

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The impact of couples educational program based basnef model on spouse support and mental health of pregnant women

Protocol summary

Summary

The main aim of this research is studying the effectiveness of couples training program based on Basnef model on spouses support and pregnant women's mental health. Specific goals include: comparing women's mental health before and after training in intervention and control groups, and comparing the elements of Basnef model such as knowledge, attitude, abstract norm, the factors needed in enabling couples from spouses support and pregnant women's mental health in intervention and control groups before and after training. Design: this study is a semi-experimental study. Method: the aim of study is presented to couples by researchers and after cooperation request, inviting spouses, and receiving paper of consent, participants enter to the study. The environment of research is health care centers of Hormozgan University of Medical Science in Bandar Abbas city. The centers selected by cluster random sampling in such a way that health care centers of Bandar Abbas city are listed and for centers are selected by random sampling among which two centers are chosen to perform couple training plan, and two other are set as control centers. Then 63 couples of these two centers are selected to receive training. The couple selection is done in a constant and accessible way. Receiving criteria include: all pregnant women and their spouses referring to the health care centers of Bandar Abbas; gestational age range is 20-30 weeks; fetus is confirmed by sonography; absence of intimate death during the past one year; delivery criteria include: taking anti-depressant medications; fetus death; renunciation or dropping out of study; the interventions based on Basnef model include: 60 minutes face training for 4 sessions in the health care centers, together with distributing educational hand book and sending a reminder message to spouses once a week. Major outcome variable: studying the effectiveness of couple training program based on Basnef model on spouses support and on eventually on pregnant women's

mental health.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301196284N6**

Registration date: **2014-12-30, 1393/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

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Maryam Modarres

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2014-08-11, 1393/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of couples educational program based basnef model on spouse support and mental health of pregnant women

Public title

Mental Health- Spouse Support- Basnef Model

Purpose

Prevention

Inclusion/Exclusion criteria

receiving criteria include : all pregnant women and their spouses referring to the heath cove center of Bandar abbas;. gestakonal age range is 20-30 wels;. fetus health is confirmed by sonography ;. absence of intimates death during the past one year;. delivery criteria include : taking anti depressant medications;. fetus death ;. renunciation or dropping out of study;.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 125

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 Tehran University of Medical sciences

Street address

f 6th, Center organization of university, edge of Qods avenue, Keshavarz blvd

City

Tehran

Postal code

1419733171

Approval date

2014-10-29, 1393/08/07

Ethics committee reference number

1851/130/93/ص

Health conditions studied**1****Description of health condition studied**

Mental health

ICD-10 code

F00-F09,F1

ICD-10 code description

Mental and behavioural disorders

Primary outcomes**1****Description**

Mental health

Timepoint

Before intervention - 4 weeks after intervention

Method of measurement

Mental health assessment Questionnaire 28

2**Description**

Spouse support

Timepoint

Before intervention- 4 weeks after intervention

Method of measurement

Spouse support questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Educational on Basnef model once a week for 4 weeks, and distribution of educational booklets and texting once a week

Category

Behavior

2**Description**

Control group: routine prenatal care

Category

Behavior

Recruitment centers**1****Recruitment center**

Name of recruitment center

Health Center number (7) in Bandarabas

Full name of responsible person

Azam Moridi

Street addressHealth Center number (7), adjacent to Lyla hospital,
Bandarabas**City**

Bandarabas

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Fax**Email**

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Tehran University of
Medical sciences**Full name of responsible person**Research assistant of Tehran University of Medical
sciences(Dr Yonessian Massoud)**Street address**5th floor,Central building of Tehran University of
Medical sciences, edge of Qods Av, Keshavarz blvd,
Tehran**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Tehran 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**

Tehran University of Medical Science

Full name of responsible person

Dr. Modares Maryam

Position

Phd Medical education

Other areas of specialty/work**Street address**Faculty of Nursing & Midwifery Tehran University of
Medical Science, Tohid square**City**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Hormozgan University of Medical Science

Full name of responsible person

Moridi Azam

Position

Masters

Other areas of specialty/work**Street address**Alley, 22 Bahman , 3 Kosar streets Deputy of
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Web page address**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