Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Email address

rafieib@sums.ac.ir

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 و 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
Increae 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
Other areas of specialty/work
Street address
Namazi Square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1647 4258
Fax
Email
akbarzadehmarzieh@ yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemeh (PBUH) College of Nursing and Midwifery Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Akbarzadeh
Position
Faculty Member, MSc in Midwifery
Other areas of specialty/work
Street address
Namazi square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1647 4258
Fax
Email
akbarzadehmarzieh@ yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz University of Medical Sciences
Full name of responsible person
Bahare Raffiee
Position
Student, MSc in Midwifery
Other areas of specialty/work
Street address
Namazi square, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1230 6790
Fax
Email
rafieib@sums.ac.ir b.rafieee@gmail.com
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