

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### EXPLORING ROLE OF SHIATSU MASSAGE AS A PAIN RELIEF IN LABOUR

#### Protocol summary

##### Study aim

To explore the role of Shiatsu Massage in labour

##### Design

Two-arm parallel intervention and comparison groups with non-blinded trial

##### Settings and conduct

This is an open-label trial study. It will be conducted at 4 maternity clinics. The participants will be divided into intervention and control groups based on the maternity clinic randomly.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria of pregnant women are: a. Primigravida or Gravida 0 (Nulliparous) b. at 37-42 weeks of gestation. c. age between 20 and 35 years. d. having a singleton and cephalic presentation. e. agree to participate in the study; The exclusion criteria of pregnant women who are having: a. severe pre-eclampsia. b. unstable hemodynamic. c. psychiatric disorder. d. comorbidities (cardiovascular, nephrology, neurology, hematology, musculoskeletal disorder) diagnosed by doctor during pregnancy. e. contraindicated for normal delivery. f. contraindicated for Shiatsu massages such as varicose veins, wounds, fractures, new scars, and areas of inflammation

##### Intervention groups

Shiatsu massage is the method of intervention in this study. Group 1: intervention group will be given a shiatsu massage. Step 1: The massage will be given at the sacral point for a 3-second rotary pressing motion. Step 2: one thumb will be placed on top of the other thumb and pressed for 3 seconds at each pressing point Step 3: the mother's hand is wrapped around the working hand to provide support. The mother will be represented by the thumb and fingers. and press for 3 seconds at each pressing point Step 4: The second knuckle index finger is placed at the highest holy point, and then with the massager body weight, the knuckle will be rotated in a straight line down the sacrum. Control group: usual care of pregnant women during labor

##### Main outcome variables

Pain score, Anxiety score,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220317054316N1**

Registration date: **2022-03-31, 1401/01/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-03-31, 1401/01/11**

Update count: **0**

##### Registration date

2022-03-31, 1401/01/11

##### Registrant information

##### Name

ISA MOHAMAD-RODI

##### Name of organization / entity

Universiti Teknologi MARA

##### Country

Malaysia

##### Phone

+60 19-345 3515

##### Email address

rodi@uitm.edu.my

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-01, 1400/10/11

##### Expected recruitment end date

2022-06-30, 1401/04/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

EXPLORING ROLE OF SHIATSU MASSAGE AS A PAIN RELIEF IN LABOUR

**Public title**

The Impact of Shiatsu Massage as a Pain Relief in Labor

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Primigravida or Gravida 0 (Nulliparous) at 37-42 weeks of gestation, age between 20 and 35 years having a singleton and cephalic presentation agree to participate in the study

**Exclusion criteria:**

severe pre-eclampsia unstable hemodynamic psychiatric disorder comorbidities (cardiovascular, nephrology, neurology, hematology, musculoskeletal disorder) diagnosed by doctor during pregnancy contraindicated for normal delivery contraindicated for Shiatsu massage such as varicose veins, wounds, fractures, new scars, and areas of inflammation

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Health Research Ethic Committe. Health Polytechnic of Ministry of health East Kalimantan

**Street address**

Jl. W. Monginsidi No.38, Sidodadi, Kec. Samarinda Ulu, Kota Samarinda, Kalimantan Timur 75243, Indonesia

**City**

Samarinda

**Postal code**

75243

**Approval date**

2022-03-28, 1401/01/08

**Ethics committee reference number**

LB.01.01/7.1/001509/2022

**Health conditions studied****1****Description of health condition studied**

pregnant women without any co-morbidities

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

pain score

**Timepoint**

T0: Baseline (at the latent phase (1 - 3 cm opening of the Os), T1: 30 minutes after intervention done at the latent phase), T2: 30 minutes after intervention given at the active (4 - 7 cm opening of the os) and transition phases (8 - 9 cm opening of the os)

**Method of measurement**

Numeric pain rating scales (NPRS)

**2****Description**

anxiety score

**Timepoint**

T0: Baseline (at the latent phase (1 - 3 cm opening of the Os), T1: 30 minutes after intervention done at the latent phase), T2: 30 minutes after intervention given at the active (4 - 7 cm opening of the os) and transition phases (8 - 9 cm opening of the os)

**Method of measurement**

Hamilton Anxiety Rating Scale (HARS)

**Secondary outcomes****1****Description**

qualitative assessment of the experience of applying shiatsu massages during labor

**Timepoint**

after deliver the baby

**Method of measurement**

phenomenology study using Question Plotting. Only tape recorder will be used in this section

**Intervention groups****1****Description**

Intervention group (Group 1): Receive Shiatsu massages. Shiatsu massage is the method of intervention in this study. Group 1: intervention group will be given a shiatsu massage. Step 1: The massage will be given at the sacral point for a 3-second rotary pressing motion. Step 2: one thumb will be placed on top of the other thumb and pressed for 3 seconds at each pressing point Step 3: the mother's hand is wrapped around the working hand to provide support. The mother will be represented by the thumb and fingers. and press for 3 seconds at each pressing point Step 4: The second knuckle index finger is placed at the highest holy point, and then with the massager body weight, the knuckle will be rotated in a straight line down the sacrum.

