Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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

Street address

Shiraz University of Medical Science, Zand Street, Shiraz

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71345-1978

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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

Street address

Technology and Research Office, Research Deputy , Shiraz University of Medical Science, Zand Street, Shiraz

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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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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