

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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
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 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

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

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