

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The Effect of couple counselling Based on marital support on anxiety and worry during pregnancy

Protocol summary

Summary

This study was designed to determine The Effect of couple counselling Based on marital support on anxiety and worry during pregnancy in Health Centers of Urmia University of Medical Sciences in 2015. This experimental study was carried out on 60 pregnancy women by Cluster sampling attending in Health Centers for prenatal care in the city of Urmia who had not previous Hospitalization and known psychological disease. The women completed the consent form and then their anxiety and worry was assessed in before intervention by Spielberger state- trait anxiety inventor, pregnancy worries were measured with the Cambridge Worry Scale. Those women were randomly entered into the study groups (30 Couple in each group). The intervention group (pregnancy women and their husband) in every visit in Once a week was counseled about the different topics of pregnancy and delivery With respect to items of concern, counseling sessions was 6-4 , each session was 45-30 minutes. The non-intervention group received the normal prenatal care. Then the anxiety scores of both groups of women were assessed at 6 weeks after intervention. Average worry and anxiety will be measured and compared before and after the intervention in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052620778N2**

Registration date: **2015-12-06, 1394/09/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-06, 1394/09/15

Registrant information

Name

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of couple counselling Based on marital support on anxiety and worry during pregnancy

Public title

The Effect of couple counselling Based on marital support on anxiety and worry during pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

age between 15-45 The second half of pregnancy pregnancy women who had not previous hospitalization and known psychological disease

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Urmia University of Medical SciencesU

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Postal code

Approval date

2015-07-23, 1394/05/01

Ethics committee reference number

IR.umsu.rec.1394.75

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger state- trait anxiety inventor

2

Description

Pregnancy worries

Timepoint

Before and after intervention

Method of measurement

Cambridge Worry Scale

Secondary outcomes

empty

Intervention groups

1

Description

The non-intervention group received the normal prenatal care.

Category

Behavior

2

Description

.The intervention group (pregnancy women and their husband) in every visit in Once a week was counseled about the different Topics of pregnancy and delivery With respect to items of concern, counseling sessions was 6-4 , each session was 45-30 minutes. The non-intervention group received the normal prenatal care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Urmia University of Medical Sciences

Full name of responsible person

Fatemeh Moghaddam Tabrizi

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical SciencesU

Full name of responsible person

Iraj Mohebbi

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Orjhans Street, Resalat Blvd
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 Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Urmia University of Medical SciencesU
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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Full name of responsible person
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Person responsible for updating data

Contact

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