

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### Effect of massage therapy on depression in pregnant women with mild depression

#### Protocol summary

##### Summary

This study is a randomized controlled clinical trial. The aim of this study is to evaluate the effect of massage therapy on depressive symptoms during pregnancy. The inclusion criteria included Gestational age less than 32 weeks ; Having a score greater than 9 and less than 18 from the Beck Depression Inventory; No history of medical or psychiatric disease; The lack of any medical or obstetrical complications in the current pregnancy; No history of miscarriage or preterm labor in previous pregnancies; ; No smoking; Singleton pregnancy and exclusion criteria include: The occurrence of side effects; The use of sedation drugs or relaxation techniques during study; Absence in the intervention sessions more than 2 sessions. The research site is all health centers in the city of ilam. The sampling is easy and allocation of Samples in each intervention and control groups will be randomly. In the massage group the interventions including stroke massage on the back, which is done by the researcher. The intervention is carried out in health centers and be done with Vaseline oil. This intervention will be 6 sessions (three consecutive weeks, during two consecutive days each time for 20 minutes). No procedure will be performed in the control group. To assess the effects of massage therapy on symptoms of depression, Beck depression scale before, immediately after the intervention and four weeks after the intervention is completed by participants in the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013021112440N1**

Registration date: **2014-02-19, 1392/11/30**

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

Last update:

Update count: **0**

##### Registration date

2014-02-19, 1392/11/30

##### Registrant information

###### Name

Ziba Taghizade

###### Name of organization / entity

Tehran University of Medical Sciences school of nursing and midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8824 4694

###### Email address

taghizad@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Tehran University of Medical Science

##### Expected recruitment start date

2014-01-16, 1392/10/26

##### Expected recruitment end date

2014-04-15, 1393/01/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of massage therapy on depression in pregnant women with mild depression

##### Public title

The effect of massage therapy on depression during pregnancy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Gestational age less than 32 weeks based on reliable LMP or ultrasound before 20 weeks of gestation in those who do not know your LMP; Having a score greater than 9 and less than 18 from the Beck Depression Inventory (mild depression); No history of recognized chronic or systemic disease; No personal or family history of mental illness or hospitalization due to recognized mental illness; The lack of any medical or obstetrical complications in the current pregnancy; No history of miscarriage or preterm labor in previous pregnancies; Not experienced stressful events during the 6 months before study; No smoking and drugs and do not drinking alcohol; Singleton pregnancy; Spontaneous pregnancy; No wound, infection or any other lesion on the back. Exclusion criteria: The occurrence of side effects such as a reaction to the oil used during the intervention; Occurrence of any stressful event during the study; The use of sedation drugs or relaxation techniques during study; Absence in the intervention sessions more than 2 sessions.

**Age**From **16 years** old to **49 years** old**Gender**

Female

**Phase**

2-3

**Groups that have been masked***No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

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**

Ethics Committee of Tehran University of Medical Science

**Street address**

Vice Chancellor for Research, Tehran University of Medical Science, Ghods St, Keshavarz Bv.

**City**

Tehran

**Postal code****Approval date**

2013-06-01, 1392/03/11

**Ethics committee reference number**

130/399/92/5

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

Mild depressive Disorder

**ICD-10 code**

F32.0

**ICD-10 code description**

Mild depressive episode

**Primary outcomes****1****Description**

Depression score

**Timepoint**

Before the intervention, immediately after intervention and 4 weeks after intervention

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes**

empty

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

Intervention group: The interventions including stroke massage on the back, which is done by the researcher (After training under the supervision of traditional medicine And obtain the required certificate to do it). The intervention is carried out in health centers and be done with Vaseline oil. This intervention will be 6 sessions (Three consecutive weeks, during two consecutive days each time for 20 minutes)

**Category**

Treatment - Other

**2****Description**

Control group : No procedure will be performed in the control group

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Number one urban health center

**Full name of responsible person**

**Street address**

Next to Tarbiat school, Ayatollah Haidari St.

**City**

Ilam

**2**

**Recruitment center**

**Name of recruitment center**

Number two urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Behind Vali Castle, Takhti St.

**City**

Ilam

**3**

**Recruitment center**

**Name of recruitment center**

Number three urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Shahid Hemmat karami st, Intersection Resalat.

**City**

Ilam

**4**

**Recruitment center**

**Name of recruitment center**

Number seven urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Beasat street, Jomhori Boulevard.

**City**

Ilam

**5**

**Recruitment center**

**Name of recruitment center**

Number four urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Imam Northern Blvd.

**City**

Ilam

**6**

**Recruitment center**

**Name of recruitment center**

Number five urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Edalat street.

**City**

Ilam

**7**

**Recruitment center**

**Name of recruitment center**

Number Six urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Below the Shahid Mustafa Khomeini Hospital.

**City**

Ilam

**8**

**Recruitment center**

**Name of recruitment center**

Number eight urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Edalat street

**City**

Ilam

**9**

**Recruitment center**

**Name of recruitment center**

Number nine urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Alleys Abdullahi, Street 24 yard.

**City**

Ilam

**10**

**Recruitment center**

**Name of recruitment center**

Number ten urban health center

**Full name of responsible person**

Zohre Ahmadi

**Street address**

Hor street.

**City**

Ilam

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Cheraghi

**Street address**

Vice Chancellor for Research, Tehran University of  
Medical Sciences. Ghods St. Keshavarz Bv.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Tehran University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zohre Ahmadi

**Position**

MSc student

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**Position**

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**City**

Ilam

**Postal code**

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**Phone**

+98 84 1334 1520

**Fax****Email**

zohre.ahmadi7025@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*