

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of relaxation techniques with spiritual interventions on the level of anxiety in nulliparous women

Protocol summary

Study aim

The effect of spirituality-based relaxation techniques on the anxiety of nulliparous women

Design

Clinical trial, with intervention and control groups, with parallel, randomized groups

Settings and conduct

Venue: Health centers, holding 8 training sessions for the intervention group, before and after the intervention for both groups, the questionnaire will be completed.

Participants/Inclusion and exclusion criteria

Admission requirements: Eligible nulliparous women referring to Shiraz health centers-Native women more than 15 weeks pregnant's week-Iranian citizenship and diploma level higher-nulliparous women with moderate to mild anxiety level (based on Beck score anxiety questionnaire 25 and less) - Willingness to participate in the study and - Not having a high-risk pregnancy (multiple births, fetal problems, etc.) - No history of specific illness (physical or mental) or taking certain medications in the mother - Not participating in educational, relaxation or physiological classes in other centers - age 18-40 years. Exclusion criteria: Participants' dissatisfaction with continuing to participate in the study in any of the research stages - Occurrence of any disease during pregnancy that takes the participant out of the normal course of pregnancy. - Occurrence of any complications or stressful events during pregnancy - Non-compliance with the study protocol (Absence of more than one session in training classes)

Intervention groups

Intervention group: holding training workshops, control group: without intervention

Main outcome variables

Anxiety rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140622018187N11**
Registration date: **2020-08-11, 1399/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Sedighe Forouhari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 987136474257

Email address

foruharis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relaxation techniques with spiritual interventions on the level of anxiety in nulliparous

women

Public title

The effect of relaxation techniques with spiritual interventions on the level of anxiety in nulliparous women referred to health centers affiliated to Shiraz University of Medical Sciences 98-99

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Eligible primiparous women referring to Shiraz health centers-Primiparous women with more than 15 weeks of gestation-Iranian citizenship and diploma level higher-Primary primiparous women with moderate to mild anxiety level (according to Beck Anxiety Questionnaire score 25 and less It) - willingness to participate in the study and - not having a high-risk pregnancy (multiple births, fetal problems, etc.) - no history of a specific disease (physical or mental) or taking a specific drug in the mother - no participation in educational, relaxation or physiological classes in other centers - age 18-40 years

Exclusion criteria:

Dissatisfaction of participants to continue participating in the study in any of the research stages - Occurrence of any disease during pregnancy that takes the participant out of the normal course of pregnancy. - Occurrence of any complications or stressful events during pregnancy - Non-compliance with the study protocol From a session in training classes)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The population of eligible women is randomly assigned to two groups using a random permutation block design. The groups are placed and if the numbers 5 to 9 are observed, two people are placed in two groups as BA permutations and we repeat this until we have 48 people in each group. Thus, the samples are divided into two groups A (intervention group) And group B (control group) are divided. Women are also informed that they will be accidentally placed in one of the groups.

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 Shiraz University of Medical Sciences

Street address

Fatemeh School of Nursing and Midwifery, Namazi Hospital, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2018-10-12, 1397/07/20

Ethics committee reference number

IR.SUMS.REC.1398.1003

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety

Primary outcomes

1

Description

Anxiety in pregnant women

Timepoint

Before and after the workshop

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the pre-intervention stage, the researcher will explain the stages and manner of the research and its objectives, and then provide the participants with an ethical consent form, then the participants of the intervention group will be asked to

participate in the prepared sessions. . The control group will also participate in routine classes that are performed in health centers (in the form of CDs provided by childbirth preparation classes). Training in the intervention group is spiritual relaxation based on virtual training and using Social networks are held in 8 sessions of less than 60 minutes and groups of 20 to 30 people. In addition, in the intervention group, a booklet of homework is provided to the participants to spend 20-30 minutes daily to do their daily homework and exercises.

Category

Lifestyle

2**Description**

Control group: In the control group, relaxation is done with the usual method in the form of training CDs of childbirth preparation classes and individually or in groups, which is done according to the routine of the centers.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health centers (public and private) affiliated to the University of Medical Sciences

Full name of responsible person

Sedighe Forouhari

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Shiraz University of Medical Science, Zand Street, Shiraz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Unes Ghasemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Sedighe Forouhari

Position

Ph.D , Supervisor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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

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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