

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effects of counselling on progressive muscle relaxation on anxiety among primigravida women referred to health care centers in Hamadan, 2015

Protocol summary

Summary

The main purpose: Effects of counselling on progressive muscle relaxation on anxiety among primigravida women referred to health care centers in Hamadan, 2015

Secondary objectives

- 1- Comparison of anxiety (explicit and implicit) before and after the intervention in the experimental group
- 2- Compare anxiety (explicit and implicit) in both experimental and control groups before the intervention, progressive muscle relaxation
- 3- Compare anxiety (explicit and implicit) in both experimental and control groups after the intervention of progressive muscle relaxation

Practical purposes: the results of this study can provide counseling program of muscle relaxation to reduce anxiety in pregnant women. This study is a semi experimental with two groups (experimental and control) with pre-test and post-test. Eligible women were referred to health centers in Hamedan city who experience their first pregnancy consecutively enrolled in the study, after obtaining informed consent. They were randomly assigned to intervention and control groups with regard to Allocation concealment. In this research, consulting in the counseling process (GATHER) during the 60-45 minute sessions will be held in two weeks. Both group will completed anxiety questionnaire in weeks 21-22. The control group only will receive routine prenatal care But experimental group in addition to routine pregnancy care will be trained muscle relaxation exercises. The experimental group was asked to do exercises at home from 21-22 weeks with the help of CD and booklets for 10 weeks, twice a day for 20 minutes each time (morning and evening) And complete the visual analog scale form to determine the relaxation. Performance of both groups at weeks 24-23 and 32-31 were evaluated again using the checklist. Inclusion criteria: The age range 18-35 years :first pregnancy and wanted pregnancy :single fetus and gestational age 22-21week :not having mental disorders, according to a psychiatrist :not having gestational diabetes, preeclampsia, bleeding, premature

rupture of membran...! ability to participate in educational classes: Minimum ability to Reading and writing: not having difficulty of hearing and vision: Not taking antidepressants : Having mild, moderate, or high anxiety exclusion criteria: Any problems in pregnancy during the study period (abruption, fetal abnormal situation, cord prolapse, bleeding, diabetes, hypertension, preterm labor and ...) Abnormal fetal heart rate patterns and decreased fetal movements in a way that may require medical intervention: unwillingness to continue cooperation: major mental and emotional changes (such as death or serious disputes)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412066888N6**
Registration date: **2015-04-19, 1394/01/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-19, 1394/01/30

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences, Department of Research and Technology

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of counselling on progressive muscle relaxation on anxiety among primigravida women referred to health care centers in Hamadan, 2015

Public title

Effects of counselling on progressive muscle relaxation on anxiety among primigravida women referred to health care centers in Hamadan, 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age range 18-35 years :first pregnancy and wanted pregnancy :single fetus and gestational age 22-21week :not having mental disorders, according to a psychiatrist :not having gestational diabetes, preeclampsia, bleeding, premature rupture of membran...: ability to participate in educational classes:Minimum ability to Reading and writing:not having difficulty of hearing and vision:Not taking antidepressants :Having mild, moderate, or high anxiety exclusion criteria:Any problems in pregnancy during the study period (abruption, fetal abnormal situation, cord prolapse, bleeding, diabetes, hypertension, preterm labor and ...) Abnormal fetal heart rate patterns and decreased fetal movements in a way that may require medical intervention: unwillingness to continue cooperation: major mental and emotional changes (such as death or serious disputes)

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: **120**

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

2015-01-21, 1393/11/01

Ethics committee reference number

5351/9/35/16/پ

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

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is

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

Anxiety

Timepoint

weeks 21-22 and 31-32

Method of measurement

Spielberger Anxiety Inventory (STAI)

Secondary outcomes**1****Description**

progressive muscle relaxation

Timepoint

week 23-24 and 31 -32

Method of measurement

Checklist

Intervention groups

1

Description

doing exercises at home from 21-22 weeks with the for 10 weeks, twice a day for 20 minutes each time (morning and evening)

Category

Other

2

Description

The control group will receive regular prenatal care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Healthcare center Samii 9

Full name of responsible person

masoome taravati

Street address

Madani settlements

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences, Department of Research and Technology

Full name of responsible person

fateme asgari

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, Department of Research and Technology

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

Street address

No. 307, Fahmideh Street, Hamadan University of Medical sciences

City

Hamadan

Postal code

65178/518

Phone

+98 81 3827 6051

Fax

Email

shobeiri@umsha.ac.ir

Web page address

Person responsible for scientific 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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Web page address

Person responsible for updating data

Contact

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No. 307, Fahmideh Street, Hamadan University of
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+98 818276051

Fax

Email

shobeiri@umsha.ac.ir

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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