Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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. physiatric 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

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Malaysia

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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 physiatric 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

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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 duirng 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

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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

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hestrinorhapifah@itkeswhs.ac.id

3

Recruitment center

Name of recruitment center

The Aminah Amin Rianta Maternity Clinic

Full name of responsible person

Hestri Norhafipah

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

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4

Recruitment center

Name of recruitment center

The Ayu Husada Maternity Clinic

Full name of responsible person

Hestri Norhafipah

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yayasan Wiyata Husada Samarinda

Full name of responsible person

Mujito Hadi

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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 Norhafipah
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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