Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
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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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Person responsible for updating data

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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