

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of educational anti anxiety protocol based on "Orem Self Care Model"on pregnant mothers anxiety and maternal-newborn attachmen

Protocol summary

Summary

This study is a clinical trial to determine the effect of anti-anxiety educational protocols based on Orem self care model on maternal anxiety and mother-infant attachment indicators is carried out Study population: All first pregnant women with 28-34 weeks gestational age that come to prenatal health care centers for prenatal care. . Inclusion criteria included having 18-35 years old - gestational age between 28-34 week - having mild to high moderate anxiety score - don't having history of mental illness, depression and chronic anxiety - Don't having major stress during the last 6 months and The main exclusion criteria include: the use of certain drugs during pregnancy affect the psyche - occurrence the anxiety-causing agent or incident during pregnancy- non-participation in more than one session of self-care classes.. sample size 34 patients in the control group and 34 patients in the intervention group(68 patients in total) Education program designed in the form of four 60-minute sessions over 4 weeks practical training and on-site training class will be held in selected health centers Given that the maternal mental health is ffective on infant health therfor the results can be compiled classes for women planning pregnancy and by providing relaxation and reduce anxiety in mothers related anxiety problems, such as preterm delivery, preeclampsia, long and painful labor and women's desire to the cesarean section delivery can be reduce and thereby reduce the costs imposed on the economy and family

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112225182N1**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Nahid Shakouri

Name of organization / entity

Mashhad univercity of medical science

Country

Iran (Islamic Republic of)

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shakourin921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational anti anxiety protocol based on "Orem Self Care Model"on pregnant mothers anxiety and maternal-newborn attachmen

Public title

The effect of educationalanti anxiety protocol on pregnant mothers anxiety and maternal-newborn attachment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. Iranian and Persian language and live in Mashhad. 2. Muslim. 3. phone back. 4. at least be literate. 5. age 18-35 years old, 6. gestational age based on LMP or sonography at the first quarter 28-34 gestational week. 7. lives with her husband and her husband's only wife. 8. having mild to moderate score anxiety. 9. obstetric complications in pregnancy is not present. (Hypertension, gestational diabetes, placenta previa, multiple pregnancies, oligohydramnios, pre-eclampsia and polyhydramnios) 10. in the current pregnancy is not a medical problem. (Heart problems, diabetes, chronic hypertension, acute respiratory problems, kidney, thyroid disorders, epilepsy, anemia, sexually transmitted diseases, infectious, neurological, tuberculosis, human immunodeficiency virus, the virus of human T lymphocytes), 11. members of a family don't have genetic abnormalities in the 12. history of infertility no. 13. history of mental illness, depression and chronic anxiety medication because it has not. 14. Mother is alive and healthy. 15. Informed consent to complete. 16. Drug abuse, alcohol and smoking, such as cigarettes and hookah is not. 17. pregnancy is wanted, is the first single. 18. In the field of medical science studying the uneducated or not. 19. During the last 6 months of stress (serious illness or spouse, death of a family member, migration, severe economic conditions, big marital disputes, accident, burglary) is not. Exclusion criteri: 1, use of certain medications effective on psychomotpr system during pregnancy by mother. (Imipramine, diazepam, amitriptyline, phenobarbital, carbamazepine, phenytoin and other drugs that affect mental) 2. Mother's unwillingness to continue cooperation in research. 3-evidence obstetric complications during pregnancy. (Vaginal bleeding, preterm labor, PROM) 4- occurrence of anxiety-causing agent or incident during pregnancy. (Death of close ones, spiritual crises, financial crises and divorce) 5- non-participation In the post-test. 6-- non-participation in more than one session of self-care classes.

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: **68**

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

Mashhad University of Medical Sciences

Street address

Mashhad Iran Student Research Committee, Faculty of Nursing@ midwifery

City

Mashhad

Postal code

Approval date

2015-08-15, 1394/05/24

Ethics committee reference number

IR.MUMS.REC.1394.333

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified Depression:

Primary outcomes

1

Description

Anxiety of Pregnant mother

Timepoint

pre intervention & 1 week after intervention

Method of measurement

Anxiety Inventory (STAI)

2

Description

Mother-infant attachment

Timepoint

1-2 week after intervention

Method of measurement

check list assessment of mother-infant attachment Avant

Secondary outcomes

empty

Intervention groups

1

Description

Self-care education program is designed in the form of four 60-minute sessions within 4 weeks in group discussion, questions and answers, presentation slides and broadcast film methods for groups of 10-15 people in the training class center of Health held by the researcher 15 minutes of the end of each training session, stretching and breathing exercises and relaxation allocated. The intervention group in addition, anti-anxiety Protocol based on Orem self care model receive the central usual care as well as. The group control only receive routine prenatal care that includes weight control, blood pressure monitoring, listen to the heartbeat of a fetus, and pregnancy tests are routinely found in their centers by midwives respected

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Daneshamooz Health Center

Full name of responsible person

Mrs. Ramezani

Street address

Dadaneshamooz Health Center- Vakil Abad Blvd.

City

Mashhad

2

Recruitment center

Name of recruitment center

Motahari health center

Full name of responsible person

Miss Khosravi

Street address

Motahari health center- Sahebalzaman square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences. Deputy of Research and Technology

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Deputy of Research and Technology, Mashhad University of Medical Sciences, Daneshgah St.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences. Deputy of Research and Technology

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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Shakouri

Position

Master student of neonatal intensive care

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Master degree in nursing

Other areas of specialty/work

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Position

Master student of neonatal intensive care

Other areas of specialty/work

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Postal code

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