

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison the effect of teaching attachment and relaxation techniques on perception of fetal movement , non stress test,anxiety level and amount of attachment in nulliparous women referred to selected hospital supervised by Shiraz Medical University 1391.

Protocol summary

Summary

The goal of this study is to Compare the effect of teaching attachment and relaxation techniques on the perception of fetal movement and non stress tests , anxiety and Maternal- Fetal Attachment level, in nulliparous women .In this study have participated 126 women with age between 18 - 35 that Spielberg score is 60 and lower that are randomly in three groups,teaching attachment techniques classes, relaxation classes and control .There are 14 women in every classes and each section will be held weekly up to 4 sections. Spielberg and Cranlly test will fill twice (beginning and end of study) in three groups and also weekly fetal movements forms are given to every women in three groups.In 4th week in intervention groups ,NST is taken 30 min before and after class. (In control group NST is taken in 4th week of study).After the study done ,anxiety , attachment ,fetal movement and NST will evaluate.In control groups Telephone follow-up will be done and after the study a teaching note will given to each women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072810418N1**

Registration date: **2012-08-19, 1391/05/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-08-19, 1391/05/29

Registrant information

Name

Bahare Raffiee

Name of organization / entity

Shiraz University Of Medical Scince

Country

Iran (Islamic Republic of)

Phone

+98 71 1230 6790

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of teaching attachment and relaxation techniques on perception of fetal movement , non stress test,anxiety level and amount of attachment in nulliparous women referred to selected hospital supervised by Shiraz Medical University 1391.

Public title

The effect of teaching attachment and relaxation techniques on anxiety and non stress test (NST)

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion Criteria: 1.nulliparous women with age between 18-35 : Without any history of mental and anatomical diseases : Without any pregnancy complications : Any history of chronic diseases : At least Third literacy tips :Willingness to participate : Signing in hospital to receiving perinatal care : low to moderate anxiety according to Spielberg tes : Do not have any history of taking tobacco. Exclusion criteria ; Don't want to take part in study any more : Occur any pregnancy complications during study : Abnormal fetal heart pattern or decrease fetal movement that needs to interfere : Taking tobacco.

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: **126**

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

1
Registry name
Shiraz Medical School Of Science
Secondary trial Id
91-6110
Registration date
1391-05-03, 773/01/-1051

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Shiraz University Of Medical Sciences
Street address
Central department of Shiraz University Of Medical Sciences,Zand Street, Shiraz
City
shiraz
Postal code

197871345
Approval date
2012-07-24, 1391/05/03
Ethics committee reference number
6110-91

2

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University Of Medical Sciences
Street address
Central department of Shiraz University Of Medical Sciences,Zand Street, Shiraz
City
Shiraz
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
91-6110

Health conditions studied

1
Description of health condition studied
pregnancy and anxiety
ICD-10 code
Z34 , f41.
ICD-10 code description
suprvision of normal pregnancy,generalized anxiety disorder

Primary outcomes

1
Description
anxiety
Timepoint
At the start of intervention- After intervention
Method of measurement
Spielberger questionnaire

2
Description
fetal maternal attachment
Timepoint
Befor of intervention- After intervention
Method of measurement
cranlly questionnaire

3
Description
Fetal movement
Timepoint
Weekly for 4 weeks
Method of measurement

Fetal movements forms

4

Description

Electrocardiographic factors (basal fetal heart rate ,acceleration)

Timepoint

4th week

Method of measurement

NST evaluation

Secondary outcomes

1

Description

Decrease anxiety level

Timepoint

Befor and after intervention (2 times)

Method of measurement

Spielberger questionnaire

2

Description

Increase fetal maternal attachment level

Timepoint

Befor and after intervention

Method of measurement

Cranlly questionnaire

3

Description

Reinforce NST

Timepoint

4TH section

Method of measurement

Interpret non stress test

Intervention groups

1

Description

intervention in second group: relaxation classes in 4 sections for a month. every section lasts for 60 to 90 min. first section: general meaning of stress ,symptoms,ways to control and relaxation meaning. second section: to get familiar with a suitable place for relaxation.third section: muscle relaxation and positive visualization section 4: breathing techniques and review of complete relaxation

Category

Behavior

2

Description

intervention in first group: teaching attachment techniques for a month (4 section weekly). first section:

to get familiar to attachment meaning . second section: to get familiar with different kinds of attachment techniques. 3th section: to get familiar with mental and physical changes in pregnancy. 4th section: to get familiar with paternal role to be connected with fetus

Category

Behavior

3

Description

control group: the summary of whole teaching topics in the form of note afte the study will done.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Marziye Akbar Zade

Street address

Hafez Hospital, Abiverdi Squer, Shiraz, Fars

City

Shiraz

2

Recruitment center

Name of recruitment center

Shooshtari Hospital

Full name of responsible person

Khadije Abdali

Street address

Shooshtari Hospital, Shariaty Squer, Shiraz, Fars.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

DR. Gholam Reza Hatam

Street address

7th Flat, Central department of Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research, Shiraz University of Medical Sciences

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**

Fatemeh College of Nursing And Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Akbarzadeh

Position

Faculty Member, MSc in Midwifery

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Web page address**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