

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect progressive muscle relaxation technique versus control group on the fear related to pregnancy and childbirth in primiparous women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of progressive muscle relaxation technique versus control group on the fear related to pregnancy and childbirth in primiparous women

Design

This is a randomized clinical trial, in which 60 eligible primiparous women will be randomly assigned to the intervention and control groups

Settings and conduct

The primiparous women who will refer to Comprehensive health Centers in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 30 years, Gestational age of 29 to 32 weeks, Monogamy, Primiparous women, Being literate, A resident of Hamadan, Ability to do exercises for 20 minutes daily, Exclusion criteria: Using opium or psychotropic drugs, Mental disorders, Pregnancy complications, Fetal malformation

Intervention groups

Intervention group: Routine prenatal care plus educating progressive muscle relaxation techniques for 30 minutes twice a week for 4 weeks Control group: Just routine prenatal care

Main outcome variables

The fear related to pregnancy and childbirth

General information

Reason for update

Change in methods due to logistic limitation

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N317**
Registration date: **2019-11-25, 1398/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-27, 1402/05/05**

Update count: **2**

Registration date

2019-11-25, 1398/09/04

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect progressive muscle relaxation technique versus control group on the fear related to pregnancy and childbirth in primiparous women: a randomized clinical

trial

Public title
Effect progressive muscle relaxation technique versus control group on the fear related to pregnancy and childbirth in primiparous women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 30 years, Gestational age of 29 to 32 weeks, Monogamy, Primiparous women, Being literate, Resident of Hamadan, Ability to do exercises for 20 minutes daily,
Exclusion criteria:
Using opium or psychotropic drugs, Mental disorders, Pregnancy complications, Fetal malformation

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City

Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-10-26, 1398/08/04
Ethics committee reference number
IR.UMSHA.REC.1398.616

Health conditions studied

1

Description of health condition studied
Fear related to pregnancy and childbirth
ICD-10 code
F40.298
ICD-10 code description
Other specified phobia

Primary outcomes

1

Description
The fear related to pregnancy and childbirth
Timepoint
Before the intervention and 4 weeks after that
Method of measurement
Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine prenatal care plus educating progressive muscle relaxation techniques for 30 minutes twice a week for 4 weeks
Category
Other

2

Description
Control group: Just routine prenatal care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health Centers in Hamadan city
Full name of responsible person

Fatemeh Zarin Moosapoor

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

aakbari4973@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Zarin Moosapoor

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Hamadan University
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Zarin Moosapoor

Position

Student of Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available