

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

**A comparative study on the effects of a self-care educational program on the effleurage massage with foot immersion and raised legs on foot physiological edema during pregnancy.**

### Protocol summary

#### Study aim

To determine and compare the effect of self-care training with foot floss massage, hydrotherapy and raised legs on physiological edema of the foot in pregnant women

#### Design

A randomized controlled clinical trial and 140 samples that are collected in stages. First, the selection of treatment centers is purposeful and then the selection of intervention days is randomly collected from three different treatment centers separately. For each intervention group, a sample is collected from one medical center and for the control group, 12 samples are collected from each center.

#### Settings and conduct

This study in the field of complementary medicine will be performed with the aim of reviewing and comparing self-care training with massage therapy, hydrotherapy and keeping the legs high, which has three intervention groups and a control group. The sample size for each group is 35 people, for each of which The intervention groups will be collected from the medical center separately and for the control group in the form of 12 samples from each medical center. In order to randomize the intervention days, Excel software is used as a function of random numbers and the days of the week are randomly determined for each group, so that the samples of each group will be unaware of how other interventions are performed.

#### Participants/Inclusion and exclusion criteria

Primiparous pregnant women referred to Mahdieh, Arash and Akbarabadi medical centers in Tehran who are eligible for inclusion in the study

#### Intervention groups

massage therapy,hydrotherapy,raised legs,control

#### Main outcome variables

Degree of foot edema,circumferences of ankle jointe, inste and metatarsophalangeal joint

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220302054163N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **prospective**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

#### Registration date

2022-03-14, 1400/12/23

#### Registrant information

##### Name

Fatemeh Asadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6620 4258

##### Email address

fatmhasdy817@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-03-21, 1401/01/01

#### Expected recruitment end date

2023-03-21, 1402/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

A comparative study on the effects of a self-care educational program on the effleurage massage with foot immersion and raised legs on foot physiological edema during pregnancy.

## Public title

The effect of massage therapy, hydrotherapy and raised legs on foot edema in pregnancy by self-care method

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

1. Pregnancy is primiparous 2. The age range is 20 to 35 years 3. Be a single pregnancy 4. Pregnancy is not the result of ART 5. The gestational age is between 30 and 40 weeks 6. Has physiological edema of the foot (in the range of +2 and more) 7. The mother does not have gestational hypertension and preeclampsia 8. The mother does not have any known systemic diseases (such as heart disease, kidney disease, lung disease, diabetes, chronic hypertension and thrombophlebitis). 9. The mother should not have rope varicose veins in the foot area. 10. No lesions are visible at the site of massage and hydrotherapy Do not take drugs that affect foot edema, such as furozamide, hydrochlorothiazide, acetazolamide and triamterene.

### Exclusion criteria:

1. The onset of gestational hypertension and preeclampsia 2. Reluctance to participate in the study and non-cooperation of the research sample at any time of the study 3. termination of pregnancy and preterm delivery for any reason 4. Failure to intervene in more than one case

## 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: **140**

## Randomization (investigator's opinion)

Randomized

## Randomization description

the sample size for each of the intervention and control groups is staged. first, the choice of treatment centers, purposefully, and then the selection of intervention days are collected randomly from three different treatment centers separately. For each of the intervention groups, the sample size will be collected from a medical center and for the control group, 12 samples will be collected from each center. In the process of randomizing intervention days, Excel computer software, random numbers function will be used.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Research Schools of Pharmacy, Nursing and Midwifery - Shahid Beheshti University

##### Street address

No.1, South Sajad jonoubi Ave, Khodayar hasani Ave, Chahardooli Blvd, Tehran Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1369636438

#### Approval date

2022-02-22, 1400/12/03

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.307

## Health conditions studied

### 1

#### Description of health condition studied

Physiological pitting edema in pregnancy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Degree of foot edema

#### Timepoint

First time: the first day of sample referral to the research environment and before the intervention, the second time: the day after the intervention

#### Method of measurement

the researcher places the index finger on the inner ankle of the specimen for 5 seconds and presses it if the indentation depth is greater than 2 mm to 4 mm and disappears in less than 15 seconds is second degree edema of the foot. If the depth of the depression is more than 4 mm to 7 mm and disappears in 15 to 30 seconds, edema of the foot is third degree. If the depth of the depression is more than 7 mm and it takes more than 30 seconds for it to disappear, the edema of the foot is grade 4.