**Category**

Treatment - Other

**2****Description**

Control group (Group 2): The pregnant women only receive usual care during pregnancy at labor.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

The Ramlah Parjib Maternity Clinic

**Full name of responsible person**

Hestri Norhafipah

**Street address**

Jl. Kadrie Oening Gang Monalisa No.77, Air Hitam, Kec. Samarinda Ulu, Kota Samarinda, Kalimantan Timur 75243, Indonesia

**City**

Samarinda

**Postal code**

75243

**Phone**

+62 812-5815-2918

**Email**

hestrinorhapifah@itkeswhs.ac.id

**2****Recruitment center****Name of recruitment center**

The Kartika Jaya Maternity Clinic

**Full name of responsible person**

Hestri Norhafipah

**Street address**

Jl. Merdeka 3 No.014, RT.088, Sungai Pinang Dalam, Kec. Sungai Pinang, Kota Samarinda, Kalimantan Timur 75117, Indonesia

**City**

Samarinda

**Postal code**

75117

**Phone**

+62 812-5815-2918

**Email**

hestrinorhapifah@itkeswhs.ac.id

**3****Recruitment center****Name of recruitment center**

The Aminah Amin Rianta Maternity Clinic

**Full name of responsible person**

Hestri Norhafipah

**Street address**

Jl. Merdeka 1, Sungai Pinang Dalam, Kec. Samarinda Utara, Kota Samarinda, Kalimantan Timur 75117, Indonesia

**City**

Samarinda

**Postal code**

75117

**Phone**

+62 812-5815-2918

**Email**

hestrinorhapifah@itkeswhs.ac.id

**4****Recruitment center****Name of recruitment center**

The Ayu Husada Maternity Clinic

**Full name of responsible person**

Hestri Norhafipah

**Street address**

Jalan Poros Samarinda Anggana, Sambutan, Kec. Sambutan, Kota Samarinda, Kalimantan Timur 75115, Indonesia

**City**

Samarinda

**Postal code**

75115

**Phone**

+62 812-5815-2918

**Email**

hestrinorhapifah@itkeswhs.ac.id

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yayasan Wiyata Husada Samarinda

**Full name of responsible person**

Mujito Hadi

**Street address**

Jl. Kadrie Oning Gg Monalisa, No 77 Samarinda

**City**

Samarinda

**Postal code**

75243

**Phone**

+62 821-4829-2967

**Email**  
hestrinorhapifah@itkeswhs.ac.id

**Grant name**  
Yayasan Wiyata Husada Samarinda

**Grant code / Reference number**  
0096/Con/II.a/YWHS/XII/2020

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Yayasan Wiyata Husada Samarinda

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**  
institut teknologi kesehatan wiyata husada samarinda

**Full name of responsible person**  
Hestri Norhapifah

**Position**  
Lecturer

**Latest degree**  
Master

**Other areas of specialty/work**  
Midwifery

**Street address**  
Jl. Kadrie Oening Gang Monalisa No.77, Air Hitam,  
Kec. Samarinda Ulu, Kota Samarinda, Kalimantan  
Timur 75243, Indonesia

**City**  
Samarinda

**Province**  
East Kalimantan

**Postal code**  
75243

**Phone**  
+62 812-5815-2918

**Email**  
hestrinorhapifah@itkeswhs.ac.id

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
institut teknologi kesehatan wiyata husada samarinda

**Full name of responsible person**  
Hestri Norhapifah

**Position**  
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**Postal code**  
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+62 812-5815-2918

**Email**  
hestrinorhapifah@itkeswhs.ac.id

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
institut teknologi kesehatan wiyata husada samarinda

**Full name of responsible person**  
Hestri Norhapifah

**Position**  
Lecturer

**Latest degree**  
Master

**Other areas of specialty/work**  
Midwifery

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**Phone**  
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**Email**  
hestrinorhapifah@itkeswhs.ac.id

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

**Title and more details about the data/document**

Exploring the Role of a Shiatsu Massage as a Pain Relief in Labor. All collected deidentified IPD. IPD will be collected for the primary and secondary outcomes only.

**When the data will become available and for how long**

Starting 1st July 2022

**To whom data/document is available**

This is only available for researchers and researchers' institutions.

**Under which criteria data/document could be used**

Data will be kept confidential by the principal investigator and can only be shared by the team

members. Data will be analyzed using statistical software. Any access to the data must obtain permission from all team members.

**From where data/document is obtainable**

data will be collected from pregnant women in labor.

Data will be kept confidential by the principal investigator. Any permission needs to contact the principal investigator.

**What processes are involved for a request to access data/document**

Any information about the data needs to contact the principal investigator for permission.

**Comments**