

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### The effect of self-care education based on Teach Back method on the mental health of pregnant mothers

#### Protocol summary

##### Study aim

Evaluate the effect of self-care education based on Teach Back method on the mental health of pregnant mothers

##### Design

Two arm parallel group randomized trial, will be conducted on 60 pregnant women referred to healthcare centers of Mashhad

##### Settings and conduct

The eligible women who will refer to healthcare centers of Mashhad, during the study period will be divided into two groups. In Intervention group, Psychological self-care educations based on Group teach back method is provided for groups of 8-10 persons (one session per week for three weeks, during 60 minute.). Training are related to (physical and mental changes in pregnancy, the role of sleep and nutrition and stress on health, signs and symptoms of depression, anxiety, and... ). After completion of training, the subject was asked to say what they understand, in their own words. If the patient has not understood the content of sessions, educator would continue to explain until the patient would fully understand the contents. Then, the patients will be given the opportunity to ask their questions and receive the proper answers. The control group will be received routine training in the health care center. Then, the mental health score in control and intervention groups will be re-evaluated 4 weeks after the training.

##### Participants/Inclusion and exclusion criteria

Iranian nationality, have the ability to read and write, have the single pregnancy, aged 18 to 45 years, gestational age between 18 to 32 weeks

##### Intervention groups

Psychological self-care educations based on group teach back method will be provided in one session per week for three weeks. The duration of each class will be 60 minutes. Subjects will be divided into groups of 8 to 10 persons. The control group received routine training in the health care center

##### Main outcome variables

mental health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170430033717N2**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **prospective**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

##### Registration date

2018-11-12, 1397/08/21

##### Registrant information

##### Name

Samaneh Jouya

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

jouyas941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-18, 1397/08/27

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of self-care education based on Teach Back method on the mental health of pregnant mothers

**Public title**

The effect of training on the mental health of pregnant mothers

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Iranian nationality Have the ability to read and write  
Aged 18 to 45 Single pregnancy No history of acute or chronic medical condition Gestational age between 32-28 weeks Lack of addiction to smoking and alcohol use Lack of stressful events occurred during the last 3 months

**Exclusion criteria:**

Not completing at least two educational sessions No tendency to cooperate with research team Having history of mental disorders Have a high risk pregnancy

**Age**

From **18 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**

Using a simple random sampling method (random table number), two health centers are selected from five health centers in Mashhad. These centers assigned to the two group of intervention and control groups using coin throw.

**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 Mashhad University of Medical Sciences

**Street address**

Daneshgah street, Ghoreshi building, Mashhad  
University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2018-10-04, 1397/07/12

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1397.030

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

Mental health of pregnant women

**ICD-10 code**

F99

**ICD-10 code description**

Mental disorder, not otherwise specified

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

Mental health score

**Timepoint**

before intervention and 4 weeks after intervention

**Method of measurement**

Goldberg Health questionnaire (GHQ)

**Secondary outcomes****1****Description**

spiritual health

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

spiritual health assessment questionnaire (Paloutzian & Ellison)

**2****Description**

hope

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

Snyder's Hope Questionnaire

**Intervention groups**

## 1

### Description

Intervention group: In intervention group Psychological self-care educations based on Group teach back method is provided for groups of 8-10 persons in each session .each participant takes part in one session per week for 3 weeks. (Each training class lasts for 60 minutes).

### Category

Behavior

## 2

### Description

Control group: The control group received routine training in the health care center

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Abas abad Health Center

#### Full name of responsible person

Dr Asna Ashar

#### Street address

No. 9th street, Kamyab Blvd.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9181111111

#### Phone

+98 51 3735 8906

#### Email

Jouyas941@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen tafaghodi

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Daneshgah Ave, Ghoreshi bulding

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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

Mashhad University of Medical Sciences

### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Samaneh Jouya

#### Position

Non-faculty trainer

#### Latest degree

Master

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Mashhad Nursing Midwifery Faculty, Doktora  
Crossroads, Ebnecina Street

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Nahid Golmakani

#### Position

Midwifery Master-Assistant Professor

#### Latest degree

Master

#### Other areas of specialty/work

Midwifery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Samaneh Jouya  
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**Latest degree**  
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**Other areas of specialty/work**  
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**Phone**  
+98 51 3761 8946  
**Email**  
Jouyas941@mums.ac.ir

## 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

No more information

### Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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