Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

Effect of couple counseling based on couples post partum depression

Protocol summary

Summary

The aim of this study is to evaluate the effect of couples counseling based on post partum depression after baby's birth . A sample size is of 84 pregnant women and their husbands. 84 pregnant women referred to health centers will be randomly selected, and then will be divided into two intervention and control groups randomly. For the intervention group counseling session from 34 weeks of pregnancy will be held. The number of counseling sessions are 4 sessions. In the control group no intervention will be done. Two months after childbirth, postpartum depression in intervention and control groups will be measured by using a questionnaire Edinburgh. Inclusion criteria: gestational age of 34 weeks and nulliparity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060828340N1**
Registration date: **2016-12-17, 1395/09/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-17, 1395/09/27

Registrant information

Name
Atefeh Yas
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Urmia University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice President of Research of University of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-11-05, 1395/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of couple counseling based on couples post partum depression

Public title

post partum depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria for womens: Nullipar of; Pre-test score of less than 9; The absence of abnormalities in the fetus; Gestational age of 34 weeks; Lack of depression known; Failure stressful event in the past 6 months Inclusion criteria for men :Lack of drug addiction; have a job; Lack of depression known Exclusion criteria:Non-attending counseling; Abnormalities in the baby or infant death; Maternal and child needs special care after birth

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **84**
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
Ethics Committee of the University of Medical Sciences
Street address
Street Jahad ،Urmia
City
Urmia
Postal code
Approval date
2016-06-10, 1395/03/21
Ethics committee reference number
IR.UMSU.rec.1395.102

Health conditions studied

1

Description of health condition studied
postpartum deprassion
ICD-10 code
f53
ICD-10 code description
Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description
postpartum deprassion
Timepoint
Before and four months after the intervention.
Method of measurement
Edinburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will participate in counseling sessions.The meetings will be held with the participation of couples in four sessions
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers
Full name of responsible person
Street address
City
uromia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Assistance for Research and Technology of Urmia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Jahad street
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Assistance for Research and Technology of Urmia 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

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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