## 2

### **Description**

ankle joint circumference

### **Timepoint**

First time: the first day of sample referral to the research environment and before the intervention, the second time: the day after the intervention

### **Method of measurement**

Inelastic meters

## 3

### **Description**

instep circumference

### **Timepoint**

First time: the first day of sample referral to the research environment and before the intervention, the second time: the day after the intervention

### **Method of measurement**

Inelastic meters

## 4

### **Description**

metatarsophalangeal joint circumference

### **Timepoint**

First time: the first day of sample referral to the research environment and before the intervention, the second time: the day after the intervention

### **Method of measurement**

Inelastic meters

## **Secondary outcomes**

## 1

### **Description**

ankle joint circumference

### **Timepoint**

First time: on the first day of sample referral with the research environment - Second time: one day after the intervention

### **Method of measurement**

Inelastic meters

## 2

### **Description**

metatarsophalangeal joint circumference

### **Timepoint**

First time: on the first day of sample referral with the research environment - Second time: one day after the intervention

### **Method of measurement**

Inelastic meters

## 3

### **Description**

instep circumference

### **Timepoint**

First time: on the first day of sample referral with the

research environment - Second time: one day after the intervention

### **Method of measurement**

Inelastic meters

## 4

### **Description**

age

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

Demographic Questionnaire

## 5

### **Description**

Job

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

Demographic Questionnaire

## 6

### **Description**

Education rate

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

Demographic Questionnaire

## 7

### **Description**

Next visit time

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## 8

### **Description**

Gestational age

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## 9

### **Description**

Number of pregnancy visits

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## **10**

### **Description**

walking

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## **11**

### **Description**

Standing time during the day

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## **12**

### **Description**

Add salt to the tablecloth

### **Timepoint**

On the first day of sample referral to the research environment, before the intervention

### **Method of measurement**

questionnaire

## **13**

### **Description**

Satisfaction with treatment

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **14**

### **Description**

Satisfaction with training

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **15**

### **Description**

Redness of the feet

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **16**

### **Description**

Inflammation of the foot

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **17**

### **Description**

leg pain

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **18**

### **Description**

Foot burning

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **19**

### **Description**

Itching in place

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **20**

### **Description**

Feeling of pain and discomfort in the uterus

### **Timepoint**

The day after the intervention

### **Method of measurement**

Complication and Satisfaction Questionnaire

## **21**

### **Description**

Edema of the foot joint

### **Timepoint**

First time: on the first day of referring the sample to the research environment, second time: on the day after the intervention

### **Method of measurement**

The researcher places the index finger above the inner ankle of the sample foot for 5 seconds and presses there if the indentation depth is more than 2 mm to 4 mm and disappears in less than 15 seconds. The depression is more than 4 mm to 7 mm and disappears within 15 to 30 seconds, the foot edema is third degree. If the depth of the depression is more than 7 mm and it takes more than 30 seconds to disappear, the foot edema is fourth degree. .

## **Intervention groups**

## 1

### Description

Intervention groups: self care with effleurage massage, self care with hydrotherapy, self care with raised legs

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Mahdieh, Arash and Akbarabadi hospitals in Tehran

#### Full name of responsible person

Fatemeh Asadi

#### Street address

Tehran, Shousha Square, Fadaian-e-Islam St., Shishegar Khaneh Alley, Mahdieh Hospital-Tehran, intersection of Shahid Bagheri Highway, Baghdarnia St., Arash Hospital, Tehran, Molavi St., Ferdows Garden Station, Akbarabadi Hospital

#### City

Tehran

#### Province

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#### Phone

+98 21 5506 2628

#### Email

fatmhasdy817@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zargari

#### Street address

Shahid Arbabi St, Yasaman St next to Ayatollah Taleghani Hospital, Shahid Chamran High way, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 2243 9770

#### Email

info@sbmu.ac.ir

#### Web page address

http://sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Shahid Beheshti University of Medical Sciences

### 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

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Masoumeh Simbar

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Midwifery

#### Street address

Tehran, Valiasr St., Niayesh Intersection, in front of Shahid Rajaei Heart Hospital, Shahid Beheshti School of Nursing and Midwifery

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#### Province

Tehran

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#### Phone

+098 21 88655356-7

#### Email

Msimbar@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Masoumeh Simbar

#### Position

Professor

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoumeh Simbar

**Position**

Professor

**Latest degree**

Ph.D.

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of Nursing and Midwifery

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

0098 21 88655366-7

**Email**

Msimbar@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The data remain confidential to the researcher at the beginning of the study

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable

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

In connection with the study protocol, a diagram has been designed which will be completed and shared after the completion of the project. The informed consent form will be completed by the sample before the start of the research

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

Available in the journal after publication

**To whom data/document is available**

All people who are interested in the article

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

Promote complementary medicine and self-care treatments and treat physiological edema of the foot during pregnancy

**From where data/document is obtainable**

Email the responsible author

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

Explain the reasons for requesting the article in the email

**Comments**