Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology and counseling on fatigue in nulliparous pregnant women

Protocol summary

Summary

The main purpose of this study is to determine the effect of consultation and foot reflexology on fatigue on nullparous pregnant women attending health centers in Hamedan. Side goals: 1. Defining the measure of fatigue in pregnant women before and after attending the intervention in 3 main groups. 2. Comparing the average measured fatigue in pregnant women before the intervention in 3 groups. 3. Comparing the average measured in pregnant women after the intervention in 3 groups. Applicable goals: Based on this study's results and if the consultation session is effective on the level of pregnant women's fatigue, it's possible to use this economical and non aggressive procedure along side with prenatal care. The current research is based on a randomized study with before and after the intervention. Around 126 pregnant women with the conditions including: 18-35 Years of Age, first and wanted pregnancy, single fetus with the gestational age of 19 to 29 weeks, after the conscious permission and randomized will be divide in 3 groups of control and experimental. In all 3 groups there will be a 30 to 45 minute introduction session on the steps of consultation (GATHER) on the subject of pre-testing. Then the qualified candidates will receive the fatigue measurement questionnaire form. The pregnant women in the first group in addition to the routine pregnancy care will receive consultation for 5 weeks (30 minutes per session - 2 times per week). At the beginning of each session, 15 minutes will be allocated to consultation and then the reflexology procedure will be applied for the rest of the session. The pregnant women in the second group in addition to the routine pregnancy care will receive consultation for 5 weeks (30 minutes per session - 2 times per week). The pregnant women in the third group(control) will receive the routine pregnancy care. At the end of week 5 all 3 group will fill out the the fatigue measurement questionnaire form. The pregnant women whom due to pregnancy issues including abnormal fetus heart patterns, reduction in feats moment, bleeding, the change in the mental and emotional state, etc whom need medical intervention will be excluded from the study. The reduction of fatigue levels will be considers at the outcome of this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508156888N11**
Registration date: **2015-10-18, 1394/07/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-18, 1394/07/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of foot reflexology and counseling on fatigue in nulliparous pregnant women

Public title
The effect of counseling and foot reflexology on fatigue in women in the first pregnancy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: The age range between 18 to 35 years old; First pregnancy and wanted pregnancy; single fetus with the ages of 19 to 29 weeks; not having mental disorders; The absence of the children or disabled spouse. Exclusion criteria: Abnormal fetal heart rate patterns and decreased fetal movements in a way that may require medical intervention; The change in the mental and emotional state
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **126**
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
Research Ethics Committee of Hamadan University of Medical Sciences
Street address
Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran
City
Hamadan
Postal code
65178
Approval date
2015-07-25, 1394/05/03
Ethics committee reference number
IR.UMSHA.REC.1394.214

Health conditions studied

1

Description of health condition studied
Fatigue
ICD-10 code
o26.8
ICD-10 code description
Exhaustion and fatigue

Primary outcomes

1

Description
Fatigue
Timepoint
Weeks 19-29
Method of measurement
Czech list fatigue assessment

Secondary outcomes

1

Description
Consulting and foot reflexology
Timepoint
Weeks 19-29
Method of measurement
Czech list fatigue assessment

Intervention groups

1

Description
The pregnant women in the first group in addition to the routine pregnancy care will receive consultation for 5 weeks (30 minutes per session - 2 times per week). At the beginning of each session, 15 minutes will be allocated to consultation and then the reflexology procedure will be applied for the rest of the session. The reflexology procedure requires the test subject to lay down on a examination bed in a quite and bright room with closed eyes in a relax position. Then after the most foot massage with the left hand hold the heels and with pressure towards the bottom of the feet while rotating the entire foot around the ankle by pressuring the solar plexus with the thumb . This procedure will take around 30 minutes for both feet and then the test subject is

required to drink a lot of liquid for 24 to 48 hours after each session.

Category

Other

2

Description

The pregnant women in the second group in addition to the routine pregnancy care will receive consultation for 5 weeks (30 minutes per session - 2 times per week).

Category

Other

3

Description

The pregnant women in the third group(control) will receive the routine pregnancy care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Healthcare center Samii 9

Full name of responsible person

Behnaz Manochehri

Street address

Madani settlements

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Bashirian Saeed

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Department of Research and Technology

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

Other areas of specialty/work

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Person responsible for updating data

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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