

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of husbands' participation in prenatal care on mental health of pregnant women

Protocol summary

Summary

The present study is an experimental study that after obtaining the necessary permits to conduct sampling at selected centers, the file number of people who are into the study of random samples Selected, and then explain the research objectives of the subject's informed consent will be obtained. and randomly divided into intervention and control groups. the intervention group before intervention required to attend training sessions wife will be explained. The curriculum planning in two two-hour sessions , according to standard Ministry of Healt, is taught together with their husbands will be held for the intervention group and the intervention group will receive telephone counseling sessions.in addition, the husband at the time of prenatal care visits is necessary.the first questionnaire (pre-test), which includes a two-part questionnaire for demographic information and their husbands, as well as "Goldberg's General Health Questionnaire "will be completed for pregnant women. Pregnant women belonging to the control group after completion of the questionnaire, will receive prenatal care routine and four weeks after the intervention in both intervention and control groups post test is done and the results will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102615163N1**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Hemmat Khodaei

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research Council of Urmia University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of husbands' participation in prenatal care on mental health of pregnant women

Public title

effect of husbands' participation on mental health of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnancy between weeks 26 to 30; ages 18 and 35; able to speak Persian and Turkish; the absence of mental illness; Uncomplicated pregnancy; lack of consumption of psychiatric drugs; Wanted

pregnancy. Exclusion criteria: Dissatisfaction and lack of interest in continuing to work absenteeism by pregnant women and their partners in training sessions, abnormalities diagnosed by fetal and neonatal death, unwanted pregnancy, complications of pregnancy at the time of intervention

Age
From **18 years** old to **35 years** old

Gender
Both

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)
Single 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 Sciences

Street address
Urmia University of Medical Sciences, Resalat Boulevard

City
Urmia

Postal code

Approval date
2013-07-23, 1392/05/01

Ethics committee reference number
92-01-33-1023

2

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
Urmia Road Nazlou

City
urmia

Postal code

Approval date
2013-07-23, 1392/05/01

Ethics committee reference number
92-01-33-1023

3

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
Road Nazlou-عقئهش

City
urmia

Postal code

Approval date
2013-06-22, 1392/04/01

Ethics committee reference number
92-01-33-1023

4

Ethics committee

Name of ethics committee
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Urmia Road Nazlou-Urmia University of Medical Sciences

City
urmia

Postal code

Approval date
2013-05-23, 1392/03/02

Ethics committee reference number
92-01-33-1023

Health conditions studied

1

Description of health condition studied
Mental health of pregnant women

ICD-10 code
F99-F99

ICD-10 code description
Mental disorder, not otherwise specified

Primary outcomes

1

Description
Mental health of pregnant women

Timepoint
Before and four weeks after the intervention

Method of measurement
Goldberg General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Before the intervention, Goldberg's General Health Questionnaire be filled by the intervention group and along with their husbands about prenatal care and psychological support during the two sessions of two hours to four weeks training is lateral. the prenatal visit in health centers where they will be accompanied by husband and also at meetings twice a week telephone advice will be given to the intervention group and four weeks after intervention, mental health questionnaire will be filled again by pregnant women and the results will be compared with the control group.

Category

Prevention

2

Description

The control group completed the Goldberg General Health Questionnaire and receive routine prenatal care and after completion of study, questionnaire filled again by this group of pregnant women and the results will be compared with the intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Health Center

Full name of responsible person

Ms.amirzehni

Street address

Babasay St. Urmia

City

Urmia

2

Recruitment center

Name of recruitment center

No. 6 Health Center

Full name of responsible person

Ms.foladi

Street address

Kashani St, Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Dr. Morteza Motazaker

Street address

Urmia University of Medical Sciences, Resalat Boulevard

City

Urmia

Grant name

ردیف پژوهشی معاونت تحقیقات و فن آوری

Grant code / Reference number

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

Yes

Title of funding source

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

Nursing and Midwifery Faculty, Urmia University of Medical Sciences

Full name of responsible person

Dr.Soheila Rabieipoor

Position

Nursing and Midwifery Faculty of Vice Chancellor for Research

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Phd degree in reproductive health field

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

Person responsible for updating data

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Hemmat Khodai

Position

Msc Student of Nursing

Other areas of specialty/work

Street address

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City