

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness and non effectiveness of psycho-educational intervention in couples and pregnant women groups on their mental health in selected health centers of Isfahancity,2015

Protocol summary

Summary

This study will be done with aim to comparing the effects of psycho-educational intervention in couples and pregnant women groups on their mental health in selected health centers of Isfahan city in 2015. this is a non blinded clinical trial. The study population will be included pregnant women with gestational age of 21-25 that refers to Navab and Amir Hamzeh and Ibn Sina centers in Isfahan, that 120 persons will selected and randomly (by lottery in three experimental and control groups (two experimental groups and one control group) will be placed. At the beginning of the study General Health Questionnaire (GHQ) and depression, anxiety and stress questionnaire ((Dass42) will provided for the three groups. Then the experimental groups (group of couples and pregnant women) within 4 weeks for 90 minutes will received the mental training and the control group will not receive any education, two weeks after the end of the study, questionnaires will be provided to participants in all three groups and mental health variables, depression, anxiety and stress in all three groups will be compared with each other. Inclusion criteria: Patient's written consent; Pregnant women with wanted pregnancies and first pregnancy; Singleton pregnancy with gestational age 21 to 25 weeks; No history of infertility and infertility treatment. Exclusion criteria: Disease or particular problem during the study; Preterm delivery; The occurrence of sudden and serious stress before completing a second phase questionnaires like (death of relatives, etc.)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012426174N1**
Registration date: **2016-03-15, 1394/12/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-15, 1394/12/25

Registrant information

Name

Zahra Akbarian

Name of organization / entity

Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Esfahan University of Medical Sciences

Expected recruitment start date

2016-03-15, 1394/12/25

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness and non effectiveness of psycho-educational intervention in couples and pregnant

women groups on their mental health in selected health centers of Isfahancity,2015

Public title
The effect of mental training in pregnancy in couples and pregnant women on women's mental health

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Patient's written consent; Pregnant women with wanted pregnancies and first pregnancy; Singleton pregnancy with gestational age 21 to 25 weeks; No acute obstetric and pregnancy-related problems; Lack of psychological illnesses ; No drug addiction of pregnant woman or her husband ; Lack of serious stress in the past 6 months; No history of infertility and infertility treatment. Exclusion criteria: Disease or particular problem during the study; Preterm delivery; The occurrence of sudden and serious stress before completing a second phase questionnaires like (death of relatives, etc.)

Age
From **15 years** old to **32 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomly draw a card

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Hezarjarib Street
City
Esfahan
Postal code

Approval date
2015-10-17, 1394/07/25
Ethics committee reference number
ir.mui.rec.1394.3.556

Health conditions studied

1

Description of health condition studied
Mental health
ICD-10 code
F99
ICD-10 code description
Mental disorder, not otherwise specified

Primary outcomes

1

Description
Mental health
Timepoint
Baseline and two weeks after the end of the study (sixth week)
Method of measurement
According to the General Health Questionnaire (GHQ)

2

Description
Depression
Timepoint
Baseline and two weeks after the end of the study (sixth week)
Method of measurement
According to depression, anxiety and stress (Dass 42)questionnaire

3

Description
Anxiety
Timepoint
Baseline and two weeks after the end of the study (sixth week)
Method of measurement
According to depression, anxiety and stress (Dass 42)questionnaire

4

Description
Stress
Timepoint
Baseline and two weeks after the end of the study (sixth week)
Method of measurement
According to depression, anxiety and stress (Dass 42)questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental groups at the beginning of the study General Health Questionnaire (GHQ) and depression, anxiety and stress questionnaire ((Dass42) will be provided to participants (group of couples and pregnant women). Then within 4 weeks for 90 minutes will received the mental training, two weeks after the end of the study, questionnaires will be provided to participants and mental health variables, depression, anxiety and stress in both groups will be studied.

Category

Behavior

2

Description

In the control group at the beginning of the study General Health Questionnaire (GHQ) and depression, anxiety and stress questionnaires ((Dass42) will be provided to participants but will not receive any education and two weeks after the end of the study, questionnaires will be provided to participants

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center Nawab Safavi

Full name of responsible person

Zahra Akbarian

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Street of Hezarjarib

City

Esfahan

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, Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Akbarian

Position

Student of Ms. Midwifery

Other areas of specialty/work

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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

empty

Analytic Code

empty

Data Dictionary

empty