

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the Effectiveness of Psychological and Psychiatric Interventions on Improving Psychological Symptoms in Pregnant Women with Psychiatric Disorders in the intervention and control groups

Protocol summary

Study aim

The aim of this study was to investigate the effects of psychological and psychological interventions on improving and improving the mental health of pregnant women.

Design

Semi-experimental intervention with parallel group control group Simple and accessible sampling (two hospitals as an intervention group and two hospitals as a control group) without blindness

Settings and conduct

Four state hospitals in Kashan were selected to have generalization capability in Kashan community. Two interventions hospitals and two hospitals were used as control groups that individuals were not aware of being in the intervention or control group.

Participants/Inclusion and exclusion criteria

The Inclusion criteria in study were all pregnant women aged 20-35 years old at 4-6 weeks of gestation and ; lack of serious physical illnesses such as diabetes, hypertension, and systematic illnesses and addictive.

Intervention groups

Interventions include: 1) Low-risk group: GHQ scores less than 23 and less than 6 and less than mild was received mental health education, stress management, training classes and training packages.2) The average risk group: a GHQ score of between 23-45, at least 6-8 mild psychological symptoms,was received low risk services, referral to a general practitioner (supportive psychotherapy and conflict resolution in the family).3) The high risk group: GHQ scores equal to or greater than 45, with mild symptoms 9 and above, were provided to the low-risk and middle-risk groups and referral to a psychiatrist.All mental health interventions were provided up to 6 months postpartum and the effect of interventions to reduce the symptoms of psychiatry in mothers was investigated.The control group received

routine treatments.

Main outcome variables

mental health of mother

General information

Reason for update

Acronym

Mental health in mothers

IRCT registration information

IRCT registration number: **IRCT20120905010746N6**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **retrospective**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

Registration date

2018-12-25, 1397/10/04

Registrant information

Name

Nasrin Abedinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Office of Mental Health and Addiction, and Office of Health, Population and Family of the Ministry of Health

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2016-02-20, 1394/12/01
Actual recruitment start date
2013-02-19, 1391/12/01
Actual recruitment end date
2016-02-20, 1394/12/01
Trial completion date
2016-02-20, 1394/12/01

Scientific title
Comparison of the Effectiveness of Psychological and Psychiatric Interventions on Improving Psychological Symptoms in Pregnant Women with Psychiatric Disorders in the intervention and control groups

Public title
psychiatric disorders in pregnant women and the effect of psychiatric and psychological interventions on mental health of pregnant women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

In this study Inclusion criteria Includes all pregnant women aged 20-35 who were 4-6 weeks pregnant.

Exclusion criteria:

Exclusion criteria excluded from the study if they had serious physical illnesses such as diabetes, hypertension, and systematic illnesses and addictive.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **206**
Actual sample size reached: **202**

Randomization (investigator's opinion)
Not 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
Tehran University of Medical Science

Street address

Central Office of Tehran University of Medical Sciences Tehran, Corner of Ghodd Street, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2011-07-18, 1390/04/27

Ethics committee reference number
15895

Health conditions studied

1

Description of health condition studied
Mental Health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
mental health mother

Timepoint
6 months after childbirth

Method of measurement
General health questionnaire (GHQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Interventions include: 1) Low-risk group: GHQ scores less than 23 and less than 6 and less than mild was received mental health education, stress management, training classes and training packages. 2) The average risk group: a GHQ score of between 23-45, at least 6-8 mild psychological symptoms, was received low risk services, referral to a general practitioner (supportive psychotherapy and conflict resolution in the family). 3) The high risk group: GHQ scores equal to or greater than 45, with mild symptoms 9 and above, were provided to the low-risk and middle-risk groups and referral to a psychiatrist. All mental health interventions were provided up to 6 months postpartum and the effect of interventions to reduce the symptoms of psychiatry in mothers was investigated.

Category
Behavior

2

Description

Control group: . The control group received routine treatments

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti

Full name of responsible person

Nasrin Abedinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry of Health and Medical Education

Full name of responsible person

Abbas Nasehi

Street address

Qods, between Zarafshan, falamak headquarters of
the Ministry of health, treatment and medical
education

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ministry of Health and Medical Education

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Abedinia

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Keshavarz Boulevard Imam Khomeini Hospital
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Psychiatric

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Only results will be announced

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only results will be announced

When the data will become available and for how long

Data will be analyzed statistically and then presented in a scientific paper

To whom data/document is available

Professionals and students

Under which criteria data/document could be used

For research

From where data/document is obtainable

My email

What processes are involved for a request to access data/document

Submit their research plan jooperation will certainly take place

Comments