

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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)

##### Phone

+98 21 6119 2357

##### Email address

abedinia@farabi.tums.ac.ir

##### 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

##### Street address

Maternal neonatal infants research center, Valiasr Hospital, Imam Khomeini Hospital, Complex Keshavarz Boulevard

##### City

Tehran

##### Province

Tehran

##### Postal code

1419155853

##### Phone

+98 21 6119 2357

##### Fax

+98 21 6659 1316

##### Email

nasrin.abedinia@gmail.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1467664961

##### Phone

+98 21 8836 3560

##### Email

ethics@hbi.ir

##### 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

##### Street address

Keshavarz Boulevard Imam Khomeini Hospital Complex vali asr hospital Family Health Research Center Maternal fetal and neonatal research center

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##### Province

Tehran

##### Postal code

1419733141

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+98 21 6119 2357

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+98 21 6659 1315

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nasrin.abedinia@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Ahmad Ali Noorbala

##### Position

Psychiatric

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Psychosomatic ward , Imam Komeini complex hospital

##### City

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## Person responsible for updating data

### 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  
**Street address**  
Vali asr Hospital , Imam Khomeini complex hospital,  
Keshavarz BLvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1419733141  
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+98 21 6119 2357  
**Fax**  
+98 21 6658 1315

**Email**  
nasrin.abedinia@gmail.com  
**Web page address**

## 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 , cooperation will certainly take place

### Comments