The effect of behavioral attachment with relaxation training on mother attachment with fetus and infant in pregnant mothers referring to Shiraz obstetric clinics -2010

Protocol summary

Summary
Mental health during pregnancy has important effect on fetus growing and babies future adaptation. This is a clinical trial research. Participants were 126 first pregnant women between 35-32 weeks, who were recruited from simple sampling method. Participants in the 2 experimental groups (relaxation group and behavioral attachment group) received an intervention that included four sessions of 90 minute classes weekly; include relaxation training and maternal–fetal interactive activities and recording them. The woman in control group received routine prenatal care only. Instruments were used in this study included information form, maternal–fetal attachment, State-trait anxiety inventory. data was analyzed by tests such as: Chi-square test, one way analysis of variance.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201109067497N1
Registration date: 2012-01-05, 1390/10/15
Registration timing: retrospective

Recruitment status
Recruitment complete

Funding source
Shiraz Univecity of Medical Sciences

Expected recruitment start date
2010-05-22, 1389/03/01

Expected recruitment end date
2010-09-23, 1389/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of behavioral attachment with relaxation training on mother attachment with fetus and infant in pregnant mothers referring to Shiraz obstetric clinics -2010

Public title
Relaxation training and attachment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: primipar; age between 18-35; gestational age 32-35 weeks; normal pregnancy; single pregnancy; wanted pregnancy and low and moderate anxiety. Exclusion criteria: heart disease; mental disorder and complication in pregnancy.

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
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Nursing & Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran
Street address
Nursing & Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran
City
Shiraz
Postal code

Approval date
2010-04-18, 1389/01/29

Ethics committee reference number
895099

Health conditions studied

1
Description of health condition studied
Anxiety
ICD-10 code
F40-F48
ICD-10 code description
Neurotic, stress-related and somatoform disorders

Primary outcomes

1
Description
Anxiety and attachment
Timepoint
Start of study, after 4 weeks and first day of delivery

Method of measurement
Anxiety Inventory

Secondary outcomes

1
Description
Complication of pregnancy and delivery
Timepoint
In pregnancy and delivery
Method of measurement
Delivery inventory

Intervention groups

1
Description
Group 1, received an intervention that included four sessions of 90 minute classes weekly, maternal–fetal interactive activities.
Category
Behavior

2
Description
Group 2 (relaxation group), received an intervention that included four sessions of 90 minute classes weekly, Jacobson relaxation training.
Category
Behavior

3
Description
Control group, the woman in control group received routine prenatal care only.
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
Shoshtary hospital
Full name of responsible person
Monireh Tousi
Street address
Shiraz University of Medical Sciences
City
Shiraz

2
Recruitment center
Name of recruitment center
Shoshtary hospital
Full name of responsible person
Street address
Shiraz University of Medical Sciences
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Akbarzadeh
Street address
Shiraz University of Medical Sciences-midwifery
University
City
Shiraz
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
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
Nursing & Midwifery Faculty, Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Akbarzadeh
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Person responsible for updating data

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report