analgesia may support its use as an additional non-pharmacological intervention to safely reduce pain and anxiety during labour and the same time it will improve the progress of delivering the baby.

Confidentiality

The confidentiality of the information provided by the mothers was guarded by the researchers. To maintain confidentiality, the researchers stored all data collection documents such as consent forms, mothers' biodata, audio recordings, and interview transcripts in a secure storage system that could only be accessed by the researchers. The recorded data was coded without any names attached. All forms of data were only used for the purposes of data analysis and the preparation of the research report.

Conflict of Interest Statement

The authors declare no conflicts of interest.

Author Contribution

Hestri Norhapifah conceptualised, collected data, and wrote the original manuscript section. Mohamad Rodi Isa contributed to hypothesis development, conceptualization, methodology and data analysis. Bahiyah Abdulah participated in planning clinical evaluations, writing reviews and editing the manuscript. Salina Mohamad contributed to the manuscript review and text adaptation.

Data Availability Statement

The data that support the findings of Shiatsu Massage in Labour Studies will be available (by password) upon request on the study's Website.

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